



FEDERAL REGISTER

Vol. 91 Tuesday,
No. 128 July 7, 2026

Pages 41521–42134

OFFICE OF THE FEDERAL REGISTER



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see www.federalregister.gov.

The seal of the National Archives and Records Administration authenticates the **Federal Register** as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at www.govinfo.gov, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, gpocusthelp.com.

The annual subscription price for the **Federal Register** paper edition is \$860 plus postage, or \$929, for a combined **Federal Register**, **Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is \$330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register**, including postage, is based on the number of pages: \$11 for an issue containing less than 200 pages; \$22 for an issue containing 200 to 400 pages; and \$33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for \$3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see bookstore.gpo.gov.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 91 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202-512-1800
Assistance with public subscriptions	202-512-1806

General online information 202-512-1530; 1-888-293-6498

Single copies/back copies:

Paper or fiche	202-512-1800
Assistance with public single copies	1-866-512-1800 (Toll-Free)

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	FRSubscriptions@nara.gov
Phone	202-741-6000

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: <https://www.gpo.gov/frsubs>.



Contents

Federal Register

Vol. 91, No. 128

Tuesday, July 7, 2026

Agriculture Department

See Animal and Plant Health Inspection Service

Animal and Plant Health Inspection Service

NOTICES

Hearings, Meetings, Proceedings, etc.:

General Conference Committee of the National Poultry Improvement Plan and 47th Biennial Conference, 41617

Census Bureau

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Data Security Requirements for Accessing Confidential Data, 41617–41619

Centers for Medicare & Medicaid Services

PROPOSED RULES

Medicare Program:

Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; etc., 41734–42032

NOTICES

Privacy Act; Matching Program, 41643–41644

Coast Guard

RULES

Safety Zone:

Corpus Christi Ship Channel, Corpus Christi, TX, 41564–41566

Commerce Department

See Census Bureau

See Industry and Security Bureau

See International Trade Administration

See National Oceanic and Atmospheric Administration

Consumer Product Safety Commission

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Safety Standard for Adult Portable Bed Rails, 41623–41624

Drug Enforcement Administration

NOTICES

Importer, Manufacturer or Bulk Manufacturer of Controlled Substances; Application, Registration, etc.:

Benuvia Operations, LLC, 41663

Education Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

William D Ford Federal Direct Loan Program Repayment Plan Selection Form, 41624

Energy Department

See Federal Energy Regulatory Commission

PROPOSED RULES

Energy Conservation Program:

Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment, 42034–42083
Review of Analytic Methods for Setting Energy Conservation Standards, 41578–41591

Environmental Protection Agency

PROPOSED RULES

Minor New Source Review Program Air Permitting Public Participation Requirements for State Implementation Plans, 41591–41604

Federal Aviation Administration

RULES

Airworthiness Directives:

Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes, 41542–41556
Bell Textron Canada Limited Helicopters, 41539–41542

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
International Role of the Federal Aviation Administration, 41729

Federal Energy Regulatory Commission

PROPOSED RULES

Revisions to Financial Forms Reporting and Filing Requirements; Correction, 41591

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 41625–41626, 41628–41630, 41632–41635

Application:

Lewis Ridge Pumped Storage, LLC, 41625
Wyoming Interstate Co., LLC, Fort Union Gas Gathering, LLC, 41626–41628

Combined Filings, 41630–41632, 41635–41636

Effectiveness of Exempt Wholesale Generator and Foreign Utility Company Status:

Canyon Peak Power LLC, Hillsboro Solar Project LLC, Bexar ProjectCo 4, LLC, etc., 41624

Hearings, Meetings, Proceedings, etc.:

The Empire District Electric Co.; Programmatic Agreement Consultation, 41630

Federal Highway Administration

NOTICES

Final Federal Agency Action:

Proposed Interstate Bridge Replacement Program in Portland, OR and Vancouver, WA, 41730–41731

Federal Reserve System

NOTICES

Change in Bank Control:

Acquisitions of Shares of a Bank or Bank Holding Company, 41637

Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 41637–41638
Proposals to Engage in or to Acquire Companies Engaged in Permissible Nonbanking Activities, 41636–41637

Federal Trade Commission

NOTICES

Granting of Requests for Early Termination of the Waiting Period under the Premerger Notification Rules, 41642–41643

Policy Statement:

Suppression of Accuracy in Artificial Intelligence Systems, 41638–41642

Federal Transit Administration

NOTICES

Final Federal Agency Action:

Proposed Interstate Bridge Replacement Program in Portland, OR and Vancouver, WA, 41730–41731

Fish and Wildlife Service

PROPOSED RULES

Endangered and Threatened Species:

Status with Section 4(d) Rule for the Kern Canyon Slender Salamander, Status for the Relictual Slender Salamander; Designation of Critical Habitat, 41606–41611

NOTICES

Permits; Applications, Issuances, etc.:

Marine Mammal Protection Act, 41653–41655

Food and Drug Administration

RULES

New Animal Drugs:

Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Application; Change of Sponsor, 41557–41564

Health and Human Services Department

See Centers for Medicare & Medicaid Services

See Food and Drug Administration

See Health Resources and Services Administration

See National Institutes of Health

PROPOSED RULES

Recission of the National Cancer Institute Clinical Cancer Education Program Regulation, 41604–41606

Health Resources and Services Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Rural Health Care Services Outreach Program Measures, 41644–41645

Homeland Security Department

See Coast Guard

See U.S. Citizenship and Immigration Services

Housing and Urban Development Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Annual Moving to Work Plan and Report Elements, Moving to Work Plan-Expansion, 41651–41653

Privacy Act; Systems of Records, 41649–41651

Indian Affairs Bureau

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Tribal Revenue Allocation Plans, 41655

Indian Gaming:

Extension of Tribal-State Class III Gaming Compact between the Yurok Tribe of the Yurok Reservation, CA, and the State of California, 41655–41656

Industry and Security Bureau

NOTICES

Section 232 National Security Investigation of Anthracite Coal, 41619–41620

Interior Department

See Fish and Wildlife Service

See Indian Affairs Bureau

Internal Revenue Service

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Information Return for Publicly Offered Original Issue Discount Instruments, 41731

International Trade Administration

NOTICES

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Scope Ruling Applications Filed, 41620–41621

International Trade Commission

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

USMCA Automotive Rules of Origin: Economic Impact and Operation, 2027 Report, 41656

Investigations; Determinations, Modifications, and Rulings, etc.:

Certain Antibody Drug Conjugates and Components Thereof and Products Containing the Same, 41656–41657

Certain Flash-Spun Nonwoven Materials and Products Containing Same, 41661–41663

Certain Ink Cartridges and Components Thereof I, 41658–41660

Certain Microcurrent Facial Toning Devices and Systems Thereof, 41661

Certain Vehicle Space Guards, 41657–41658

Passenger Vehicle and Light Truck Tires from China, 41661

Prestressed Concrete Steel Wire Strand from Argentina, Colombia, Egypt, Indonesia, Italy, Malaysia, Netherlands, Saudi Arabia, South Africa, Spain, Taiwan, Tunisia, Turkey, Ukraine, and the United Arab Emirates, 41660–41661

Justice Department

See Drug Enforcement Administration

NOTICES

Proposed Consent Decree:

CERCLA, 41663–41664

Legal Services Corporation

NOTICES

Meetings; Sunshine Act, 41664

National Institutes of Health**NOTICES**

Hearings, Meetings, Proceedings, etc.:

Center for Scientific Review, 41646–41648

National Institute of Diabetes and Digestive and Kidney Diseases, 41646

Office of the Secretary, 41645–41646

National Oceanic and Atmospheric Administration**RULES**

International Fisheries:

Pacific Tuna Fisheries; Conservation and Management Measures for Tropical Tunas in the Eastern Pacific Ocean for 2026 and Beyond, 41570–41577

Pribilof Islands Administration; Dogs Prohibited, 41566–41570

PROPOSED RULES

Reef Fish Fishery of the Gulf of America; Amendment 62, 41611–41616

NOTICES

Permits; Applications, Issuances, etc.:

Taking of Endangered and Threatened Species; Permit No. 23861, 41621–41623

Nuclear Regulatory Commission**PROPOSED RULES**

Implementation of the National Environmental Policy Act, 42086–42133

NOTICES

Facility Operating and Combined Licenses:

Applications and Amendments Involving Proposed No Significant Hazards Considerations, etc., 41665–41670

Hearings, Meetings, Proceedings, etc.:

Tennessee Valley Authority; Clinch River Nuclear Site, Unit 1, 41664–41665

Meetings; Sunshine Act, 41665

Personnel Management Office**RULES**

Performance Appraisal for General Schedule, Prevailing Rate, and Certain Other Employees, 41521–41539

Postal Regulatory Commission**NOTICES**

New Postal Products, 41670–41671

Securities and Exchange Commission**NOTICES**

Application:

Goehring and Rozenzweig Investment Funds and Goehring and Rozenzweig Associates, LLC, 41715–41716

Muzinich Aviation Income Fund (mAIR) and Muzinich and Co., Inc., 41723

Civil Monetary Penalty Inflation Adjustment, 41722–41723

Self-Regulatory Organizations; Proposed Rule Changes:

Chicago Mercantile Exchange Inc., 41676–41689

Financial Industry Regulatory Authority, Inc., 41673–41676, 41723–41725

MIAX PEARL, LLC, 41671–41673

New York Stock Exchange LLC, 41702–41707

NYSE American LLC, 41696–41702

NYSE American LLC and NYSE Arca, Inc., 41689–41696

NYSE Arca, Inc., 41716–41722

Texas Stock Exchange LLC, 41707–41715

Small Business Administration**NOTICES**

Licenses; Exemptions, Applications, Amendments, etc.:

Small Business Investment Company, 41725

State Department**NOTICES**

Agency Information Collection Activities; Proposals,

Submissions, and Approvals:

Brokering Approval (License), 41725–41726

Privacy Act; Systems of Records, 41726–41729

Transportation Department

See Federal Aviation Administration

See Federal Highway Administration

See Federal Transit Administration

RULES

Airline Refunds and Other Consumer Protections, 41556–41557

Treasury Department

See Internal Revenue Service

NOTICES

Interest Rate Paid on Cash Deposited to Secure U.S.

Immigration and Customs Enforcement Immigration

Bonds, 41731–41732

U.S. Citizenship and Immigration Services**NOTICES**

Agency Information Collection Activities; Proposals,

Submissions, and Approvals:

Application for Civil Surgeon Designation, 41648–41649

Separate Parts In This Issue**Part II**

Health and Human Services Department, Centers for

Medicare & Medicaid Services, 41734–42032

Part III

Energy Department, 42034–42083

Part IV

Nuclear Regulatory Commission, 42086–42133

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

5 CFR

351	41521
430	41521
537	41521

10 CFR**Proposed Rules:**

2	42086
30	42086
40	42086
50	42086
51	42086
52	42086
53	42086
54	42086
61	42086
70	42086
72	42086
76	42086
110	42086
430 (2 documents)	41578,
	42034
431	41578

14 CFR

39 (2 documents)	41539,
	41542
260	41556
399	41556

18 CFR**Proposed Rules:**

141	41591
260	41591
357	41591
369	41591

21 CFR

516	41557
520	41557
522	41557
524	41557
529	41557
556	41557
558	41557

33 CFR

165	41564

40 CFR**Proposed Rules:**

51	41591

42 CFR**Proposed Rules:**

52d	41604
413	41734
416	41734
419	41734
427	41734
488	41734

50 CFR

216 (2 documents)	41566,
	41570
300	41570

Proposed Rules:

17	41606
622	41611

Rules and Regulations

Federal Register

Vol. 91, No. 128

Tuesday, July 7, 2026

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 351, 430, and 537

[Docket ID: OPM-2025-0273]

RIN 3206-AP06

Performance Appraisal for General Schedule, Prevailing Rate, and Certain Other Employees

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing a final rule to increase the efficiency and effectiveness of performance management for non-Senior Executive Service (SES) employees, including General Schedule (GS) and prevailing rate employees. This final rule eliminates unnecessary summary level patterns; removes the prohibition of a forced, or standardized, distribution of performance rating levels; eliminates mandatory review of Level 1 ratings; removes the option to grieve a rating of record; requires a supervisory critical element for all supervisors covered under this subpart; and requires OPM to conduct biennial certifications of agency appraisal systems.

DATES:

Effective date: August 6, 2026.

Compliance date: Compliance with § 430.208(e)(1) and (2) is required beginning January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

Noah Peters, Senior Advisor to the Director, 202-606-8046 or by email at performance-management@opm.gov.

SUPPLEMENTARY INFORMATION:

Background

The Civil Service Reform Act (CSRA) of 1978 established a new framework for merit-based personnel management in the Federal Government, including reforms to the performance appraisal system for Federal employees. When

Congress debated and passed this legislation, a major concern was that the existing appraisal system did not meaningfully measure employee performance.¹ The Senate Committee on Governmental Affairs observed that performance ratings were frequently inflated, failed to meaningfully distinguish among levels of performance, and were often assigned without sufficient rigor or accountability. Supervisors were often reluctant to assign low ratings, so ratings were not regarded as reliable indicators of performance. Performance ratings therefore lost much of their management value. As a result, the appraisal system provided little practical support for personnel decisions and did not function as an effective tool for managing employee performance.

Pursuant to CSRA, OPM is responsible for promulgating governmentwide regulations governing Federal performance management systems under chapter 43 of title 5, United States Code. Under this authority, OPM issues regulations applicable to non-SES employees, including GS and prevailing rate employees, as well as senior-level and scientific or professional employees referred to as “senior professionals” (SP). Among its statutory responsibilities, OPM is required to review the appraisal systems covering these employees to ensure they comply with statutory requirements² and design personnel systems that provide governmentwide standards that sustain a culture that cultivates and develops a high-performing workforce.³ Where OPM finds that an agency’s system fails to meet statutory and regulatory requirements, OPM is authorized to direct agencies to implement an appropriate system or correct its operations to meet those requirements.⁴

Throughout the 1980s and early 1990s, Federal performance management operated under a centralized regulatory framework established by OPM in 1983.⁵ The system standardized appraisal processes

through establishment of a five-level rating structure and by formally tying performance ratings to pay, awards, and promotion decisions. While intended to strengthen accountability and create a performance-based civil service, the framework often produced limited differentiation among employees, administrative complexity, and inconsistent enforcement of performance standards. By the early 1990s, policymakers increasingly viewed the system as overly rigid and insufficiently responsive to agency management needs, prompting calls for greater flexibility and decentralization. When developing the non-SES performance appraisal regulations at part 430, subpart B, in 1995, OPM adopted recommendations by the National Performance Review for flexible, decentralized performance management.⁶ This move towards agency flexibility and decentralization was a stark contrast to the highly detailed regulatory requirements of the mid-1980s—a time when there was a strong policy interest in achieving governmentwide uniformity. Aside from a few minor changes in the late 1990s, the appraisal regulations at part 430, subpart B, have remained in place and unchanged, failing to adapt to the evolving mission needs of the Federal workforce.

For decades, oversight agencies have specifically identified performance management as an area that requires improvement and reform. As early as the 1980s, the Merit Systems Protection Board (MSPB) reported that Federal performance appraisal systems often failed to meaningfully distinguish between levels of performance and that ratings were frequently concentrated at higher levels.⁷ More recently, the Government Accountability Office (GAO) has noted the challenges and failures of the current performance management appraisal system.⁸ Notably, a 2016 GAO report found that 99% of

⁶ 60 FR 43936 (Aug. 23, 1995).

⁷ U.S. Merit Systems Protection Board, *Toward Effective Performance Management in the Federal Government: A Report to the President and the Congress of the United States*, at V (July 1988), https://www.mspb.gov/studies/studies/Toward_Effective_Performance_Management_in_the_Federal_Government_317713.pdf.

⁸ GAO, *Federal Workforce, Opportunities Exist for OPM to Further Innovation in Performance Management*, at 2 (Nov. 2018), <https://www.gao.gov/assets/700/695639.pdf>.

¹ S. Rep. No. 95-969, at 44-45 (1978), reprinted in *Legislative History of the Civil Service Reform Act of 1978*, Vol. 2 (1979).

² 5 U.S.C. 4304(b)(1).

³ 5 U.S.C. 1103(c)(2)(D).

⁴ 5 U.S.C. 4304(b)(3).

⁵ 48 FR 49472 (Oct. 25, 1983).

permanent, non-SES employees received performance ratings at or above Fully Successful.⁹ This inflation in performance ratings continued into the 2020s as detailed in the proposed rule.¹⁰ OPM has attempted to curb ratings inflation and increase accountability through non-regulatory efforts, including issuing a 2019 memorandum encouraging agencies to increase rigor in performance management through well-developed performance standards that make clear distinctions among what is required to achieve performance at the various performance levels.¹¹ Despite these recent attempts, data from the Federal Employee Viewpoint Survey (FEVS) and GAO show that only 42–51% of Federal employees believe that their supervisors distinguish and recognize performance in a meaningful way.¹² It is clear that doing more of the same is not going to improve performance management in the Federal Government.

Recognizing that reforms to Federal performance management are long overdue, President Trump issued Presidential Memoranda and Executive Orders that establish a high-performing Federal workplace culture where excellent performance is celebrated and rewarded, and low performance is swiftly addressed by appropriate actions.¹³ Accordingly, OPM issued a memorandum titled “Performance Management for Federal Employees.”¹⁴ In that guidance, OPM noted that it is “reforming employee performance management across the Federal Government to ensure that it shall reward individual initiative, skills, performance and hard work.”¹⁵ OPM further stated that “performance management across the Federal

workforce has fallen short” and “has resulted in a lack of accountability and inflated performance ratings.”¹⁶ OPM also designed an extensive performance management toolkit and playbook providing all employees with critical performance management best practices.¹⁷

In response to these historical and enduring challenges, OPM determined that updates to its performance appraisal regulations for non-SES employees are necessary. On February 24, 2026, OPM issued a proposed rule at 91 FR 8780 pursuant to its regulatory authority at 5 U.S.C. 4305. As described in the proposed rule, these updates will strengthen agencies’ ability to evaluate performance accurately and fairly, ensure that high performance is recognized and rewarded, and align workforce management with mission accomplishment. These changes are necessary to promote a culture of accountability and excellence across the Federal workforce—one that reflects both the Government’s evolving operational demands and its longstanding commitment to a merit-based civil service.

Digest of Public Comments

In response to the proposed rule, OPM received 626 comments during the 30-day public comment period. These responses came from a range of sources: 602 individuals—including current and former civil servants, scientists, attorneys, and researchers—plus 4 Federal agencies, 11 organizations such as employee advocacy groups and professional associations, 8 unions, and a member of Congress.

Of the 626 comments received, all were posted and made available to the public in the docket at <https://www.regulations.gov/docket/OPM-2025-0273>. At the conclusion of the public comment period, OPM reviewed and analyzed the comments. Comments on the rule ranged from supportive to categorical rejection.

The comments are summarized below, together with suggestions for revisions that were considered and either fully or partially adopted, or declined, along with OPM’s reasoning. The first section addresses general or overarching comments, while subsequent sections discuss feedback related to specific parts of the regulation that OPM proposed to revise.

General Comments

Some commenters were supportive of the rule, such as Commenter 0332¹⁸ who stated, “These are great changes proposed. Please move forward.” Commenter 0008 expressed support for OPM updating the “antiquated evaluation system” currently in place. Several commenters, such as 0072, 0044, 0161, 0101, and 0225, acknowledged that performance appraisal reform is warranted and that improvements to the current system may be needed; however, these commenters also generally opposed the approaches taken in the proposed rule, particularly the use of standardized distribution and modifications to the procedures for assigning employee ratings. Most commenters either opposed the rule as a whole or objected to one or more of the major provisions of the rule, such as standardized distribution, elimination of negotiated grievance procedures under 5 U.S.C. 7121, and elimination of the requirement for mandatory review of a Level 1 (“Unacceptable”) rating of record.

Commenters 0517, 0549, 0554, and others argued that OPM failed to provide sufficient time to address the proposed rule given its “foundational change in the appraisal of federal employees.” The commenters suggested that at least another 60 days should be provided to allow those impacted and other interested parties to provide substantive comments. Respectfully, OPM provided sufficient time for the public to review the proposed rule and submit comments. As multiple appellate courts have held, a 30-day comment period is generally the minimum needed to comply with the Administrative Procedure Act (APA).¹⁹ Moreover, the more than 600 comments received during the public notice period raised a variety of issues and arguments, as further explored below, which indicates that the comment period provided adequate opportunity for the

⁹ GAO, *Federal Workforce: Distribution of Performance Ratings Across the Federal Government*, 2013, at 5 (May 9, 2016), <https://www.gao.gov/assets/680/677016.pdf>.

¹⁰ 91 FR 8780, 8782 (Feb. 24, 2026).

¹¹ OPM, *Applying Rigor in the Performance Management Process and Leveraging Awards Programs for a High-Performing Workforce*, at 1–2 (July 12, 2019), https://www.opm.gov/chcoc/transmittals/2019/applying-rigor-performance-management-process-and-leveraging-awards-programs-high-performing_508_0.pdf.

¹² OPM, *OPM FEVS Dashboard* (last accessed June 1, 2026), <https://www.opm.gov/fevs/reports/opm-fevs-dashboard/>; note 8 at 19.

¹³ See, e.g., E.O. 14284, *Strengthening Probationary Periods in the Federal Service*, 90 FR 17729 (April 24, 2025); E.O. 14171, *Restoring Accountability to Policy-Influencing Positions Within the Federal Workforce*, 90 FR 8625 (Jan. 20, 2025); *Restoring Accountability for Career Senior Executives*, 90 FR 8481 (Jan. 30, 2025); *Return to In-Person Work*, 90 FR 8251 (Jan. 28, 2025).

¹⁴ OPM, *Performance Management for Federal Employees* (June 17, 2025), <https://www.opm.gov/chcoc/latest-memos/performance-management-for-federal-employees.pdf>.

¹⁵ *Id.* (internal quotation marks omitted).

¹⁶ *Id.* at 2.

¹⁷ www.opm.gov/policy-data-oversight/performance-management/.

¹⁸ References to comments provide the location of the item in the public record (that is, the four-digit number associated with the location in the docket). Comments filed in response to the proposed rule are available at <https://www.regulations.gov/comment/OPM-2025-0273-nnnn>, where nnnn is the comment number.

¹⁹ See *Chamber of Com. of the U.S. v. U.S. Sec. & Exch. Comm’n*, 85 F.4th 760, 779 (5th Cir. 2023) (“... the APA generally requires only a minimum thirty-day comment period.”); see also *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1484 (9th Cir. 1992) (“Although the APA mandates no minimum comment period, some window of time, usually thirty days or more, is ... allowed for interested parties to comment.”).

public to provide meaningful input into the rule.

In the subsequent sections, we discuss and address comments related to the specific portion of the regulation to which each comment applied.

Standardized Distribution

In the proposed rule, OPM proposed removing the existing prohibition on a forced, or standardized, distribution of performance ratings, and instead proposed to authorize OPM to establish and maintain a standardized distribution of some or all rating levels that agencies must apply.

Consistency With 5 U.S.C. 4302

A number of commenters, including 0004, 0011, 0101, 0115, 0161, 0377, 0468, and others, asserted that the use of a standardized distribution of performance ratings conflicts with 5 U.S.C. 4302(c), which requires that performance appraisal systems permit the accurate evaluation of job performance on the basis of objective criteria related to the job in question. Commenters argued that standardized distribution requires supervisors to rate employees relative to one another rather than against established performance standards, thereby introducing non-performance-based factors into rating determinations. These commenters further stated a standardized distribution approach may result in employees receiving inaccurate ratings that do not reflect their actual job performance.

OPM respectfully disagrees that the final rule is inconsistent with 5 U.S.C. 4302. The statute requires that appraisal systems “to the maximum extent feasible, permit the accurate evaluation of job performance on the basis of objective criteria . . . related to the job in question for each employee or position under the system;”²⁰ it does not prescribe or prohibit a specific rating methodology or preclude the use of a standardized distribution to differentiate among levels of performance. Under this final rule, agencies remain responsible for establishing performance plans with clear, job-related expectations and for evaluating employees against those expectations. The phrase “to the maximum extent feasible” allows for the performance standards to include a standardized distribution framework. This framework provides a structured mechanism to support consistent application of performance distinctions; it does not authorize ratings based on non-performance factors or require

agencies to disregard evidence of individual performance against established performance standards.

OPM rejects commenters’ arguments that comparative judgments through the implementation of standardized distribution will lead to inaccurate ratings. As explained in the proposed rule, any human judgment is by nature comparative.²¹ Thus, the quality of an evaluation is improved by ensuring that it is comparative in nature (that is, involving relative judgments of a target in comparison to other individuals and groups), instead of absolute (that is, involving judgments on scales that do not reference others).²² One study, for example, concluded that “[t]he relatively few studies that have investigated the validity of comparative performance appraisal methods have tended to support their validity.”²³ It found significant evidence from “at least three important and quite different domains that comparative evaluative judgments of the self or others may be more advantageous than absolute evaluative judgments.”²⁴ This suggests that comparative judgments among employees, by utilizing a standardized distribution of ratings, will more accurately and objectively measure individual performance than one that prohibits any comparative judgments between employees and requires that any measurement of employee performance be framed in absolute terms.

Further, OPM intends to require agencies to apply a standardized distribution at the appropriate aggregate level as opposed to supervisors applying the rating limits within their own work unit or office. Therefore, the requirement to differentiate between relative levels of performance through the use of a standardized distribution operates only after employees are assessed against established performance standards, as required by 5 U.S.C. 4302(c)(3), and, consequently, does not replace or supplant those standards. The concern put forth by commenters claiming that distributional requirements create tension with statute because they involve relative comparison is baseless. The final rule does not require the mechanical application of quotas without regard to

objective, job-related performance evidence. Rather, it requires agencies to exercise informed judgment in the evaluation of rigorous performance objectives aligned to the duties of the position within a structured framework designed to support accurate differentiation.

Finally, OPM also notes that the current system suffers from the same flaws that the commenters warn about in adopting the proposed rule— inaccurate performance ratings. The evidence clearly shows that the Federal Government’s approach to performance management has long struggled to accurately measure employee performance.²⁵ During the public comment period, the Departments of Labor and Treasury (Commenters 0226 and 0375, respectively) describe how they have suffered from a leniency bias that inflates performance ratings and ties their supervisors’ hands when attempting to hold their employees accountable for poor performance. The Department of Labor identified how it issued 70–80% of its employees’ performance ratings at the highest two levels and rarely used the lowest two rating levels. The Department of the Treasury, likewise, identified suffering from the same problem and concluded that a standardized distribution of performance ratings may be the only path forward to disrupting the persistent pattern of ratings inflation. OPM credits these agencies’ experiences and agrees that this final rule is the best way to address these long-standing challenges.

Merit System Principles

Several commenters asserted that the use of standardized distribution of performance ratings conflicts with merit system principles under 5 U.S.C. 2301. They argued that the requirement to distribute ratings using a standardized distribution framework undermines the principle that employees should be treated fairly and equitably under section 2301(b)(2) because similarly performing employees may receive different ratings based on distribution targets rather than individual performance (e.g., commenters 0064, 0242, 0377, and 0520). Other commenters, including 0477 and 0554, asserted that standardized distribution may increase the risk of arbitrary action contrary to section 2301(b)(8)(A) by requiring supervisors to differentiate among employees even where performance differences are minimal or not clearly defined. Similarly, other commenters expressed concern that standardized distribution of

²¹ Kedia G, Mussweiler T, Linden DE. *Brain mechanisms of social comparison and their influence on the reward system*. *Neuroreport*. 2014 Nov 12;25.

²² Goffin RD, Olson JM. *Is It All Relative? Comparative Judgments and the Possible Improvement of Self-Ratings and Ratings of Others*. *Perspect. Psychol. Sci.* 2011 Jan; 6(1):48–60.

²³ *Id.* at p. 50.

²⁴ *Id.* at 53.

²⁵ See notes 7 and 9.

²⁰ 5 U.S.C. 4302(c)(1) (emphasis added).

performance ratings could increase the risk of bias, favoritism, retaliation, or politicization of performance evaluations (e.g., commenters 0003, 0031, 0173, 0288, 0498, and 0557).

OPM does not agree that use of a standardized rating system would deny employees fair or equitable treatment or subject them to arbitrary action. The merit system principles do not prohibit agencies from rating employees based upon a comparison of individual employee performance. They instead guard against personnel decisions based on factors other than merit. Under the final rule, supervisors will continue to evaluate employee performance based on their assessments of their employees' individual performance against established performance standards. Afterwards, agencies at the appropriate aggregate level will apply the standardized distribution of performance ratings consistent with OPM guidance. Agencies will apply OPM guidance at a higher level, which will mitigate commenters' concerns that individual supervisors will make subjective, non-merit-based judgments about employee performance when deriving comparative judgments. Moreover, by requiring agencies to limit the highest ratings to the most accomplished, agencies will be required to truly focus on mission-driven performance that contributes to organizational performance, thereby promoting the effective and efficient use of the Federal workforce and enhancing alignment with the merit system principles.²⁶ To further alleviate commenters' concerns, OPM will amend § 430.209 in the final rule to make clear that agency performance appraisal systems and programs must be administered consistent with the merit system principles, and OPM will amend § 430.210 to make clear that OPM will enforce such compliance.

Additionally, this rule promotes fair and equitable treatment by incentivizing agencies to focus on individual performance that drives mission accomplishment and, therefore, rewards the highest performance. The current system suffers from leniency bias whereby supervisors arbitrarily issue inflated performance ratings to avoid confrontation, lack of support from management, or other factors that undermine the performance management evaluation process.²⁷ The current system also suffers from a

sustained lack of trust that employee performance is fairly evaluated and rewarded.²⁸ This rule realigns incentives away from 'defensive medicine' towards an approach where agencies are incentivized to clearly define performance standards, prioritize mission objectives, and accurately evaluate and reward employees' performance. See 5 U.S.C. 4302(c)(4) and (6). Employee performance ratings will still be based on individual merit and individual performance—not on irrelevant factors like race, political affiliation, or religion. Supervisors who assign ratings based on personal favoritism would continue to violate merit system principles regardless of the rating structure in place, while a standardized distribution would reinforce objective, performance-based differentiation. Thus, distinguishing employees based on relative performance does not conflict with the principle of fair and equitable treatment without regard to prohibited factors such as race, color, religion, sex, national origin, age, or political affiliation (5 U.S.C. 2301(b)(2)); rather, it reflects fair and equitable treatment by basing outcomes on job-related performance. Similarly, the prohibition on arbitrary action, personal favoritism, or coercion for partisan political purposes (5 U.S.C. 2301(b)(8)) is directed at improper motives and conduct, not at performance-based distinctions.

Commenter 0161 claimed that a standardized distribution specifically conflicts with the merit system principle at 5 U.S.C. 2301(b)(6), which requires that employees be retained on the basis of the adequacy of their performance. Similarly, commenters 0004 and 0248 voiced concern that adequate performers who happen to be part of high-performing teams would be particularly negatively affected by standardized distribution, presuming that supervisors may be required to rate a portion of their subordinates at Level 1 ("Unacceptable").

Any argument that this final rule negatively affects an employee's ability to be retained on the basis of the adequacy of their performance is unfounded. As previously mentioned, OPM intends that the standardized distribution will apply only to the assignment of the highest performance rating levels (Levels 4 and 5) and will not impose limitations on any of the levels at or below Level 3 ("Fully Successful"), such as a "quota" requiring the issuance of a certain amount of Level 1 ("Unacceptable")

ratings. Because Level 3 represents fully adequate performance and remains unrestricted, the application of a standardized distribution will not require an employee to receive lower than a Level 3 rating, invalidating concerns over associated performance-based demotion or removal. As such, OPM concludes that a standardized distribution does not interfere with an employee's ability to be retained on the basis of the adequacy of their performance and, therefore, does not conflict with 5 U.S.C. 2301(b)(6).

Several commenters, including 0159, 0206, 0553, and 0558, objected to the proposed rule's provision that excepted service employees appointed under Schedules C and G may be excluded from the standardized distribution requirements. Commenters assumed that the exclusion was designed to provide an unfair advantage to political appointees. For example, one commenter stated, "These employees, who are in the excepted service and often political or policy-making positions (90 FR 34753), would not be subject to rating caps that career non-SES employees must follow. This exemption creates two separate systems and gives these groups a built-in advantage in obtaining higher ratings and access to awards." Comment 0206.

OPM notes that, since the publication of the proposed rule, it exempted employees appointed under Schedules C and G from the provisions of subchapter I of chapter 43 of title 5, U.S.C.²⁹ Thus, such employees will no longer be required under OPM regulations to receive performance ratings. Despite this exclusion from chapter 43, Schedule C and G employees are still subject to the administrative freeze on discretionary awards, bonuses, and similar payments, such as performance awards and General Schedule quality step increases.³⁰ Thus, employees appointed under Schedules C and G will not be rewarded with higher performance ratings and receive greater awards.

Justification of Policy Change

Commenters 0225 and 0468 asserted that OPM's proposal to permit standardized distribution is inconsistent with OPM's prior regulatory determinations, including its 1979 and

²⁶ 5 U.S.C. 2301(b)(5).

²⁷ GAO, *Issues Related to Poor Performers in the Federal Workplace*, GAO-05-812R (Jun. 29, 2005), 19–21, <https://www.gao.gov/assets/gao-05-812r.pdf>. See also note 6 at v-vi.

²⁸ See note 12.

²⁹ Scott Kupor, Memorandum, "Exclusion of Schedule C and G General Schedule positions from Subchapter I of Chapter 43 of Title 5, United States Code: Performance Appraisal," April 28, 2026, <https://www.opm.gov/chcoc/latest-memos/exclusion-of-schedule-c-and-g-general-schedule-positions-from-subchapter-i-of-chapter-43-of-title-5-united-states-code-performance-appraisal.pdf>.

³⁰ *Id.*

1995 final rules in which OPM barred “preestablished distributions of expected levels of performance (such as a requirement to rate on a bell curve)” because such practices could “interfere with appraisal of actual performance,”³¹ and later concluded that forced distribution systems were “incompatible with effective performance management.”³²

Commenter 0615 argues that OPM did not consider OPM’s prior reasons for authorizing union grievances for performance ratings. These commenters argued that OPM has not adequately explained its departure from these prior positions or provided sufficient support to justify reversing them. They further contended that the proposal reflects a change in policy that is not accompanied by a reasoned explanation addressing OPM’s earlier findings and conclusions.

OPM respectfully disagrees that it has not articulated a sufficient reason for departing from its prior statements. As the Supreme Court held in *F.C.C. v. Fox Television Stations*, the APA requires, as relevant here, that OPM provide a reasoned explanation and show awareness that there is, in fact, a change in policy.³³ The Court also held that an agency’s reasoning need not prove to be a better solution than the status quo but rather that there are good reasons the agency believes support the change in policy.³⁴

The 1979 and 1995 rulemakings cited by commenters reflected OPM’s judgments at that time based on the record and policy considerations then before the agency. As noted above, one of the central objectives of the CSRA was to reform how Federal agencies accurately assess employee performance. Thus, it was entirely reasonable for OPM to pin its hopes on the CSRA delivering on its promise when issuing its performance appraisal regulations in 1979. And while OPM may have been persuaded in 1995 that forced distributions were incompatible with effective performance management, it is now clear to OPM that changes are necessary to address Congress’ concerns of effective performance management. OPM’s reevaluation of its performance appraisal system and program regulations is entirely reasonable in light of current conditions: longstanding concerns regarding the lack of

meaningful differentiation in performance ratings across the Federal workforce. OPM does not agree that the final rule is unsupported by evidence or rests solely on policy preference. As discussed in the proposed rule, OPM considered multiple sources of information in crafting its determination, including governmentwide data on rating distributions and employee perceptions of performance differentiation. During the comment period agencies informed OPM they supported the proposed changes and believed they would be beneficial. (See comments 0226, 0374, and 0375). OPM credits this agency feedback. OPM has also considered commenters’ arguments regarding prior policy, the available research, and potential alternatives.

Other commenters including 0101, 0157, 0161, 0521, 0553, and 0558, asserted that OPM failed to consider the potential for disparate impact on certain groups of employees. Commenters asserted that research on standardized distribution has demonstrated the potential for discriminatory effects and that OPM should have conducted a disparate impact analysis prior to proposing the rule. Commenter 0553 specifically cited *Griggs v. Duke Power Co.*, 401 U.S. 424 (1971), highlighting that “[f]ederal law prohibits employment practices with an unjustified disparate impact on protected classes.”

OPM considered commenters’ concerns regarding potential workforce impacts, including claims that standardized distribution could have differential effects across employee populations. However, the final rule establishes a facially neutral performance management framework that requires agencies to evaluate employees based on objective, job-related performance standards and does not direct or permit consideration of protected characteristics. Nothing in this final rule authorizes agencies to administer performance appraisal systems in a manner that violates Title VII, the Rehabilitation Act, the Age Discrimination in Employment Act, or any other applicable nondiscrimination requirement. The rule requires ratings to be based on job-related performance standards and objective performance evidence. OPM will consider compliance with legal requirements as part of its certification and oversight process, and may require corrective action where agency implementation is inconsistent with law, regulation, or OPM policy.

Consideration of Empirical Evidence

Although OPM has provided data demonstrating inflated performance ratings and cited empirical evidence in the proposed rule recognizing the potential benefits (and areas for caution) regarding standardized distribution, several commenters (e.g., Commenters 0005, 0082, 0101, 0225, 0468, and 0534) disagree with OPM’s interpretations or conclusions and also cite research that counterargues the benefits of forced distribution systems. For example, Commenter 0082 cited studies that found standardized distribution in a team setting significantly reduces knowledge sharing (e.g., Loberg, Nüesch & Foege³⁵) and that found standardized distribution may reduce citizenship behaviors and increase counterproductive performance over time (e.g., Moon, Scullen & Latham³⁶).

OPM reviewed the empirical studies and findings highlighted by the commenters. In the proposed rule, OPM noted that the literature on standardized distribution reflects a broad range of findings with respect to its efficacy and potential impacts on collaboration, morale, and perceptions of fairness. However, OPM does not agree that the existence of contrary or mixed research findings precludes adopting the changes in the final rule. The APA does not require agencies to resolve all disagreements in the academic literature or to demonstrate that a policy is supported by uniform empirical consensus. OPM has considered the evidence cited in the proposed rule and in comments and has determined that the amendments made in the final rule are necessary to address longstanding concerns regarding the lack of meaningful differentiation in performance ratings across the Federal workforce.

Assuming *arguendo* that the potential concerns identified in the research literature may arise to some extent or in some context(s), OPM has determined that the current degree of rating inflation has so egregiously undermined the credibility and accountability of performance appraisal systems that implementing a standardized

³⁵ Loberg, F., Nüesch, S., & Foege, J.N., *The Impact of Forced Distribution Rating Systems on Knowledge Sharing and Team Performance*, Journal of Management Control, Vol. 32, 395–423 (2021), available at <https://www.sciencedirect.com/science/article/pii/S0167268121001827>.

³⁶ Moon, H., Scullen, S.E., & Latham, G.P., *Precarious Curve Ahead: The Effects of Forced Distribution Rating Systems on Organizational Citizenship Behavior and Counterproductive Work Behavior*, Human Resource Management Review, Vol. 26, No. 2, 166–179 (2016), available at <https://www.sciencedirect.com/science/article/abs/pii/S1053482215300024>.

³¹ 44 FR 45587, 45590 (Aug. 3, 1979).

³² 60 FR 43936, 43936 (Aug. 23, 1995).

³³ *F.C.C. v. Fox Television Stations*, 556 U.S. 502, 515–16 (2009) (explaining the requirements under the APA that an agency provide a reasoned explanation when changing its position).

³⁴ *Id.*

distribution is the best alternative. Accordingly, OPM concludes that this final rule reflects a reasonable policy judgment, based on the administrative record as a whole, to improve the effectiveness and credibility of performance appraisal systems, notwithstanding some differing views expressed in the research literature.

Impact on Individual Employee Morale and Productivity

Several commenters asserted that implementing a standardized distribution would have demoralizing and demotivating effects on individual employees leading to reduced performance over time (e.g., Commenters 0002, 0003, 0004, 0013, 0037, 0105, 0159, 0294, and 0522). For instance, Commenter 0013 highlighted that the study by Berger, Harbring, and Sliwka cited in the proposed rule³⁷ found that introducing a standardized or quota-based rating system into a previously lenient rating culture can lead to an initial increase in productivity but then a drop-off. Other commenters argued that there are “more than 40 research studies” criticizing the use of “Forced Distribution Rating Systems (FDRS)” for their negative impacts on teamwork, trust, and long-term engagement. Other commenters (e.g., 0508 and 0549) asserted that the proposed rule will trigger a brain drain of technical talent.

OPM does not agree that the findings of Berger et al. (2010)³⁸ demonstrate that standardized distribution reduces employee motivation in the context of this final rule. To the extent the study identifies a decline in performance following the introduction of a standardized distribution, the authors attribute that effect to changes in employee expectations and reference points—specifically, where employees previously experienced more lenient ratings and higher bonus outcomes. Thus, the observed decline reflects a transitional adjustment in expectations rather than an inherent flaw in the structure of a differentiated rating system.

OPM acknowledges that some studies identify risks associated with rigid forced-ranking systems, including reduced collaboration, knowledge

sharing, and morale in certain settings. OPM gives those studies limited weight here because the final rule does not require a fixed percentage of employees to receive low ratings, does not require work-unit-level stack ranking, and preserves the requirement that ratings be based on job-related performance standards and actual performance evidence. In addition, each agency will have the latitude to determine how it may apply the distribution among components, grade levels, or supervisory status. This flexibility allows a governmentwide distribution to be equitable as well as tailored to ensure optimal performance within each agency. OPM also recognizes that even upper rating caps may affect employee expectations and workplace culture. For that reason, OPM will monitor implementation through the biennial certification process and may refine distribution criteria based on agency data, including evidence bearing on collaboration, mission performance, rating accuracy, and merit system compliance.

Even if OPM credited commenters’ citation to these various studies to support their criticisms of the rule, OPM concludes that the potential benefits of authorizing a standardized distribution of ratings outweigh the purported costs of overhauling a performance appraisal system that has failed over the last 40-plus years to enable Federal agencies to accurately assess the job performance of their employees, promote a culture of high performance, and hold employees accountable for poor performance. As Commenter 0450 points out, the private sector has not found a generally accepted or industry-specific solution to performance management and often uses different approaches in search of the same outcome. OPM believes that continuing down the same path as it has since the passage of the CSRA will only produce the same distrust and performance outcomes plaguing Federal agencies. OPM will closely evaluate implementation of this final rule through biennial certification and refine criteria as warranted by data and agency experience.

Impact on Teamwork and Cooperation

A number of commenters argued that standardized distribution will negatively affect teamwork, knowledge sharing, and cooperation (e.g., 0015, 0025, 0037, 0319, 0468, and 0524). Commenters 0015 and 0319 cited various studies on relative performance evaluation systems that report potential adverse effects on cooperation, including reduced knowledge sharing and increased competition among

employees rather than contribution to collective outcomes. These commenters contend that such systems are poorly suited to Federal work, which often depends on collaboration and shared mission performance.

OPM has considered the studies cited by commenters regarding the potential effects of forced distribution systems on teamwork, collaboration, and knowledge sharing. The cited research, including experimental research on relative performance evaluation systems, generally examines models that rely on strict rank ordering or zero-sum competition among employees. OPM does not agree that these findings are directly applicable to the approach adopted in the final rule.

The final rule does not establish a forced ranking model that must be inflexibly applied for all performance ratings and across every individual team. OPM intends only to require a limit on the upper rating levels, measured at the appropriate aggregate agency level, while continuing to require that all performance ratings be based on objective, job-related performance standards. The final rule does not require agencies to assign a fixed percentage of employees to the lowest rating level or to evaluate employees solely on a comparative basis. At this time, “OPM is not requiring or suggesting any forced ratings distributions at these levels.”³⁹ Accordingly, OPM concludes that the potential adverse effects identified in the cited research—such as reduced knowledge sharing, diminished collaboration, and increased competition—are not relevant to OPM’s approach as adopted in this final rule. Because agencies must continue to rate employees against established performance standards rather than against one another and are not required to place a fixed proportion of employees in the lowest rating category, the concerns associated with strict, zero-sum ranking systems do not apply.

In accordance with longstanding OPM and GAO guidance, individual performance appraisals should align with achievement of organizational and team goals.⁴⁰ OPM believes that by making competencies like teamwork, problem-solving, collaboration, and mentoring critical elements in individual performance plans, agencies

³⁷ Berger, J., Harbring, C., & Sliwka, D., *Performance Appraisals and the Impact of Forced Distribution: An Experimental Investigation*, IZA Discussion Paper No. 5020 (2010), available at <https://www.econstor.eu/bitstream/10419/36830/1/63078180X.pdf>.

³⁸ Some commenters cited to a 2013 study by the same authors. Berger, J., Harbring, C., & Sliwka, D., “Performance appraisals and the impact of forced distribution—an experimental investigation,” *Management Science*, 2013, v. 59(1).

³⁹ OPM, “Bad Management?!” available at: <https://www.opm.gov/news/secrets-of-opm/bad-management/>.

⁴⁰ GAO, *Creating a Clear Linkage between Individual Performance and Organizational Success*, GAO-03-488 (March 2003) (noting, as a key practice, “[a]llign[ing] individual performance expectations with organizational goals”).

will be able to maintain important collaborative and team-focused efforts and reward and incentivize employees to work together in support of team goals.

Concerns over teamwork and collaboration may also be ameliorated by agencies granting awards for team achievements and by applying the standardized distribution the appropriate aggregate agency level. OPM will not require agencies to apply standardized distribution at a level that is too small to support meaningful differentiation. OPM expects distribution requirements to be applied at an appropriate aggregate level and with exceptions or adjustments where warranted by mission, occupational structure, small population size, unusual rating-cycle circumstances, or other factors identified in OPM criteria. Agencies remain responsible for ensuring that ratings are based on job-related performance standards, actual performance evidence, and merit system principles, and for using awards and other forms of recognition in a way that supports collaboration and high performance.

Use in Private Industry

Commenters such as 0032, 0104, 0169, 0225, 0517, 0629 and others argued standardized distribution has been tested and abandoned by major private-sector organizations due to its negative effects, and that OPM has not explained why it would succeed in the Federal Government where it failed elsewhere. Commenter 0450 asserts that the proposed rule rests on an implied assumption that the private sector's preferred solution is forced rankings despite evidence that private sector organizations have long experimented with a variety of performance management approaches without converging on a universal or industry standard approach.

OPM notes that commenters' assertions that private sector organizations have largely abandoned standardized distribution of performance ratings are inaccurate. One recent report estimates that 30 percent of Fortune 500 companies use some form of standardized or forced distribution in their performance evaluations.⁴¹ OPM acknowledges that certain private-sector organizations have moved away from rigid "stack ranking" systems and that systematic review of studies on standardized distributions

(e.g., Wijayanti, Sholihin, Nahartyo (2024))⁴² report mixed findings regarding their effects. However, the evolution of private-sector performance management practices reflects not an abandonment of performance differentiation, but a shift away from inflexible quota systems—particularly those requiring assigning a fixed percentage of employees to the lowest rating categories. Many organizations continue to employ structured mechanisms to differentiate performance, such as placing constraints on the number of the highest ratings to ensure that ratings distributions reflect differences in contribution. Accordingly, the private-sector experience cited by commenters does not demonstrate that limiting the concentration of top performance ratings is inherently ineffective or inappropriate. Rather, it supports the conclusion that organizations continue to rely on structured differentiation to ensure that performance ratings meaningfully reflect differences in employee contributions and can be used to allocate rewards in a credible manner.

Further, even if private sector companies have abandoned standardized distributions of performance ratings, there are meaningful reasons to use standardized distributions in the specific context of the civil service. As OPM noted in its proposed rule, private sector companies do not operate under a statutory mandate requiring that they have performance appraisal systems that permit the accurate evaluation of performance. But, under 5 U.S.C. 4302(c)(1), non-SES employees operate under just such a statutory mandate. In addition, the Federal Government is entrusted with many critical responsibilities from veterans' health care to law enforcement to disaster relief to fighting pandemics. When employees in the Federal Government fail to perform at a high level, these crucial, life-or-death missions are compromised. Further, unlike the private sector, the Federal Government lacks a profit motive to ensure meaningful evaluations of its employees.

Commenter 0450 also raises concerns with OPM's focus on standardizing the distribution of performance ratings without addressing other challenges, such as supervisor quality, leniency bias, and the administrative burden of performance management. OPM agrees

with the commenter that these challenges must also be addressed to reform how the Federal Government approaches performance management. OPM recently published a notice of proposed rulemaking proposing to amend parts 432 and 752 to streamline the process for holding employees accountable for poor performance and misconduct.⁴³ In that rulemaking, OPM also proposes to amend part 412 to improve training on performance management and employee accountability. OPM believes these two rulemakings address some of the challenges raised by the commenter. This final rule also addresses, head-on, leniency bias in agencies where supervisors issue inflated performance ratings. The final rule authorizes a standardized distribution of ratings, which OPM intends to apply only to the highest rating levels, so as to require agencies to make meaningful distinctions in employee performance ratings. Between this final rule and the proposed rulemaking, OPM is taking much needed action to address the challenges of an antiquated, failing performance management system.

Interaction With Other Rulemakings

Commenters 0104, 0157, 0468, 0520, 0616 and others claim that OPM has not adequately addressed how this rule will interact with other pending rules. For instance, OPM is simultaneously pursuing a reduction in force rule that prioritizes ratings over tenure or length of service for determining retention standing. The commenters argue this makes ratings more consequential in the event of a reduction in force. The asserted interactions with other proposed rules are less clear, but the premise appears to be that the proposed rules collectively discourage submitting public comments by demoralizing potential commenters.

OPM is committed to significant Federal workforce reforms to promote a workplace culture of high performance and employee accountability. The fact that OPM has taken action to address long-standing issues is not based on a desire to impede the public from submitting comments but rather a desire to address longstanding performance management problems plaguing Federal agencies and employees.

OPM notes that commenters had an opportunity to submit comments during the public comment period for each of its rulemakings including the proposed rule on reductions in force, and OPM continues to receive higher comment response rates than it has historically

⁴¹ "Stack Ranking—All You Need to Know," Medium (April 3, 2020) <https://medium.com/@corvisio/stack-ranking-all-you-need-to-know-a5339c27ad83>.

⁴² Wijayanti, A., Sholihin, M., Nahartyo, E., & Supriyadi, S., *What do we know about the forced distribution system: A systematic literature review and opportunities for future research*, Management Review Quarterly (2024).

⁴³ 91 FR 40444 (July 2, 2026).

received. OPM will respond to relevant concerns if or when it issues a final rule in each rulemaking.

OPM observes, however, that performance ratings have long affected retention standing in a reduction in force. Such usage is consistent with 5 U.S.C. 3502(a), which requires that OPM issue regulations that “give due effect” to, *inter alia*, “performance ratings” in determining retention standing among competing employees in a reduction in force. *See Am. Fed’n of Gov’t Emps., AFL–CIO v. Off. of Pers. Mgmt.*, 821 F.2d 761, 765 (D.C. Cir. 1987). Further, 5 U.S.C. 4302(a)(3) contemplates using appraisal results as a basis for training, rewarding, reassigning, promoting, reducing in grade, retaining, and removing employees. Thus, the interaction between this rulemaking and OPM’s reduction in force (RIF) rulemaking does not represent an unexplained gap in OPM’s reasoning, but a longstanding feature of the Title 5 statutory scheme.

Further, this rule is complementary to OPM’s reduction in force proposal, as it seeks to ensure that performance appraisal systems accurately evaluate employee performance while better distinguishing levels of performance. A rule that makes performance matter more in RIF retention and a rule that seeks to improve the accuracy and differentiation of performance ratings address complementary parts of the same merit-based personnel system.

OPM appreciates all commenters submitting feedback to the proposed changes to authorize a standardized distribution of performance rating levels. While OPM acknowledges the significance of the change and for the reasons above, this final rule authorizes the use of a standardized distribution of performance rating levels. These amendments retain the longstanding requirement that a rating of record be based on the evaluation of job performance, while removing the categorical prohibition on methods that limit or require particular summary levels. Under the final rule, agencies are required to follow OPM guidance in implementing a standardized distribution of rating levels when issuing employee performance ratings. This change permits OPM to require and enforce an agency-wide and government-wide distribution of performance ratings among all covered non-SES employees.⁴⁴ The final rule

clarifies that OPM retains discretion to determine the scope and structure of any standardized distribution, including which rating levels are subject to distribution requirements. OPM intends that any standardized distribution will limit only the highest rating levels (*e.g.*, Levels 4 and 5), rather than prescribing limits for all rating levels.

Finally, the rule text at 5 CFR 430.208(d) expressly provides that comparing, categorizing, and ranking employees on the basis of their performance are practices that may be used for the purpose of assigning a summary level. This change is necessary to support implementation of a standardized distribution of performance ratings while preserving the principle that ratings must reflect employees’ demonstrated performance against established standards.

Together, these changes align the regulatory text with OPM’s determination that comparative evaluation mechanisms are necessary to improve differentiation in performance ratings and to address documented rating inflation across agencies.

Summary Levels and Patterns

As discussed in the proposed rule, OPM proposed to amend 5 CFR 430.208(e) to eliminate summary level patterns with a Level 2 summary level between Level 1 (“Unacceptable”) and Level 3 (“Fully Successful”), and summary level patterns in which Level 4 was the highest summary level. In effect, this change eliminates Level 2 as an available summary level and retains only those summary level patterns that meaningfully promote differentiation in performance. Agencies retain flexibility to select among the remaining available patterns consistent with the requirements of 5 CFR part 430, subpart B.

Several commenters (*e.g.*, Commenters 0002, 0004, 0027, 0031, 0036, and 0068) expressed concern that eliminating the Level 2 summary rating level would reduce the ability to distinguish among varying levels of performance and creates an “all-or-nothing” rating structure. Commenters argue that Level 2 provides an intermediate rating that allows supervisors to recognize gradations in performance between Level 1 and Level 3 and that removing this level could reduce the accuracy of performance evaluations.

OPM does not agree that eliminating the Level 2 summary rating level results in a meaningful loss of nuance in performance evaluations. The purpose of summary ratings is to provide a clear, meaningful assessment of whether an

employee meets established performance expectations. Arguments that eliminating the Level 2 summary rating will remove important granularity in rating employee performance are not supported given the extremely infrequent use of that rating level. OPM’s oversight of agency non-SES performance appraisal systems revealed that, for agencies using a five-level summary rating system, only 0.3 percent of non-SES employees were rated at Level 2 for the fiscal years 2022 to 2024.⁴⁵ The minimal use of a Level 2 rating indicates that agencies rarely rely on this summary level to distinguish performance. Supervisors remain responsible for identifying and addressing performance deficiencies at the element level, including providing feedback, documenting deficiencies, and taking appropriate corrective action where needed. Accordingly, OPM does not believe that eliminating the Level 2 rating will prevent agencies from identifying or addressing performance issues or providing employees with required opportunities to improve.

Commenters 0098 and 0206 asserted that a Level 2 rating serves as a mechanism for identifying employees whose performance requires improvement but is not “Unacceptable,” thereby allowing agencies to address marginal performance without resorting to adverse action. This commenter further stated that “Under 5 U.S.C. chapter 43 and established merit system principles, agencies must be able to identify and develop employees whose performance is inadequate but recoverable,” implying that there is a statutory basis for continued use of the Level 2 summary level.

OPM respectfully disagrees. Neither chapter 43 nor the merit system principles require use of a Level 2 summary level or any particular number or naming of summary levels. The statutory obligation to identify, assist, and, where necessary, take action with respect to employees whose performance does not meet required standards does not depend on the availability of a separate Level 2 summary rating. This is reflected in the fact that the currently existing rating patterns of A, B, C, and E do not provide for a Level 2 summary rating.⁴⁶ This rule does not create new ratings patterns but merely limits agency selections from among the existing ratings patterns.

The final rule eliminates Level 2 as a summary rating level. It does not prevent agencies from providing

⁴⁴ OPM notes that standardized distribution for senior professionals will be addressed under separate final rule. *See* Office of Personnel Management and Office of Management and Budget, *Managing Senior Professional Performance*, 91 FR 8763 (Feb. 24, 2026) (proposed rule).

⁴⁵ Non-SES/SP ratings data submitted by individual agencies.

⁴⁶ 5 CFR 430.208(d)(1).

feedback, coaching, or assistance before performance becomes unacceptable. When an employee's performance fails to meet established standards in one or more critical elements, agencies remain required to provide assistance consistent with 5 U.S.C. 4302(c)(5) and § 430.207(c), as redesignated.

Also, merit system principle #6 (5 U.S.C. 2301(b)(6)) states that "employees should be retained on the basis of the adequacy of their performance, inadequate performance should be corrected, and employees should be separated who cannot or will not improve their performance to meet required standards."⁴⁷ This principle conveys that an employee's retention should be based on the adequacy of performance and does not require the use of a Level 2 summary rating level between "Unacceptable" and "Fully Successful." Under the final rule, "adequate performance" is considered performance that meets the "Fully Successful" performance standards. As OPM explained in the proposed rule, any pattern of summary levels that has two levels below "Fully Successful" creates unnecessary complexity without meaningful distinction. The Merit Systems Protection Board (MSPB) also noted the failings of a Level 2 rating, noting it "is a difficult level of performance to define" because "it makes possible a situation that managers, employees, and members of the public may find intolerable: an employee who is not performing the job satisfactorily, yet cannot be removed for performance and who remains in the position at a full salary."⁴⁸

A few commenters (e.g., Commenters 0055, 0226, 0374, 0375, and 0621) expressed support for the proposed change, stating that reducing the number of summary rating levels would simplify performance appraisal systems, improve clarity, and help address rating inflation. Commenter 0621 further recommended that, if the Level 2 summary rating is eliminated, OPM should also eliminate the use of "non-critical elements" because current regulations preclude assigning a Level 1 ("Unacceptable") summary rating based on consideration of non-critical elements.⁴⁹

OPM agrees that eliminating redundant patterns of summary levels will improve clarity and promote more meaningful distinctions in performance

outcomes. A more streamlined rating framework reduces ambiguity and supports more consistent application of performance standards across organizations. However, OPM does not agree that elimination of the Level 2 summary rating level warrants the removal of non-critical elements. Non-critical elements serve an important and distinct function within performance appraisal systems for employees covered by this subpart. Specifically, they allow agencies to assess and communicate expectations related to important aspects of performance that, while not rising to the level of a critical element, contribute to overall effectiveness, teamwork, and mission accomplishment.

Lastly, a few commenters (e.g., 0022 and 0587) expressed concerns about the readiness of agencies to implement the reforms under the proposed rule. OPM considered these concerns and determined it appropriate to delay compliance with 5 CFR 430.208(e)(1) and (2) until January 1, 2027, as described in the effective date of the rule. This delay will allow agencies to complete Fiscal Year 2026 performance appraisals using all five summary level ratings, including Level 2, as appropriate. Under the final rule, agencies will move to new performance appraisal systems without a Level 2 rating beginning at the start of Fiscal Year 2027. Agencies currently using a summary level pattern with Level 2 will have sufficient time to complete the performance appraisal cycle for Fiscal Year 2026 including issuing ratings of record with the option of assigning a Level 2 rating. OPM believes this additional time will allow agencies to complete the transition to a new performance appraisal system including making appropriate changes to their human resources information systems, policies, and procedures.

After consideration of the comments, OPM has determined that eliminating summary level patterns that utilize a Level 2 summary level will promote clearer and more consistent application of performance standards. Under the final rule, there is only one summary rating level—Level 1 ("Unacceptable")—that represents when a non-SES employee's performance fails to meet the fully successful standards. This amendment aligns with OPM's statutory mandate to improve the accuracy and consistency of performance appraisal systems. By eliminating unnecessary patterns of summary levels, agencies will be better positioned to make clear and accurate distinctions between performance that is "Fully Successful" and

"Unacceptable." The rule also eliminates ambiguity with respect to "Outstanding" performance, which under the final rule is identified only by a Level 5 rating. Accordingly, OPM removes Patterns C, D, F, G, and H, retains Patterns A and B, and redesignates Pattern E as C.

Eliminate Assistance for Marginal Performance

Since OPM is eliminating the Level 2 summary rating, OPM is also removing the provision at 5 CFR 430.207(c), which required appraisal programs to provide assistance whenever performance is determined to be below "Fully Successful" or equivalent but above "Unacceptable."

A number of commenters, including 0062, 0068, 0206, 0240, 0285 and others, objected to removing this requirement because they perceive it as reducing the opportunity for employees to receive assistance if their performance drops below "Fully Successful." Relatedly, Commenter 0521 questioned how eliminating the provision for assistance under 5 CFR 430.207(c) complies with the statutory requirement that performance appraisal systems provide for "assisting employees in improving unacceptable performance." 5 U.S.C. 4302(c)(5).

OPM emphasizes that the regulation at 5 CFR 430.207(c) stated that appraisal programs should provide assistance whenever performance is determined to be below "Fully Successful" or equivalent but above "Unacceptable." Because the final rule eliminates the Level 2 summary level, there are no corresponding performance standards defining Level 2 performance. Therefore, any time an employee's performance is determined to be below "Fully Successful," agencies are required under 5 U.S.C. 4302(c)(5) to provide assistance to improve the unacceptable performance. Hence, opportunity for assistance is not diminished under the final rule. Additionally, employees who demonstrate unacceptable performance remain entitled to an opportunity to demonstrate acceptable performance before being reassigned, reduced in grade, or removed.⁵⁰

Furthermore, OPM's performance management guidance emphasizes the importance of communication between supervisors and employees, and OPM instructed agencies to establish policies that require more frequent check-ins to ensure supervisors are providing necessary performance-related feedback

⁴⁷ 5 U.S.C. 2301(b)(6).

⁴⁸ MSPB, *Determining an Acceptable Level of Competence for Step Increases* (Apr. 2021), https://www.mspb.gov/studies/researchbriefs/Determining_an_Acceptable_Level_of_Competence_for_Step_Increases_1823371.pdf.

⁴⁹ 5 CFR 430.208(b)(2).

⁵⁰ 5 U.S.C. 4302(c)(6) and 5 CFR 430.204(b)(1)(v).

to their subordinates.⁵¹ These resources for agencies, combined with the increased emphasis on frequent communication and performance feedback, address commenters' concerns regarding employees whose performance falls below "Fully Successful" during the appraisal period.

Limited Use of Pattern A

OPM determined that use of Pattern A ("pass/fail") is reasonable for a limited number of populations in which comparing, categorizing, and ranking of employees is impractical or impossible. In the final rule, Pattern A may only be used for seasonal employees, teachers, General Schedule grades 1–4, and Federal Wage System employees. This change promotes meaningful performance-based differentiation by ensuring the vast majority of employees covered by this rulemaking are subject to a summary level pattern other than Pattern A.

OPM received little feedback on this provision. Commenter 0206 argues that restricting Pattern A to the aforementioned groups creates structural inequity by making rating options tied to grade level as opposed to job characteristics. Commenter 0206 also asserts that employees subject to this rating pattern may have limited recognition and award opportunities. Other commenters asserted that the proposed rule would impose costly system changes.

OPM disagrees that this provision creates structural inequities based on grade level. OPM's intent is for agencies to utilize summary level patterns that, to the greatest extent possible, promote differentiation in performance, while reserving Pattern A for positions where a more detailed rating structure is not practicable. The regulatory framework is designed to provide flexibility while ensuring that performance appraisal systems are appropriate to the nature of the work being performed, and agencies retain discretion to design rating structures consistent with regulatory requirements and organizational needs. Limiting Pattern A to specified categories of employees reflects longstanding practice in which simplified rating structures have been appropriate for these positions. This does not preclude agencies from utilizing Patterns B or C for these groups of employees or from recognizing or rewarding high performance through the use of Pattern A.

OPM also acknowledges that this rule may require agencies to modify their human resources information systems to

accommodate the changes in this rule. However, commenters fail to provide any specific reason or argument that these changes may be costly. While OPM believes that agencies may incur some non-zero cost to adjust their information systems, such costs are de minimis. Even so, OPM views the costs of these changes as necessary to free agencies from the burden of a performance management appraisal system that has proven ineffective for the last 40-plus years. For these reasons, OPM is adopting in the final rule its proposal limiting the use of Pattern A.

Higher-Level Review and Approval

OPM proposed eliminating the requirement for mandatory higher-level review and approval of a Level 1 ("Unacceptable") rating of record to further streamline performance appraisal processes and eliminate procedural hurdles that impede accountability. Several commenters expressed concern that eliminating this requirement removes an important safeguard against error, inconsistency, and potential abuse (e.g., Commenters 0030, 0098, 0152, 0203, 0224, and 0289). Commenters argued that higher-level review provides a critical check on supervisory decisions and helps ensure that highly consequential Level 1 ratings are applied accurately and consistently.

OPM recognizes the importance of ensuring that all performance ratings, including Level 1 ratings, are applied accurately and consistently. However, OPM does not agree that mandatory higher-level review in all cases is necessary to achieve these objectives. As explained in the proposed rule, mandating an additional level of review and approval adds unnecessary complexity, delays corrective action, and may be redundant in streamlined agency structures. For example, where the rating official is already a senior leader or where the agency structure does not support additional layers of review, a mandatory higher-level review requirement may provide little incremental value. It is also important to note that this change does not prohibit higher-level review or approval of a Level 1 rating of record; it simply removes the regulatory mandate that such review and approval occur in every case. Agencies retain discretion to establish internal review processes where appropriate, including authorizing the use of the administrative grievance procedures to review performance ratings, and OPM expects agencies to maintain effective oversight of performance management practices. Further, OPM notes that Level 1 ratings

are extremely rare. Relevant data⁵² show that only approximately 0.1 percent of employees receive an "Unacceptable" rating. Given this very limited usage, removal of a mandatory review step for such ratings will not have a widespread impact on Federal employees. Instead, the change targets a narrow category of clearly defined poor performance while preserving all substantive statutory protections and allowing agencies to tailor their oversight mechanisms to their organizational structures.

Some commenters, including 0159, 0553, and 0558, asserted that eliminating the requirement for mandatory higher-level review of Level 1 ratings raises due process concerns because such ratings may ultimately serve as the basis for a performance improvement plan (PIP), demotion, or removal action under chapter 43 of title 5, United States Code. Commenter 0159 specifically cited *Cleveland Board of Education v. Loudermill*, 470 U.S. 532 (1985), arguing that higher-level review helps satisfy constitutional due process protections before an employee may be deprived of continued Federal employment.

OPM respectfully disagrees that eliminating mandatory higher-level review of a Level 1 rating of record deprives employees of constitutionally required due process protections. A rating of record, by itself, does not constitute an adverse action or independently deprive an employee of a protected property interest in continued employment. Commenters' reliance on *Loudermill* is misplaced. *Loudermill* does not establish that employees have a vested property interest in higher-level review of a performance rating. Rather, it addresses the minimum procedural protections required before a tenured public employee may be deprived of continued employment. A Level 1 summary rating by itself does not remove an employee from Federal service or otherwise deprive the employee of a property interest. Instead, it initiates a process governed by chapter 43 of title 5, United States Code,⁵³ and OPM's regulations at 5 CFR part 432, under which employees are provided notice of unacceptable performance and an opportunity to demonstrate acceptable performance before any performance-based action may be taken. If an employee fails to improve to the "Fully Successful" level, the agency must then provide notice of the proposed action and comply with applicable statutory and regulatory

⁵¹ See note 14.

⁵² See note 45.

⁵³ See 5 U.S.C. 4303.

procedures, including concurrence by a higher-level official before a removal or reduction in grade may occur.

Further, although the final rule removes the governmentwide requirement for mandatory higher-level review of all Level 1 ratings, agencies remain free to establish such review requirements through internal policy or procedure where appropriate. Employees also retain multiple avenues to raise concerns regarding allegedly arbitrary, retaliatory, or discriminatory ratings, including administrative grievances, whistleblower disclosures, prohibited personnel practice complaints, and equal employment opportunity complaints. Accordingly, OPM concludes that the final rule does not eliminate or otherwise conflict with constitutional due process requirements.

Commenter 0152 argued that higher level review is necessary because “performance issues are a result of systemic failures, such as inadequate training or a lack of clear guidance, which cannot be solved by penalizing the employee.”

OPM disagrees that performance issues are generally the result only of systemic failures. While OPM acknowledges that there are several factors that play a role in whether an employee is successful in his or her position, OPM is unpersuaded by Commenter 0152’s broad, unsupported assertion that poor performance is primarily attributable to such factors. That is not to say OPM is not addressing systemic issues that may affect performance management outcomes. As noted above, OPM is proposing regulatory reforms intended to improve how agencies recognize excellence and address poor performance. In addition, OPM has taken separate action to improve hiring processes and outcomes⁵⁴ and to hold supervisors accountable for addressing poor performance within their organizations.⁵⁵ These efforts complement, rather than substitute for, agency responsibility to evaluate and address individual performance consistent with statutory and regulatory requirements.

OPM has carefully considered these comments and concludes that eliminating the requirement for mandatory higher-level review of Level 1 ratings does not impede due process, nor will it reduce fairness or accuracy

in performance evaluations. The final rule provides agencies with appropriate flexibility to manage performance appraisal processes, including the discretion to provide higher-level reviews of any rating level through internal policy. Therefore, OPM is not adopting commenters’ recommendations to retain the mandatory higher-level review and approval of Level 1 ratings of record.

Eliminate Negotiated Grievance Procedures

OPM proposed amending 5 CFR 430.208 to clarify the finality of a rating of record and to establish explicit limitations on the mechanisms by which such ratings may be challenged. Specifically, the amendment provides that a rating of record, once issued with all appropriate reviews and approvals, constitutes the agency’s final determination of an employee’s performance for the appraisal period, subject only to those reconsideration processes expressly provided by regulation. As a result, ratings of record are not subject to negotiated grievance procedures or arbitration under 5 U.S.C. 7121, regardless of collective bargaining coverage. This change represents a departure from prior practice, under which a rating of record could, in certain circumstances, be modified as a result of a grievance, complaint, or other formal proceeding. OPM notes, however, that the revision to 5 CFR 430.208 does not preclude the use of negotiated grievance procedures established under 5 U.S.C. 7121 to challenge a rating of record in all cases. Where a collective bargaining agreement contains a provision that permits a bargaining unit employee to grieve a rating of record and the agreement is in effect before the date this rule is prescribed, such a grievance will continue up until the term of the agreement expires.⁵⁶ Once the term of the agreement expires, grievances over ratings of record will no longer be subject to any negotiated grievance procedures or arbitration under 5 U.S.C. 7121.

Several commenters (e.g., Commenters 0161, 0165, 0569, and 0421) asserted that OPM lacks statutory authority to prohibit employees from contesting ratings of record through negotiated grievance procedures. Commenters argued that under the Federal Labor Relations Authority’s decision in *Nat’l Treasury Emps. Union and Internal Revenue Serv.*, 31 FLRA 181 (1988) (*NTEU*), OPM cannot prohibit grievances under a negotiated

grievance procedure through a governmentwide regulation unless expressly authorized by Congress under 5 U.S.C. 7121, and that ratings of record are not among the matters excluded in section 7121(c).

OPM disagrees that the FLRA’s decision is controlling as it is no longer good case law. In *NTEU*, the FLRA held that OPM’s governmentwide regulation prohibiting grievances over non-selections for promotion was inconsistent with 5 U.S.C. 7121. The FLRA’s holding relied on an earlier D.C. Circuit’s opinion in *EEOC v. FLRA*, 744 F.2d 842 (D.C. Cir. 1984) (*EEOC*) where that court stated that there is no evidence that Congress intended for governmentwide regulations to limit the scope of the negotiated grievance procedure under section 7121.⁵⁷ Five years after *NTEU*, the D.C. Circuit revisited *EEOC* in *Dep’t of Treasury v. FLRA*, 996 F.2d 1246 (D.C. Cir. 1993) (*Treasury*) to determine whether a governmentwide regulation barring grievances is consistent with section 7121.⁵⁸ The D.C. Circuit overturned *EEOC* and held that under 5 U.S.C. 7117(a)(1) an agency may “pull a subject out of the bargaining process by issuing a government-wide rule that creates a regime inconsistent with bargaining.”⁵⁹

Consistent with the D.C. Circuit’s opinion in *Treasury*, OPM is prohibiting labor unions from negotiating and agencies agreeing to a proposal that authorizes grievances over ratings of record under section 7121. In doing so, OPM notes that performance ratings, in and of themselves, do not constitute adverse actions subject to independent statutory appeal rights. To the extent a rating of record is used as the basis for a subsequent personnel action that is otherwise appealable or able to be grieved under applicable law, employees retain any applicable procedural rights attached to that action. However, the rating of record itself will not be subject to challenge through negotiated grievance procedures. Accordingly, OPM concludes that the final rule establishes reforms consistent with 5 U.S.C. 7121 and falls within OPM’s statutory authority to regulate performance appraisal systems under chapter 43.

Several commenters (e.g., Commenters 0002, 0044, 0053, 0206, 0288, 0377, 0418, and 0616) asserted that eliminating the opportunity to challenge performance ratings through negotiated grievance procedures

⁵⁴ OPM, Memorandum, “Merit Hiring Plan,” May 29, 2025, <https://www.opm.gov/chcoc/transmittals/2025/Merit%20Hiring%20Plan%2025-292025%20FINAL.pdf>.

⁵⁵ See note 14.

⁵⁶ See 5 U.S.C. 7116(a)(7).

⁵⁷ *NTEU* at 200 (citing *EEOC v. FLRA*, 744 F.2d 842, 851 (DC 1984)).

⁵⁸ *Treasury* at 1251–53.

⁵⁹ *Id.*

undermines due process protections. These commenters argued that grievance procedures provide employees with a meaningful opportunity to contest inaccurate or unfair ratings and serve as an important safeguard against arbitrary decision-making. Commenter 0377 asserted that prohibiting labor union grievances over ratings of record is contrary to law under *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532 (1985).

OPM does not agree that the final rule eliminates any required due process protections or is inconsistent with *Loudermill*. *Loudermill* addresses the procedural protections required when the government seeks to deprive an employee of a protected property interest and requires notice and an opportunity to respond prior to such deprivation. Ratings of record, standing alone, do not constitute an adverse action or a deprivation of a property interest and therefore do not independently trigger the due process protections described in *Loudermill*. Moreover, where a performance rating forms the basis for a subsequent performance-based or adverse action under 5 U.S.C. chapters 43 or 75, respectively, employees retain all applicable procedural protections provided by Congress. This includes entitlement to advance notice, an opportunity to respond, a right to representation, and a decision taking into account the employee's response. Most employees also benefit from the ability to appeal such actions to the Merit Systems Protection Board. The proposed rule does not alter these protections. Further, employees continue to enjoy protections against prohibited personnel practices under 5 U.S.C. 2302 including filing complaints with the Office of Special Counsel. Employees also retain protections under the many anti-discrimination laws enforced by the Equal Employment Opportunity Commission. Taken together, these statutory protections ensure that eliminating challenges to ratings through negotiated grievance procedures does not undermine due process or reduce the integrity of the performance appraisal process.

Other commenters, including 0003, 0007, 0031, 0059, 0206, 0288, 0498, and 0629, claim that challenging ratings through negotiated grievance procedures is a necessary check on supervisory inaccuracy and bias, including favoritism, retaliation, or arbitrary decision-making. Others characterize the procedures as necessary for ensuring fair and equitable treatment required by merit system principles

(e.g., Commenters 0053, 0288, and 0319).

OPM acknowledges the importance of fair and accurate performance appraisals but disagrees that negotiated grievance procedures are an appropriate or necessary mechanism to achieve that objective. As OPM explained in the proposed rule, grievance arbitrators are poorly positioned to substitute their judgment for that of supervisors in these areas, particularly where the dispute centers on the relative level of performance (e.g., “Fully Successful” versus “Outstanding”) rather than a clear procedural or legal violation. These arbitrators are particularly ill-equipped to assess performance ratings assigned under a standardized distribution, as they generally review an individual record and may not have access to the full agencywide rating-distribution context.

OPM notes that grievances over ratings have not been limited to correcting clearly erroneous or unjustified low ratings. Instead, cases show that negotiated grievance procedures have frequently been used to contest ratings that are already at or above the “Fully Successful” level, with the objective of obtaining the highest possible rating.⁶⁰ Such cases demonstrate the propensity to use grievance procedures not as a safeguard against improper low ratings, but as a mechanism to relitigate performance determinations. This prospect creates incentives for supervisors to avoid assigning lower ratings that may be subject to challenge, especially those that could result in adverse action. In this regard, the current system has tended to bias ratings upward, not downward, but bias in any direction nonetheless undermines the meaningful differentiation of performance that chapter 43 is intended to achieve.

Lastly, as discussed earlier, existing statutory safeguards remain in place to ensure fair and equitable treatment and address concerns regarding bias, retaliation, or improper conduct. Employees retain many paths to ensure they receive a fair assessment of their performance. Further, OPM is amending § 430.209 and § 430.210 to expressly require agencies to administer their performance appraisal systems in accordance with the merit system principles set forth in 5 U.S.C. 2301 and that OPM will take effective action to correct any violations. OPM is revising

the Authority citation for part 430 to reflect this addition.

After careful consideration of the comments, OPM has determined that excluding performance ratings from negotiated grievance procedures is appropriate to promote consistency, accountability, and integrity in performance appraisal systems. OPM has considered commenters' statutory and policy concerns but concludes that the final rule reflects a reasonable and lawful exercise of its authority to regulate performance appraisal systems on a governmentwide basis. OPM concludes that the provision preserves necessary due process safeguards against supervisory bias; employees retain all procedural protections required by law in connection with adverse actions; and agencies maintain internal review mechanisms to ensure the accuracy and consistency of performance evaluations. OPM further finds that the existing grievance framework has contributed to longstanding concerns regarding rating inflation, gives arbitrators with little experience in agency operations the final word on performance ratings, and has frequently been used to challenge ratings at or above the “Fully Successful” level, rather than to address clear violations of law or regulation. By clarifying the finality of ratings of record and limiting their review to appropriate internal processes, the final rule promotes supervisory accountability, supports more meaningful differentiation of performance, and aligns performance management practices with the statutory framework under chapter 43. Accordingly, OPM adopts the amendments to § 430.208 as proposed.

Supervisory Critical Element

As OPM explained in the proposed rule, supervisors are responsible for accurately assessing employee performance and play a critical role in ensuring the integrity of agency performance management systems. However, in the absence of clearly defined and consistently applied expectations for supervisory performance, agencies may lack an effective mechanism to evaluate how well supervisors carry out these responsibilities. This gap can contribute to inconsistent application of performance standards, diminished accountability, and, in some cases, inflated ratings or insufficient action to address poor performance. A supervisory critical element provides a clear, formal basis for evaluating supervisory performance management responsibilities, including setting

⁶⁰ See, e.g., *Def. Logistics Ag. and AFGE Local 987*, 71 FLRA 1029 (2020); *Farm Serv. Agency and AFGE Local 3354*, 56 FLRA 679 (2000); *Dep't of Veterans Affairs and NAGE Local R4-78*, 47 FLRA 797 (1993).

expectations, providing feedback, and addressing performance deficiencies. Establishing such an element ensures that supervisory performance is assessed against defined criteria and reinforces the expectation that supervisors are accountable for effective performance management practices. Accordingly, to strengthen accountability and promote more consistent and accurate performance evaluations, OPM proposed amending 5 CFR 430.206(b) to require that a supervisory critical element be included in the performance plans of all supervisors covered under 5 CFR part 430, subpart B.

Several commenters, including 0002 and 0044, expressed concern that the requirement could impose unrealistic or overly burdensome expectations on supervisors, noting that supervisors already face significant administrative and operational demands. Commenter 0044 further noted that mandating a supervisory critical element across all agencies may not fully reflect the diversity of supervisory roles within the Federal Government and may reduce agencies' flexibility to tailor performance plans to mission-specific responsibilities.

Respectfully, OPM disagrees with commenters' concerns. In 2025, OPM published guidance consistent with the President's commitment to transform the Federal bureaucracy, including promoting a high-performance Federal workplace culture.⁶¹ This guidance required agencies to take steps to improve their supervisory, managerial, and executive corps, including mandatory performance management training and tying certain supervisor and managerial performance plans to driving a culture of accountability. These requirements are not burdensome. Supervisors, managers, and executives are already subject to training requirements under OPM regulations.⁶² Moreover, it is a core competency of all Federal supervisors and managers, regardless of technical specialization or the uniqueness of positions, to hold employees accountable.⁶³ OPM does not view linking this core competency to performance plans as unduly burdensome as these expectations have always been critical to their positions. Nonetheless, OPM will be mindful of

the commenters' concerns if and when it issues new or revised guidance.

Commenter 0161 expressed support, in principle, for requiring a supervisory critical element but also voiced concern that, if supervisors are evaluated under the new critical element based on the distribution of ratings they assign, it could create an incentive for supervisors to issue lower ratings to their subordinates, regardless of the subordinates' actual level of performance.

OPM appreciates the commenter's concern and confirms that the performance of non-SES supervisors will not be evaluated based on the ratings they issue to their subordinates. OPM issued performance management guidance⁶⁴ containing the verbatim language of the new supervisory critical element titled, "Holding Employees Accountable," and its associated performance standards. The critical element focuses on process-based actions such as modeling self-accountability, holding subordinates accountable, rewarding excellent performance, addressing poor performance in a timely manner, and taking appropriate action when employees report concerns of illegal conduct or waste, fraud, or abuse. It does not involve evaluating supervisors based on the ratings distribution of their subordinates. OPM intends for agencies to apply the standardized distribution requirements at the agency or department level as opposed to the work unit level. As such, ratings issued by an individual supervisor will not need to strictly adhere to the overall rating limits that apply to the agency. OPM also notes that it is possible the commenter conflated the supervisory critical element requirement with an SES-specific requirement in the same guidance—that senior executives who supervise 10 or more subordinate SES must describe, in their annual performance narrative, the rating distribution of subordinate SES and how that distribution reflects the performance of their organization. That requirement does not apply to non-SES supervisors.

Commenter 0068 and others suggested that improvements to performance management should focus on enhanced training, clearer standards, and improved oversight, rather than the addition of new regulatory requirements. OPM agrees that improving performance management requires a multifaceted approach. To that end, as discussed above, OPM has proposed changes to other regulations

that improve training for supervisory, managerial, and executive leaders. OPM also provided free training resources⁶⁵ to assist agencies and supervisors in effectively carrying out performance management responsibilities, including methods for identifying and addressing poor performance and how to develop and discuss relevant performance goals and objectives with employees. In addition, OPM encourages agencies to provide supervisors with appropriate training and resources to carry out their responsibilities.

After careful consideration of the comments, OPM has determined that requiring a supervisory critical element is an appropriate and necessary component of a modern performance management system. The requirement promotes accountability, reinforces effective supervisory practices, and supports fair and consistent evaluation of supervisory responsibilities across the Federal workforce. Therefore, OPM is amending 5 CFR 430.206(b) as proposed, by adding a new subparagraph (9), requiring that a supervisory critical element be included in the performance plans of all supervisors covered under 5 CFR part 430, subpart B.

Biennial Appraisal System Certifications

In the proposed rule, OPM proposed amending 5 CFR 430.210(b) to establish a requirement that agency performance appraisal system(s) and program(s) be evaluated and certified by OPM biennially. The purpose of this requirement is to ensure that agency appraisal systems and programs are implemented in a manner consistent with statutory and regulatory requirements, as well as OPM performance management guidance. This change supports OPM's broader objective of strengthening accountability and consistency across agencies, which is particularly important given changes in this final rule, including the provision authorizing OPM to establish and maintain a standardized distribution of rating levels.

Commenter 0002 objected to the proposal, arguing that "[a]gencies already operate under strict oversight." Under 5 U.S.C. 4304(b), OPM is required to review each performance appraisal system developed by an agency and to direct agencies to make appropriate corrections where such systems do not meet statutory

⁶¹ See note 14.

⁶² 5 CFR part 412, subpart A.

⁶³ <https://www.opm.gov/policy-data-oversight/classification-qualifications/general-schedule-qualification-standards/specialty-areas/supervisory-guide/>.

⁶⁴ See note 14.

⁶⁵ OPM, *New Governmentwide Supervisory Training* (Dec. 3, 2025), <https://www.opm.gov/chcoc/published-memos/new-governmentwide-supervisory-training.pdf>.

requirements. In practice, OPM fulfills this responsibility by reviewing and approving newly developed appraisal systems and requiring reapproval when agencies make substantive changes. However, where appraisal systems remain in place for extended periods without modification, OPM may have limited opportunity to evaluate how those systems are being applied and whether they continue to meet statutory and regulatory requirements. The biennial review and certification requirement addresses this gap by providing for regular, structured oversight of both the design and application of agency appraisal systems.

OPM sought this certification requirement to improve its oversight of agencies' performance appraisal systems in response to surveys showing long-held skepticism among Federal employees that current performance appraisal systems meaningfully differentiate between levels of performance.⁶⁶ Coupled with ratings distribution data that consistently show dramatically inflated performance ratings,⁶⁷ these trends demonstrate that performance management systems covered by 5 CFR part 430, subpart B, are not functioning as effective instruments for performance differentiation, accountability, or workforce development. As such, additional oversight is warranted.

Commenters 0002, 0041, 0042, 0044, 0098, 0130, 0253, 0398, 0403, and 0448 argue that this requirement would impose significant administrative burden on agencies without clear benefits.

OPM acknowledges these concerns. While OPM intends for the certification requirement to build upon existing agency processes and oversight mechanisms, rather than create duplicative or unnecessarily burdensome reporting requirements, OPM agrees that there could be a substantial administrative burden if the biennial review and certification process involves evaluating all agency appraisal systems and corresponding appraisal programs. Agencies may have several appraisal programs established under a single appraisal system. OPM notes that an "appraisal system" is the agency's framework of policies and parameters (*i.e.*, guidelines, boundaries, limits) for the administration of performance appraisal programs, and an "appraisal program" is the specific procedures and requirements established under the policies and parameters of an agency appraisal

system. Historically, there has been no requirement for OPM to review or approve agency appraisal programs, and OPM is confident that sufficient oversight can be achieved solely through evaluating agencies' application of their performance appraisal systems. Therefore, OPM is finalizing the biennial review and certification requirements in 5 CFR 430.210(b) with an amendment to the proposed language to only require recertification of appraisal systems and to remove agency performance appraisal programs from the requirement.

Commenters 0206, 0421, and 0514 voiced concern over the provision in 5 CFR 430.210 authorizing OPM to recommend an agency's aggregate awards spending be reduced based on an unfavorable certification result. Commenter 0206 specifically stated it "risks penalizing employees for systemic issues related to agency leadership, training, or implementation—factors outside individual employee control."

OPM recognizes that agency leadership is primarily responsible for ensuring compliance and that any consequences of an unfavorable certification determination may affect employees. However, in exercising its review and certification authority, OPM will ensure that any recommendations or actions resulting from an unfavorable certification determination are based on data-driven criteria that OPM is required to issue. The intent is to improve system integrity, not to impose punitive measures. OPM further notes that appraisal system certification has been a longstanding requirement for SES and SP appraisal systems and that agencies have successfully implemented those requirements for many years. Furthermore, the outcomes associated with SES and SP certification determinations are significantly more consequential, as those certifications are directly tied to statutory pay limitations. Unlike SES/SP certification, the non-SES/SP certification process created by this rule does not itself impose statutory pay caps or alter individual pay entitlements. OPM may, however, recommend prospective aggregate awards spending limitations to OMB.

Conversely, Commenters 0013 and 0225 provided general support for the certification requirement or acknowledged that it could enhance consistency, oversight, and accountability across agencies, particularly when considered alongside other proposed reforms. Commenter 0013 remarked that the proposed rule improves OPM's oversight role. OPM agrees and concludes that enhanced

oversight through a required biennial review and certification process is an appropriate mechanism for improving rigor and consistency of performance management across the Federal Government. Accordingly, OPM is adopting the proposed amendment to 5 CFR 430.210 with the modification described above.

Conforming Amendments

As proposed, OPM is making conforming changes to 5 CFR parts 351 and 537 to adjust cross-references. In an unrelated rulemaking, OPM has proposed revisions to the reduction in force regulations found in 5 CFR part 351. 91 FR 10904 (March 5, 2026). If that rulemaking is finalized, these conforming changes would be incorporated into that revised text.

Finally, OPM is also making other changes to 5 CFR part 430, subpart B in this final rule. OPM is correcting references to out-of-date operating manuals at § 430.209(b) and (e). In response to comments asserting that standardized distribution could undermine merit-system principles, OPM is clarifying at 5 CFR 430.209(g) and 430.210(c) that agency appraisal systems and appraisal programs must be administered consistent with the merit system principles set forth under 5 U.S.C. 2301 and that OPM may require corrective action where systems fail to meet applicable legal and regulatory requirements.

Expected Impact of This Rulemaking

A. Statement of Need

OPM is issuing this rule pursuant to its authority to issue regulations governing performance appraisals for non-SES employees in subchapter I of chapter 43 of title 5, United States Code. As discussed in the Background, the purpose of this rule is to modernize and strengthen the performance management framework for non-SES employees under 5 CFR part 430, subpart B. The current regulatory structure has remained largely unchanged for decades. Therefore, it no longer reflects the operational realities or accountability standards necessary for today's Federal workforce. This has led to persistent issues going unaddressed—including inflated performance ratings, limited differentiation between successful and unsuccessful performance, and uneven agency compliance with statutory performance appraisal requirements. Despite OPM's non-regulatory efforts to improve rigor in the performance management process, ratings inflation remains particularly acute, leading OPM

⁶⁶ See note 12.

⁶⁷ See notes 9 and 45.

to conclude that comprehensive regulatory reform is needed. By providing for the establishment of a standardized distribution of some or all rating levels, streamlining certain appraisal processes to strengthen accountability for poor performance, and requiring OPM to biennially review and certify agency non-SES appraisal systems, this rule is designed to promote increased accuracy and credibility in performance appraisals.

B. Impact

OPM is making these revisions to increase the efficiency and effectiveness of performance management for employees that make up the biggest percentage of all Federal employees: non-SES employees. Removing the regulatory prohibition on standardized distribution and authorizing OPM to establish and maintain a standardized distribution of some or all rating levels is expected to produce a more normalized distribution of performance ratings. These changes will require agencies to refocus efforts on ensuring that there are meaningful distinctions in non-SES performance ratings.

OPM expects that the implementation of a standardized distribution, in conjunction with the provisions in this rule that eliminate barriers to accountability, will incentivize improved performance of non-SES employees, who will no longer expect to receive the highest ratings without demonstrating superior performance relative to the other non-SES employees in their agency. Those non-SES employees who continue to perform at a level that is less than fully successful will be more swiftly held accountable. Over time, these improvements are expected to result in higher-performing organizations, more responsive public service, and renewed public trust in the integrity and effectiveness of the Federal workforce.

OPM's biennial evaluation and certification of agency appraisal systems will serve as a structured mechanism for agencies to demonstrate compliance, identify deficiencies, and receive technical assistance from OPM regarding the operation and application of their performance appraisal system(s). OPM expects that this process will enhance interagency comparability and help ensure that non-SES appraisal systems continue to conform with applicable law, regulation, and OPM policy.

Reliance Interests

In addition to the concerns identified above, some commenters expressed concern with the impacts of the

proposed rule. Commenter 0260 asked OPM to consider the impacts of the proposed rule on "technical professionals, workforce quality, and the government's ability to recruit and retain qualified engineers and other specialists." The commenter, however, did not offer more to explain how the proposed rule would impact these issues. Other commenters similarly raised issues of productivity, retention, and morale. OPM believes that the final rule will remedy the problem of inflation of performance ratings and, therefore, restore integrity and confidence in the performance management appraisal process. This, in turn, is expected to incentivize employees to focus on delivering mission-driven results and to enable agencies to better distinguish and reward high performance. As a result, the Federal workforce, including technical professionals, should see better alignment between performance expectations and mission priorities and more appropriate recognition for demonstrated performance. OPM does not foresee an impact on recruitment but acknowledges that those employees who have grown accustomed to inflated performance ratings may receive lower ratings and fewer awards. OPM views the final rule as realigning incentives so that such employees will work closely with their supervisors to understand performance expectations and identify additional ways to contribute to their agencies' success. Where employees are dissatisfied with these changes, including expectations about their individual performance, OPM anticipates some may choose to leave their current agencies for another or Federal service altogether. OPM believes it is far too speculative to estimate how many employees may leave Federal service or how that might impact agencies.

Some commenters raised concerns with the impact of the rule on collective bargaining agreements. One commenter noted that OPM explained in the preamble how a final rule would interact with collective bargaining agreements but objected that this explanation appeared in a footnote rather than in regulatory text. As discussed in the proposed rule, OPM acknowledges that a collective bargaining agreement may contain provisions that are in effect before the date the final rule is prescribed.⁶⁸ If such a conflict arises, the provisions in the collective bargaining agreement would control until the term of the agreement expires. OPM does not agree

with the notion that this principle of Federal labor law should be codified in the regulatory text of the final rule. There is adequate and well-established FLRA case law that provides guidance to agencies on how to apply new governmentwide regulations.

OPM acknowledges, however, that any pending grievances or arbitrations concerning ratings of record that continue past the term of a collective bargaining agreement authorizing grievances over ratings of record may be affected by the final rule. In these situations, OPM expects agencies to assert that such grievances are no longer arbitrable and that any arbitrator therefore lacks authority to adjudicate the dispute. Agencies are encouraged, where appropriate, to convert these grievances to administrative grievances to the extent they are consistent with their internal administrative grievance policies. OPM also reminds labor unions and agencies that they may engage in collective bargaining, as appropriate, in anticipation of these changes to provide greater certainty to their employees.

C. Costs

This final rule affects most Federal agencies—ranging from cabinet-level departments to small independent agencies—that have employees covered under 5 CFR part 430, subpart B. Individuals employed by these agencies will spend time updating their performance appraisal system(s), program(s), policies, and plans to prepare for implementation before the end of Fiscal Year 2026. Typically, an agency's human resources staff are responsible for these tasks. Therefore, for this cost analysis, the assumed average salary rate of Federal employees performing this work will be the rate in 2026 for GS-14, step 5, in the Washington, DC, locality pay table (\$163,104 annual locality rate and \$78.15 hourly locality rate). We assume the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate, resulting in an assumed labor cost of \$156.30 per hour. We estimate that, in the first year following publication of the final rule, this will require an average of 22,500 hours of work governmentwide, resulting in estimated costs of about \$23,445 per agency and about \$3,516,750 governmentwide. Additionally, USAPerformance, an IT tool used by many agencies to service their performance management systems, will be updated to reflect the removal of summary level patterns where Level 4 is the highest summary level or that include a Level 2 summary level. We

⁶⁸ 5 U.S.C. 7116(a)(7).

estimate that this will require 400 hours of work at the rate of \$390 per hour, resulting in an estimated cost of \$156,000. There are also approximately 48 other agency-specific IT systems used for performance management requiring the same update. OPM estimates the cost to each agency will be similar to that of USAPerformance, resulting in an estimated \$7,488,000 in total costs to update these other systems.

To comply with the regulatory changes in this rule, OPM must evaluate and certify the operation and application of agency performance appraisal system(s) and program(s) on a biennial basis. We estimate that, in the first year following publication of the final rule, this will require 150 hours of work by OPM employees with an average hourly cost of \$156.30. This work will result in estimated costs in that first year of implementation of about \$23,445.

OPM anticipates that the regulatory changes in this rule will not substantially increase the ongoing administrative costs to agencies (including any administrative costs associated with OPM's biennial review of agency appraisal system(s)) because the regulation provides cost-saving provisions such as eliminating mandatory review of Level 1 ("Unacceptable") ratings of record and eliminating challenges to ratings of record through the grievance provisions of 5 U.S.C. 7121, thereby eliminating those associated labor costs.

A small number of commenters raised concerns regarding the potential costs associated with implementing the rule. Commenter 0161 asserted that the rule does not account for increased workload associated with performance improvement plans and adverse actions, while Commenter 0225 suggested that the changes could lead to increased costs related to employment disputes, including adverse action and EEO litigation.

OPM does not agree that the final rule will result in material increases in the types of costs identified by the commenters. With respect to performance improvement plans and adverse actions, these processes are already required under existing statutory frameworks and are part of routine performance management responsibilities. The final rule does not impose new requirements in these areas but is intended to improve the accuracy and credibility of performance ratings, which may reduce the need for corrective actions driven by unclear or inflated evaluations. With respect to potential litigation-related costs, OPM

notes that the final rule does not alter the legal standards governing adverse actions or EEO claims, nor does it create new bases for challenge. Any such costs are contingent on agency-specific implementation and compliance with existing legal requirements, rather than the structure of the rule itself. Nor do commenters identify or explain how litigation costs may increase as a result of the proposed rule. Accordingly, OPM concludes that the cost estimates provided in the proposed rule do not need to be amended.

D. Benefits

Since 5 CFR part 430, subpart B, covers positions that include GS and prevailing rate employees, its impact is governmentwide. Non-SES employees are the backbone of the Federal Government and are, therefore, critical to the operation of an effective and efficient government. The application of a standardized distribution within the non-SES employee performance appraisal system will reinforce the understanding that success as a Federal employee is aligned to the appropriate rating at the fully successful level. By establishing a limit on the number of non-SES employees who can receive a rating above the fully successful level, there will be a clear distinction of the highest performers across an agency and the Federal Government. Agencies will no longer be able to rate the vast majority of their non-SES employees at the highest performance ratings, thus encouraging employees to strive for increased levels of performance and ultimately provide better results for the Government and the American public.

The removal of summary level patterns that include a "Level 2" also simplifies and increases the rating accuracy of non-SES employees. A "Level 2" rating is rarely used and can be confusing because it creates a performance rating that allows an employee to remain in their position when their performance is not "Fully Successful." Its removal eliminates redundancy, simplifies rating scales, and allows agencies to more clearly distinguish between satisfactory and unsatisfactory performance. This simplification will also help supervisors communicate expectations more clearly and apply performance standards more consistently across the workforce.

The new biennial certification requirement will also strengthen OPM's oversight of non-SES employees and aid in continuous improvement. The establishment of a biennial oversight mechanism will ensure that OPM and all impacted Federal agencies are complying with the congressional

requirements of 5 U.S.C. 4302. Recurring certification will aid OPM in identifying inconsistencies or deficiencies in agency appraisal systems, promote best practices across the Government, and enable OPM to provide targeted technical assistance where needed. This ongoing review process will foster greater accountability, transparency, and uniformity in the administration of performance appraisal systems, thereby improving public confidence in Federal workforce management.

E. Regulatory Alternatives

An alternative to this rulemaking is to not permit standardized distributions and instead issue further guidance encouraging agencies to be increasingly rigorous in their management of non-SES performance to promote meaningful distinctions in non-SES performance. However, OPM has concluded this is not a viable option. Previous attempts to achieve this result through guidance have not been successful in curbing inflated non-SES employee ratings. Without the ability to place limits on the ratings of non-SES employees, there will almost certainly continue to be a pervasive inflation of ratings and a lack of accountability and meaningful distinction in performance ratings.

Another alternative to this rulemaking is to keep all patterns of summary levels that include a "Level 2." Instead, OPM could issue further guidance on the appropriate use of any ratings below a "Level 3," and instruct agencies to hold employees in this rating level more accountable. However, the use of a summary level pattern that includes a "Level 2" has not aided agencies in meaningfully distinguishing between performers at different rating levels, as evidenced by the extremely rare use of the Level 2 rating.

Another alternative to this rulemaking is to not create a biennial certification requirement. Instead, OPM could issue further guidance encouraging agencies to be increasingly rigorous in managing the performance of their non-SES employees. OPM could exercise its authority and include a more rigorous review of agency performance management results in its human capital oversight, conducted by OPM's Office of Merit Systems Accountability and Compliance. Oversight agencies have noted for decades that there are issues with the performance management of Federal employees and guidance has proven to be ineffective at materially improving an agency's performance management system. By contrast, a biennial certification requirement will guarantee a regular, recurring review of

each agency's performance management system and require compliance with 5 CFR part 430, subpart B. Therefore, the biennial certification requirement will better aid OPM and the Federal Government as a whole in meeting the statutory requirements for performance management systems.

F. Severability

If any of the provisions of this rule as finalized are held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, it shall be severable from its respective section(s) and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances. For example, if the implementation of a standardized distribution of ratings were held to be unenforceable, the remaining provisions established by this final rule would remain in effect.

Regulatory Compliance

A. Regulatory Flexibility Act

The Director of OPM certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities because it will apply only to Federal agencies and employees.

B. Regulatory Review

OPM has examined the impact of this rule as required by E.O.s 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for economically significant rules as defined by section 3(f)(1) of E.O. 12866. This rulemaking does not reach that threshold but has otherwise been designated a "significant regulatory action" under section 3(f) of E.O. 12866. This rule is not considered an E.O. 14192 regulatory action because it imposes no more than de minimis costs.

C. Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 13132, it is determined that this final rule does not have sufficient federalism implications

to warrant preparation of a Federalism Assessment.

D. Civil Justice Reform

This regulation meets the applicable standards set forth in section 3(a) and (b)(2) of E.O. 12988.

E. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that would impose spending costs on State, local, or tribal governments in the aggregate, or on the private sector, in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold is currently approximately \$206 million. This rulemaking will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, in excess of the threshold. Thus, no written assessment of unfunded mandates is required.

F. Congressional Review Act

The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs has determined this rule does not meet the criteria listed in 5 U.S.C. 804(2). In addition, this is a rule relating to agency management or personnel and does not come within the meaning of the term "rule" as used in 5 U.S.C. 804(3). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

G. Paperwork Reduction Act

This regulatory action will not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act.

List of Subjects

5 CFR Part 351

Administrative practice and procedure, Government employees.

5 CFR Part 430

Decorations, Government employees.

5 CFR Part 537

Administrative practice and procedure, Government employees, Students, Wages.

Signing Statement

The Director of OPM, Scott Kupor, reviewed and approved this document and has authorized the undersigned to electronically sign and submit this document to the Office of the Federal Register for publication.

Office of Personnel Management.

Jerson Matias,

Federal Register Liaison.

Accordingly, for the reasons stated in the preamble, OPM amends 5 CFR parts 351, 430, and 537 as follows:

PART 351—REDUCTION IN FORCE

■ 1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 1302, 3502, 3503; E.O. 14284, 90 FR 17729; 5 CFR 2.2(c). Sec. 351.801 also issued under E.O. 12828, 58 FR 2965.

Subpart E—Retention Standing

§ 351.504 [Amended]

■ 2. In § 351.504, remove each reference to "430.208(d)" and add in its place "430.208(e)".

PART 430—PERFORMANCE MANAGEMENT

■ 3. The authority citation for part 430 is revised to read as follows:

Authority: 5 U.S.C. 2301, chapter 43 and 5307(d).

Subpart B—Performance Appraisal for General Schedule, Prevailing Rate, and Certain Other Employees

■ 4. Amend § 430.206 by revising paragraph (b)(6) and adding paragraph (b)(9) to read as follows:

§ 430.206 Planning performance.

* * * * *

(b) * * *

(6) A performance plan established under an appraisal program that uses only two summary levels (pattern A as specified in § 430.208(e)(1)) shall not include non-critical elements.

* * * * *

(9) The performance plan of any supervisor covered under this subpart must include a supervisory critical element comprised of supervisory requirements established by OPM and agency-established criteria for protecting whistleblowers, as required by 5 U.S.C. 4302(b).

§ 430.207 [Amended]

■ 5. Amend § 430.207 by:

■ a. Removing paragraph (c); and

■ b. Redesignating paragraph (d) as paragraph (c).

■ 6. Revise and republish § 430.208 to read as follows:

§ 430.208 Rating performance.

(a) As soon as practicable after the end of the appraisal period, a written, or otherwise recorded, rating of record must be given to each employee.

(1) A rating of record must be based only on the evaluation of actual job performance for the designated appraisal period.

(2) An agency must not issue a rating of record that assumes a level of performance by an employee without an actual evaluation of that employee's performance.

(3) Except as provided in paragraph (i) of this section, a rating of record is final when it is issued to an employee with all appropriate reviews and signatures.

(b) Rating of record procedures for each appraisal program must include a method for deriving and assigning a summary level as specified in paragraph (d) of this section based on appraisal of performance on critical elements and, as applicable, non-critical elements.

(1) A Level 1 summary ("Unacceptable") must be assigned if and only if performance on one or more critical elements is appraised as "Unacceptable."

(2) Consideration of non-critical elements must not result in assigning a Level 1 summary ("Unacceptable").

(c) OPM may establish, and refine as needed, a standardized distribution of some or all rating levels which agencies must apply when rating employees, except that employees appointed under Schedules C or G in the excepted service may be excluded from such standardized distribution requirements, as determined by OPM.

(d) The method for deriving and assigning a summary level, as may be established by OPM as described in paragraph (c) of this section, may involve comparing, categorizing, and ranking employees or groups on the basis of their performance. Such procedures may also be used, where otherwise authorized by law and regulation, to inform award determinations and promotion decisions.

(e) *Summary levels.* (1) An appraisal program must use one of the following patterns of summary levels, but Pattern A may only be used for seasonal employees, teachers, General Schedule grades 1–4, and Federal Wage System employees:

Pattern	Summary level				
	1	2	3	4	5
A	X		X		
B	X		X		X
C	X		X	X	X

(2) Within any of the patterns shown in paragraph (e)(1) of this section, summary levels must comply with the following requirements:

(i) Level 1 through Level 5 are ordered categories, with Level 1 as the lowest and Level 5 as the highest;

(ii) Level 1 is "Unacceptable";

(iii) Level 3 is "Fully Successful" or equivalent; and

(iv) Level 5 is "Outstanding" or equivalent.

(3) The term "Outstanding" may be used only to describe the summary level "Level 5."

(4) The designation of a summary level and its pattern shall be used to provide consistency in describing ratings of record and as a reference point for applying other related regulations, including, but not limited to, assigning additional retention service credit under § 351.504 of this chapter.

(5) Under the provisions of § 351.504(e) of this chapter, the number of years of additional retention service credit established for a summary level of a rating of record shall be applied in a uniform and consistent manner within a competitive area in any given reduction in force, but the number of years may vary:

(i) In different reductions in force;

(ii) In different competitive areas; and

(iii) In different summary level patterns within the same competitive area.

(f) The rating of record or performance rating for a disabled veteran must not be lowered because the veteran has been absent from work to seek medical treatment as provided in Executive Order 5396.

(g) When a rating of record cannot be prepared at the time specified, the appraisal period must be extended. Once the conditions necessary to complete a rating of record have been met, a rating of record must be prepared as soon as practicable.

(h) Each rating of record must cover a specified appraisal period. Agencies must not carry over a rating of record prepared for a previous appraisal period as the rating of record for a subsequent appraisal period(s) without an actual evaluation of the employee's performance during the subsequent appraisal period.

(i) When either a regular appraisal period or an extended appraisal period ends and any agency-established deadline for providing ratings of record passes or a subsequent rating of record is issued, an agency must not produce or change retroactively a rating of record that covers that earlier appraisal period except that a rating of record may be changed—

(1) Within 60 days of issuance based upon an informal request, as specified in agency policies and procedures, by the employee;

(2) As a result of a formal proceeding permitted by law or regulation, other than a negotiated grievance procedure barred by paragraph (k) of this section, that results in a final determination by appropriate authority that the rating of record must be changed or as part of a bona fide settlement of a formal proceeding; or

(3) Where the agency determines that a rating of record was incorrectly recorded or calculated.

(j) A performance rating may be prepared at such other times as an appraisal program may specify for special circumstances including, but not limited to, transfers and performance on details.

(k) Subject to 5 U.S.C. 7116(a)(7), a rating of record may not be challenged through the negotiated grievance procedures established under 5 U.S.C. 7121.

■ 7. Amend § 430.209 by revising paragraphs (b), (e), and (g) and adding paragraph (h) to read as follows:

§ 430.209 Agency responsibilities.

* * * * *

(b) Transfer the employee's most recent ratings of record, and any subsequent performance ratings, when an employee transfers to another agency or is assigned to another organization within the agency in compliance with part 293 of this chapter and instructions in the OPM Guide to Personnel Recordkeeping;

* * * * *

(e) Report ratings of record data to OPM in compliance with instructions in the OPM Guide to Human Resources Reporting;

* * * * *

(g) Ensure that agency performance appraisal system(s) and performance appraisal program(s) are administered consistent with the merit system principles set forth under 5 U.S.C. 2301; and

(h) Take any action required by OPM to ensure conformance with applicable law, regulation, and OPM policy.

■ 8. Amend § 430.210 by revising paragraphs (b) and (c) to read as follows:

§ 430.210 OPM responsibilities.

* * * * *

(b) OPM must evaluate and certify the operation and application of an agency's performance appraisal system(s) on a biennial basis. OPM may recommend that the Office of Management and Budget limit an agency's aggregate awards spending based on an unfavorable evaluation. OPM must issue biennial certification criteria and policy.

(c) If OPM determines that an appraisal system or program does not meet the requirements of applicable law, regulation, or OPM policy, including but not limited to the merit system principles set forth under 5 U.S.C. 2301, it shall direct the agency to implement an appropriate system or program or to take other corrective action.

PART 537—REPAYMENT OF STUDENT LOANS

■ 9. The authority citation for part 537 continues to read as follows:

Authority: 5 U.S.C. 2301, 2302, and 5379(g). E.O. 11478, 3 CFR, 1966–1970 Comp., p. 803, unless otherwise noted; E.O. 13087, 63 FR 30097, 3 CFR, 1998 Comp., p. 191; and E.O. 13152, 65 FR 26115, 3 CFR, 2000 Comp., p. 264.

§ 537.108 [Amended]

■ 10. In 5 CFR 537.108(b), remove the reference to “5 CFR 430.208(d)” and add in its place a reference to “5 CFR 430.208(e)”.

[FR Doc. 2026–13715 Filed 7–6–26; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–3476; Project Identifier MCAI–2025–01366–R; Amendment 39–23395; AD 2026–13–12]

RIN 2120–AA64

Airworthiness Directives; Bell Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2025–09–03, which applied to certain Bell Textron Canada Limited (Bell) Model 430 helicopters. AD 2025–09–03 reduced the life limits on the main rotor (M/R) clevises, universal bearings, and universal to pitch link bolts and required re-identifying the M/R pitch link assemblies with new part numbered assemblies. Since the FAA issued AD 2025–09–03, the FAA received comments proposing changes to the actions of AD 2025–09–03. This AD requires changes to the actions in AD 2025–09–03 and addresses the comments received on that AD. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 11, 2026.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of May 13, 2025 (90 FR 17547, April 28, 2025).

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–3476; 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 address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario, K1A 0N5, CANADA; phone: (888) 663–3639; email: TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca. You may find the Transport Canada material on the Transport Canada website at tc.canada.ca/en/aviation.

- You may may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–3476.

FOR FURTHER INFORMATION CONTACT:

Alexis Whitaker, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 15590; phone: (516) 228–7309; email: alexis.j.whitaker@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2025–09–03, Amendment 39–23024 (90 FR 17547, April 28, 2025) (AD 2025–09–03). AD 2025–09–03 applied to certain Bell Model 430 helicopters. AD 2025–09–03 was prompted by Transport Canada AD CF–2024–40, dated December 3, 2024 (Transport Canada AD CF–2024–40) (also referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada. AD 2025–09–03 was prompted by an in-flight failure of the main rotor pitch link clevis due to

fatigue damage caused by excessive wear of the universal bearing. AD 2025–09–03 required a visual inspection of the M/R clevis, rod end, and a certain part-numbered universal bearing; performing a purge grease; performing a magnetic particle inspection after each detailed visual inspection of each M/R clevis; and depending on the inspection results, removing or replacing certain parts, and performing additional actions. AD 2025–09–03 also required recurring inspections of each M/R clevis and each universal bearing. Additionally, AD 2025–09–03 required reducing the life limits of affected parts and re-identifying the M/R pitch link assemblies with new part numbered assemblies. The FAA issued AD 2025–09–03 to detect and address wear and damage of the M/R pitch link assembly components. The unsafe condition, if not addressed, could result in crack initiation at the M/R clevis neck and failure of the M/R pitch link, which could result in loss of control of the helicopter.

The NPRM was published in the **Federal Register** on April 7, 2026 (91 FR 17610). The NPRM was prompted by comments from Bell and Superior Aviation Services requesting changes to the required actions of AD 2025–09–03, specifically in regard to some of the exceptions in the regulatory text of AD 2025–09–03.

In the NPRM, the FAA proposed to require all the actions of AD 2025–09–03 and proposed to replace the requirement of performing a magnetic particle inspection after every detailed inspection with a conditional requirement.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–3476.

Discussion of Final Airworthiness Directive

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

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

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

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Transport Canada AD CF–2024–40, which was approved for incorporation by reference as of May 13, 2025 (90 FR 17547, April 28, 2025). Transport Canada AD CF–2024–40 specifies procedures for verifying rotorcraft historical records to determine the total accumulated hours air time of certain parts, replacing the M/R pitch link assembly components that have exceeded their life limit, re-identifying the M/R pitch link assemblies, and performing a detailed inspection of the

pitch link tube assembly, rod end assembly, and universal to pitch link bolt.

Transport Canada AD CF–2024–40 also specifies procedures for performing repetitive detailed inspections of the M/R clevises and universal bearings (including hardware) and depending on the inspection results, replacing any part that does not meet inspection criteria or further corrective actions. Additionally, Transport Canada AD CF–2024–40 specifies procedures for performing a purge grease, performing a magnetic particle inspection and either replacing any M/R clevis with cracks or replacing any missing cadmium plating. Furthermore, Transport Canada AD CF–2024–40 specifies reporting any cracks or M/R clevises with damage beyond published limits to Bell Product Support Engineering.

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.

Differences Between This AD and the MCAI

The MCAI requires replacing M/R pitch link assembly part number 430–010–411–109, –109FM, –111, and –111FM before they exceed their life limit. This AD does not contain that requirement because those assemblies do not have a life limit and are replaced on-condition as required by the Airworthiness Limitations Section.

Costs of Compliance

The FAA estimates that this AD affects 29 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
Review records to determine total time on each part.	.25 work-hour × \$85 per hour = \$22	\$0	\$22	\$638.
Inspect the pitch link tube assembly, rod end assembly and universal to pitch link bolt.	4 work-hours × \$85 per hour = \$340	0	\$340	\$9,860.
Inspect the M/R pitch link clevis.	2 work-hours × \$85 per hour = \$170	0	\$170 per inspection cycle	\$4,930 per inspection cycle.
Inspect the universal bearing and hardware.	2 work-hours × \$85 per hour = \$170	0	\$170 per inspection cycle	\$4,930 per inspection cycle.
Re-identify components	1 work-hour × \$85 per hour = \$85	0	\$85	\$2,465.
Perform a magnetic particle inspection.	4 work-hours × \$85 per hour = \$340	0	\$340 per inspection cycle	\$9,860 per inspection cycle.

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

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

helicopters that might need these repairs or replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace an M/R clevis	4 work-hours × \$85 per hour = \$340	\$432	\$772 per part.
Replace a universal bearing	4 work-hours × \$85 per hour = \$340	\$3,566	\$3,906 per part.
Replace a universal to pitch link bolt	4 work-hours × \$85 per hour = \$340	\$374	\$714 per part.
Replace missing cadmium plating	4 work-hours × \$85 per hour = \$340	\$0	\$340.
Replace a pitch link tube assembly or rod end assembly ...	4 work-hours × \$85 per hour = \$340	\$6,463	\$6,803 per part.

Authority for This Rulemaking

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

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

This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect

on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2025–09–03, Amendment 39–23024 (90 FR 17547, April 28, 2025); and

■ b. Adding the following new airworthiness directive:

2026–13–12 Bell Textron Canada Limited:
Amendment 39–23395; Docket No. FAA–2026–3476; Project Identifier MCAI–2025–01366–R.

(a) Effective Date

This airworthiness directive (AD) is effective August 11, 2026.

(b) Affected ADs

This AD replaces AD 2025–09–03, Amendment 39–23024 (90 FR 17547, April 28, 2025).

(c) Applicability

This AD applies to Bell Textron Canada Limited (Bell) Model 430 helicopters, serial numbers 49001 through 49129 inclusive, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6220, Main rotor head.

(e) Unsafe Condition

This AD was prompted by an in-flight failure of the main rotor (M/R) pitch link clevis (clevis) due to fatigue damage caused by excessive wear of the universal bearing. The FAA is issuing this AD to detect and

address wear and damage of the M/R pitch link assembly components. The unsafe condition, if not addressed, could result in crack initiation at the M/R clevis neck and failure of the M/R pitch link, which could result in loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

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, Transport Canada AD CF–2024–40, dated December 3, 2024 (Transport Canada AD CF–2024–40).

(h) Exceptions to Transport Canada AD CF–2024–40

(1) Where Transport Canada AD CF–2024–40 refers to its effective date, this AD requires using May 13, 2025, the effective date of AD 2025–09–03.

(2) Where Transport Canada AD CF–2024–40 requires compliance in terms of hours air time, this AD requires using hours time-in-service.

(3) Where Transport Canada AD CF–2024–40 uses the term “new” in the definition of “serviceable part,” this AD requires replacing that text with “new (zero hours time-in-service)”.

(4) Where any paragraph in Transport Canada AD CF–2024–40 specifies performing a magnetic particle inspection (MPI) if any suspected defects are found as a result of the DI [detailed inspection], this AD requires replacing that text with “if any suspected defects (evidenced by linear indications) are found on the M/R clevis as a result of the detailed inspection”.

Note 1 to paragraph (h)(4): a linear indication is defined as an indication for which the longest dimension is at least three times longer than the smallest one.

(5) Where Part I paragraph A.8. and Part III paragraph B. of Transport Canada AD CF–2024–40 specify to purge grease the bearings, for this AD those actions are not required if already accomplished when doing Part I paragraph A.7 and Part III paragraph A. of Transport Canada AD CF–2024–40.

(6) Where Part I paragraph A.9. of Transport Canada AD CF–2024–40 specifies to re-identify the main rotor pitch link assemblies and sub-components, for this AD those actions are not required if already accomplished when doing Part I paragraphs A.2. through A.4. of Transport Canada AD CF–2024–40.

(7) Where Part I paragraph B. of Transport Canada AD CF–2024–40 specifies to “replace each component listed in Table 1 of the Bell ASB before exceeding the applicable airworthiness life limit indicated in Table 4–1 of the applicable ALS [Airworthiness Limitations Section]”, for this AD that requirement does not apply to M/R pitch link assemblies part numbers 430–010–411–109, –109FM, –111, and –111FM, as those parts are replaced on-condition.

(i) No Reporting Requirement

Although the material referenced in Transport Canada AD CF–2024–40 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 Alexis Whitaker, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY; phone: (516) 228–7309; email: alexis.j.whitaker@faa.gov.

(l) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on May 13, 2025 (90 FR 17547, April 28, 2025).

(i) Transport Canada AD CF–2024–40, dated December 3, 2024.

(ii) [Reserved]

(4) For Transport Canada material identified in this AD, contact Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; phone: 888–663–3639; email: TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca. You may find this material on the Transport Canada website at tc.canada.ca/en/aviation.

(5) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 10101 Hillwood Parkway, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(6) 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 June 29, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–13685 Filed 7–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–7211; Project Identifier MCAI–2026–00665–T; Amendment 39–23403; AD 2026–13–52]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The FAA previously sent this AD as an emergency AD to all known U.S. owners and operators of these airplanes. This AD was prompted by a report of several missing or broken high pressure valve (HPV) butterfly clips found in a repair shop. This AD prohibits dispatching an airplane under certain dispatch provisions corresponding to master minimum equipment list (M MEL) items for the wing anti-ice system, wing anti ice pressure sensor, fan air valve (FAV), bleed air systems, engine bleed pressure regulating shutoff valve (PRSOV), HPV, and pack bleed air leak and overheat detection loop; and prohibits dispatching an airplane if certain crew alerting system (CAS) messages and associated info messages are displayed. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 7, 2026. Emergency AD 2026–13–52, issued on June 29, 2026, which contains the requirements of this amendment, was effective with actual notice.

The FAA must receive comments on this AD by August 21, 2026.

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

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

- *Fax:* 202–493–2251.

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

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

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2026–7211; 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.

FOR FURTHER INFORMATION CONTACT: Michael Bumbaugh, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3522; email: Michael.Bumbaugh@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–2026–7211; Project Identifier MCAI–2026–00665–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 Michael Bumbaugh, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3522; email: Michael.Bumbaugh@faa.gov. Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued Emergency AD 2026–13–52, dated June 29, 2026 (the emergency AD), to address an unsafe condition on all Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. The FAA sent the emergency AD to all known U.S. owners and operators of these airplanes. The emergency AD prohibits dispatching an airplane under certain dispatch provisions corresponding to M MEL items for the wing anti-ice system, wing anti ice pressure sensor; FAV, bleed air systems, engine bleed PRSOV, HPV, and pack bleed air leak and overheat detection loop; and prohibits dispatching an airplane if certain CAS messages and associated info messages are displayed.

The emergency AD was prompted by Transport Canada Emergency AD CF–2026–33R1, dated June 24, 2026 (Transport Canada Emergency AD CF–2026–33R1) (also referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada, to correct an unsafe condition on all Airbus Canada Limited Partnership (ACLP) Model BD–500–1A10 and BD–500–1A11 airplanes. The MCAI states it was reported to ACLP that several missing or broken HPV butterfly clips were found in a repair shop. An ACLP assessment has determined that failure of the butterfly clip may not be readily detected during operation and could remain latent until the next scheduled inspection or until secondary effects occur (e.g., bleed leak or overheat indications). Failure of the butterfly clip may also lead to degradation of the valve sealing function. This condition, if not detected and corrected, could result in the inability to properly isolate the bleed system when required, uncontrolled hot

air leakage, overheating of critical airplane structures and components, and degradation of structural integrity.

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](https://www.regulations.gov) under Docket No. FAA–2026–7211.

Related Material

Transport Canada Emergency AD CF–2026–33R1 specifies a prohibition to dispatch an airplane under the provisions of the minimum equipment list (MEL) items corresponding to certain MMEL items and certain CAS messages and associated info messages.

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 described 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 prohibits dispatching an airplane under the dispatch provisions of the operator’s MEL items corresponding to certain dispatch provisions of MMEL items 30–11–00, Wing Anti-Ice System; 30–12–01, Wing Anti Ice Pressure Sensor; 36–11–92, Fan Air Valve (FAV); 36–12–00, Bleed Air Systems; 36–12–01, Engine Bleed Pressure Regulating Shutoff Valve (PRSOV); 36–12–05, HPV; and 36–21–03, Pack Bleed Air Leak and Overheat Detection Loop. This AD also prohibits dispatching an airplane if certain CAS messages and associated info messages are displayed.

Interim Action

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

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 required the immediate adoption of Emergency AD 2026–13–52 issued on June 29, 2026, to all known U.S. owners and operators of these airplanes. The FAA found that the risk to the flying public justified forgoing notice and comment prior to adoption of this rule because failure of the HPV butterfly clip may lead to degradation of the valve sealing function and consequent inability to properly isolate the bleed system when required, uncontrolled hot air leakage, overheating of critical airplane structures and components, and degradation of structural integrity. This could lead to loss of control of the airplane. These conditions still exist, therefore, 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 211 airplanes of U.S. registry. The FAA has received no definitive data on which to base the cost estimate for prohibiting dispatch of an airplane under the specified provisions and conditions. This cost may vary significantly among operators.

Authority for This Rulemaking

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

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

with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2026–13–52 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–23403; Docket No. FAA–2026–7211; Project Identifier MCAI–2026–00665–T.

(a) Effective Date

The FAA issued Emergency Airworthiness Directive (AD) 2026–13–52 on June 29, 2026 (also referred to as the emergency AD), directly to affected owners and operators. As a result of such actual notice, the emergency AD was effective for those owners and operators on the date it was received. This AD contains the same requirements as the emergency AD and, for those who did not receive actual notice, is effective on July 7, 2026.

(b) Affected ADs None.	(e) Unsafe Condition This AD was prompted by a report of several missing or broken high pressure valve (HPV) butterfly clips found in a repair shop. The FAA is issuing this AD to address failure of an HPV butterfly clip, which may remain latent and lead to secondary effects (e.g., bleed leak or overheat conditions) and degradation of the valve sealing function. The unsafe condition, if not addressed, could result in the inability to properly isolate the bleed system when required, uncontrolled hot air leakage, overheating of critical airplane structures and components, and degradation of structural integrity.	(f) Compliance Comply with this AD within the compliance times specified, unless already done. (g) Dispatch Prohibitions (1) As of the effective date of this AD, no person may dispatch an airplane under the operational procedures of the operator's minimum equipment list items corresponding to the operational procedures of the Master Minimum Equipment List (MMEL) items listed in tables 1 and 2 to paragraph (g)(1) of this AD.
(c) Applicability This AD applies to all Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD-500-1A10 and BD-500-1A11 airplanes, certificated in any category.		
(d) Subject Air Transport Association (ATA) of America Code 36, Pneumatic.		

Table 1 to paragraph (g)(1) - Prohibited ice and rain protection MMEL items

30. Ice and Rain Protection

Sequence No.	Item	1	2	3	4
11-00	Wing Anti-Ice System				
1)	High Pressure Valve (HPV)	C	2	1	(O) Except for ER operations, may be inoperative provided: a) Associated bleed system is selected OFF, b) Crossbleed valve (CBV) is verified operative, c) Flight is conducted under single bleed configuration at or below FL 310, d) Equipment bay smoke detectors are verified operative, e) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and f) FLAP 4 landings are prohibited in icing conditions.
2)	Temperature Sensor	A	2	1	(O) Except for ER operations beyond 120 minutes, both temperature sensor elements on left or right side may be inoperative provided: a) WING ANTI-ICE is selected OFF, b) Associated wing anti-ice valve is verified closed, c) INFO message 30 WING A/ICE FAULT - L(R) WING A/ICE PRESS SNSR INOP is not displayed for the same side, d) Airplane is not operated in known or forecast icing conditions, e) L ICE DET FAIL (Caution) is not displayed, f) R ICE DET FAIL (Caution) is not displayed, and g) Repairs are made after one flight.

30. Ice and Rain Protection

Sequence No.	Item	1	2	3	4
2)	Temperature Sensor (Cont'd)	C	2	1	(O) Except for ER operations, may be inoperative provided: a) Wing Anti Ice (WAI) system is selected OFF, b) Crossbleed Valve (CBV) is selected MAN CLSD, c) Associated wing anti-ice valve is verified closed, d) L ICE DET FAIL (Caution) is not displayed, e) R ICE DET FAIL (Caution) is not displayed, f) Same side engine bleed pressure regulating shutoff valve (PRSOV) and air conditioning pack are selected OFF, g) PRSOV is verified closed, h) Airplane is not operated in known or forecast icing conditions, i) Flight is conducted in single bleed and single pack configuration at or below FL 310, j) Both equipment bay smoke detectors are operative, and k) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative). NOTE: If APU bleed air is used during takeoff or in-flight operation is conducted in accordance with AFM chapter 2, APU BLEED AIR limitations.
4)	Temperature Control Function	C	2	1	(O) Except for ER operations, may be inoperative provided: a) Associated bleed system is selected OFF, b) Crossbleed valve (CBV) is verified operative, c) Flight is conducted in single bleed configuration at or below FL 310, d) Both air conditioning packs are operative, e) Equipment bay smoke detectors are verified operative, f) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems inoperative), and g) FLAP 4 landings are prohibited in icing conditions.

30. Ice and Rain Protection

Sequence No.	Item	1	2	3	4
12-01	Wing Anti Ice Pressure Sensor	C	2	1	(M)(O) Except for ER operations, may be inoperative provided: - Wing anti-ice (WAI) system is selected OFF, - Crossbleed valve (CBV) is selected MAN CLSD, - Associated WAI valve is secured closed, - Both ice detection systems are operative, - Same side engine bleed pressure regulating shutoff valve (PRSOV) and air conditioning pack are considered inoperative, and - Aircraft is not operated in known or forecast icing conditions.
1)	30 WING A/ICE FAULT - L WING A/ICE PRESS SNSR INOP (INFO message)	C	-	-	(O) Except for ER operations, may be displayed provided: - Wing anti-ice (WAI) system is selected OFF, - Left wing anti ice valve (WAIV) is verified closed, - L ICE DET FAIL (Caution) is not displayed, - R ICE DET FAIL (Caution) is not displayed, - Left wing anti-ice temperature sensor is verified operative, - Aircraft is not operated in known or forecast icing conditions.
2)	30 WING A/ICE FAULT - R WING A/ICE PRESS SNSR INOP (INFO message)	C	-	-	(O) Except for ER operations, may be displayed provided: - Wing anti-ice (WAI) system is selected OFF, - Right wing anti ice valve (WAIV) is verified closed, - L ICE DET FAIL (Caution) is not displayed, - R ICE DET FAIL (Caution) is not displayed, - Right wing anti-ice temperature sensor is verified operative, - Aircraft is not operated in known or forecast icing conditions.

Table 2 to paragraph (g)(1) - Prohibited pneumatic MMEL items**36. Pneumatic**

Sequence No.	Item	1	2	3	4
11-92	Fan Air Valve (FAV)				
1)		C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Associated FAV is secured CLOSED, b) Associated bleed system is selected OFF and not used, c) Flight is conducted in single bleed configuration at or below FL 310, d) Both air conditioning packs are operative, e) Both equipment bay smoke detectors are operative, f) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), g) FLAP 4 landings are prohibited in icing conditions, and h) Crossbleed valve (CBV) is verified operative.
2)		C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Associated FAV is secured CLOSED, b) Associated bleed system is selected OFF and not used, c) Integrity of the associated engine bleed duct is verified, d) Flight is conducted at or below FL 310, e) Both air conditioning packs are operative, f) Both equipment bay smoke detectors are operative, g) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), h) FLAP 4 landings are prohibited in icing conditions, and i) Crossbleed valve (CBV) is verified operative.

36. Pneumatic

Sequence No.	Item	1	2	3	4
11-92	Fan Air Valve (FAV) (Cont'd)				
3)		C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Associated FAV is secured CLOSED, b) Associated bleed system is selected OFF and not used, c) Associated air conditioning pack is selected OFF, d) Flight is conducted at or below FL 310, e) Both equipment bay smoke detectors are operative, f) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and g) FLAP 4 landings are prohibited in icing conditions. NOTE: If APU bleed air is used during takeoff or in-flight, operating is conducted in accordance with AFM Chapter 2, APU BLEED AIR limitations.
4)		C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Associated FAV is secured CLOSED, b) Associated bleed system is selected OFF and not used, c) Associated air conditioning pack is selected OFF, d) Integrity of the associated engine bleed duct is verified, e) Flight is conducted at or below FL 310, f) Both equipment bay smoke detectors are operative, g) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and h) FLAP 4 landings are prohibited in icing conditions. NOTE: If APU bleed air is used during takeoff or in-flight, operating is conducted in accordance with AFM Chapter 2, APU BLEED AIR limitations.

36. Pneumatic

Sequence No.	Item	1	2	3	4
11-92	Fan Air Valve (FAV) (Cont'd)				
5)		B	2	0	(M)(O) Except for ER operations, both may be inoperative provided: a) Both LH and RH bleed systems are selected OFF and not used, b) Both FAVs are secured CLOSED, c) Flight is conducted in an unpressurized configuration at or below 10,000 ft. MSL, d) Airplane is not operated in known or forecast icing conditions, e) No passengers are carried, and f) Fuel tank inerting system (FTIS) is considered inoperative.
12-00	Bleed Air System				
1)	Engine	C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Associated bleed system is selected OFF, b) Associated high pressure shutoff valve (HPV) is secured CLOSED, c) Associated pressure regulating shutoff valve (PRSOV) is secured CLOSED, d) Integrity of the associated engine bleed duct is verified, e) Crossbleed valve (CBV) is verified operative, f) Flight is conducted in single bleed configuration at or below FL 310, g) Both equipment bay smoke detectors are operative, h) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and i) FLAP 4 landings are prohibited in icing conditions.

36. Pneumatic

Sequence No.	Item	1	2	3	4
12-00	Bleed Air System (Cont'd)				
1)	Engine (Cont'd)	B	2	0	(M)(O) Except for ER operations, both may be inoperative provided: a) Both LH and RH bleed systems are selected OFF and not used, b) Both LH and RH high pressure shutoff valves (HPV) are secured CLOSED, c) Both LH and RH pressure regulating shutoff valves (PRSOV) are secured CLOSED, d) Flight is conducted in an unpressurized configuration at or below 10,000 ft. MSL, e) Airplane is not operated in known or forecast icing conditions, f) No passengers are carried, and g) Fuel tank inerting system (FTIS) is considered inoperative.
12-00	Bleed Air System (Cont'd)				
2)	Pressure Sensor	C	2	1	One may be inoperative provided the associated side bleed system is considered inoperative.
12-00	Bleed Air System (Cont'd)				
4)	Temperature Sensor Element	C	4	2	(O) Except for ER operations, both temperature sensor elements on left or right side may be inoperative provided: a) Associated bleed system is selected OFF, b) Crossbleed valve (CBV) is verified operative, c) Flight is conducted at or below FL 310, d) Equipment bay smoke detectors are verified operative, e) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and f) FLAP 4 landings are prohibited in icing conditions.

36. Pneumatic

Sequence No.	Item	1	2	3	4
12-01	Engine Bleed Pressure Regulating Shutoff Valve (PRSOV)	C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Affected valve is secured CLOSED, b) Associated engine bleed system is selected OFF, c) Flight is conducted at or below FL 310, d) Both air conditioning packs are operative, e) Both equipment bay smoke detectors are operative, f) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and g) FLAP 4 landings are prohibited in icing conditions.
12-01	Engine Bleed Pressure Regulating Shutoff Valve (PRSOV) (Cont'd)	C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Affected valve is secured CLOSED, b) Associated engine bleed system is selected OFF and not used, c) Associated air conditioning pack is selected OFF, d) Flight is conducted at or below FL 310, e) Both equipment bay smoke detectors are operative, f) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and g) FLAP 4 landings are prohibited in icing conditions. NOTE: If APU bleed air is used during takeoff or in-flight, operation is conducted in accordance with AFM chapter 2, APU BLEED AIR limitations.
12-01	Engine Bleed Pressure Regulating Shutoff Valve (PRSOV) (Cont'd)	C	2	1	(O) Except for ER operations, one may be inoperative provided: a) Associated bleed system is selected OFF, b) Crossbleed valve (CBV) is verified operative, c) Flight is conducted at or below FL 310, d) Equipment bay smoke detectors are verified operative, e) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and f) FLAP 4 landings are prohibited in icing conditions.

36. Pneumatic

Sequence No.	Item	1	2	3	4
12-01	Engine Bleed Pressure Regulating Shutoff Valve (PRSOV) (Cont'd)	B	2	0	(M)(O) Except for ER operations, both may be inoperative provided: a) Both valves are secured CLOSED, b) L BLEED and R BLEED are selected OFF, c) Flight is conducted unpressurized at or below 10,000 ft. MSL, d) Airplane is not operated in known or forecast icing conditions, e) No passengers are carried, and f) Fuel tank inerting system (FTIS) is considered inoperative.
12-01	Engine Bleed Pressure Regulating Shutoff Valve (PRSOV) (Cont'd)	C	2	0	(M)(O) Except for ER operations, both may be inoperative provided: a) Both valves are secured CLOSED, b) APU bleed system is operated during flight, c) Both air conditioning packs are operative, d) Flight is conducted at or below 23,000 ft., per Airplane Flight Manual (AFM) Chapter 2 "APU Bleed Air Limitations", e) Passenger load is limited per Airplane Flight Manual (AFM) Chapter 2 "APU Bleed Air Limitations", f) Airplane is not operated in known or forecast icing conditions, and g) Both equipment bay smoke detectors are operative.
12-05	High Pressure Shutoff Valve (HPV)	C	2	1	(M)(O) Except for ER operations, one may be inoperative provided: a) Associated bleed system is selected OFF, b) Associated high pressure shutoff valve (HPV) is secured CLOSED, c) Associated pressure regulating shutoff valve (PRSOV) is secured CLOSED, d) Crossbleed valve (CBV) is verified operative, e) Flight is conducted at or below FL 310, f) Both equipment bay smoke detectors are operative, g) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operation with Airplane Systems Inoperative), and h) FLAP 4 landings are prohibited in icing conditions.

36. Pneumatic

Sequence No.	Item	1	2	3	4
12-05	High Pressure Shutoff Valve (HPV) (Cont'd)	C	2	1	(O) Except for ER operations, one may be inoperative provided: a) Associated bleed system is selected OFF, b) Crossbleed valve (CBV) is verified operative, c) Flight is conducted at or below FL 310, d) Equipment bay smoke detectors are verified operative, e) Operations are conducted in accordance with Airplane Flight Manual (AFM) Supplement 5 (Operations with Airplane Systems Inoperative), and f) FLAP 4 landings are prohibited in icing conditions.
12-05	High Pressure Shutoff Valve (HPV) (Cont'd)	B	2	0	(M)(O) Except for ER operations, may be inoperative provided: a) Both LH and RH bleed systems are selected OFF and not used, b) Both LH and RH high pressure shutoff valves (HPV) are secured CLOSED, c) Both LH and RH pressure regulating shutoff valves (HPV) are secured CLOSED, d) Flight is conducted in an unpressurized configuration at or below 10,000 ft. MSL, e) Airplane is not operated in known or forecast icing conditions, f) No passengers are carried, and g) Fuel tank inerting system is considered inoperative.
21-03	Pack Bleed Air Leak and Overheat Detection Loop				
1)	Left Pack Zone				

36. Pneumatic

Sequence No.	Item	1	2	3	4
a)	Inoperative not annunciated by 36 LEAK DET FAULT - LOOP REDUND LOSS (INFO message)	C	2	0	(M)(O) May be inoperative provided: a) Except for engine start, APU bleed is selected OFF, b) Left Pressure Regulating Shutoff Valve (PRSOV) is considered inoperative, c) Left pack is considered inoperative, d) Except for engine start, Crossbleed Valve (CBV) is selected MAN CLSD, e) Fuel tank inerting system is considered inoperative, f) Wing Anti-Ice (WAI) system is selected OFF, g) Aircraft is not operated in known or forecast icing conditions, and h) Verify no additional loops have faulted before each flight.
21-03	Pack Bleed Air Leak and Overheat Detection Loop (Cont'd)				
1)	Left Pack Zone (Cont'd)				
b)	Inoperative annunciated by 36 LEAK DET FAULT - LOOP REDUND LOSS (INFO message)	C	2	0	(M)(O) May be inoperative provided: a) Except for engine start, APU bleed is selected OFF, b) Left Pressure Regulating Shutoff Valve (PRSOV) is considered inoperative, c) Left pack is considered inoperative, d) Except for engine start, Crossbleed Valve (CBV) is selected MAN CLSD, e) Fuel tank inerting system is considered inoperative, f) Wing Anti-Ice (WAI) system is selected OFF, g) Aircraft is not operated in known or forecast icing conditions, h) Integrity of the left pack bleed air ducting and structure adjacent to and surrounding the inoperative sensing element(s) is verified, and i) Verify no additional loops have faulted before each flight.

36. Pneumatic

Sequence No.	Item	1	2	3	4
21-03	Pack Bleed Air Leak and Overheat Detection Loop (Cont'd)				
2)	Right Pack Zone				
a)	Inoperative not annunciated by 36 LEAK DET FAULT - LOOP REDUND LOSS (INFO message)	C	2	0	(M)(O) May be inoperative provided: a) Right Pressure Regulating Shutoff Valve (PRSOV) is considered inoperative, b) Right pack is considered inoperative, c) Except for engine start, Crossbleed Valve (CBV) is selected MAN CLSD, d) Wing Anti-Ice (WAI) system is selected OFF, e) Aircraft is not operated in known or forecast icing conditions, and f) Verify no additional loops have faulted before each flight.
21-03	Pack Bleed Air Leak and Overheat Detection Loop (Cont'd)				
2)	Right Pack Zone				
b)	Inoperative annunciated by 36 LEAK DET FAULT - LOOP REDUND LOSS (INFO message)	C	2	0	(M)(O) May be inoperative provided: a) Right Pressure Regulating Shutoff Valve (PRSOV) is considered inoperative, b) Right pack is considered inoperative, c) Except for engine start, Crossbleed Valve (CBV) is selected MAN CLSD, d) Wing Anti-Ice (WAI) system is selected OFF, e) Aircraft is not operated in known or forecast icing conditions, f) Integrity of the right pack bleed air ducting and structure adjacent to and surrounding the inoperative sensing element(s) is verified, and g) Verify no additional loops have faulted before each flight.

(2) As of the effective date of this AD, no person may dispatch an airplane if any crew alerting system (CAS) message and associated info message identified in paragraph (g)(2)(i) through (xviii) of this AD is displayed.

(i) L WING A/ICE LO HEAT (Caution): 30 L WING A/ICE LO HEAT—CTRL TEMP INOP (Info).

(ii) L WING A/ICE LO HEAT (Caution): 30 L WING A/ICE LO HEAT—L HPV FAIL CLSD (Info).

(iii) L WING A/ICE LO HEAT (Caution): 30 L WING A/ICE LO HEAT—L WING A/ICE TEMP SNSR INOP (Info).

(iv) L WING A/ICE OVHT (Caution): 30 L WING A/ICE OVHT—L WING A/ICE TEMP SNSR INOP (Info).

(v) R WING A/ICE LO HEAT (Caution): 30 R WING A/ICE LO HEAT—CTRL TEMP INOP (Info).

(vi) R WING A/ICE LO HEAT (Caution): 30 R WING A/ICE LO HEAT—R HPV FAIL CLSD (Info).

(vii) R WING A/ICE LO HEAT (Caution): 30 R WING A/ICE LO HEAT—R WING A/ICE TEMP SNSR INOP (Info).

(viii) R WING A/ICE OVHT (Caution): 30 R WING A/ICE OVHT—R WING—A/ICE TEMP SNSR INOP (Info).

(ix) WING A/ICE FAULT (Advisory): 30 WING A/ICE FAULT—L WING A/ICE VLV LEAK (Info).

(x) WING A/ICE FAULT (Advisory): 30 WING A/ICE FAULT—R WING A/ICE VLV LEAK (Info).

(xi) AIR SYSTEM FAULT (Advisory): 36 AIR SYSTEM FAULT—L BLEED MON PRESS SNSR INOP (Info).

(xii) AIR SYSTEM FAULT (Advisory): 36 AIR SYSTEM FAULT—R BLEED MON PRESS SNSR INOP (Info).

(xiii) L BLEED FAIL (Caution): 36 L BLEED FAIL—L BLEED TEMP SNSR INOP (Info).

(xiv) L BLEED FAIL (Caution): 36 L BLEED FAIL—L HPV FAIL CLSD (Info).

(xv) L BLEED FAIL (Caution): 36 L BLEED FAIL—L PRESS REG SOV INOP (Info).

(xvi) R BLEED FAIL (Caution): 36 R BLEED FAIL—R BLEED TEMP SNSR INOP (Info).

(xvii) R BLEED FAIL (Caution): 36 R BLEED FAIL—R HPV FAIL CLSD (Info).

(xviii) R BLEED FAIL (Caution): 36 R BLEED FAIL—R PRESS REG SOV INOP (Info).

(h) 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 (i) of this AD and email to: AMOC@faa.gov. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(i) Additional Information

For more information about this AD, contact Michael Bumbaugh, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206-231-3522; email: Michael.Bumbaugh@faa.gov.

(j) Material Incorporated by Reference

None.

Issued on July 1, 2026.

Brian Knaup,

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

[FR Doc. 2026-13655 Filed 7-2-26; 11:15 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 260 and 399

[Docket No. DOT-OST-2022-0089, DOT-OST-2025-2285]

RIN 2105-AF04, 2105-AF36

Airline Refunds and Other Consumer Protections

AGENCY: Office of the Secretary of Transportation (OST), U.S. Department of Transportation.

ACTION: Notification of enforcement discretion.

SUMMARY: The U.S. Department of Transportation (Department or DOT) is extending its current enforcement discretion, announced on December 5, 2025, regarding specific refund regulations. Under current regulations, a flight assigned a different flight number than was active at the time of ticket purchase is considered a “cancelled flight,” making the consumer eligible for a prompt refund and related notifications. The Department is extending its discretion to not enforce these requirements for renumbered flights, provided that the passenger is rebooked on a flight with a new number and the flight operates without any “significant change or delay” as defined in its regulations. This extension provides the Department with the necessary time to complete the pending rulemaking addressing the definition of a flight cancellation.

DATES: As of July 7, 2026, the Department is extending the pause on the enforcement of airline refunds requirements regarding cancelled flights under 14 CFR parts 260 and 399 for flights that are merely renumbered. This enforcement discretion is extended for 1-year from the date of this publication, expiring on July 7, 2027.

ADDRESSES: This notification of enforcement discretion may be viewed online at www.regulations.gov using the docket numbers listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year.

An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at www.federalregister.gov and the Government Publishing Office's website at www.GovInfo.gov.

FOR FURTHER INFORMATION CONTACT:

Clereece Kroha or Blane Workie, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, 202-366-9342 (phone), 202-366-7152 (fax), clereece.kroha@dot.gov, or blane.workie@dot.gov (email).

SUPPLEMENTARY INFORMATION: On April 26, 2024, DOT published a final rule titled “Refunds and Other Consumer Protections” (Refund I) (89 FR 32760). Under that rule, a “cancelled flight” was defined in a way that classified a flight operated under a different flight number as a new flight, meaning the original flight was considered cancelled and subject to refund requirements. The rule also requires carriers to provide notifications to affected consumers that they are entitled to a refund when a flight cancellation or significant delay or change occurs. Following the implementation of Refund I, multiple airlines submitted requests highlighting the necessity of flight renumbering for logistical reasons (such as switching between mainline and regional service) and the general lack of material impact on passengers. Upon review, DOT determined that consumers face no inherent harm from routine flight renumbering, and, on December 5, 2025, published a notification of enforcement discretion (90 FR 55999) announcing no enforcement of these specific ticket refund and notification requirements until June 30, 2026.

The Department is engaged in a rulemaking titled “Airline Refunds and Other Consumer Protections III” (Refund III), identified by RIN 2105-AF36. Among other things, this proposed rule aims to reduce unnecessary regulatory burdens by modifying the definition of a flight cancellation that would entitle consumers to ticket refunds. Because the Refund III rulemaking remains pending, the Department is extending the enforcement pause for an additional 1-year period from the date of this publication. Taking this interim step avoids imposing counterproductive operational and technical difficulties on airlines while the rulemaking process is ongoing.

This enforcement discretion remains temporary and strictly limited. It applies solely to situations where a flight is given a different flight number but the passenger is successfully rebooked on

the new flight without experiencing a “significant change or delay” (e.g., changes to departure/arrival times by three or more hours domestically, changes in departure/arrival airports, or downgrades in class of service). If a flight number change is accompanied by any such significant delay or disruptions, standard consumer refund mandates remain fully enforceable.

This extension does not prejudice the outcome of the pending Refund III rulemaking. Furthermore, it does not alter any other consumer protections established in other DOT rulemakings, including airlines’ obligations to offer free rebooking when a change to a smaller aircraft means a passenger’s wheelchair or scooter can no longer be accommodated. It also does not alter how U.S. carriers report on-time performance data to the Department pursuant to 14 CFR part 234.

Issued in Washington, DC, under authority delegated in 49 CFR 1.27(n):

Gregory Zerzan,
General Counsel.

[FR Doc. 2026–13675 Filed 7–6–26; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2026–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Application; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during January, February, and March 2026. The animal drug regulations are also being

amended to improve their accuracy and readability.

DATES: This rule is effective July 7, 2026.

FOR FURTHER INFORMATION CONTACT:

James Delaney, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, James.Delaney@fda.hhs.gov, 240–402–5677.

SUPPLEMENTARY INFORMATION:

I. Approval of Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and CNADAs during January, February, and March 2026, as listed in table 1.

Documentation of environmental review required under the National Environmental Policy Act, summaries of the basis of approval under the Freedom of Information Act (FOIA summaries), and marketing exclusivity and patent information are available at Animal Drugs @FDA: <https://animaldrugsatfda.fda.gov/adafda/views/#/search>.

TABLE 1—ORIGINAL, CONDITIONAL, AND SUPPLEMENTAL APPLICATIONS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2026

Date of approval	Applica- tion No.	Sponsor (drug labeler code ¹)	Product name	Effect of the action	21 CFR sections
December 4, 2025	141–167	Intervet, Inc. (000061)	EXZOLT CATTLE–CA (fluralaner topical solution).	Conditional approval	516.900
January 9, 2026	200–828	Parnell Technologies Pty. Ltd. (068504).	nixiFLOR (florfenicol and flunixin meglumine) injectable solution.	Original approval as a generic copy of NADA 141–299.	556.290(b)(2) 522.956
January 9, 2026	141–615	Pegasus Laboratories, Inc. (055246).	KBROVET	Original approval	516.1858 520.1858
January 12, 2026	200–833	Felix Pharmaceuticals Pvt. Ltd. (086101).	Maropitant Citrate Chewable Tablets.	Original approval as a generic copy of NADA 141–262.	520.1315
January 13, 2026	200–831	Norbrook Laboratories Ltd.	Defendazole (fenbendazole)	Original approval as a generic copy of RLNAD NADA 128–620.	520.905a
January 13, 2026	141–518	Intervet, Inc. (000061)	BRAVECTO PLUS (fluralaner and moxidectin topical solution).	Supplemental approval	524.1001
January 15, 2026	141–575	Boehringer Ingelheim Animal Health USA, Inc. (000010).	VETMEDIN Solution (pimobendan oral solution).	Supplemental approval	520.1782
January 20, 2026	141–554	Boehringer Ingelheim Animal Health USA, Inc. (000010).	NEXGARD PLUS (afoxolaner, moxidectin, and pyrantel chewable tablets).	Supplemental approval	520.35
January 29, 2026	200–761	Cronus Pharma Specialities India Private Ltd. (069043).	Cronoquin Tablets (marbofloxacin tablets).	Original approval as a generic copy of NADA 141–151.	520.1310
January 30, 2026	200–830	Parnell Technologies Pty. Ltd. (068504).	Sevoflurane (sevoflurane)	Original approval as a generic copy NADA 141–103.	529.2110
February 6, 2026	200–838	Felix Pharmaceuticals Pvt. Ltd. (086101).	Atipamezole Hydrochloride Injection (atipamezole hydrochloride) sterile injectable solution.	Original approval as a generic copy of NADA 141–033.	522.147
February 23, 2026	200–822	Baxter Healthcare Corporation (010019).	ANIRANE (isoflurane)	Original approval as a generic copy of NADA 135–773.	529.1186
February 23, 2026	200–841	Felix Pharmaceuticals Pvt. Ltd. (086101).	Firocoxib Tablets for Horses (firocoxib).	Original approval as a generic copy of NADA 141–458.	520.928
March 9, 2026	200–804	Cronus Pharma Specialities India Private Ltd. (069043).	Robenacoxib Injection (robenacoxib) Injectable Solution.	Original approval as a generic copy of NADA 141–443.	522.2075
March 10, 2026	095–735	Elanco, US Inc. (058198)	Rumensin 113 (monensin Type A medicated article).	Supplemental approval	558.355
March 16, 2026	141–599	Intervet, Inc. (000061)	BRAVECTO QUANTUM (fluralaner for extended-release injectable suspension).	Supplemental approval	522.998
March 23, 2026	141–616	Zoetis (054771)	DECTOMAX –CA1 (doramectin injection).	Supplemental approval	516.570

¹ See 21 CFR 510.600(c) for sponsor addresses.

II. Withdrawal of Approval of Applications

Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom (drug labeler code 043264), requested

that FDA withdraw approval of two NADAs listed in table 2 because these products are no longer marketed. Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861 (drug labeler code 054925), requested that

FDA withdraw approval of four ANADAs listed in table 2 because these products are no longer marketed. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

TABLE 2—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN DURING JANUARY, FEBRUARY, AND MARCH 2026

Date of withdrawal of approval	Application No.	Product name	21 CFR section
February 27, 2026	047–955	ROMPUN 20 mg/mL	522.2662
February 27, 2026	200–408	Butorphanol Tartrate Injection 2 mg/mL	522.246
February 27, 2026	200–183	Vet Beta-Gen (gentamicin sulfate, betamethasone valerate)	524.1044b
February 27, 2026	200–188	Betagen Topical Spray (gentamicin sulfate, betamethasone valerate)	524.1044f
February 27, 2026	200–196	Miconosol (miconazole nitrate lotion/spray 1%)	524.1443
February 27, 2026	200–229	TRI–OCTIC Ointment (gentamicin sulfate, betamethasone valerate, clotrimazole)	524.1044g

III. Changes of Sponsor

The sponsors of the approved applications listed in table 3 have

informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another

sponsor. The regulations cited in table 3 are amended to reflect these actions.

TABLE 3—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING JANUARY, FEBRUARY, AND MARCH 2026

Application No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR section
200–771 ... 141–614 ... 200–683 ...	Methimazole solution LAVERDIA (verdinexor tablets) CYCLEGUARD and MONOVET (melengestrol acetate Type A liquid medicated article and monensin Type A medicated article).	Norbrook Laboratories Ltd. (055529) Anivive Lifesciences Inc. (086121) Zoetis (054771)	Virbac AH, Inc. (051311) Dechra, Ltd. (043264) Phibro (066104)	520.1376 520.2700 558.342
139–235 ...	BIO–COX and BACIFERM (salinomycin sodium Type A medicated article and bacitracin zinc Type A medicated article to be used in the manufacture of Type C medicated feeds.	Do	Do	558.550
114–794 ...	AMPROL HI–E and BACIFERM (amprolium with ethopabate Type A medicated article and bacitracin zinc Type A medicated article).	Do	Do	558.58
134–830 ...	Coban and Albac (monensin Type A medicated article and bacitracin zinc Type A medicated article).	Do	Do	558.355

IV. Technical Amendments

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

- 21 CFR 520.522 is amended to revise language updated on the labeling for “Conditions for Use.”
- 21 CFR 558.625 is amended to revise language updated on the labeling for “Indications for Use” and “Limitations” with ractopamine hydrochloride.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)). Although deemed a rule under the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability” and is not

subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866.

List of Subjects

21 CFR Part 516

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

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

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

21 CFR Part 558

Animal drugs, Animal feeds.
Therefore, under the Federal Food, Drug, and Cosmetic Act and under

authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 516, 520, 522, 524, 529, 556, and 558 are amended as follows:

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

- 1. The authority citation for part 516 continues to read as follows:

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

- 2. In § 516.570, revise paragraph (c)(2) to read as follows:

§ 516.570 Doramectin.

* * * * *

(c) * * *

(2) *Indications for use.* For prevention and treatment of infestations caused by New World screwworm (*Cochliomyia*

hominivorax) larvae (myiasis), and prevention of reinfestation for 21 days.

* * * * *

■ 3. Add § 516.900 to subpart E to read as follows:

§ 516.900 Fluralaner.

(a) *Specifications.* Each milliliter (mL) of solution contains 50 milligrams (mg) of fluralaner

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 2.5 mg per kilogram (1.13 mg per one pound).

(2) *Indications for use.* For the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) and treatment and control of cattle fever tick (*Rhipicephalus microplus*) in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Environmental temperature affects the withdrawal period. Cattle must not be slaughtered for human consumption within 98 days of treatment. If cattle are continuously exposed to temperatures at or above 60 °F after product administration, then cattle may be slaughtered for human consumption 44 days after treatment. Violative residues may result if cattle are exposed to temperatures below 60 °F after administration and are slaughtered at 44 days. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows: use in these cattle may cause drug residues in milk and/or calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

§ 516.1858 [Removed]

■ 4. Remove § 516.1858.

**PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS**

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

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

■ 6. In § 520.35, revise paragraph (c)(2) to read as follows:

§ 520.35 Afoxolaner, moxidectin, and pyrantel.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the

treatment and control of adult hookworm (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) and roundworm (*Toxocara canis* and *Toxascaris leonina*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), and *Haemaphysalis longicornis* (longhorned tick) infestations for 1 month in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

■ 7. In § 520.43, revise paragraph (c)(2) to read as follows:

§ 520.43 Afoxolaner.

* * * * *

(c) * * *

(2) *Indications for use.* Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); and the treatment and control of *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month; and for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

■ 8. Add § 520.136 to read as follows:

§ 520.136 Atinivicitinib tablets.

(a) *Specifications.* Each tablet contains 4.8, 7.2, 21.6, or 31.6 milligrams (mg) of atinivicitinib.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 0.36 to 0.54 mg atinivicitinib per pound (0.8 to 1.2 mg atinivicitinib per kilogram) of body weight, once daily, with food.

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis in dogs 6 months of age and older.

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

■ 9. In § 520.522, revise paragraph (d)(1) introductory text to read as follows:

§ 520.522 Cyclosporine.

* * * * *

(d) * * *

(1) *Dogs.* Use capsules described in paragraph (a)(1) of this section or solution as described in paragraph (a)(2) of this section as follows:

* * * * *

■ 10. In § 520.905a, revise paragraph (b) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

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

(1) No. 000061 as in paragraph (e) of this section.

(2) No. 055529 as in paragraphs (e)(2) and (4) of this section.

* * * * *

■ 11. In § 520.928, revise paragraph (b)(2) to read as follows:

§ 520.928 Firocoxib tablets.

* * * * *

(b) * * *

(2) Nos. 000010, 055246, and 086101 for use of the product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

* * * * *

§ 520.1310 [Amended]

■ 12. In § 520.1310, in paragraph (b)(1), remove “Nos. 017033, 054771, and 086117” and in its place add “Nos. 017033, 054771, 069043, and 086117”.

■ 13. In § 520.1315, revise paragraphs (a) and (b) to read as follows:

§ 520.1315 Maropitant.

(a) *Specifications.* (1) Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

(2) Each chewable tablet contains 16, 24, 60, or 160 mg maropitant as maropitant citrate.

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

(1) Nos. 054771, 086101, and 086117 for use of the product described in paragraph (a)(1) of this section as in paragraph (c) of this section.

(2) No. 086101 for use of the product described in paragraph (a)(2) of this section as in paragraph (c) of this section.

* * * * *

§ 520.1376 [Amended]

■ 14. In § 520.1376, in paragraph (b), remove “055529” and in its place add “051311”.

- 15. In § 520.1782, revise paragraph (c)(2) to read as follows:

§ 520.1782 Pimobendan solution.

* * * * *

(c) * * *

(2) *Indications for use.* For the delay of onset of congestive heart failure (CHF) in dogs with Stage B2 preclinical myxomatous mitral valve disease (MMVD). Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly. For the management of the signs of mild, moderate, or severe CHF in dogs due to clinical MMVD or dilated cardiomyopathy (DCM); for use with concurrent therapy for CHF (e.g., furosemide, etc.) as appropriate on a case-by-case basis.

* * * * *

- 16. Add § 520.1858 to read as follows:

§ 520.1858 Potassium bromide chewable tablets.

(a) *Specifications.* Each chewable tablet contains 250 or 500 milligrams (mg) potassium bromide.

(b) *Sponsor.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 25 to 68 mg per kilogram (11 to 31 mg per pound) of body weight. The dosage should be adjusted based on monitoring of clinical response of the individual patient.

(2) *Indications for use.* For the control of seizures associated with idiopathic epilepsy in dogs.

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

§ 520.2700 [Amended]

- 17. In § 520.2700, in paragraph (b), remove “086121” and in its place add “043264”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- 18. The authority citation for part 522 continues to read as follows:

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

§ 522.147 [Amended]

- 19. In § 522.147, in paragraph (b), remove “Nos. 015914, 052483, 068504, and 069043” and in its place add “Nos. 015914, 052483, 068504, 069043, and 086101”.

- 20. In § 522.246:

- a. Remove paragraph (b)(2);
■ b. Redesignate paragraph (b)(3) as paragraph (b)(2); and

- c. Revise newly redesignated paragraph (b)(2).

The revision reads as follows:

§ 522.246 Butorphanol.

* * * * *

(b) * * *

(2) Nos. 000061, 017033, and 059399 for use of the product described in paragraph (a)(3) of this section as in paragraph (d)(3) of this section.

* * * * *

§ 522.533 [Amended]

- 21. In § 522.533, remove and reserve paragraphs (a)(2), (b)(2), and (c)(2).

§ 522.728 [Removed]

- 22. Remove § 522.728.

§ 522.956 [Amended]

- 23. In § 522.956, in paragraph (b), remove “No. 000061” and in its place add “Nos. 000061 and 068504”.

- 24. In § 522.998, revise paragraph (c)(2) to read as follows:

§ 522.998 Fluralaner.

* * * * *

(c) * * *

(2) *Indications for use.* Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); for the treatment and control of tick infestations *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), and *Amblyomma maculatum* (Gulf Coast tick) for 12 months in dogs and puppies 6 months of age and older; and for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 months in dogs and puppies 6 months of age and older.

* * * * *

§ 522.2075 [Amended]

- 25. In § 522.2075, in paragraph (b), remove “No. 058198” and in its place add “Nos. 058198 and 069043”.

§ 522.2662 [Amended]

- 26. In § 522.2662, in paragraph (b)(3), remove “Nos. 043264 and 061651” and in its place add “No. 061651”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

- 27. The authority citation for part 524 continues to read as follows:

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

- 28. In § 524.1001, revise paragraph (c)(2) to read as follows:

§ 524.1001 Fluralaner and moxidectin.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati*, fourth-stage larvae, immature adults, and adults) and hookworm (*Ancylostoma tubaeforme*, fourth-stage larvae, immature adults, and adults); kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Haemaphysalis longicornis* (Asian longhorned tick), and *Amblyomma maculatum* (Gulf Coast tick)) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

* * * * *

§ 524.1044b [Amended]

- 29. In § 524.1044b, in paragraph (b), remove “Nos. 000061 and 054925” and in its place add “No. 000061”.

§ 524.1044f [Amended]

- 30. In § 524.1044f, in paragraph (b), remove “Nos. 000061, 017033, 054925, 058005, and 058829” and in its place add “Nos. 000061, 017033, 058005, and 058829”.

- 31. In § 524.1044g:

- a. Remove paragraph (b)(2);
■ b. Redesignate paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3), respectively, and

- c. Revise paragraph (c)(1)(i).

The revision reads as follows:

§ 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

* * * * *

(c) * * *

(1) * * *

(i) From 7.5- or 15-g tubes; 10-, 12.5-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

* * * * *

§ 524.1443 [Amended]

- 32. In § 524.1443, in paragraph (b)(2), remove “Nos. 054925 and 058829” and in its place add “No. 058829”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

- 33. The authority citation for part 529 continues to read as follows:

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

§ 529.1186 [Amended]

■ 34. In § 529.1186, in paragraph (b), remove “Nos. 017033, 054771, and 065085” and in its place add “Nos. 010019, 017033, 054771, and 065085”.

§ 529.2110 [Amended]

■ 35. In § 529.2110, in paragraph (b), remove “Nos. 017033, 054771, and 065085” and in its place add “Nos. 017033, 054771, 065085, and 068504”.

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

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

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

■ 37. In § 556.290, add paragraph (b)(2) and revise paragraph (c) to read as follows:

§ 556.290 Fluralaner.

* * * * *

(b) * * *

(2) *Cattle*. (i) Liver (target tissue): 500 ppb.

(ii) Muscle: 350 ppb.

(c) *Related conditions of use*. See §§ 516.900 and 520.999 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 39. In § 558.58, revise paragraph (e)(4) to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

(e) * * *

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* * * *	* * * *	* * * *	* * * *	* * * *
(4) Amprolium 113.5 and ethopabate 36.3.	Bacitracin (as feed grade bacitracin zinc) 4 to 50.	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from <i>Eimeria acervulina</i> , <i>E. maxima</i> , and <i>E. brunetti</i> is likely to occur; for improved feed efficiency.	Feed as the sole ration from the time birds are placed on litter until past the time when coccidiosis is ordinarily a hazard, up to 16 weeks of age. If losses exceed 0.5% in a 2-day period, obtain an accurate diagnosis and follow the instructions of your veterinarian or poultry pathologist. Do not feed to chickens producing eggs for human consumption. Not for chickens over 16 weeks of age. Do not feed as a treatment for outbreaks of coccidiosis. Do not change the litter while giving this feed unless absolutely necessary. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter..	066104
* * * *	* * * *	* * * *	* * * *	* * * *

* * * *

■ 40. In § 558.342, revise paragraph (e)(1)(iv) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * *	* * * *	* * * *	* * * *	* * * *
(iv) 0.25 to 0.5	Monensin, 10 to 40	Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> .	At the rate of 0.5 to 2.0 lb/head/day, a Type C top-dress medicated feed containing 0.25 to 2 g melengestrol acetate per ton must be top dressed onto or mixed at feeding with a Type C medicated feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day. See § 558.355(d) of this chapter. Monensin as provided by No. 016592 or 058198; melengestrol acetate as provided by No. 016952, 066104, or 058198 in § 510.600(c) of this chapter.	016592 066104 058198

* * * *

■ 41. In § 558.355, revise paragraphs (a), (e)(1)(xi), (e)(4)(v) introductory text, and (e)(4)(v)(A) to read as follows:

§ 558.355 Monensin.

(a) *Specifications*. Type A medicated articles containing 45, 60, 90.7, 110, or 113.4 grams monensin, USP, per pound.

* * * * *

(e) * * *

(1) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xi) 90 to 110	Bacitracin (as feed grade bacitracin zinc), 4 to 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Not for broiler breeder replacement chickens. Bacitracin zinc as provided by No. 054771 in 510.600(c) of this chapter.	066104

(4)

Monensin amount	Indications for use	Limitations	Sponsor
(v) 1,620 grams per ton of mineral granules as specified in paragraph (e)(4)(v)(A) of this section.	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) or in a dry lot and replacement beef and dairy heifers: For increased rate of weight gain, and for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement.	016592 058198

(A) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082
Sodium chloride (salt)	24.37	6-04-152
Dried cane molasses	20.0	4-04-695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6-02-632
Cane molasses	3.0	4-04-696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix ¹	2.5	
Monensin Type A article, 90.7 grams per pound ²	0.89	
Antidusting oil	1.0	

¹ Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

² To provide 1,620 g monensin per ton, use 17.8 lb (0.89%) of a monensin Type A medicated article containing 90.7 g monensin per pound. If using a monensin Type A medicated article containing 113.4 grams monensin per pound, use 14.2 lb (0.71%), subtracting ground limestone.

* * * *

■ 42. In § 558.550, revise paragraph (e)(1)(v) to read as follows:

§ 558.550 Salinomycin.
(e) * * *
(1) * * *

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(v) 40 to 60	Bacitracin (as feed grade bacitracin zinc), 10 to 50.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for increased rate of weight gain.	Feed as the sole ration. The dosage of salinomycin sodium should be adjusted to meet the severity of coccidial challenge, which varies with environmental and management conditions. Do not feed to chickens producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses. Do not use in Type C medicated feeds containing pellet binders. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	016592 066104

* * * * *

§ 558.625 Tylosin.

■ 43. In § 558.625, revise paragraphs (e)(1)(v), (x), and (xiii) to read as follows:

(e) * * *
(1) * * *

Tylosin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(v) 40 or 100	Ractopamine hydrochloride, 4.5 to 9	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, control of swine dysentery associated with <i>Brachyspira hyodysenteriae</i> , and control of porcine proliferative enteropathies (PPE, ileitis) associated with <i>Lawsonia intracellularis</i> in finishing swine weighing at least 150 lb and fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. Not for use in swine intended for breeding.	Feed as the sole ration to finishing swine weighing at least 150 lb for the last 45 to 90 lb (group average) of weight gain prior to slaughter. Feed 100 g of tylosin per ton of complete feed for at least three weeks, followed by 40 g tylosin per ton of complete feed until pigs reach market weight. Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine hydrochloride as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter.	016592 054771 058198

Tylosin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(x) 40 to 100	Ractopamine hydrochloride, 4.5 to 9	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, the treatment and control of swine dysentery associated with <i>Brachyspira hyodysenteriae</i> , and control of porcine proliferative enteropathies (PPE, ileitis) associated with <i>Lawsonia intracellularis</i> immediately after medicating with tylosin in drinking water in finishing swine weighing at least 150 lb and fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. Not for use in swine intended for breeding.	Feed as the sole ration to finishing swine weighing at least 150 lb for the last 45 to 90 lb (group average) of weight gain prior to slaughter. Feed 40 to 100 grams of tylosin per ton of complete feed for 2 to 6 weeks immediately after medicating with tylosin in drinking water (250 mg tylosin per gallon) for 3 to 10 days as in § 520.2640(e)(3) of this chapter. Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine hydrochloride as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter.	
(xiii) 100	Ractopamine hydrochloride, 4.5 to 9	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and control of porcine proliferative enteropathies (PPE, ileitis) associated with <i>Lawsonia intracellularis</i> in finishing swine weighing at least 150 lb and fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. Not for use in swine intended for breeding.	Feed as the sole ration to finishing swine weighing at least 150 lb for the last 45 to 90 lb (group average) of weight gain prior to slaughter. Feed 100 g of tylosin per ton of complete feed for 21 days. Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine hydrochloride as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter.	016592 054771 058198

* * * * *

Grace R. Graham,Deputy Commissioner for Policy, Legislation,
and International Affairs.

[FR Doc. 2026-13716 Filed 7-6-26; 8:45 am]

BILLING CODE 4164-01-P

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

[Docket Number USCG-2026-0930]

RIN 1625-AA00

**Safety Zone; Corpus Christi Ship
Channel, Corpus Christi, 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 Corpus
Christi Ship Channel, in Port Aransas

near beacons “9” and “10.” The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by an underwater obstruction. Entry of vessels or persons into this temporary safety zone is prohibited unless specifically authorized by the Captain of the Port, Sector Corpus Christi or a designated representative.

DATES: This rule is effective without actual notice from July 7, 2026 through 11:59 p.m. on July 8, 2026. For the purposes of enforcement, actual notice will be used from July 1, 2026 until July 7, 2026.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG-2026-0930.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Lieutenant Timothy Cardenas, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361-244-4784, email Timothy.J.Cardenas@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 emergency diving and salvage operations will occur within the Corpus Christi Ship Channel near Port Aransas, TX. Hazards from this project include but are not limited to deployment of heavy equipment which will obstruct vessel traffic, continuous diving operations, and various other activities which create underwater hazards for workers and the public. The Captain of the Port (COTP) Sector Corpus Christi has determined that potential hazards associated with diving and salvage operations are a safety concern for anyone within the work area. 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.

Because of these potential hazards, 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. The Coast Guard was notified of this event on July 1, 2026, and we must establish this safety zone immediately to protect personnel, vessels, and the marine environment. Therefore, we do not have enough time to solicit and respond to comments.

For the same reason, 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 from July 1, 2026 through July 8, 2026. The safety zone will cover all navigable waters in the Corpus Christi Ship Channel within the following points: Point 1 at 27°50'20.77" N, 097°03'04.43" W, thence to Point 2 at 27°50'27.87" N, 097°02'58.02" W, thence to Point 3 at 27°50'07.72" N, 097°02'20.09" W, thence to Point 4 at 27°49'59.59" N, 097°02'27.36" W; thence returning to Point 1. Vessels and persons will not be allowed to enter the zone during this time, unless authorized by the Captain of the Port.

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 *et seq.*), 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(d) 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.T08–0930 to read as follows:

§ 165.T08–0930 Safety Zone; Corpus Christi Ship Channel, Corpus Christi, TX.

(a) *Location.* The following area is a safety zone: All waters of the Corpus Christi Ship Channel from surface to bottom, encompassed by a line connecting the following points beginning at: Point 1 at 27°50'20.77" N, 097°03'04.43" W, thence to Point 2 at 27°50'27.87" N, 097°02'58.02" W, thence to Point 3 at 27°50'07.72" N, 097°02'20.09" W, thence to Point 4 at 27°49'59.59" N, 097°02'27.36" W and along the shoreline back to the beginning point. 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 Corpus Christi (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 (800) 874–2143. 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 11:59 a.m. July 1, 2026 p.m. to 11:59 p.m. July 8, 2026.

T.H. Bertheau,

Captain, U.S. Coast Guard, Captain of the Port Sector Corpus Christi.

[FR Doc. 2026-13681 Filed 7-6-26; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 216

[Docket No. 260630-0155]

RIN 0648-BN39

Pribilof Islands Administration; Dogs Prohibited

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

ACTION: Interim final rule.

SUMMARY: NMFS is creating an exception to the prohibition on landing dogs on the Pribilof Islands to allow the Regional Administrator to authorize independently certified and trained rodent detection dogs to be deployed to detect and prevent the establishment of invasive rodents. Invasive rodents could have significant consequences for the wildlife species that live and breed on the Pribilof Islands and the health and food security of community members. Public comments received expressed broad support for the proposed rule with some minor clarifications. NMFS is publishing this interim final rule to allow public comment on the decision to authorize certified and trained rodent detection dogs to pre-emptively inspect vessels or cargo. This action supports Tribal, local, and Federal agency efforts intended to promote the goals and objectives of the Fur Seal Act (FSA), the Marine Mammal Protection Act (MMPA), and other applicable laws.

DATES: Effective August 6, 2026. Submit comments on or before August 6, 2026.

ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS-2025-0405, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit <https://www.regulations.gov> and type NOAA-NMFS-2025-0405 in the Search box. Click the “Comment” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to the Assistant Regional Administrator, Protected Resources Division, Alaska Region NMFS, P.O. Box 21668, Juneau, AK 99802-1668.

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 <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address), 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).

Electronic copies of the Regulatory Impact Review prepared for this interim final rule may be obtained from <https://www.regulations.gov>.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this interim final rule may be submitted to the Assistant Regional Administrator, Protected Resources Division, Alaska Region NMFS, P.O. Box 21668, Juneau, AK 99802-1668, and to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by using the search function (collection of information 0648-0699).

FOR FURTHER INFORMATION CONTACT:

Michael Williams, NMFS Alaska Region, 907-271-5117, michael.williams@noaa.gov.

SUPPLEMENTARY INFORMATION:

Authority for Action

The FSA (16 U.S.C. 1161-1169b) requires the NMFS Alaska Regional Administrator, acting pursuant to delegated authority, to administer Federal lands of the Pribilof Islands and ensure that activities on such Federal lands are consistent with the purposes of conserving, managing, and protecting northern fur seals, *Callorhinus ursinus*, and other wildlife. NMFS is authorized to promulgate regulations necessary for the administration of the Pribilof Islands (16 U.S.C. 1169), which NMFS has promulgated at 50 CFR part 216, Subpart G-Pribilof Islands Administration. NMFS manages northern fur seals consistent with both the FSA and MMPA.

Background

NMFS published a notice of proposed rulemaking and request for comments

(90 FR 57442; December 11, 2025) (Proposed Rule) to create an exception in 50 CFR 216.82 to authorize the use of trained and certified rodent detection dogs to prevent the establishment of invasive rodents on the Pribilof Islands. Current regulations prohibit the landing of any dogs at the Pribilof Islands in order to prevent the molestation of the fur seal herds (50 CFR 216.82). NMFS has interpreted the molestation of the fur seal herds to include physical disturbance and disease transmission by a dog or its feces.

In the Proposed Rule, NMFS summarized that the Pribilof Islands are rat-free as well as the history of invasive rodent detection and eradication since the 1990s. Rodent detection dogs are the most cost-effective tool to prevent invasive rodent infestations.

The introduction of an invasive rat (or invasive rodent) could have significant ecological consequences for the indigenous species that live and breed on the islands, including northern fur seals, which have been designated as depleted under the MMPA (53 FR 17888; May 18, 1988). Invasive rodents include brown rats or Norway rats, black rats or roof rats, mice, and other less common species. Mice do not pose the same wildlife risk as rats, but have been observed killing seabird chicks, and also have a human health and zoonotic disease risk. Black rats generally avoid water, but have been observed on one of the Aleutian Islands. Dutch Harbor, which has invasive rats, is the closest port to the Pribilof Islands and is often the origin for local and regional cargo vessels, barges, and aircraft. Fishing vessels, many of which originate from Dutch Harbor, come to St. Paul and St. George for fuel, resupply, and emergencies. The risk of rodent introductions to the Pribilof Islands is also growing primarily due to increased vessel traffic in the sub-arctic and Arctic for tourism. Vessels are the primary source of introductions of rats to islands worldwide (Drake and Hunt 2008).

In the Proposed Rule, NMFS described the need to create the exception to the current regulatory prohibition by allowing the Regional Administrator to authorize the use of rodent detection dogs to respond to any incidents that could otherwise lead to the establishment of a rodent population on any of the Pribilof Islands. NMFS believes the ecological benefits of successfully detecting and eradicating any invasive rodents on the Pribilof Islands outweigh the manageable risks of molestation of the fur seal herd and disease transmission from dogs or their feces. After careful review and consideration of public comments,

NMFS has determined that landing independently certified and trained rodent detection dogs, subject to certain conditions to be imposed by NMFS, would not create any significant environmental risk to fur seals or other wildlife populations on the Pribilof Islands. These conditions include: (1) the only dogs that could be authorized on the Pribilof Islands are rodent detection dogs independently certified to have been trained for that purpose; (2) the certified rodent detection dog(s) will undergo any quarantine period required by the State of Alaska; (3) any such dog must have current immunizations and health certifications required by the State of Alaska and any additional immunizations required by NMFS to protect indigenous wildlife of the Pribilof Islands; (4) any such dog must be under constant control (*i.e.*, voice, electronic, or leash) by a professional dog handler; and (5) the handler will be responsible for feces management, including collecting all feces, securing all feces from exposure to indigenous wildlife, and disposing of all feces by incineration on the island from which it is collected.

A trained rodent detection dog cannot be self-certified by the handler or owner of the dog. The handler or owner must obtain and maintain certification by any accredited canine scent detection association, company, or organization, and the Pribilof Island landowner seeking authorization must then provide that independent certification to the NMFS Alaska Regional Administrator when submitting a request via email to PribilofRodentDogApp@noaa.gov for authorization to land a rodent detection dog on a Pribilof Island. There are independently certified and trained rodent detection dogs available through the U.S. Department of Agriculture and several private organizations.

The regulation will continue to prohibit the landing of dogs on the Pribilof Islands for any other purpose, including as household pets.

To minimize disease transmission, any dogs must have proof of current immunizations and health certifications required by the State of Alaska and NMFS, and the handler will be responsible for collecting and disposing of all feces. The exception is limited to a total of 180 days per deployment and is triggered when a dog or dogs are necessary for rodent detection on an island to prevent the establishment of a rodent population on any of the Pribilof Islands. If two islands have separate deployments, the dogs deployed to each island will be subject to separate 180-day limits. The 180-day period starts on the date of the dog's arrival on the

island and is calculated by the total number of days the dog is present on that island. If for any reason the dog needs to depart prior to reaching the 180-day limit, only those days that a dog was present on that island count toward the limit, and certified and trained rodent detection dog(s) will be allowed to return to the island for the remainder of the 180-day period if necessary for rodent detection. Each 180-day period will apply to the island and circumstances for which it was authorized. If new circumstances emerge after a 180-day period expires, the Regional Administrator will consider whether to authorize a new 180-day period based on the evidence available, including evidence of the presence of any rodents.

NMFS intends for this action to apply to the Pribilof Islands, not just St. Paul and St. George, because the risk of shipwrecks introducing rodents is also possible on the uninhabited islands.

Effects

The establishment of invasive rodents on the Pribilof Islands could result in negative environmental and public health impacts. Environmental impacts, such as reduced wildlife populations, would impact the wildlife-viewing tourist economy managed by the local Alaska Native Corporations on St. Paul Island (Tanadgusix Corporation, TDX) and St. George Island (Tanaq Corporation) and the communities of St. Paul and St. George that rely on marine and terrestrial species breeding on the Pribilof Islands for subsistence purposes and food security.

Implementing this interim final rule will help prevent the establishment of invasive rodents on the Pribilof Islands, which in turn protects the wildlife-tourist economy, subsistence resources that contribute to food security and the mixed cash-subsistence economy, and public health costs from rodent-borne diseases. This exception creates the flexibility and opportunity for landowners on the Pribilof Islands to hire and utilize the services of an independently certified and trained rodent detection dog handler to prevent invasive rodents from establishing a population on the Pribilof Islands. Entities that are directly regulated by this rule are limited to any Pribilof Islands landowner who requests invasive rodent detection services and the service provider. Landowners on the Pribilof Islands include the Federal government, municipal governments of St. Paul and St. George, and the TDX Corporation and Tanaq Corporation. In addition to private companies, other Federal agencies, such as the U.S.

Department of Agriculture, may have rodent detection dogs available.

The use of independently certified and trained rodent detection dogs will help to successfully locate and eradicate any invasive rodents from the Pribilof Islands, which will protect sensitive wildlife, subsistence resources necessary to maintain food security, wildlife and communities that may be exposed to invasive rodent-borne diseases, and the small wildlife tourism economy on the Pribilof Islands. Therefore, it is expected that the rulemaking could have a beneficial economic effect by creating the opportunity to detect invasive rodents on the Pribilof Islands with independently certified and trained dogs.

Comments and Responses

NMFS received comments on the Proposed Rule from the Aleut Community of St. Paul Island, Tribal Government (ACSPI), the Marine Mammal Commission (Commission), the U.S. Fish and Wildlife Service (USFWS), and five individuals. All commenters supported NMFS's proposed rule to create an exception to allow the use of rodent detection dogs to prevent the establishment of invasive rodent populations on the Pribilof Islands. A summary of the comments requesting clarifications and NMFS's responses follows.

Comment 1: One commenter requested clarification of the landowners on the Pribilof Islands who could potentially apply for authorization from the NMFS Alaska Regional Administrator and offered an alternative that NMFS may consider requests from all Federal, state, local, and Tribal governments and Alaska Native Corporations in Alaska.

Response 1: We have clarified in the preamble of this interim final rule that only Pribilof Island landowners can apply for the exception. There are many Alaska Native Corporations, local governments, and Tribal governments in Alaska that have limited knowledge or interest in the Pribilof Islands, and NMFS believes the limitation of Pribilof Islands landownership for potential applicants is appropriate. NMFS did not make any edits to the regulatory text, which continues to state that under this exception a "Pribilof Island landowner must submit a request for authorization to land a rodent detection dog on a Pribilof Island in writing to the NMFS Alaska Regional Administrator."

Comment 2: One commenter requested clarification on whether NMFS intended for dogs to be used only in response to a rodent detection on

island or whether dogs may be used pre-emptively to inspect vessels or cargo to prevent a rodent introduction.

Response 2: The impetus to create the regulatory exception was to respond to the possible rat observation on St. Paul in 2024, based on the time and costs associated with the prior rat detection and eradication effort that was not able to use a rodent detection dog. NMFS had not contemplated this standard of prevention in the proposed rule (90 FR 57442; December 11, 2025) but rather contemplated that dogs would be deployed *in response* to evidence of rodent presence on a Pribilof Island. In consultation with Tribal and Federal agencies, NMFS has determined that pre-emptive inspections are preferable to surveys after a rodent is detected on island. NMFS believes the use of independently certified and trained rodent detection dogs for pre-emptive inspections will help to successfully locate and eradicate any invasive rodents from the Pribilof Islands, which will protect sensitive wildlife, subsistence resources and food security, public health, and the tourism economy. The current island infrastructure and capacity for dog detection of rodents is that initial detection of a rodent(s) will continue to occur through the rodent prevention efforts that exist on the Pribilof Islands. That is, either a visual or photographic sighting of a live or dead invasive rodent, invasive rodent feces, or damaged food or household items consistent with the presence of invasive rodents will provide the basis for a landowner to apply for the exception, but it will not be a requirement for NMFS's acceptance of an application for review and consideration. We do recognize that the closest cargo port is in Dutch Harbor and potential for any departing vessel to carry invasive rodents exists. Detector dog inspections of arriving vessels or cargo would greatly improve biosecurity on the Pribilof Islands to prevent an introduction of invasive rodents unlike the current reactionary monitoring. We have therefore clarified and amended the regulatory text such that the regulation allows for pre-emptive inspection using rodent detection dogs. Whether pre-emptive inspections can proceed with or without quarantine infrastructure and staff capacity on the Pribilof Islands is unknown. The same 180-day duration of the exception would still apply to the pre-emptive inspections. NMFS is interested in learning whether, in light of its shift to authorizing dogs pre-emptively, if easier or more streamlined mechanisms to

prevent the establishment of invasive rodents exist.

Comment 3: One commenter recommends that the regulations specifically require independent certification and specify that dog handlers cannot certify themselves.

Response 3: NMFS agrees that independent certification of a rodent detection dog is the requirement and has added clarifying regulatory text and further explanation about this requirement in the preamble.

Comment 4: One commenter recommends that the regulations include additional restrictions when rodent detection activities are conducted near northern fur seal haulouts and rookeries during portions of the year when fur seals are present.

Response 4: NMFS agrees there may be a need for additional restrictions if it is determined that dog search activities will be required near northern fur seals or other hauled out pinnipeds. NMFS has revised the regulatory text in § 216.82 paragraph (b)(2) indicating that, “. . . Administrator may authorize the landing of one or more independently certified and trained rodent detection dogs and impose any *additional* conditions on their use on the specified Pribilof Island.” We believe this clause with the inclusion of “additional” provides the Regional Administrator appropriate authority for the circumstances described by this commenter and that the Regional Administrator may include any other additional conditions deemed necessary to minimize or mitigate unforeseen risks.

Comment 5: One commenter recommends NMFS require that dogs to be landed on the Pribilof Islands be vaccinated against other common diseases of dogs that can kill fur seals. Specifically, at a minimum, that NMFS require dogs to be vaccinated against canine distemper and parvovirus.

Response 5: NMFS agrees vaccination of dogs against a disease that can harm or kill fur seals should be required and have added clarifying text that, in addition to State requirements, NMFS will require vaccinations consistent with the latest evidence of diseases capable of harming or killing fur seals.

Changes to the Proposed Rule

NMFS made four changes to the regulatory text at 50 CFR 216.82. First, NMFS removed the requirement (formerly at paragraph (b)(1)(i)) of “evidence of rodent presence on a Pribilof Island” to allow for pre-emptive inspections of vessels or cargo. This change aligns with the intent of the Proposed Rule, *i.e.*, allowing the

Regional Administrator to authorize the use of rodent detection dogs to detect and prevent the establishment of invasive rodents on the Pribilof Islands. As discussed above, one commenter specifically requested clarification on whether dogs may be used pre-emptively to inspect vessels or cargo to prevent a rodent introduction. After considering the commenter's request for clarification, NMFS determined that the pre-emptive use of rodent detection dogs will be more effective than reactionary monitoring alone to prevent the establishment of invasive rodents on the Pribilof Islands. NMFS seeks public comment on such pre-emptive use and will issue a subsequent final rule responding to any comments received. Second, NMFS changed the requirement at paragraph (b)(1)(i) that “certification that the dog has been trained for rodent detection” to “independent certification by an accredited canine scent detection association, company, or organization that the dog has been trained for rodent detection” to prevent self-certification by owners or handlers. NMFS made conforming edits to paragraphs (b)(2) and (b)(3) to “independently certified and trained rodent detection dog.” Third, NMFS changed the requirement at paragraph (b)(1)(iv) that “current immunization and health certifications required by the State of Alaska” to “current immunization and health certifications required by the State of Alaska and NMFS Alaska Regional Administrator” to ensure that NMFS may require additional immunizations for canine diseases capable of harming or killing marine mammals. This would include immunizations for distemper and parvovirus in addition to the State of Alaska vaccination requirement of rabies. Last, NMFS changed the requirement at paragraph (b)(2) to add “additional” to the text “and impose any additional conditions on their use on the specified Pribilof Island” to authorize the Regional Administrator to impose any conditions necessary on the deployment of rodent detection dogs on the Pribilof Islands to mitigate potential impacts to indigenous wildlife, such as additional restrictions if it is determined that dog search activities will be required near northern fur seals or other hauled out pinnipeds. This ensures that any unforeseen risks from the use of dogs are accommodated within the current regulatory framework.

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this interim final rule is consistent with the FSA (16 U.S.C. 1161–1169b), the MMPA, and other applicable laws. In

the development of this interim final rule, NMFS worked with the Tribal governments of St. Paul Island and St. George Island pursuant to their signed co-management agreements with NMFS under the MMPA (16 U.S.C. 1388(a)).

National Environmental Policy Act (NEPA)

Subject to further consideration after public comment, NMFS has determined that this action is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement in accordance with 42 U.S.C. 4336(a)(2) and Section V of NOAA's Policies and Procedures for Compliance with NEPA and Related Authorities (Companion Manual for NAO 216–6A). NMFS intends to adopt U.S. Fish and Wildlife Service's (USFWS) categorical exclusion (CE) determination for its action of deploying tools to detect and locate a rat on St. Paul Island, including temporary use of a trained rat detection dog. This action is substantially the same as the action covered by USFWS's CE determination—a category of actions that does not normally have a significant effect on the quality of the human environment; is not connected to a larger action; and does not involve extraordinary circumstances precluding use of the CE. NMFS reviewed the CE in the context of using detection dogs for pre-emptive inspections of vessels or cargo. Since pre-emptive inspections would occur in secured facilities within the developed harbor areas of either St. Paul or St. George Island for periods not to exceed 180 days in duration NMFS determined the action is substantially the same as the action covered by USFWS's CE determination. NMFS has prepared a memorandum to the record documenting NMFS's adoption of USFWS's CE determination.

Executive Order 12866

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

Executive Order 14192

This interim final rule is an Executive Order 14192 deregulatory action.

Executive Order 13175

The ACSPI and USFWS have requested that NMFS implement this rule to revise the FSA regulations to authorize rodent detection dogs to land on the Pribilof Islands. NMFS has worked collaboratively and had frequent communication with the ACSPI and the Traditional Council of St. George Island (TCSGI) as part of a multi-agency invasive rodent task force. NMFS also

notified the local Alaska Native Corporations on St. Paul Island (Tanadgusix Corporation, TDX) and St. George Island (Tanaq Corporation) about the opportunity for public comment on the proposed rule regarding the landing of rodent detection dogs on the Pribilof Islands. After one commenter requested clarification on the pre-emptive deployment of rodent detection dogs, NMFS again conferred with the ACSPI and the TCSGI. Given the level of Tribal engagement in the course of responding to this issue and developing the proposed rule and interim final rule, Tribal consultation was not held specifically for the proposed rule.

A Tribal summary impact statement under section (5)(b)(2)(B) and (c)(2) of E.O. 13175 was not required for this interim final rule because this action does not impose substantial direct compliance costs on Alaska Native Tribal Governments and this action does not preempt Tribal law. A Tribal summary impact statement is not required and has not been prepared.

Regulatory Impact Review (RIR)

An RIR was prepared to assess costs and benefits of available regulatory alternatives. A copy of this analysis is available from NMFS (see **ADDRESSES**).

Regulatory Flexibility Act

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

Collection-of-Information Requirements

This interim final rule requests a revision to and extension of a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This rule revises the existing requirements for the collection of information 0648–0699, Pribilof Islands: Administration and Taking for Subsistence Purposes, by adding an exception to 50 CFR 216.82. This exception would allow landowners to request to bring an independently certified rodent detection dog to the Pribilof Islands to detect and prevent the establishment of invasive rodents. Public reporting burden for this application is estimated at 20 hours.

This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information.

Public comment is sought regarding whether this proposed collection of information is necessary for the proper performance of the agency's functions, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Submit comments on these or any other aspects of the collection of information at www.reginfo.gov/public/do/PRAMain. Notwithstanding any other provision of the 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 PRA, unless that collection of information displays a currently valid OMB Control Number.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be contrary to the public interest. NMFS published the Proposed Rule and invited public comment for a 30-day period. NMFS received eight comments from individuals, the ACSPI, the USFWS, and the Commission. In response to public comments received, NMFS made changes to the regulatory text. One of the changes allows NMFS to authorize rodent detection dogs for pre-emptive use to prevent the establishment of rodents on the Pribilof Islands. During the notice and comment period, the Commission specifically requested clarification on whether dogs may be used pre-emptively to inspect vessels or cargo to prevent a rodent introduction. The pre-emptive use of rodent detection dogs in addition to reactionary monitoring will: (1) be more effective than reactionary monitoring alone to prevent the establishment of invasive rodents on the Pribilof Islands; and (2) falls within the scope of the Proposed Rule. As stated in the Proposed Rule, the revisions to the regulations will “authorize the landing of certified and trained rodent detection dogs . . . for the sole purpose of detecting and eradicating invasive rodents” (emphasis added). Therefore, the pre-emptive use of rodent detection dogs to detect any rodents on vessels or

in cargo before they could cause significant adverse impacts to the wildlife indigenous to the Pribilof Islands falls within the scope of the Proposed Rule. NMFS invites the public to submit additional comments on such pre-emptive use and will issue a subsequent final rule addressing any comments received.

NMFS has determined that another round of prior notice and comment before implementing the regulations would be contrary to the public interest because any further delay could have significant adverse impacts to the wildlife indigenous to the Pribilof Islands, subsistence practices and food security, public health, and the tourism economy. As discussed in the preamble and in the Proposed Rule, under this interim final rule, NMFS may authorize the temporary use of rodent-detection dogs to locate rodents and prevent their establishment on the Pribilof Islands pursuant to the FSA. Finalizing this rule will allow for the beneficial use of rodent-detection dogs, consistent with the new regulatory requirements, rather than deferring implementation for another round of prior notice and comment. Given the various regulatory requirements for the use of rodent-detection dogs and the many practical and logistical hurdles in transporting a dog to the Pribilof Islands, finalizing this rule now will also provide sufficient time for landowners and dog handlers to consider the use of such dogs for rodent detection, either pre-emptively or in response to invasive rodents on island.

References

Drake, D.R., Hunt, T.L. Invasive rodents on islands: Integrating historical and contemporary ecology. *Biological Invasions* 11, 1483–1487 (2009). <https://doi.org/10.1007/s10530-008-9392-1>.

List of Subjects in 50 CFR Part 216

Alaska, Pribilof Islands.

Dated: June 30, 2026.

Kelly Denit,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 216 as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. Revise § 216.82 to read as follows:

§ 216.82 Dogs prohibited.

(a) In order to prevent molestation of fur seal herds, the landing of any dogs at Pribilof Islands is prohibited.

(b) The NMFS Alaska Regional Administrator may authorize the landing of independently certified and trained rodent detection dogs on an island in the Pribilof Islands, subject to the following:

(1) A Pribilof Island landowner must submit a request for authorization to land a rodent detection dog on a Pribilof Island in writing to the NMFS Alaska Regional Administrator and must include the following information:

(i) Independent certification by an accredited canine scent detection association, company, or organization that the dog has been trained for rodent detection;

(ii) Certification that the dog will be under the constant voice, electronic, or leash control of a professional dog handler, or otherwise confined, while on the Pribilof Island;

(iii) Proof that the dog has undergone any quarantine period required by the State of Alaska;

(iv) Current immunization and health certifications required by the State of Alaska and NMFS Alaska Regional Administrator;

(v) The number of dogs expected to be used;

(vi) The professional dog handler's written plan for collecting and incinerating dog feces;

(vii) The expected duration and location of rodent searches on the Pribilof Island; and

(viii) Any other information requested by the Alaska Regional Administrator.

(2) After receipt of a complete request, within 10 days, the NMFS Alaska Regional Administrator may authorize the landing of one or more independently certified and trained rodent detection dogs and impose any additional conditions on their use on the specified Pribilof Island.

(3) No independently certified and trained rodent detection dog authorized by the NMFS Alaska Regional Administrator may be on the specified Pribilof Island for more than 180 total days from landing on that Island.

[FR Doc. 2026–13684 Filed 7–6–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 216 and 300

[Docket No. 260629–0154]

RIN 0648–BO29

International Fisheries; Pacific Tuna Fisheries; Conservation and Management Measures for Tropical Tunas in the Eastern Pacific Ocean for 2026 and Beyond

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

ACTION: Final rule.

SUMMARY: NMFS is issuing regulations under the Tuna Conventions Act (TCA) of 1950, as amended, to implement resolutions adopted at the 103rd Meeting of the Inter-American Tropical Tuna Commission (IATTC) in September 2025. The final rule also implements several provisions of Resolution C–19–04 (Resolution to Mitigate Impacts on Sea Turtles) that were not previously implemented and makes technical corrections to regulations for fishing under the Agreement on the International Dolphin Conservation Program (AIDCP). The management measures in this rule apply to fishing vessels targeting tropical tuna (*i.e.*, bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), and skipjack tuna (*Katsuwonus pelamis*)) in the eastern Pacific Ocean (EPO). This rule is necessary for the conservation and management of tropical tuna stocks in the EPO and for the United States to satisfy its obligations as a member of the IATTC.

DATES: This rule is effective July 7, 2026.

ADDRESSES: A plain language summary of this rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2025-1362>.

Copies of supporting documents that were prepared for this rule, including the regulatory impact review (RIR) are available via the Federal e-Rulemaking Portal: <http://www.regulations.gov>, docket NOAA–NMFS–2025–1362, or contact Tyler Lawson, NMFS West Coast Region Portland Office, 1201 NE Lloyd Blvd., Suite 1100, Portland, OR 97205, or tyler.lawson@noaa.gov.

Send comments on aspects of the collection of information to the **ADDRESSES** above, and by email to OIRA_Submission@omb.eop.gov, or fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT:

Tyler Lawson, NMFS WCR, at (503) 230-5421, tyler.lawson@noaa.gov.

SUPPLEMENTARY INFORMATION:**Background on the IATTC**

The United States is a member of the IATTC, which was established under the 1949 Convention for the Establishment of an Inter-American Tropical Tuna Commission (1949 Convention). In 2003, the IATTC updated the 1949 Convention through the adoption of the Convention for the Strengthening of the IATTC Established by the 1949 Convention between the United States of America and the Republic of Costa Rica (Antigua Convention). The Antigua Convention entered into force in 2010. The United States acceded to the Antigua Convention on February 24, 2016. The full text of the Antigua Convention is available at: https://www.iatcc.org/PDFFiles2/Antigua_Convention_Jun_2003.pdf.

The IATTC consists of 21 member nations and 5 cooperating non-member nations. The IATTC is responsible for the conservation and management of tuna and tuna-like species in the IATTC Convention Area. The IATTC Convention Area is defined as waters of the EPO within the area bounded by the west coast of the Americas and by 50° N latitude, 150° W longitude, and 50° S latitude. The IATTC maintains a scientific research and fishery monitoring program and regularly assesses the status of tuna, sharks, and billfish stocks in the IATTC Convention Area to determine appropriate catch limits and other measures deemed necessary to promote sustainable fisheries and prevent the overexploitation of these stocks.

International Obligations of the United States Under the Antigua Convention

As a Party to the Antigua Convention and a member of the IATTC, the United States is legally bound to implement decisions of the IATTC under the TCA of 1950, as amended, 16 U.S.C. 951 *et seq.* (Pub. L. 114-81). The TCA directs the Secretary of Commerce, in consultation with the Secretary of State and, with respect to enforcement measures, the U.S. Coast Guard, to promulgate such regulations as may be necessary to carry out the United States' obligations under the Antigua Convention, including recommendations and decisions adopted by the IATTC. 16 U.S.C. 955(a). The authority of the Secretary of Commerce to promulgate such regulations has been delegated to NMFS.

IATTC Resolutions on Tropical Tuna Conservation, Fish Aggregating Devices, and Mitigating Impacts on Sea Turtles To Be Implemented by This Rulemaking

The 103rd Meeting of the IATTC was held in Panama City, Panama, in September 2025. At this meeting, the IATTC adopted Resolutions C-25-01 (Conservation Measures for Tropical Tunas In The Eastern Pacific Ocean During 2026 and 2027-2028) and C-25-07 (Amends and Replaces Resolution C-24-06 on Fish-Aggregating Devices). At the 94th Meeting of the IATTC in Bilbao, Spain, in July 2019, the IATTC adopted Resolution C-19-04 (Resolution to Mitigate Impacts on Sea Turtles). This section summarizes those three resolutions, all of which contain measures that are implemented by this rule, as discussed in the next section.

Resolution C-25-01 (Conservation Measures for Tropical Tunas in the Eastern Pacific Ocean During 2026 and 2027-2028)

Many of the measures in Resolution C-25-01 are identical in content to those contained in the previous tropical tuna resolution (C-24-01; Conservation Measures for Tropical Tuna in the Eastern Pacific Ocean During 2025-2026), which NMFS implemented in a May 23, 2025 final rule (90 FR 22023); the regulations implemented through that rule are in effect unless and until they are amended or replaced. Specifically, Resolution C-25-01 continues, unchanged, the following measures from the previous resolution (C-24-01): catch limits of bigeye tuna caught in the EPO for longline vessels greater than 24 meters in overall length, catch limit transfer requirements for bigeye tuna, a requirement that all tropical tuna be retained and landed (with some exceptions), the corralito closure area, and restrictions on the use and design of fish aggregating devices (FADs).

In addition to continuing the existing measures discussed in the previous paragraph, Resolution C-25-01 expands fishing opportunities by reducing the current purse seine closure period from 72 days to 64 days. As discussed further under the Classification section, this reduction of eight closure days provides substantial additional fishing opportunities for the U.S. fleet, allowing vessels to make additional purse seine sets and increase revenue. This reduction in closure days is consistent with advice from the IATTC scientific staff, who provided options for reducing closure days based on the current stock status of tropical tuna stocks. Because of

the reduced number of closure days, Resolution C-25-01 also adjusts the current closure date periods for class size 5 and 6 purse seine vessels and creates a new alternative for class size 4 purse seine vessels to choose their own closure of 64 consecutive days at any time of the year. Class size 4 purse seine vessels are also no longer eligible to request a closure day exemption due to force majeure due to the flexibility to select closure days.

The Resolution also removes beaching of a FAD as a circumstance that allows for deactivating a FAD satellite buoy and requires that vessels and vessel operators report if the FAD satellite buoy is turned on or off.

Additionally, the Resolution requires a one-time assessed contribution to be paid by all class size 4-6 purse seine vessels listed as active on the IATTC Regional Vessel Register (RVR) at any point during the 2026 calendar year. These vessels must pay an amount equal to \$6.16 per cubic meter of well capacity. Payment for such vessels is due by June 30, 2026, or for vessels entering the RVR after January 15, 2026, is due prior to the vessel's inclusion in the RVR, along with its AIDCP vessel assessment. These assessed contributions will be used to support the enhancement of the IATTC's Regional Tuna Tagging Program (RTTP) to allow for estimation of growth, natural mortality and abundance of tropical tuna, swordfish, and sharks.

Resolution C-25-01 will expire at the end of 2026 "unless the scientific advice provided by IATTC staff and the IATTC Scientific Advisory Committee in 2026 through the management strategy evaluation process confirms the effectiveness of the measures in place," in which case the Resolution would remain in force until December 31, 2028.

Resolution C-25-07 (Amends and Replaces Resolution C-24-06 on Fish-Aggregating Devices)

Resolution C-25-07 continues measures from Resolution C-23-03, which NMFS implemented in a December 6, 2024 final rule (89 FR 96906). These measures establish requirements for vessels that choose to recover FADs for the purpose of final disposal or recycling and a reporting requirement for information associated with recovered FADs and also continue to prohibit the use of tender vessels.

For vessels engaged in FAD recovery activities, the Resolution amends the current data reporting provision to allow vessels and operators to either enter recovery data directly into the IATTC's online FAD recovery database

or to report the data by completing and submitting a specified FAD sighting form.

Resolution C-19-04 (Resolution To Mitigate Impacts on Sea Turtles)

The IATTC adopted Resolution C-19-04 in 2019, which revised measures from prior resolutions on bycatch. Several of the new measures in Resolution C-19-04 still need to be implemented and are included in this rule. These measures are: (1) modified procedures for what to do if a sea turtle is sighted in the net or entangled during net roll; (2) requirements for purse seine vessels to carry onboard safe handling tools (e.g., dip nets) for the release of sea turtles and to promptly release sea turtles observed entangled in a FAD; and (3) a requirement for purse seine vessels to record all observed sea turtle interactions using specified minimum data fields (e.g., species ID, size, release condition).

Final Regulations

This rule includes minor changes to part 300, subpart C of title 50 of the Code of Federal Regulations (CFR). The rule applies to U.S. commercial fishing vessels using purse seine or longline gear to catch tropical tuna in the IATTC Convention Area. Most of the measures in Resolution C-25-01 do not need to be implemented through this rule because, as noted previously, they continue existing measures that are already codified and do not expire. These include the following provisions of C-25-01:

- A 750 metric ton (mt) catch limit on bigeye tuna caught by longline vessels greater than 24 meters in overall length in the IATTC Convention Area (50 CFR 300.25(a)(2));
- Requirements for additional closure days for class size 4-6 purse seine vessels that exceed specified annual catch levels for bigeye tuna (50 CFR 300.25(e)(2));
- Provisions related to transferring longline catch limits for bigeye tuna between IATTC members (50 CFR 300.25(a)(5));
- Requirements related to stowing gear during time/area closure periods (50 CFR 300.25(e)(7));
- Restrictions on the number of active FADs allowed (50 CFR 300.28(c));
- A requirement that all tropical tuna be retained on board and landed (with certain exceptions) (50 CFR 300.27(a)); and
- Prohibitions against failing to comply with gear-stowing restrictions, retention requirements, and FAD-related restrictions (50 CFR 300.24(e), (f), (m), (nn), (oo), and (pp)).

This rule modifies certain fishing restrictions on purse seine vessels, in accordance with Resolution C-25-01. The modifications include reducing the current purse seine closure period from 72-days to 64-days (see 50 CFR 300.25(e)(1)), allowing class size 4 purse seiners to choose their own closure of 64 consecutive days at any time of the year (see 50 CFR 300.25(e)(1)(ii)), and removing class 4 purse seine vessels from the class sizes that are eligible to request a closure day exemption due to force majeure (see 50 CFR 300.25 (e)(5)). The rule also removes beaching of a FAD as a circumstance that allows for deactivating a FAD satellite buoy (previously in 50 CFR 300.28(d)(2)) and adds a requirement to report whether or not the echosounder is on or off in the active FAD reporting provisions (see 50 CFR 300.22(c)(2)).

The rule also requires class size 4-6 U.S. purse seiners to pay a one-time assessed contribution of \$6.16 per cubic meter of well capacity. This amounts to a one-time cost of \$185,447 for the entire U.S. large purse seine fleet. These funds will be used for a tuna tagging project which IATTC scientists have deemed necessary to ensure that adequate data are collected to complete future tropical tuna stock assessments. Because this is a one-time fee, it will not be codified in the CFR. The owner or managing owner of a class size 4-6 purse seine vessel is required to submit the vessel assessment fee directly to the IATTC, not to NMFS, no later than June 30, 2026, or for vessels entering the RVR after January 15, 2026, fees are due prior to the vessel's inclusion in the IATTC RVR, along with the vessel's AIDCP vessel assessment. NMFS will coordinate with vessel owners requesting to be on the RVR after January 15, 2026, and communicate with vessels where this fee is applicable.

As noted in the previous section, Resolution C-25-01 is set to expire at either the end of 2026 or the end of 2028. However, NMFS does not intend for these regulations to expire concurrently with the Resolution. Instead, because the IATTC will likely continue to adopt similar conservation and management measures upon expiration of this Resolution, and to avoid a lapse in the management of the fishery that may occur between expiration of the regulations and implementation of new measures adopted by the IATTC, these regulations will remain in effect unless and until they are amended or replaced.

The TCA gives NMFS the authority to promulgate such regulations as may be necessary to carry out the United States'

international obligations under the Convention and this chapter, including recommendations and decisions adopted by the Commission. 16 U.S.C. 955(a). In past years, NMFS has implemented IATTC resolutions for specific calendar years, and this approach has at times led to lapses in management in the affected fisheries in subsequent years. Given the time-consuming nature of the U.S. domestic rulemaking process, combined with the increasingly frequent delayed adoption of IATTC resolutions, implementing domestic measures that do not expire unless and until new measures are in place is necessary to carry out the United States' international obligations under the Antigua Convention and the TCA because it will ensure there is no lapse in management of the tropical tuna fishery in the EPO.

Thus, these regulations will remain in effect until they are amended or replaced. NMFS intends to publish rules to implement new resolutions adopted by the IATTC as expeditiously as possible; however, this approach would allow existing regulations to remain in force and prevent any lapse in regulatory coverage caused by expirations.

In addition to the regulations to implement Resolution C-25-01, this rule also implements new FAD provisions from Resolution C-25-07 related to restrictions on satellite buoy deactivations. Specifically, vessel owners and operators are required to keep their FAD satellite buoys active when they drift south of 10° S and west of 100° W and to share their position with FAD recovery programs or other vessels capable of retrieving FADs for final disposal (see 50 CFR 300.28(d)(4)). If vessels and vessel operators would like these buoys to be considered "non-fishing FADs" (which is defined in § 300.21) and excluded from active FAD limits, this can be done provided that:

- i. The buoys send data on location only for recovery purposes;
- ii. The vessel or vessel operator instructs the buoy service provider to share the FAD location with recovery programs and other vessels capable of retrieving FADs and the location data are no longer shared with the vessel or vessel operator;
- iii. The location data will be shared with a frequency of at least one position per day;
- iv. The position will not be visible to the owner of the FAD and will not be set on;
- v. The buoys emit location for at least 6 months when drifting in the area defined in this paragraph; and,
- vi. The echosounder is turned off and this status is reported to the IATTC.

In addition to the new FAD provision, this rule also implements an alternative to paper FAD recovery reporting forms,

in that vessel owners and operators are allowed to directly enter FAD recovery data into the IATTC's online FAD Recovery database to fulfill existing reporting requirements (see 50 CFR 300.22(c)(5)), with the goal of providing flexibility and making existing regulations less burdensome. NMFS will update its West Coast Highly Migratory Species Logbook web page with the new specified recovery form as well as information on how to directly enter FAD recovery data into the database: <https://www.fisheries.noaa.gov/west-coast/sustainable-fisheries/west-coast-highly-migratory-species-logbooks>. Because this information is typically collected and reported to the IATTC by observers, if a vessel has an observer onboard that is submitting this information, FAD recovery data does not need to be separately collected and reported by the vessel owners and operators.

This rule also implements measures in Resolution C-19-04 that were not previously implemented after the Resolution was adopted.

First, to be consistent with the language in Resolution C-19-04, this rule amends the current regulatory requirement in 50 CFR 300.27(c)(2) for purse seine vessel procedures when a sea turtle is entangled during net roll. The amended language includes specifics on hauling the net over the turntable and moving the main boom in order to ensure the sea turtle can be released alive.

Additionally, the rule requires purse seine vessels to carry onboard safe handling tools (e.g., dip nets) for the release of sea turtles (see 50 CFR 300.27(c)(5)). Furthermore, the rule requires owners/operators/vessel crew of purse seine vessels to promptly release unharmed, to the extent practicable, all sea turtles observed entangled in FADs (see 50 CFR 300.27(c)(6)).

This rule also adds new recordkeeping and reporting requirements to specify that purse seine vessels are required to report all sea turtle interactions by purse seine gear as part of current logbook reporting requirements in 50 CFR 300.22(a). The regulation includes a list of the minimum data fields required to satisfy this reporting and also a list of additional data that should be included if available (see 50 CFR 300.22(e)). To comply with this provision, purse seine vessels that do not fish on FADs and use the "IATTC Regional Purse Seine Logbook" must enter the minimum data fields in the "Remarks" column of the logbook, and purse seine vessels that do fish on FADs and use the "Logbook for

purse seine vessels that fish on Fish Aggregating Devices" must enter minimum data fields not already on the logbook in the "Comments/Observations" column of the logbook.

Finally, this rule removes the current regulatory requirement in 50 CFR 300.27(c)(1) for purse seine vessels to have speedboats stationed close to the point where the net is lifted out of the water to assist in the release of sea turtles from a purse seine net. This regulation was put in place in 2001 to implement a 2000 IATTC resolution on bycatch (e.g., Resolution C-00-08), and was continued in subsequent IATTC bycatch resolutions, until finally being removed under Resolution C-19-04. The regulation (i.e., § 300.27(c)(1)) is therefore amended for consistency with Resolution C-19-04 and also due to human safety concerns for the crew operating a speed boat in varying weather conditions on the high seas. Moreover, recent discussions with the IATTC on updated best handling and release practices indicate having speedboats near the net can cause sea turtles to actively evade rescue and dive deeper into the net, consequently becoming more entangled. The amended regulatory language also clarifies that sea turtles must be safely released when sighted in the net.

In addition to implementing provisions from the IATTC resolutions, as discussed above, this rule also makes technical corrections to outdated contact information, cross-references, and hyperlinks in regulations for fishing under the AIDCP at 50 CFR 216.24 and in 50 CFR 300.24. Specifically, § 216.24(b)(4) and (6) include cross-references to RVR regulations in 50 CFR part 300, subpart C; however, those cross-references—which were to subparagraphs in § 300.22(b)—became outdated when NMFS slightly reorganized 50 CFR part 300, subpart C in a March 28, 2022 final rule (87 FR 17248), in part by moving the regulations pertaining to the RVR from § 300.22(b) to § 300.23. The rule also removes fax and email contacts that are no longer in use. Other than updating the contact information and cross-references to the RVR regulations, this rule does not make any other changes to § 216.24(b)(4) and (6). For the same reason, two cross-references within part 300, subpart C (specifically, in § 300.24(i)) are updated by this rule to reflect the current location of the RVR regulations; this rule makes no other changes to those regulations.

In the event a court were to invalidate some but not all aspects of this rule, NMFS intends that the remaining

aspects of the rule be severable to the extent possible.

Classification

The NMFS Assistant Administrator has determined that this rule is consistent with the TCA and other applicable laws.

Pursuant to 5 U.S.C. 553(b)(B), the NMFS Assistant Administrator finds good cause to waive prior notice and the opportunity for public comment, as following such procedures for this action would be impracticable, unnecessary, and contrary to the public interest. As a Member of the IATTC and a Party to the Antigua Convention, the United States is obligated to implement resolutions adopted by the IATTC. NMFS is authorized to implement those resolutions under the Tuna Conventions Act and must report U.S. compliance with implementation to the IATTC on an annual basis. The IATTC resolutions being implemented by this rule are already in effect. And the specific provisions of those resolutions being implemented by this rule are largely prescriptive, which means there is no alternative action that could be taken with respect to those provisions, nor could public comment provide new information that would change the requirements of those provisions. Providing prior notice and opportunity for public comment would therefore further delay U.S. compliance with its international obligations without providing associated benefits to the regulated community or fishery.

The NMFS Administrator finds good cause under 5 U.S.C. 553(d)(3) for this rule to take effect upon public inspection in the **Federal Register**. Pursuant to 5 U.S.C. 553(d)(3), delaying the rule's effective date would also be contrary to the public interest because it would delay the availability of increased flexibilities and fishing opportunities offered by this rule, including the 8-day reduction in the required closure period, which could limit fishery participants' ability to realize the full level of economic opportunity the rule provides and have an impact on the annual revenue of the purse seine fleet. In addition, affected members of the public are already on notice of, and had an opportunity to provide some input on the development of, the measures implemented by this rule, because many of them attended or sent professional representatives to attend the relevant IATTC annual meetings and were involved in briefings and discussions with State Department and NOAA officials and staff, both prior to and during those annual meetings.

Furthermore, NMFS notes that it provided actual notice to all affected vessel owners and operators via email on several occasions that payment for the one-time assessed contribution would be due by June 30, 2026. Vessel owners and operators were notified on March 4, 2026, and were sent a reminder, that included bank information necessary to make the payment, on May 5, 2026. As of June 18, 2026, payments have already been paid for nearly half of the vessels. A follow-up reminder was sent to the owners and operators of the vessels for which payment remained outstanding. As mentioned previously, these funds will be used for a tuna tagging project which IATTC scientists have deemed necessary to ensure that adequate data are collected to complete future tropical tuna stock assessments, particularly skipjack tuna which is the target of the U.S. large purse seiners. U.S. industry representatives were present at the 103rd meeting of the IATTC where this measure was negotiated and supported the U.S. Section of the IATTC to advocate for including a requirement for payment of these funds by June 30 in the Resolution because the regulated entities greatly desire the benefits to the fleet from the updated skipjack assessment.

As soon as the rule is filed, NMFS will send notice of the rule via email to owners of vessels that are affected by this rule.

In conclusion, NMFS finds that the 30-day delay in effective date does not apply to this final rule pursuant to 5 U.S.C. 553(d)(3).

Executive Order 12866

This rule has been determined to be significant for purposes of Executive Order 12866. This action would update management measures for the U.S. large purse seine and longline fisheries in the EPO, which provide an average of \$159 million of commercial fishing opportunity for large purse seine vessels and an average of \$387,976 for longline vessels based on ex-vessel revenue from 2022–2024. Consistent with Executive Order 14276, this final rule implements provisions of IATTC Resolution C–25–01 to increase flexibility and fishing opportunity by reducing closure days for U.S. purse seine vessels from 72 days to 64 days. NMFS estimates that based on the average catch of large U.S. purse seine vessels from 2022–2024 and the average market rates, each vessel can make approximately \$56,000 to \$73,000 per day (average of \$65,000 per day; assuming 1 set per vessel per day). There are currently 18 large U.S. purse seine vessels on the IATTC RVR, which

means that every extra day of fishing could be worth an average of approximately \$1.0 million to \$1.3 million in additional ex-vessel revenue for the large U.S. purse seine fleet, with fluctuations due to the amount of catch and price of tuna. With the current closure day arrangement, some U.S. large purse seine vessels can opt to go fish the WCPO in the WCPFC Convention Area. However, industry representatives advocated for this closure day reduction to provide them additional flexibility to fish in the EPO as much as possible. Additionally, these vessels would likely lose several days of fishing time to transit from the EPO to the WCPO. Some U.S. large purse seine vessels do not cross over to the WCPO to fish during closures and would be sitting idle at port during closure periods. The increased catch from U.S. vessels as a result of the closure day reductions would strengthen our Nation's seafood supply chain by increasing American tropical tuna landings by up to 5,740 metric tons per year. Additionally, the final rule implements provisions of Resolutions C–25–07 related to the use of FADs and also several provisions of Resolution C–19–04 on sea turtles that were not previously implemented.

If NMFS does not take action to implement Resolutions C–25–01, C–25–07, and C–19–04, the United States will not satisfy international obligations as a Member of the IATTC and Party to the Antigua Convention. In addition, if the final rule is not implemented, the vessel owners and operators of large purse seine vessels will still have to abide by a longer 72 day closure period, will not have a new provision for non-fishing FADs, will not gain the added FAD recovery reporting flexibility, and would not have in place all the sea turtle mitigation provisions adopted by the IATTC.

In the alternative, by implementing provisions of Resolutions C–25–01, C–25–07, and C–19–04 as proposed, NMFS will maintain and extend measures for size class 6 purse seine vessels that are intended to manage fishing for tropical tuna stocks in the IATTC Convention Area. These actions are not expected to substantially change the typical fishing practices of affected vessels, and any impact to the income of U.S. commercial vessels would be minor. The gains in fully implementing this Resolution and contributing to the overall conservation of tropical tuna, as well as fulfilling the international obligations of the United States, are expected to outweigh any potential costs to affected entities. In conclusion, it is determined that the described

action will be an economically viable and better alternative relative to the alternative of not taking action to implement the provisions of Resolutions C–25–01, C–25–07, and C–19–04 as proposed.

Executive Order 14192

This final rule is considered an Executive Order 14192 deregulatory action.

Executive Order 13175

NMFS has determined that this action 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; therefore, consultation with Tribal officials under E.O. 13175 is not required, and the requirements of sections (5)(b) and (5)(c) of E.O. 13175 also do not apply. A Tribal summary impact statement under section (5)(b)(2)(B) and section (5)(c)(2) of E.O. 13175 is not required and has not been prepared.

Paperwork Reduction Act

This rule contains changes to the collection of information requirement for the purposes of the Paperwork Reduction Act (PRA) of 1995. NMFS is amending the supporting statement for the “West Coast Region Pacific Tuna Fisheries Logbook, Fish Aggregating Device Form, and Observer Safety Reporting” Office of Management and Budget (OMB) PRA requirements (OMB Control No. 0648–0148), to include the data collection requirements for U.S. purse seine vessel owners and operators to report all observed sea turtle interactions using specified minimum data fields (e.g., species ID, size, release condition), unless that information is already collected and submitted to the IATTC by an observer onboard the vessel. Additionally, for existing FAD reporting data collection requirements, vessel owners and operators will be allowed to directly enter FAD recovery data into the IATTC's online FAD Recovery database to fulfill reporting requirements as an alternative to entering and submitting data in the FAD recovery data form provided by the Highly Migratory Species (HMS) Branch. This added flexibility aims to improve and modernize how data are collected to better reflect what is happening on the water. Finally, active FAD reporting requirements are amended to add a requirement to report whether or not the echosounder is on or off.

NMFS estimates that the public reporting burden for the collection of information for reporting sea turtle interactions will average 3 minutes per form, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number. All currently approved NOAA collections of information may be viewed at: <https://www.reginfo.gov/public/do/PRAMain>.

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, and a proposed rule is not being published, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

List of Subjects in 50 CFR Parts 216 and 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: June 30, 2026.

Kelly Denit,

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

For the reasons set out in the preamble, NMFS amends 50 CFR parts 216 and 300 as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. Amend § 216.24 by revising paragraphs (b)(4) and (b)(6)(iii)(A) through (F) to read as follows:

§ 216.24 Taking and related acts in commercial fishing operations including tuna purse seine vessels in the eastern tropical Pacific Ocean.

* * * * *

(b) * * *

(4) *Application for vessel permit.* To apply for an ETP vessel permit, a vessel owner or managing owner must complete, sign, and submit the appropriate form and submit any required payment of the permit

application fee to the Administrator, West Coast Region, allowing at least 15 days for processing. Application forms and instructions for their completion are available from NMFS. To request that a vessel in excess of 400 short tons (362.8 mt) carrying capacity be categorized as active on the Vessel Register under § 300.23(c) of this title in the following calendar year, the owner or managing owner must submit the vessel permit application, payment of the vessel permit application fee, and payment of the vessel assessment fee no later than September 15 for vessels for which a DML is requested for the following year, and no later than November 30 for vessels for which a DML is not requested for the following year.

* * * * *

(6) * * *

(iii) * * *

(A) The owner or managing owner of a purse seine vessel for which a DML has been requested must submit the vessel assessment fee to the IATTC, no later than September 15 of the year prior to the calendar year for which the DML is requested. Payment of the vessel assessment fee must be consistent with the fee for active status on the Vessel Register under § 300.23(c)(2)(ii) of this title.

(B) The owner or managing owner of a purse seine vessel for which active or inactive status on the Vessel Register, as defined in § 300.21 of this title, has been requested, but for which a DML has not been requested, must submit payment of the vessel assessment fee to the IATTC, no later than November 30 of the year prior to the calendar year in which the vessel will be listed on the Vessel Register. Payment of the vessel assessment fee is required only if the vessel is listed as active and is required to carry an observer, or if the vessel is listed as inactive and exceeds 400 short tons (362.8 mt) in carrying capacity. Payment of the vessel assessment fee must be consistent with the vessel's status, either active or inactive, on the Vessel Register in § 300.23(c) of this title.

(C) The owner or managing owner of a purse seine vessel that is permitted and authorized under an alternative international tuna purse seine fisheries management regime in the Pacific Ocean must submit the vessel assessment fee to the IATTC, prior to obtaining an observer and entering the ETP to fish. Consistent with § 300.23(a)(1) of this title, this class of purse seine vessels is not required to be listed on the Vessel Register under § 300.23(c) of this title in order to purse seine for tuna in the ETP during a single

fishing trip per calendar year of 90 days or less. Payment of the vessel assessment fee must be consistent with the fee for active status on the Vessel Register under § 300.23(c)(2) of this title.

(D) The owner or managing owner of a purse seine vessel listed as inactive on the Vessel Register at the beginning of the calendar year, and who requests active status on the Vessel Register under § 300.23(c)(2) of this title during the year, must pay the vessel assessment fee associated with active status, less the vessel assessment fee associated with inactive status that was already paid, before NMFS will request the IATTC Director change the status of the vessel from inactive to active. Payment of the vessel assessment fee is required only if the vessel is required to carry an observer.

(E) The owner or managing owner of a purse seine vessel not listed on the Vessel Register at the beginning of the calendar year and who requests to replace a vessel removed from active status on the Vessel Register under § 300.23(h)(2) of this title during the year, must pay the vessel assessment fee associated with active status only if the vessel is required to carry an observer, before NMFS will request the IATTC Director change the status of the vessel to active.

(F) Payments will be subject to a 10 percent surcharge if received under paragraph (b)(6)(iii)(E) of this section for vessels that were listed as active on the Vessel Register in the calendar year prior to the year for which active status was requested; or if received after the dates specified in paragraph (b)(6)(iii)(A) or (B) of this section for vessels for which active status is requested if the vessel was listed as active during the year the request was made. Payments will not be subject to a 10 percent surcharge if received under paragraph (b)(6)(iii)(C) or (D) of this section, or if received under paragraph (b)(6)(iii)(E) of this section for vessels that were not listed as active on the Vessel Register in the calendar year prior to the year for which active status was requested. Payments will also not be subject to a 10 percent surcharge if received after the date specified in paragraph (b)(6)(iii)(B) of this section for vessels for which inactive status is requested, or for vessels for which active status is requested if the vessel was not listed as active during the year the request was made. Payment of all vessel assessment fees described in this section must be made to the IATTC.

* * * * *

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 3. The authority citation for part 300, subpart C, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*

■ 4. Amend § 300.21 by adding, in alphabetical order, the definition for “Non-fishing FAD” to read as follows:

§ 300.21 Definitions.

* * * * *

Non-fishing FAD means a FAD drifting in the area as defined in § 300.28(d)(4) and where the satellite buoy sends location data only for recovery purposes; buoy locations are provided by the buoy service providers; location data are shared with a frequency of at least one position per day for at least 6 months; the position is not visible for the owner of the FADs; and the echosounder is reported as ‘off.’

* * * * *

■ 5. Amend § 300.22 by revising paragraph (c)(2) and adding paragraph (e) to read as follows:

§ 300.22 Recordkeeping and reporting requirements.

* * * * *

(c) * * *

(2) *Reporting on Active FADs.* U.S. vessel owners and operators must record or maintain daily information on buoy location and acoustic data for all Active FADs that have been deployed in the water in the IATTC Convention Area and report that information to the IATTC, using a format and address provided by the HMS Branch. Daily information on buoy location must include date, time, buoy identifier, latitude, longitude, IMO number, speed, and whether or not the echosounder is on or off. Daily acoustic data will vary depending on the buoy company, but must include company, buoy identifier, latitude, longitude, date, time, and available layers of data. Further instructions on reporting data specific for different buoys companies are available in a compliance guide. This information must be submitted for each calendar month no later than 90 days after the month covered by the report.

* * * * *

(e) *Sea turtle interaction reporting.* The owner and operator of a purse seine fishing vessel of the United States that interacts with a sea turtle while commercially fishing in the Convention Area must ensure that the incident is recorded on the log that is required by paragraph (a) of this section, unless that information is already reported to the IATTC by an observer.

(1) *Required information.* The log of sea turtle interactions must include the following information:

- (i) Number of individual sea turtles with which the vessel interacted;
- (ii) Date of interaction;
- (iii) Location of interaction (latitude and longitude of interaction);
- (iv) Fishing gear type;
- (v) Species identification;
- (vi) Size (*i.e.*, curved or straight carapace length); and,
- (vii) Capture and release condition (*e.g.*, live/injured/dead).

(2) *Supplemental information.* If available, the log of sea turtle interactions should also include the following:

- (i) The anatomical hooking location (*e.g.*, flipper, mouth/jaw, swallowed, entangled);
- (ii) Amount of gear left on the animal, if applicable (*e.g.*, estimated length of line); and,
- (iii) Any associated photographs.

■ 6. Amend § 300.24 by revising paragraphs (i), (j), and (qq) to read as follows:

§ 300.24 Prohibitions.

* * * * *

(i) Fail to report information when requested by the Regional Administrator under § 300.23.

(j) Fail to record or submit information required under § 300.22(b), (d), or (e).

* * * * *

(qq) Fail to provide FAD data as described under § 300.28(d)(5).

* * * * *

■ 7. Amend § 300.25 by revising paragraphs (e)(1) through (4), the introductory text of paragraph (e)(5), and paragraph (e)(5)(v) to read as follows:

§ 300.25 Fisheries management.

* * * * *

(e) * * *

(1) *64-day closure.* A U.S. commercial purse seine fishing vessel that is of class size 4–6 (carrying capacity of more than 182 metric tons) may not be used to fish with purse seine gear in the Convention Area for 64 days during the following periods:

(i) For class size 5–6 purse seine vessels:

(A) From 0000 hours Coordinated Universal Time (UTC) August 6 to 2400 hours UTC October 8; or

(B) From 0000 hours UTC November 9 to 2400 hours UTC January 11 of the following year.

(ii) For class size 4 purse seine vessels a closure of 64 consecutive days must be observed at any time of the year.

(2) *Additional closure days for vessels that exceed bigeye tuna catch levels.*

(i) U.S. purse seine vessels that exceed a certain annual catch level of bigeye tuna must increase the number of closure days they observe in the following year, as specified in table 1 to this paragraph (e)(2).

(ii) The additional days of closure must be added to the closure period indicated in paragraph (e)(1) of this section. For class 5–6 vessels observing the first closure period, the additional days must be added at the beginning of the closure period. For class 5–6 vessels observing the second closure period, the additional days must be added to the end of the closure period. For class 4 vessels, the additional days must be added consecutively to their chosen days of closure. The HMS Branch will confirm the determination of annual catch levels for U.S. purse vessels based on information provided by the IATTC and notify any U.S. vessel that exceeds a given catch level.

TABLE 1 TO PARAGRAPH (E)(2)

Catch level (mt) exceeded	Additional closure days observed
1,200	10
1,500	13
1,800	16
2,100	19
2,400	22

(3) *Choice of closure period.* (i) A class size 5–6 vessel owner, manager, or association representative of a vessel that is subject to the requirements of paragraph (e)(1) of this section must provide written notification to the Regional Administrator declaring which closure period identified in paragraph (e)(1) of this section their vessel will observe in that year. This written notification must be submitted by email to wcr.hms@noaa.gov and must be received no later than May 15 of the relevant calendar year. The written notification must include the vessel name and registration number, the closure dates that will be observed by that vessel, and the vessel owner or managing owner's name, signature, business address, and business telephone number.

(ii) A class size 4 vessel owner, manager, or association representative of a vessel that is subject to the requirements of paragraph (e)(1) of this section must provide written notification to the Regional Administrator declaring which consecutive 64 days of closure that vessel will observe in that year. This written notification must be submitted

by email to wcr.hms@noaa.gov and must be received no later than 30 days prior to the start of the closure. The written notification must include the vessel name and registration number, the closure dates that will be observed by that vessel, and the vessel owner or managing owner's name, signature, business address, and business telephone number.

(4) *Default closure period.* If written notification is not submitted per paragraph (e)(3)(i) of this section for a class size 5–6 vessel subject to the requirements under paragraph (e)(1) of this section, that vessel must observe the second closure period under paragraph (e)(1)(i)(B) of this section. If written notification is not submitted per paragraph (e)(3)(ii) of this section for a class size 4 vessel subject to the requirements under paragraph (e)(1) of this section, that vessel must observe a closure period from 0000 hours Coordinated Universal Time (UTC) October 28 to 2400 hours UTC December 31.

(5) *Request for exemption due to force majeure.* A class size 5–6 vessel may request a reduced closure period if a *force majeure* event renders the vessel unable to proceed to sea outside one of the two closure periods specified in paragraph (e)(1)(i) of this section for at least 75 continuous days. A vessel will only be eligible for an exemption due to *force majeure* if the vessel was disabled in the course of fishing operations by mechanical and/or structural failure, fire, or explosion.

(v) An exemption due to force majeure will apply to only the closure period required under paragraph (e)(1) of this section. Vessels that are both granted a reduced 40-day initial closure period due to force majeure under this paragraph (e)(5) and required to observe additional closure days for exceeding bigeye tuna catch levels under paragraph (e)(2) of this section must observe the reduced closure period

consecutively with the additional closure days by adding the additional closure days to either the beginning of the first reduced closure period or the end of the second reduced closure period.

* * * * *

■ 8. Amend § 300.27 by revising paragraph (c)(1) and (2) and adding paragraphs (c)(5) and (6) to read as follows:

§ 300.27 Incidental catch and tuna retention requirements.

* * * * *

(c) * * *

(1) Whenever a sea turtle is sighted in the net, vessel owners and operators must take all reasonable steps to ensure its safe release.

(2) If a sea turtle is entangled during net roll, the net should be hauled over the turntable to a height of 2 meters, the main boom should be moved to starboard or to port (depending on the vessel's direction) and the net should be rolled back, so that the crew can release the turtle from the netting as soon as possible, and return it to the sea if it is active. Net roll should not start again until the turtle has been disentangled and released.

* * * * *

(5) Vessels must carry on board, and employ, when appropriate, dip nets able to lift and lower sea turtles to and from vessels. Dip nets must follow the design specified in § 660.712(b)(3) of this title.

(6) All sea turtles observed entangled in fish-aggregating devices (FADs) must be promptly released unharmed.

* * * * *

■ 9. Amend § 300.28 by revising paragraph (d) to read as follows:

§ 300.28 FAD restrictions.

* * * * *

(d) *Restrictions on satellite buoy deactivations.* A vessel owner or operator that deactivates a satellite buoy attached to a FAD must comply with the reporting requirements for buoy

deactivations in § 300.22(c)(3). A U.S. vessel owner or operator shall deactivate a satellite buoy attached to a FAD that was activated in the IATTC Convention Area only in the following circumstances:

(1) Complete loss of signal reception;

(2) Appropriation of a FAD by a third party;

(3) Temporarily during a selected closure period;

(4) For being outside of the area between the meridians 150° W long. and 100° W long., and the parallels 8° N lat. and 10° S lat.; the area between the meridian 100° W long. and the coast of the American continent and the parallels 5° N lat. and 15° S lat. FADs drifting south of 10° S lat. and west of 100° W long. must not be deactivated and the vessels or vessel operators must share their position with FAD recovery programs or other vessels capable of retrieving FADs for final disposal. These FADs will be considered “non-fishing FADs” and excluded from active FAD limits in paragraph (c) of this section if:

(i) The buoys send location data only for recovery purposes;

(ii) The vessel or vessel operator instructs the buoy service provider to share the FAD location with recovery programs and other vessels capable of retrieving FADs and the location data are no longer shared with the vessel or vessel operator;

(iii) The location data is shared with a frequency of at least one position per day;

(iv) The position is not visible to the owner and the FAD will not be set on;

(v) Location data is shared for at least 6 months when drifting in the area defined in this paragraph; and

(vi) The echosounder is turned off and this status is reported to the IATTC; or

(5) Transfer of ownership.

* * * * *

[FR Doc. 2026–13666 Filed 7–6–26; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 91, No. 128

Tuesday, July 7, 2026

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

DEPARTMENT OF ENERGY

10 CFR Parts 430 and 431

[EERE-2022-BT-OT-0004]

Energy Conservation Program: Review of DOE's Analytic Methods for Setting Energy Conservation Standards

AGENCY: Office of Critical Minerals and Energy Innovation, Department of Energy.

ACTION: Request for information and request for comments.

SUMMARY: The U.S. Department of Energy ("DOE" or the "Department") requests comment regarding the assumptions, models, and methodologies that DOE uses in setting energy conservation standards for covered products and equipment. Relatedly, DOE also requests comments on the report summarizing the work conducted by the National Academies of Sciences, Engineering, and Medicine ("NASEM") Committee on Review of Methods for Setting Building and Equipment Performance Standards. DOE also welcomes the submission of data, peer-reviewed studies, and other relevant information related to how DOE might implement NASEM report recommendations and to DOE's analytical methodology for evaluating energy conservation standards in general.

DATES: Written comments and information are requested and will be accepted on or before September 8, 2026.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at www.regulations.gov. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE-2022-BT-OT-0004, by any of the following methods:

(1) *Email:*
ASmethodreview2022OT0004@ee.doe.gov. Include the docket number

EERE-2022-BT-OT-0004 in the subject line of the message.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop CM-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. If possible, please submit all items on a compact disc ("CD"), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop CM-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles ("faxes") will be accepted. For detailed instructions on submitting comments and additional information on this process, see section V of this document (Submission of Comments).

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at www.regulations.gov/#!docketDetail;D=EERE-2022-BT-OT-0004. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through www.regulations.gov. The docket for the related proceeding to consider updates to DOE's Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products is available at www.regulations.gov/docket/EERE-2025-BT-STD-0001.

FOR FURTHER INFORMATION CONTACT:

Appliance Standards Program, U.S. Department of Energy, Office of Critical Minerals and Energy Innovation, CM-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Email:

ApplianceStandardsQuestions@ee.doe.gov.

Mr. Peter Cochran, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 586-4798. Email: Peter.Cochran@hq.doe.gov.

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287-1445 or by email: ApplianceStandardsQuestions@ee.doe.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Authority
 - A. Statutory Requirements
 - B. Evaluation of Statutory Requirements
- III. Recommendations From the NASEM Report and DOE's Solicitation for Comments
 - A. Problem Statement and Market Failure
 - 1. Uncertainty and Variability
 - B. Technology Assessment
 - C. Key Considerations for Economic Justification Pursuant to EPCA
 - 1. Consumer Effects
 - 2. Manufacturer Effects
 - 3. Life-Cycle Cost and Energy Savings
 - 4. Market Effects
 - 5. Emissions
 - D. Data Collection
 - E. Effects on Power Systems
- IV. Summary of Analysis-Related Topics Raised in Comments on the Process Rule RFI
- V. Additional Analytic Topics
 - A. Repair and Installation Cost Assumptions
 - B. Modeling Retirement and Replacement
 - C. Analytic Timeline
 - D. Baseline
 - E. Methodological Support of 42 U.S.C. 6295(o) Analysis
- VI. Submission of Comments
- VII. Approval of the Office of the Secretary

I. Background

The Department of Energy ("DOE") is seeking information and public comment related to the agency's forthcoming update of the analytic framework used to carry out requirements in the Energy Policy Conservation Act (42 U.S.C. 6291, *et seq.*; "EPCA"). For example, under 42 U.S.C. 6295(o), DOE utilizes this analytic framework to address statutorily required criteria for prescribing new or amended energy

conservation standards (“ECS”). DOE is also proposing updates to the Department’s “Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment” at 10 CFR part 430, subpart C, appendix A (“appendix A” or “Process Rule”). This analytic framework request for information (“RFI”) is a separate but related action to address analytic methodology in greater technical detail. More specifically, DOE is issuing this analytic framework RFI to solicit comment on DOE’s analytical methodologies that support execution of the Process Rule.

On December 18, 2017, DOE published in the **Federal Register** an RFI on the Process Rule. 82 FR 59992. In response to that Process Rule RFI, DOE received a variety of comments regarding, among other things, its analytical methodologies. These comments were addressed in a notice of proposed rulemaking (“NOPR”) regarding that Process Rule that DOE published in the **Federal Register** on February 13, 2019. 84 FR 3910, 3936–3938. The Department decided that conducting an additional peer review of the analytical methods used in its energy conservation standards rulemakings would be beneficial in evaluating these comments and determining what improvements, if any, could be made to its analytical methodologies. *Id.* DOE chose the National Academies of Sciences, Engineering, and Medicine (“NASEM”) to conduct the peer review and entered into a contract with NASEM on July 15, 2019. NASEM completed the peer review and transmitted to DOE its report, “Review of Methods Used by the U.S. Department of Energy in Setting Appliance and Equipment Standards,” (“NASEM Report”) on January 7, 2022.¹

On April 17, 2025, DOE published in the **Federal Register** an RFI seeking comments and information from interested parties to assist DOE in identifying potential modifications to its Process Rule. 90 FR 16093. In this 2025 Process Rule RFI, DOE noted that it intends to more closely review the assumptions, models, and methodologies used in setting energy conservation standards for consumer products and equipment. Many of these topics were addressed in the report issued by NASEM and have been the

subject of comments submitted by stakeholders in recent energy conservation standards rulemakings. DOE stated that the recommendations in the NASEM report, as well as other conceptual considerations, will be considered by DOE in a separate RFI, which will more specifically request stakeholder comments on those topics. In the 2026 Process Rule NOPR, DOE summarizes comments received in response to the RFI for the 2026 Process Rule that relate to analytic methodology.² This analytic framework RFI represents the follow-up request for comments that was previously described by DOE and is referenced in the 2026 Process Rule NOPR.

For ease of use, this RFI is organized based on the findings and recommendations contained in the NASEM report and on the topics raised in stakeholder comments that DOE has received related to its analytical methodologies that were submitted as part of its 2025 Process Rule RFI. DOE seeks comment on how to appropriately consider actions that are consistent with the requirements of EPCA and are responsive to the NASEM report recommendations, as well as aligning with Executive Orders 12866, 14154, and 14303, OMB Circular A–4, and related guidance which are discussed in the paragraphs that follow.

There are multiple Executive Orders with which this effort is consistent. On January 20, 2025, the President issued Executive Order 14154, “Unleashing American Energy” (E.O. 14154). 90 FR 8353 (Jan. 29, 2025). The Executive order stated the policy of the United States with regard to energy production and management. Among the stated elements of this policy at sections 2(f)–(h) of E.O. 14154 are to safeguard the American people’s freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and showerheads, and to promote market competition and innovation within the manufacturing and appliance industries; to ensure that the global effects of a rule, regulation, or action shall, whenever evaluated, be reported separately from its domestic costs and benefits, in order to promote sound regulatory decision making and prioritize the interests of the American people; and to guarantee that all executive departments and agencies provide opportunity for public comment and rigorous, peer-reviewed scientific analysis.

On May 23, 2025, the President issued Executive Order 14303, “Restoring Gold Standard Science.” 90 FR 22601 (May 29, 2025). Section 3 of that Executive order instructed the Director of the Office of Science and Technology Policy (“OSTP”) to issue guidance for agencies on implementation of “Gold Standard Science,” meaning science that is reproducible; transparent; communicative of error and uncertainty; collaborative and interdisciplinary; skeptical of findings and assumptions; structured for falsifiability of hypotheses; subject to unbiased peer review; accepting of negative results as positive outcomes; and without conflicts of interest. Further guidance was issued by OSTP on June 23, 2025.³

As DOE updates its analytic framework, these efforts will also be consistent with the “Final Information Quality Bulletin for Peer Review” (“the Peer Review Bulletin”) that calls for qualified specialists to peer review influential scientific information disseminated by the Federal government. 70 FR 2664 (Jan. 14, 2005). As defined in the Peer Review Bulletin, “scientific information” means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. *Id.* at 70 FR 2675. In response to the Peer Review Bulletin, DOE conducted a peer review of the analyses used in a typical energy conservation standards rulemaking: screening and engineering analysis; price markups analysis; life-cycle cost and payback period analyses; consumer sub-group analysis; shipments analysis and national impact analysis; manufacturer impact analysis; utility impact analysis; environmental assessment; employment impact analysis; and the regulatory impact analysis. DOE presented the results of the peer review in a report that was issued in February of 2007.⁴

II. Authority

A. Statutory Requirements

This analytic framework update is consistent with DOE’s responsibilities under EPCA in setting ECS. The following section outlines key EPCA requirements in setting ECS and elaborates on economic concepts that correspond to those requirements. This RFI is intended to inform and improve DOE’s applied methodologies in

¹ The NASEM Report is available at www.nap.edu/catalog/25992/review-of-methods-used-by-the-us-department-of-energy-in-setting-appliance-and-equipment-standards.

² See www.regulations.gov/docket/EERE-2025-BT-STD-0001.

³ See www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf.

⁴ See <https://www.energy.gov/cmei/articles/building-technologies-office-bto-peer-review-2007>.

meeting the requirements of EPCA at 42 U.S.C. 6295(o)–(q).

DOE may not prescribe a standard: (1) for certain products, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B); 42 U.S.C. 6313(a)(6)(A)–(C); 42 U.S.C. 6316(a)) In determining whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i); 42 U.S.C. 6313(a)(6)(B)(ii); 42 U.S.C. 6316(a)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, to consider the following seven statutory factors:

- (1) The economic impact of the standard on the manufacturers and consumers;
 - (2) The savings in operating costs, throughout the estimated average life of the products (*i.e.*, life-cycle costs), compared with any increase in the price of, or in the initial charges for, or maintenance expenses of, the products which are likely to result from the standard;
 - (3) The total projected amount of energy, or as applicable, water, savings likely to result directly from the standard;
 - (4) Any lessening of the utility or the performance of the products likely to result from the standard;
 - (5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;
 - (6) The need for national energy and water conservation; and
 - (7) Other factors DOE considers relevant.
- (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII); 42 U.S.C. 6313(a)(6)(B)(ii)(I)–(VII); 42 U.S.C. 6316(a))

Furthermore, the new or amended standard must result in a significant conservation of energy (42 U.S.C. 6295(o)(3)(B); 42 U.S.C. 6313(a)(6)(A)–(C); and 42 U.S.C. 6316(a)) and comply with any other applicable statutory provisions.

B. Evaluation of Statutory Requirements

This analytic framework RFI seeks information, public comment, and/or data on methodological and conceptual tools aimed at a more complete and updated analysis of these statutory factors. The scope of the seven economic justification factors covers a wide array of economic concepts:

1. The economic impact of the standard on the manufacturers and consumers: This factor, which broadly lays out economic impacts to manufacturers and consumers, should be taken into consideration in setting conservation standards regardless of whether those impacts may be readily quantifiable or not. Readily quantifiable effects include

potential energy and water savings, assuming that consumers' distribution of consumption of energy and water does not change appreciably over time. Currently, DOE folds some of these impacts into the agency's life-cycle cost and payback period analysis. Manufacturers' compliance costs are also readily quantifiable using information collected through government data collections, public comment, DOE's tear-downs and other engineering efforts, purchase of proprietary information, and other sources. There are other economic effects that are more difficult to capture on both the consumer and manufacturer sides. Estimating changes in consumers' consumption of substitutes (*e.g.*, used and refurbished appliances) and complimentary goods (*e.g.*, dryers if purchasing washers; detergent choices) as a result of a conservation standard is more difficult. For example, if a clothes washer energy and water conservation standard were to adversely impact cleaning or rinsing performance, consumers that experience any such negative impacts on product performance could potentially alter their usage patterns, for example by using more energy-intensive settings more frequently (*e.g.*, Extra-Hot temperature setting); using more water-intensive cycle options (*e.g.*, Deep Fill option; extra rinse cycles); using non-regulated cycles (*e.g.*, Heavy Duty cycle); or re-washing clothing that has not been cleaned sufficiently. Such changes to consumer usage patterns may counteract the energy and water savings that DOE has estimated would be achieved at the higher efficiency level (*see* 89 FR 19026, 19117 (March 15, 2024)). Similarly, if the same standard also affects how clothing is washed, then consumers may buy more powerful and expensive detergent (complimentary good) in reaction. Alternatively, if a new clothes washer standard materially increases purchase and installation costs for that appliance, consumers may choose not to purchase a clothes dryer when those purchases are very often bundled as complimentary goods. This change could result in losses to society from foregone market exchanges and losses in consumer satisfaction where preferences would typically lean towards a bundled purchase. In addition, new standards may cause manufacturers to divert resources away from improving features that consumers want. While not exhaustive, the above examples illustrate that quantitative estimates of potential energy and water savings and compliance costs alone may not adequately capture the full range of important effects.

2. The savings in operating costs, throughout the estimated average life of the products (*i.e.*, life-cycle costs), compared with any increase in the price of, or in the initial charges for, or operating and maintaining expenses of, the products which are likely to result from the imposition of the standard: DOE is already explicitly taking this factor into consideration in the agency's life-cycle cost analysis and payback period analysis and recognizes there are elements of consumer behavior and welfare, as well as considerations of the useful life of the appliance, that are not currently captured in this analysis.

3. The total projected amount of energy, or as applicable, water savings likely to result directly from the standard: DOE already explicitly takes this factor into consideration in the agency's life-cycle cost analysis and national impact analysis and recognizes there are elements of consumer behavior and welfare, such as in earlier stated examples, that may affect these estimates but are not currently captured in this analysis.

4. Any lessening of the utility or the performance of the products likely to result from the standard: Consumers value different attributes of products differently. Some may value the energy and/or water efficiency savings more than the cycle time in clothes washers. Others may value cycle time more than the energy and/or water efficiency savings. Others may place value in how effectively any residual detergent is rinsed from the clothing, or how much moisture is removed from the clothing during the final spin portion of the wash cycle. If changes in energy and/or water conservation standards were to lead to a reduction in certain aspects of cleaning or rinsing performance, then certain consumers may be less satisfied with their clothes washers. Although these types of effects may be more difficult to assess quantitatively than potential energy and/or water savings and compliance costs, they nonetheless should be addressed. On the other hand, consumer purchases often reveal preferences for such functions, and by statute, DOE must consider these changes in utility and performance relative to products in existence at the time a regulation being contemplated.

5. The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard: Lessening of competition is a concern that DOE takes seriously. Increases in market power or significant market consolidation would likely further reduce consumer choices and lead to material increases in the prices of covered products. DOE currently applies a market concentration index (HHI) in evaluating the lessening of market competition. While this index is a helpful indicator, DOE is considering other indicators of lessening competition. Market competition can decline when fewer manufacturers participate in the market or fewer manufacturers choose to produce some product categories. When consumer purchases do not decrease by much as prices rise (in economic terms: demand is relatively inelastic) and competition decreases, manufacturers are able to set prices higher without sharply reducing the number of units sold. For example, consumers often replace large appliances such as water heaters, heat pumps, air conditioners, or refrigerators when they break down, which may result in less price flexibility for the consumer. The result is greater benefits for manufacturers (who sell fewer units at a higher price), reduced benefits for consumers (who buy fewer units at a higher price), and some loss to society (units that could have been produced and sold at lower prices are not produced and benefit no one). To account for the impacts of reduced competition, DOE is considering an analysis that more formally

incorporates consumer responsiveness to changes in price (price-elasticity of demand) and the likely price impacts in markets where high consolidation already exists.⁵

6. The need for national energy and water conservation: enhanced energy efficiency, where economically justified, improves the Nation's energy security and strengthens the economy. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. DOE conducts a utility impact analysis to estimate how standards may affect the Nation's needed power generation capacity.

7. Other factors DOE finds relevant: In the past, the Secretary has exercised discretion under factor seven for considerations such as impacts of standards on certain subgroups such as small manufacturers or low-income senior citizens. DOE's comparative analysis can be applied to such distributional outcomes as well, and DOE continues to explore other discretionary considerations. One such consideration may be to explicitly state that the Secretary has determined that any proposed standard for which costs (including consumer welfare losses and losses to society from lost market exchanges) exceed benefits (including energy and operating cost savings) will presumptively be considered as not economically justified. More generally, the Secretary has sufficient discretion to apply a "walk up approach" under EPCA.

Energy Conservation and the Energy Paradox

The potential for appliance and other covered product buyers to voluntarily forego improvements in energy efficiency that seemingly offer savings exceeding their initial costs is one example of what is often termed the "energy efficiency gap" or "energy efficiency paradox." Economic theory predicts that, holding all else equal, individuals will purchase more expensive energy-efficient appliances and other covered products if they expect future savings on energy expenditures to offset the higher upfront purchase costs.⁶ If buyers fully internalize the expected energy savings that result from higher efficiency in their appliances and other covered products purchase decisions, manufacturers will presumably supply any improvements that buyers demand, and appliances and other covered products prices will fully reflect future energy cost savings that consumers would realize from owning—and

potentially reselling—more energy-efficient models, if secondary markets exist. In this case, a regulation that induces increased energy efficiency of appliances and other covered products will impose net private costs on appliance and other covered product owners and can only result in social benefits through correcting other market failures (e.g., imperfect information or internalizing other negative spillover effects). If instead, regulations are issued based on the premise that consumers systematically "undervalue" cost savings generated by improvements in energy efficiency when choosing among competing models, then more stringent energy efficiency standards may lead manufacturers to adopt improvements in energy efficiency that buyers would not choose despite the cost savings they offer.

Whether the value of the resulting realized energy savings will improve consumer welfare depends on if and why consumers appear to undervalue future energy expenditures. If the apparent "undervaluation" is due to factors that are missing from the analysis—e.g., tradeoffs with product functions and attributes such as cleaning performance, increased cycle times when in energy saver mode, or changes in the starkness, warmth, or hue of light bulbs—these hidden or missing costs may be offsetting some or all of the value of energy savings and may not result in additional social benefits. The appearance of such a gap, between the level of energy efficiency that would minimize consumers' overall expenses and what they actually purchase, is typically based on engineering calculations that compare the initial cost of providing higher energy efficiency to the discounted present value of the resulting savings in future energy costs, and such analyses will not typically capture the above variables. If instead undervaluation is due to consumer or manufacturer inattention to future energy costs resulting from a market failure such as an information asymmetry, then the value of energy savings is a social benefit of the regulation. How potential buyers value improvements in the energy efficiency of new appliances and other covered products is, therefore, an important issue when assessing the benefits and costs of government regulation. There is a large body of empirical literature examining this issue, which comes to varying conclusions about the extent that consumers value these future energy expenditures. As noted in the Office of Management and Budget ("OMB")

Circular A-4 (2003),⁷ "individual preferences of the affected population should be a guiding principle in the regulatory analysis." This literature and its implications for DOE's analysis will be explored further in DOE's analytic framework update effort. DOE solicits comment on methodological approaches and literature relevant to the Energy Paradox.

III. Recommendations From the NASEM Report and DOE's Solicitation for Comments

The NASEM peer review committee organized its findings and recommendations across five areas: (1) framework for developing regulations; (2) assessing current models: engineering and technology cost and technology performance; (3) economic analysis of standards; (4) consideration of alternatives to a national standards program; and (5) addressing the needs of a changing world. The committee provided most advice on how to characterize uncertainty in DOE's analysis and data collections that would improve the quality of analysis.

The section discusses each of the recommendations and how they relate to DOE's rulemaking process for energy conservation standards. This section also highlights specific NASEM recommendations relevant to comments from stakeholders in response to the Process Rule RFI. DOE is organizing NASEM recommendations by analytic topics and notes that each recommendation may touch on multiple topics.

C. Problem Statement and Market Failure

The NASEM report includes four recommendations regarding DOE's justification for energy conservation rules. These recommendations center around making DOE's EPCA analysis consistent with the requirements under OMB Circular A-4, given statutory requirements. In particular the NASEM recommendations discussed market failures or other motivation for federal intervention.

Specifically, the NASEM report recommendations include:

- **RECOMMENDATION 2-2:** DOE should pay greater attention to the justification for the standards, as required by executive orders and the EPCA requirement that standards be economically justified. DOE should attempt to find significant failures of private markets or irrational behavior by

⁷ Office of Management and Budget. (2003). Circular A-4: Regulatory Analysis: https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4.

⁵ The Herindahl-Hirschman Index.

⁶ These additional up-front costs include more than just the cost of the technology necessary to improve energy economy; because consumers have a scarcity of resources, it also includes the opportunity cost of any other desirable features that consumers give up when they choose the more energy-efficient appliances and other covered products.

consumers in the no-standards case and should consider such a finding as being necessary to conclude that standards are economically justified.

- **RECOMMENDATION 4-13:** DOE should place greater emphasis on providing an argument for the plausibility and magnitude of any market failure related to the energy efficiency gap in their analyses. For some commercial goods in particular, there should be a presumption that the market actors behave rationally unless DOE can provide evidence or argument to the contrary.

- **RECOMMENDATION 4-14:** The committee recommends that DOE give greater attention to a broader set of potential market failures on the supply side, including not just how standards might reduce the number of competing firms, but also how they might impact price discrimination, technological diffusion, and collusion.

DOE solicits further comment on how the agency should use cost-benefit analysis when determining whether Federal energy conservation standards would be economically justified under EPCA.⁸ This request applies generally and with respect to identification of market failure or other behaviors that do not allow efficient allocation of resources, as well as the significance of those market failures or other problems.

DOE solicits further comment on how the Department can provide statements and evidence on: (1) demonstration of market failure relevant to the covered products; (2) existence of the energy paradox or energy savings gap in the covered residential product markets; and (3) existence of the energy paradox or energy savings gap for commercial and industrial covered products.

1. Uncertainty and Variability

The NASEM recommended that DOE incorporate methods to better reflect underlying uncertainties in the analysis and variability in consumer use patterns and present those more fully. The uncertainties and variabilities identified by NASEM are central to the seven factors that DOE considers for economic justification under EPCA, in particular economic effects on consumers and manufacturers, savings

in operating costs, and the total projected amount of energy and water savings. As a result, while this recommendation pertains to DOE's overall analytic structure and approach, it also has downstream effects on the Key Considerations for Economic Justification Pursuant to EPCA discussed in section III.D of this document. Specifically, the report includes the following recommendation:

- **RECOMMENDATION 4-15:** In order to evaluate the economic costs and benefits of a standard, DOE should present the distribution of costs and benefits estimated in its models when (1) uncertain parameters are represented by probability distributions and (2) parameters that vary across geographic and other relevant dimensions are disaggregated. The uncertainty or variability the parameters represent should be compounded or propagated—properly accounting for any correlations—throughout the calculation. This methodology is necessary for the markup analysis and manufacturer impact analysis (Recommendation 4-2), the shipments analysis (Recommendation 4-4), and all components of the life-cycle cost analysis (Recommendations 4-5 and 4-7). Where multiple sources of uncertainty must be combined for the final benefits result, as with net benefits depending on both the shipments analysis and the appliance unit cost and performance, the subcomponents should be reported as well (Recommendation 4-5).

DOE presents estimates for benefits and costs of energy conservation standards⁹ and recognizes that there is a significant amount of variability in how consumers use their regulated products. Capturing these distinctions clarifies the allocation of costs and benefits for DOE's standards and reflects variability and uncertainties associated with model inputs. Understanding variability and uncertainties is an important part of properly interpreting the results of DOE's analysis.

On this topic, DOE solicits comment on: (1) which critical inputs DOE should prioritize in incorporating variability; (2) how DOE should propagate probabilistic assessment throughout the agency analysis; (3) how DOE should present results taking into account these variabilities and uncertainties; and (4) how DOE should guard against ill-advised practices in accounting for variability and uncertainty (e.g., use of

Monte Carlo simulation using a distribution derived from small sample sizes).

D. Technology Assessment

The NASEM report includes two recommendations that touch on DOE's assessment of technology that should inform the estimation of the baseline technology which incorporates technology evolution, adoption of technology as a result of energy conservation standards, and technology taxonomy. This assessment is an important input in DOE's determination as to whether an energy conservation standard is technologically feasible, as required by 42 U.S.C. 6295(o)(2)(A). Specifically, the NASEM recommendations include:

- **RECOMMENDATION 3-1:** DOE should consider technologies that are at early, pre-competitive technological readiness levels and have promise for use in consumer products and commercial/industrial equipment as part of product population analyzed, even if it seems plausible that they will be screened out in later stages of the analysis such as in the Screening Analysis made during the Notice of Proposed Rulemaking. DOE should continue to use the tools at its disposal, such as reconsidering a previously excluded technology, to avoid prematurely screening-out innovative technologies.

- **RECOMMENDATION 3-2:** DOE should adopt a taxonomy for labeling the readiness of technologies, such as technology readiness level or "TRL" as it is widely known.

Chapter 3 of the NASEM Report focuses on DOE's screening and engineering analyses. During the early phase of the rulemaking process, the Department will typically develop a list of design options for consideration. Initially, the design options will encompass all those technologies considered to be technologically feasible. DOE will then conduct a screening analysis to determine which technology options will be considered as part of the engineering analysis.

The design options that are not eliminated by this screening will then form the basis for DOE's engineering analysis. The engineering analysis uses these design options to develop cost-efficiency relationships for the product or equipment in question. These cost-efficiency relationships are then used to develop efficiency levels, which serve as the basis for the proposed trial standard levels.

The NASEM report found that "The current screening analysis is conservative and may force the

⁸ 42 U.S.C. 6295(o)(2)(B). In addition to statutory requirements, significant regulatory actions (including guidance documents) must adhere to E.O. 12866 and Circular A-4 (if found economically significant). The NASEM also recommended that, consistent with the requirements of EPCA, DOE move engineering technical support documents to appendices and reorient the agency's cost-benefit analysis to be more economically focused and consistent with the requirements of E.O. 12866 and Circular A-4 (see, e.g., NASEM recommendation 2-1).

⁹ DOE presents aggregate benefits and costs using social discount rates of 3% and 7% and incorporates low-growth and high-growth scenarios from the Energy Information Administration's (EIA) *Annual Energy Outlook (AEO)*.

exclusion of some otherwise desirable technology options. The most effective appliance efficiency standards would encourage the development and eventual adoption of innovative technology. Other agencies use alternative methods in their own technology evaluations for identifying a technology's readiness, such as the technological readiness level ("TRL") taxonomy developed originally by the National Aeronautics and Space Administration ("NASA").¹⁰

DOE requests comment on how the agency can reflect technology evolution that would have occurred even without energy conservation standards and whether the agency's modeling of TSLs and ELs reflect technology adoption caused by the energy standards.

DOE requests further comments on alternatives for how DOE might best meet these specific NASEM recommendations.

E. Key Considerations for Economic Justification Pursuant to EPCA

EPCA directs DOE to select the standard that represents the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A); 42 U.S.C. 6316(a)) EPCA also states that "[i]n determining whether a standard is economically justified, the Secretary shall, after receiving views and comments furnished with respect to the proposed standard, determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering [the seven enumerated factors]." (42 U.S.C. 6295(o)(2)(B)(i))

It is within this statutory context that NASEM provided DOE with the recommendations in the following sections. NASEM specifically notes that "EPCA, as amended, authorizes DOE to issue standards to 'achieve the maximum improvement in energy [or water] efficiency . . . which the Secretary determines is technologically feasible and economically justified,' which involves evaluating 'whether the benefits of the standard exceed its burdens.'" ¹¹ These recommendations are central to DOE's assessment of the benefits and burdens of its standards, and, as a result, whether a proposed standard meets the statutory criteria for being economically justified.

2. Consumer Effects

The NASEM report explicitly recognizes that when consumers buy

covered products, they are buying bundles of attributes including potential energy savings. Energy savings is not the only attribute, and may not even be a determining factor in the selection of a given appliance. To that end, the NASEM recommends that DOE collect data on consumer choice and use a discrete choice model to analyze the potential trade-offs consumers are making when purchasing covered products. These trade-offs will likely affect DOE's estimates of life-cycle costs and shipments (*i.e.*, aggregate demand), as NASEM recommends modeling differences in purchase behavior between the baseline and different TSLs. Consumer purchasing behavior should include effects on shipment data when it involves direct rebound.

Specifically, the NASEM report recommends:

- **RECOMMENDATION 5-1:** The RIA [Regulatory Impact Analysis] should be grounded in an appreciation of consumer needs beyond reduced energy costs. The RIA should analyze not only the impact of appliance and equipment standards but also the additional impact of measures within a framework that includes the following:

- The portfolio of voluntary elements of demand-side management; and
- Impact of standards on the overall power system external and internal to the building and of the natural gas supply and transmission and distribution.

- **RECOMMENDATION 4-3:** DOE should collect data on consumer choices in appliance markets and estimate a discrete choice model of consumer behavior to quantify the trade-offs that consumers face from changes in appliance performance.

- **RECOMMENDATION 4-5:** DOE should make changes to the Technical Support Documents underpinning its rulemakings to clearly communicate the dependence of the life-cycle cost ("LCC") calculation on shipments assumptions and thereby add clarity on the interpretation of LCC savings. In order to clarify the engineering scope of a standard, apart from consumer demand estimates, the technical support documents should include (1) LCC savings for one consumer choosing between purchasing a baseline product or purchasing a TSL and (2) LCC savings for one consumer that could continue to own a baseline product or replace it with a TSL and (3) life-cycle cost savings for products or equipment that meet a given TSL as compared to the baseline without adjusting for the assumed current and future distribution of sales (shipments).

- **RECOMMENDATION 4-9:** For purposes of calculating changes in energy use, DOE should consider direct rebound wherever possible; if DOE believes there to be minimal rebound, they should document the reasons why. However, consumer welfare should be understood to benefit from rebound, rather than be harmed by it, notwithstanding the implied increase in energy use. Approximations of the welfare gain from rebound can be incorporated wherever sufficient information allows.

- **RECOMMENDATION 4-4:** The committee recommends that DOE propagate the uncertainty in the shipments model's input parameters and present the full range of shipment estimates.

- **RECOMMENDATION 4-7:** DOE should improve the accuracy of its estimates of all of the LCC calculation components by (1) taking full advantage of disaggregated data to account for geographical and temporal variability when available, (2) specifying probability distributions instead of one-point estimates and compounding or propagating the uncertainty they represent throughout the calculation, (3) better recording the data collected by RECS to avoid losing information provided by respondents, (4) better documenting the engineering analysis to obtain disaggregated probabilistic information necessary for the LCC, (5) prioritizing the collection of information for parameters likely to have a significant impact such as the lifetime of a product (*i.e.*, durability), and (6) validating the assumptions made in previous analyses with data collection through the engineering analyses, focus groups with manufacturers, retailers, consumers, and other means.

To evaluate the economic impacts of a potential standard on consumers, in particular the potential life-cycle cost savings resulting from reduced energy consumption, DOE uses a model based on data reflecting the historic overall market distributions of product efficiency levels within the evaluated consumer sample. As explained in previous energy conservation standards rulemakings, there is a complex set of factors, with sometimes opposing effects, affecting the markets for the various types of products and equipment for which DOE sets efficiency standards, including whether consumers may consider purchasing alternative products.¹² Because of

¹⁰ NASEM Report at p. 4.

¹¹ NASEM Report at p. 2.

¹² For example, see discussion in the December 2023 Consumer Furnaces Final Rule, sections IV.F.8 to IV.F.11 (covering various consumer preference

limitations on data, DOE's analysis assumes historic market distributions persist across efficiency levels and products. In other words, unless presented with evidence to the contrary, DOE assumes market share and covered product classes remain at the levels prior to the setting of a new ECS, and that those shares and products remain in place over the 30-year time horizon over which DOE currently analyzes ECS in both the baseline and potential standards cases. In cases where additional consumer preference data are identified (e.g., empirically observed demand elasticity estimates for the covered products), they are utilized to inform the life-cycle costs or to establish bounding scenarios. Where such data do not exist, DOE often assumes an elasticity, typically ranging from 0.5, to 1, to 1.5 to reflect changes in demand due to changes in projected price resulting from a policy change. This approach does not capture other behavioral changes, for example, switching between covered product categories (e.g., consumers who need to replace their refrigerators switching from French door models to side-by-side models or top freezer models, which would be captured with cross-price elasticities). Such changes may substantially affect shipment projections as well as projected energy savings.

Stakeholders have in various rulemakings submitted comments recommending changes to this analytical approach. In the absence of specific information or more detailed and disaggregated data that would support an alternative approach, DOE seeks specific comments and any other relevant information that would inform evaluation of refinements to this portion of the analysis for any or all product classes. For relevant confidential business information ("CBI"), DOE seeks information on collection practices that would be helpful and notes that CBI practices are established and utilized under the Paperwork Reduction Act ("PRA") across the Federal Government and at 10 CFR 1004.11.

By specifying an explicit consumer model that allows trade-offs of covered product attributes and using more disaggregated data, DOE may be able to account for the benefits and costs of energy conservation standards more completely and be able to forecast market reactions more accurately. Recall that the determinants of demand for goods include price of the goods, good attributes, and relevant substitute and

complimentary goods. By explicitly modeling trade-offs between product attributes and potential energy savings attributable to different TSLs, DOE would be able to forecast more accurately how consumer demand may change for each TSL where each TSL would encompass different energy savings and product attributes (e.g., decreased cleaning and or rinsing performance for higher energy savings). DOE's current approach is intended to analyze the benefits and costs of changing energy conservation standards by focusing solely on the attribute of energy savings. DOE commits to developing a consumer choice model that allows trade-offs between different attributes and energy savings that are reflected in the distribution of consumer choices by product efficiency level, as such a model would allow examination of effects that are specified in EPCA statutory factors due to changes in energy conservation standards and incorporate changes in demand between different products within a covered product category and any reduction in demand due to price changes. DOE requests comment on best approaches to model any and all effects specified in the statutory factors.

DOE is committed to undertaking steps to implement the NAS recommendations on incorporating consumer effects into the agency RIAs. DOE acknowledges that building agency capacity to conduct such analysis will take time and resources. While DOE builds this analytic capacity, DOE seeks comment on how to undertake and present consumer effects analysis in the near term so that these important effects can be accounted for in the interim (e.g. qualitatively), while satisfying the statutory obligation to balance the seven factors.

DOE requests comment on how best to present qualitative effects of its regulations until new processes are in place to provide a more robust quantitative analysis, consistent with the NASEM recommendations and the general purpose of this RFI.¹³

¹³ With regard to qualitative effects, Circular A-4 states: "When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them." While the Circular is unambiguous that quantified estimates are preferable to qualitative ones, these qualitative effects should be summarized and presented clearly for both the public and policymakers. The Circular also instructs agencies to differentiate between major and minor qualitative effects, and to provide transparency: "When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs."

DOE also solicits comment on the types of models the agency should build in response to the NASEM recommendations. A discrete choice model allows for full trade-offs between product attributes. This model would need to interact with DOE's model that represents manufacturer choice to produce products either by assuming that producers minimize total costs to comply with a new standard or assuming that producers maximize total profit when reacting to changes in the minimum energy conservation standard (e.g., there will be a segment of aggregate demand for higher energy conservation than the new minimum energy conservation standard). How should DOE identify the most important product features that should be incorporated into the consumer model? As with any model, all features cannot be incorporated explicitly, and important features should be identified to make the model workable. How should DOE collect data to support a consumer choice model (see more on in section III.D of this document for NASEM recommendations on data collection)?

3. Manufacturer Effects

The NASEM report includes recommendations on how DOE should consider manufacturer effects, including:

- **RECOMMENDATION 3-5:** DOE should expand the Cost Analysis segment of the Engineering Analysis to include ranges of costs, patterns of consumption, diversity factors, energy peak demand, and variance regarding environmental factors.

- **RECOMMENDATION 4-2:** To account properly for uncertainty and variability across manufacturers, DOE should report ranges for the input values that feed the GRIM [Government Regulatory Impact Model] model and run GRIM with the lower bound and upper values in the observed ranges. To make the MIA more transparent, DOE should present its estimates of financial parameters and cost of capital from publicly available sources and then report the adjusted values after the responses to interviews have been considered.

- **RECOMMENDATION 4-6:** DOE should improve the representation of variability and uncertainty on Installed Costs by considering the variation in costs components across states and by leveraging the engineering analysis to obtain a probabilistic characterization of costs components.

The NASEM did not offer advice on the overall structure of the cost model. Instead, the NASEM advice focuses on

incorporating variability in costs, consumption, and other inputs to the GRIM and MIA analyses and on better presentation of parameter variability and uncertainty of results, such as including ranges rather than point estimates and better presentation of financial parameters such as cost of capital from publicly available sources (e.g., Federal Reserve Bank of St. Louis). DOE also received comments in response to the Process Rule RFI related to NASEM recommendation 3–5: “DOE should expand the Cost Analysis segment of the Engineering Analysis to include ranges of costs, patterns of consumption, diversity factors, energy peak demand, and variance regarding environmental factors.” DOE solicits comment on how the agency analysis can incorporate this advice in accounting for variability in inputs, presenting ranges rather than point estimates, and using probabilistic characterization of both inputs and outputs of the analysis. DOE also seeks comment on data collections that DOE may need to undertake to support these advances in the manufacturing analysis. Finally, DOE solicits comments on whether a further wholesale re-examination of modeling cost impacts should be undertaken. In particular, are there methodologies that can be applied in place of or in addition to the GRIM and MIA analyses?

4. Life-Cycle Cost and Energy Savings

The NASEM report includes recommendations on how DOE should consider life-cycle cost and energy savings, including:

- **RECOMMENDATION 3–3:** DOE should characterize the uncertainty on the efficiency rating in its analyses. Rather than providing a “point” estimate of efficiency, DOE should provide a range that reflects the variability in energy consumption under different uses and consumer behavior. This should reflect the need to account for the uncertainty arising from the range of conditions under which a consumer may use a product and then using those use-case ranges to establish sensitivity studies so that efficiency can be communicated as a range rather than a single estimate.

- **RECOMMENDATION 4–6:** DOE should improve the representation of variability and uncertainty on Installed Costs by considering the variation in costs components across states and by leveraging the engineering analysis to obtain a probabilistic characterization of costs components.

- **RECOMMENDATION 4–7:** DOE should improve the accuracy of its estimates of all of the LCC calculation

components by (1) taking full advantage of disaggregated data to account for geographical and temporal variability when available, (2) specifying probability distributions instead of one-point estimates and compounding or propagating the uncertainty they represent throughout the calculation, (3) better recording the data collected by RECS to avoid losing information provided by respondents, (4) better documenting the engineering analysis to obtain disaggregated probabilistic information necessary for the LCC, (5) prioritizing the collection of information for parameters likely to have a significant impact such as the lifetime of a product (i.e., durability), and (6) validating the assumptions made in previous analyses with data collection through the engineering analyses, focus groups with manufacturers, retailers, consumers, and other means.

The NASEM’s recommendations on life-cycle analysis center on increasing accuracy and the precision of the life-cycle analysis by incorporating disaggregated data as much as possible, as well as better reflecting the underlying probability distribution throughout the analysis. NASEM found the LCC to overly rely on point estimates and urged better documentation of the analytic steps. Collecting data on product attributes like durability, as well as a range of installation costs, are helpful to more accurate modeling of consumer demand for the products.

DOE requests comments on how to: (1) incorporate disaggregated data that increase the accuracy and precision of the agency estimates, particularly in capturing changes in consumer demand would affect the overall conclusions of the LCC; (2) present the analytic steps of the life-cycle analysis more clearly. DOE further requests insights into how to more clearly present life-cycle analysis steps and results as they correspond to the range of identified TSLs and ELs to better inform public comment. DOE also requests insights into product attributes that are important to consumer demand that may affect purchasing behavior for each category of relevant goods (e.g., switching from gas water heater to electric water heater and relevant energy consumption rebound). Finally, DOE requests general comments on the Department’s LCC approach and whether further revisions to this analysis, such as the addition or substitution of other methodologies or models, might improve estimates.

5. Market Effects

The NASEM report includes recommendations on how to analyze potential price effects attributable to energy conservation standards. The report states that DOE should put more emphasis on analyzing price effects based on observed market-based markups, potential industry consolidation due to competing firms leaving the market and potential for collusion, potential price discrimination between product classes, type and rate of technology diffusion, and other factors that will affect market price for covered products. The NASEM recommendations note that DOE should allow for incorporation of these effects such that the price can increase, stay relatively the same, or even decrease, and not otherwise restrict the model.

Specifically, the report includes:

- **RECOMMENDATION 4–1:** DOE should put greater weight on *ex post* and market-based evidence of markups to project a more realistic range of likely effects of a standard on prices, including the possibility that prices may fall. This would improve future analyses.

- **RECOMMENDATION 4–4:** The committee recommends that DOE propagate the uncertainty in the shipments model’s input parameters and present the full range of shipment estimates.

- **RECOMMENDATION 4–14:** The committee recommends that DOE give greater attention to a broader set of potential market failures on the supply side, including not just how standards might reduce the number of competing firms, but also how they might impact price discrimination, technological diffusion, and collusion.

As explained in previous rulemakings,¹⁴ DOE uses the historical Producer Price Index (“PPI”) data from the Bureau of Labor Statistics (“BLS”) as a proxy of the historical time series of production cost for a product or equipment that is addressed in the rulemaking and assumes that increases in cost will be fully passed through to consumers. DOE relies on the “learning” or “experience” curves that generally suggest a downward trend in costs. Experience curve analysis implicitly includes factors such as efficiencies in labor, capital investment, automation, materials prices, distribution, and economies of scale at an industry-wide level. In the

¹⁴ See, for example, the Direct Final Rule (DFR) on Energy Conservation Standards for Refrigerators, Refrigerator-Freezers, and Freezers, published in the **Federal Register** on January 17, 2024 (89 FR 3026). Product prices are addressed in section IV.F.2 of the DFR. 89 FR 3026, 3056–3057 (Jan. 17, 2024).

experience curve method, the real cost of production declines with the cumulative production or “experience” manufacturing a product.

Although there is considerable empirical evidence supporting use of an experience or learning curve (or a generalized price trend) to model price declines over time for various types of products and equipment,¹⁵ DOE has in previous rulemakings received comments from stakeholders questioning the methodology and underlying data. In response to these comments, DOE notes that its utilization of the PPI data stems in large part from the limited data availability on historical manufacturing costs broken down by different components. Still, DOE acknowledges that regressing the dependent variable of price on PPI will reduce or eliminate the substantive robustness and meaning of price forecasts. Further, PPI shifts consumption baskets over time, which is inconsistent with DOE’s assumption that the shares of covered products do not change over the 30-year analytic time horizon. In addition, DOE acknowledges the simplified learning curve model employed does not control for autocorrelation while at the same time utilizing time series data. Finally, DOE acknowledges that future price changes can be more robustly modeled, such as through an examination of changes in marginal cost, which is an approach other agencies have applied in forecasting price.¹⁶

DOE solicits comment on how the agency can model consumer and manufacturer behaviors that result in market reactions to the energy conservation standards. In response to a new standard, manufacturers must comply and may incur additional manufacturing costs. These costs will be passed onto consumers, fully or in part depending on applicable elasticities, and consumers will react by adjusting their purchase in various ways, including by delaying purchases or seeking a similar good in secondary markets if such markets exist. DOE solicits comments on (1) empirical estimates of consumer demand

elasticities, manufacturer supply elasticities, (2) how to account for secondary markets, (3) how to conduct price forecasting (rather than exclusively relying on the use of PPI or other indices of inflation); (4) how to account for industry consolidation; and (5) how to account for product differentiation and price discrimination, if relevant. DOE also solicits comment on data requirements and sources for this type of modeling. Finally, DOE solicits comment on whether and which methodological tools and approaches can be employed in addition to or as replacement of existing approaches to model manufacturer and consumer responses to possible ECS.

6. Emissions

Under EPCA, the Secretary exercises his discretion in determining which additional factors should be considered in making a determination regarding economic justification. In DOE’s 2026 Process Rule proposal, the Secretary has proposed that DOE will no longer consider environmental emissions as a factor in determining economic justification. The NASEM recommended that DOE monetize all meaningful emission changes that are attributable to energy conservation standards, and at the time of the NASEM recommendations, DOE was estimating such changes as part of the ECS analysis. As DOE is proposing to no longer consider environmental emissions as a factor in determining economic justification, DOE is not specifically seeking information related to this NASEM recommendation.

F. Data Collection

The NASEM report provides advice on future data collections that DOE would need to undertake in order to run more rigorous and disaggregated models of consumers and manufacturers behavior in relation to effects of energy conservation standards. The NASEM recommends collecting ex-post market data on consumer behavior, producer behavior, energy consumption, and environmental impacts that allow variability and probabilistic assessment when appropriate. Also, NASEM recommends that in-situ or real-life energy consumption information may be better than modeled or test data, as consumption behavior may affect overall energy usage, such as through a rebound effect.

Specifically, the NASEM report includes the following:

- **RECOMMENDATION 2–3:** DOE should commit to collecting data necessary to conduct more rigorous ex post analysis of the effects of standards

on consumers, producers, energy consumption, and environmental impacts.

- **RECOMMENDATION 3–4:** DOE should launch a study to investigate improved methods for data acquisition and analysis for use in setting and revising standards. This study should include an overview of where DOE helps enable collection of these data now and how they can improve that process at minimum impact on manufacturers.

- **RECOMMENDATION 4–1:** DOE should put greater weight on ex post and market-based evidence of markups to project a more realistic range of likely effects of a standard on prices, including the possibility that prices may fall. This would improve future analyses.

- **RECOMMENDATION 4–3:** DOE should collect data on consumer choices in appliance markets and estimate a discrete choice model of consumer behavior to quantify the trade-offs that consumers face from changes in appliance performance.

- **RECOMMENDATION 4–7:** DOE should improve the accuracy of its estimates of all of the LCC calculation components by (1) taking full advantage of disaggregated data to account for geographical and temporal variability when available, (2) specifying probability distributions instead of one-point estimates and compounding or propagating the uncertainty they represent throughout the calculation, (3) better recording the data collected by RECS [the Residential Energy Consumption Survey] to avoid losing information provided by respondents, (4) better documenting the engineering analysis to obtain disaggregated probabilistic information necessary for the LCC, (5) prioritizing the collection of information for parameters likely to have a significant impact such as the lifetime of a product (*i.e.*, durability), and (6) validating the assumptions made in previous analyses with data collection through the engineering analyses, focus groups with manufacturers, retailers, consumers, and other means.

- **RECOMMENDATION 4–8:** DOE should seek to gather and make use of in situ performance data wherever possible to account for any performance gaps. When estimates of in situ performance data are unavailable, DOE should include a qualitative assessment of the potential for a performance gap. Indicators of performance include maintenance requirements and product lifetime as well as energy and water consumption.

- **RECOMMENDATION 4–16:** DOE should obtain better data for improving

¹⁵ For example, see: Weiss, M., M. Junginger, M. K. Patel, and K. Blok (2010): “A Review of Experience Curve Analyses for Energy Demand Technologies.” *Technological Forecasting and Social Change*, 77(3), pp. 411–428 (available at: doi.org/10.1016/j.techfore.2009.10.009) (last accessed October 22, 2025).

¹⁶ DOE’s current approach often assumes full pass through. Depending on industry structure of firms that produce covered products, this assumption may lead to erroneous conclusions about price change and demand change. DOE plans to peer review a more robust model on price forecasting going forward.

the economic analyses of appliance and equipment performance standards. Empirical data are needed on markups (Recommendation 4–1), consumer choices in appliance markets (Recommendation 4–3), and in situ performance (Recommendation 4–8). Some of this information can come from relatively simple changes to current surveys and studies, including engineering analyses of the Appliance and Equipment Standards Program and the Residential Energy Consumption Survey (Recommendation 4–7).

• **RECOMMENDATION 4–17:** Ex post analyses can validate assumptions made in prior standards and evaluate the implications of prior forecasts’ inaccuracies and mistakes. DOE should use such ex post analyses routinely to improve forward-looking standards iteratively.

Currently, DOE relies on a variety of sources including, but not limited to:

Household surveys:

- US EIA, Residential Energy Consumption Survey (“RECS”) ¹⁷
- US Census, American Housing Survey (“AHS”) ¹⁸
- Federal Reserve, Survey of Consumer Finances (“SCF”) ¹⁹
- US Census, Population data ²⁰
- Decision Analyst, American Home Comfort Study ²¹

Consumer Surveys:

- Various market research companies ²²
- Various public Lawrence Berkeley National Laboratory (“LBNL”) reports summarizing results of consumer surveys conducted by LBNL ²³

Field Metering:

- Pecan Street ²⁴
- Various public LBNL reports summarizing results of field metering studies conducted by LBNL ²⁵

Review of Permits:

- US Census, Survey of Construction (“SOC”) ²⁶

Company Surveys:

- EEI Typical electricity bill data ²⁷

- US EIA, Commercial Building Energy Consumption Survey (“CBECS”) ²⁸
- Household Energy Supplier Monthly Bills

- US EIA, RECS billing data ²⁹
- Weather Data

- NOAA Weather data ³⁰

Manufacturer Interviews Conducted Under Non-disclosure Agreements (“NDA”)

DOE requests comment on these common data sources used in the rulemaking process, including whether they already address any of the NASEM recommendations, and whether any other available data sources would inform DOE’s rulemaking analysis with more detailed or additional data addressing similar topics. DOE solicits further comments on any other specific data elements that DOE should collect that inform promulgation of energy conservation standards.

DOE solicits further comments on appropriate methods that can be used to ensure quality control of the scientific information noted above, including when additional peer review would be necessary.

G. Effects on Power Systems

The NASEM provided recommendations on how energy conservation standard analysis should take into account effect on power systems and emissions thereof. As noted previously, in the 2026 Process Rule proposal, the Secretary has exercised his discretion under EPCA to discontinue analyzing emissions impacts as part of his economic justification determination. Regarding the upstream impact to power generation, the NASEM report recommended the following:

- **RECOMMENDATION 3–6:** DOE should consider Demand Response readiness as a factor in cost-efficiency calculations. This necessitates the inclusion of power system benefits not currently considered.

- **RECOMMENDATION 4–10:** DOE should credit as economically valuable

those features and innovations that save consumers money and enable appliances to contribute to grid efficiency and reliability.

• **RECOMMENDATION 4–11:** To estimate changes in emissions during the compliance year, DOE should estimate for each state, the changes in the hourly load curve that would result from the adoption of an energy efficiency standard during a full year. Using these estimates, the National Energy Modeling System can incorporate different assumptions about decarbonization of the U.S. electricity system such as the natural gas prices and the penetration of renewable energy and energy storage and estimate a range of emissions changes for each relevant region and time.

DOE is committed to reflecting ongoing changes in the electricity generation system and implications to energy conservation standard analysis, and welcomes comment on how best to do so.

IV. Summary of Analysis-Related Topics Raised in Comments on the Process Rule RFI

As mentioned previously, in response to the 2025 Process Rule RFI, DOE received several comments on topics related to analytic methodologies used by DOE to consider and set standards. These topics also relate to some of the NASEM recommendations, as discussed in section II of this document. The list of commenters on the 2025 Process Rule RFI is summarized in Table 1. In the 2026 Process Rule NOPR also recently published in the **Federal Register**, DOE summarizes comments on analytic methodologies it has received. The NOPR also indicated that DOE would consider analytic comments as part of a separate process. Relevant comments from the 2025 Process Rule RFI are acknowledged below, though discussed in more detail in the Process Rule NOPR.

¹⁷ <https://www.eia.gov/consumption/residential/index.php>.

¹⁸ <https://www.census.gov/programs-surveys/ahs.html>.

¹⁹ <https://www.federalreserve.gov/econres/scfindex.htm>.

²⁰ <https://www.census.gov/topics/population.html>.

²¹ <https://www.decisionanalyst.com/syndicated/homecomfort/>.

²² See e.g., AcuPOLL® Precision Research, Inc. Survey of Consumer Ceiling Fan Usage and Operations. 2014.

²³ See e.g., https://eta-publications.lbl.gov/sites/default/files/lighting_report_2022-1220_final.pdf.

²⁴ <https://www.pecanstreet.org/>.

²⁵ See e.g., <https://eta-publications.lbl.gov/sites/default/files/lbnl-6868e.pdf>.

²⁶ <https://www.census.gov/construction/soc/index.html>.

²⁷ <https://netforum.eei.org/eweb/DynamicPage.aspx?WebCode=SubPubSearch&pager=12&Site=EEIEWEB&EEIEWEBTOKEN=>.

²⁸ <https://www.eia.gov/consumption/commercial/>.

²⁹ <https://www.eia.gov/consumption/residential/index.php>.

³⁰ <https://www.ncei.noaa.gov/access/metadata/landing-page/bin/iso?id=gov.noaa.ncdc:C00679>.

³¹ The Air-Conditioning, Heating, and Refrigeration Institute (“AHRI”); Air Movement and Control Association (“AMCA”); International Association of Home Appliance Manufacturers (“IAHAM”); Consumer Technology Association (“CTA”); Hearth, Patio & Barbecue Association (“HPBA”); Heating, Air-Conditioning, Refrigeration Distributors International (“HARDI”); National Association of Manufacturers (“NAM”); National Automatic Merchandising Association (“NAMA”); North American Association of Food Equipment Manufacturers (“NAFEM”); National Electrical Manufacturers Association (“NEMA”); Plumbing-Heating-Cooling Contractors Association (“PHCC”); Plumbing Manufacturers International (“PMI”); and Power Tool Institute (“PTI”).

TABLE 1—COMMENTERS WITH WRITTEN SUBMISSIONS RELATED TO ANALYTICAL METHODOLOGIES IN RESPONSE TO THE APRIL 2025 PROCESS RULE RFI

Commenter(s)	Abbreviation	Comment No. in the docket*	Commenter type
AHRI, AMCA, AHAM, CTA, HPBA, HARDI, NAM, NAMA, NAFEM, NEMA, PHCC, PMI, PTI ³¹ .	Joint Commenters	24	Trade Associations.
Air Conditioning Contractors of America	ACCA	38	Trade Association.
Air-Conditioning, Heating, and Refrigeration Institute	AHRI	28	Trade Association.
ASHRAE	ASHRAE	12	Trade Association.
Manufactured Housing Institute	MHI	21	Trade Association.
National Association of Home Builders	NAHB	19	Trade Association.
National Electrical Manufacturers Association	NEMA	23	Trade Association.
National Multifamily Housing Council and National Apartment Association.	NMHC and NAA	29	Trade Association.
North American Association of Food Equipment Manufacturers	NAFEM	13	Trade Association.
Pool & Hot Tub Alliance	PHTA	27	Trade Association.
Bradford White Corporation	BWC	34	Manufacturer.
Burnham Holdings, LLC	BHI	16	Manufacturer.
Lennox International Inc	Lennox	26	Manufacturer.
Rinnai America Corporation	Rinnai	11	Manufacturer.
WM Technologies LLC	WM Technologies	14	Manufacturer.
Zero Zone, Inc	Zero Zone	15	Manufacturer.
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Consumer Federation of America, National Consumer Law Center.	Joint Advocates	31	Environmental and Energy-Efficiency Advocates.
Ceres, Inc	Ceres	22	Environmental and Energy-Efficiency Advocates.
Northwest Energy Efficiency Alliance	NEEA	36	Environmental and Energy-Efficiency Advocates.
ONE Gas, Inc	ONE Gas	37	Utility.
American Gas Association, American Public Gas Association, National Propane Gas Association.	Joint Gas Associations	25	Utility Associations.
American Public Power Association	APPA	20	Utility Association.
Edison Electric Institute	EEL	35	Utility Association.
National Rural Electric Cooperative Association	NRECA	17	Utility Association.
Hawaii State Energy Office; Washington State Department of Commerce.	State Agencies	33	State Agencies.
Heidi King Consulting	Heidi King Consulting	30	Consultant.
Mark Strauch	Strauch	18	Individual.

* EERE-2025-BT-STD-0001.

DOE received several comments pertaining to the analysis conducted in support of the development of energy conservation standards, including comments on the methodology and development of input values related to the general approach,³² as well as comments pertaining to specific analyses, including: (1) the engineering analysis;³³ (2) the markups analysis;³⁴ (3) the energy use and life-cycle cost analysis;³⁵ (4) the environmental

analysis;³⁶ and full-fuel-cycle energy metrics;³⁷ (5) the monetization of emissions analysis;³⁸ (6) the utility impact analysis;³⁹ and (7) the manufacturer impact analysis.⁴⁰ Some comments on the general approach overlap with recommendations in chapters 2 through 4 of the NASEM report. Some comments on the engineering analysis overlap with recommendations in chapter 3 of the NASEM report. Some comments on the markups analysis, energy use and life-cycle cost analysis, the environmental analysis, the monetization of emissions

analysis, the utility impact analysis, and the manufacturer impact analysis overlap with recommendations in chapter 4 of the NASEM report.

DOE further received additional comments specific to the following topics: (1) the approach to evaluate hard-to-quantify effects⁴¹ and evaluate market failures;⁴² (2) the cumulative regulatory burden analysis;⁴³ (3) considerations of any potential supply chain constraints;⁴⁴ (4) fuel neutrality and analysis of fuel switching;⁴⁵ and (5) the need for retrospective review and validation of existing standards prior to

³² (BHI, No. 16 at pp. 5–6; BWC, No. 34 at p. 5; Joint Commenters, No. 24 at pp. 3–4; AHRI, No. 28 at pp. 2, 7–8, 11–12; Joint Gas Associations, No. 25 at pp. 23–24, 37–38; APPA, No. 20 at p. 1; Joint Advocates, No. 31 at pp. 2–3; EEI, No. 35 at p. 2; State Agencies, No. 33 at p. 2; Heidi King Consulting, No. 30 at pp. 1–3; Lennox, No. 26 at pp. 6–7).

³³ (Joint Gas Associations, No. 25 at p. 22; Strauch, No. 18 at p. 1; NAFEM, No. 13 at p. 8).

³⁴ (Joint Gas Associations, No. 25 at p. 22; Lennox, No. 26 at p. 7).

³⁵ (ACCA, No. 38 at p. 2; AHRI, No. 28 at pp. 4, 7; EEI, No. 35 at p. 2; Joint Gas Associations, No. 25 at pp. 22–24; Joint Advocates, No. 31 at p. 3; Lennox, No. 26 at p. 7; NAHB, No. 19 at p. 4; NMHC and NAA, No. 29 at pp. 2–5; ONE Gas, No.

37 at pp. 2–3; ONE Gas, No. 37 at pp. 2–3; Rinnai, No. 11 at pp. 3, 6–8).

³⁶ (APPA, No. 20 at p. 5; Ceres, No. 22 at p. 5; NEEA, No. 36 at p. 3; EEI, No. 35 at p. 5).

³⁷ (Joint Gas Associations, No. 25 at pp. 18–19; ONE Gas, No. 37 at pp. 4–5; Rinnai, No. 11 at pp. 3, 7–8).

³⁸ (AHRI, No. 28 at p. 10; BWC, No. 34 at p. 5; Ceres, No. 22 at p. 4; State Agencies, No. 33 at p. 2; Strauch, No. 18 at p. 2; NAHB, No. 19 at p. 5; NAFEM, No. 13 at p. 7; Zero Zone, No. 15 at p. 5).

³⁹ (ONE Gas, No. 37 at p. 4).

⁴⁰ (ACCA, No. 38 at p. 2; NAFEM, No. 13 at pp. 2–3; Rinnai, No. 11 at pp. 3, 6).

⁴¹ (Heidi King Consulting, No. 30 at p. 5; Lennox, No. 26 at p. 5; NEMA, No. 23 at p. 6–7; NRECA, No. 17 at p. 2).

⁴² (Joint Gas Associations, No. 25 at pp. 21, 22; Heidi King Consulting, No. 30 at p. 3; Rinnai, No. 11 at p. 9).

⁴³ (AHRI, No. 28 at p. 4; Lennox, No. 26 at p. 6; PHTA, No. 27 at pp. 1–2).

⁴⁴ (APPA, No. 20 at pp. 2–3; EEI, No. 35 at pp. 2–3).

⁴⁵ (Joint Gas Associations, No. 25 at pp. 11–15, 17; Rinnai, No. 11 at pp. 9, 12).

initiating new rulemakings.⁴⁶ Some of these comments overlap with recommendations in chapters 2 through 4 of the NASEM report. For example, market failures and retrospective analyses are discussed in more than one chapter of the NASEM report.

V. Additional Analytic Topics

In addition to the NASEM report and comments received in the April 2025 Process Rule RFI, DOE has also received comments during previous energy conservation standards rulemakings regarding specific aspects of its analysis. In this section, DOE has identified specific analytic issues on which DOE has previously received such comments and on which the Department is interested in seeking additional information that may inform future revisions or refinements to those analytical methods. These specific topics are addressed in the following paragraphs.

A. Repair and Installation Cost Assumptions

As part of its analysis of the potential economic effects of an efficiency standard, DOE considers installation, repair, and maintenance costs where appropriate. Repair costs are associated with repairing or replacing product components that have failed in an appliance; maintenance costs are associated with maintaining the operation of the product.⁴⁷ Typically, small incremental increases in product efficiency entail no, or only minor, changes in repair and maintenance costs compared to baseline efficiency products. In the absence of specific evidence indicating otherwise, DOE typically conducts its analysis under the assumption that repair and maintenance costs will not vary by efficiency level and, thus, have no direct impact on the economic basis for a standard. DOE also endeavors to estimate installation costs and has received comment in the past that space and retrofit considerations are not always captured or fully captured. However, for some products, sufficient data and information exist to support specific installation, repair, and/or maintenance costs for higher-efficiency products. In those cases, the differential costs are incorporated into the analysis. To ensure this approach remains valid, DOE is interested in receiving any comments or information

that may suggest consideration of an alternative approach, taking into consideration that this may vary significantly by the type of product or equipment being evaluated.

B. Modeling Retirement and Replacement

As part of its analysis of the impact on consumer life-cycle costs and product shipments following the implementation of a new or amended efficiency standard, DOE models product lifetime using a survival function, typically based on a Weibull distribution. The survival function is calibrated using available data on average product or equipment lifetime from survey data, manufacturer product literature, confidential manufacturer interviews, and other studies in the literature. DOE also may conduct sensitivity analyses with varying survival functions when available information indicates substantial uncertainty in typical product or equipment lifetimes.

DOE often also analyzes the potential impact of consumers choosing to repair their product or equipment at the end of life instead of purchasing a new product or equipment as a result of a higher minimum energy standard level. This extended repair option may be chosen by a fraction of consumers, which will delay the purchase of a new product or equipment, thereby reducing short-term shipments and reducing potential energy savings from a new or amended efficiency standard. Over time, this effect disappears as consumers eventually replace their product or equipment.

DOE has received comments on this methodology in previous rulemakings and is interested in receiving any additional data or information that may inform revisions or refinements to this approach, taking into consideration that this may vary significantly by the type of product or equipment being evaluated. DOE is also interested in comments regarding the assumptions regarding recurring shipments for covered products as they are repeated across the 30-year time horizon.

C. Analytic Timeline

DOE has historically used 30 years as the agency's primary analytic time horizon. This choice reflects the agency's goal of comparing benefits and costs of different agency actions on the same basis across time. As a sensitivity, DOE has also used 9-year analysis timeframe that reflects the agency rulemaking cycle (*i.e.*, the 6-year review cycle plus the 3-year lead time provision under EPCA). One major

deficiency of these two timelines is the lack of covered product-specific information, such as useful life or design cycle. Conducting analysis over specific covered product lifetime horizons may increase accuracy and the transparency of the analysis. DOE seeks comment the agency's choice of analytic timeline for analysis, including whether as a routine application, the 30-year time horizon should be replaced or paired with product-life-specific time horizons.

D. Baseline

Typically, DOE's energy efficiency standards are set such that significant portion of the market is already meeting or exceeding the standards (*e.g.*, 30%), such that the real effect of DOE's standards is to increase the speed of adoption of energy-efficient appliances. As a result, the rate of technological advance assumed in the baseline is material to the quantification of benefits and costs. For example, a baseline that assumes market evolution toward greater energy or water efficiency even in the absence of a new standard would result in benefits attributed to the standard tending to decline over time as the hypothetical market in the baseline "catches up" with the efficiency levels required by the standard. DOE seeks comment on whether its current approach adequately models the adoption of more efficient technologies over time in the absence of a Federal standard.

Request for Comments

DOE is requesting comments on actions DOE should take in response to any of the recommendations in NASEM Report, as well as any of the additional analysis topics described in this RFI. DOE also specifically requests comments on the following topics as key factors to improving the effectiveness and confidence in analytic methodology for appliance and equipment performance standards.

- Specific refinements to analytic inputs that provide meaningful improvements to DOE analysis while avoiding data requests that present undue burden on manufacturers and other industry stakeholders, and also protect consumer privacy;
- Making data used for analysis transparent and accessible. When balancing the protection of proprietary information held by manufacturers and other industry stakeholders, best practices are used to ensure replicability of analysis;
- How to prioritize various updates and additions to DOE's analysis efforts,

⁴⁶ (ACCA, No. 38 at p. 2; Joint Gas Associations, No. 25 at pp. 26–28; NAHB, No. 19 at p. 4; Rinnai, No. 11 at p. 10).

⁴⁷ This effect is not consumers repairing older covered products in lieu of replacing them with products that meet the minimum energy conservation standards.

including increased use of retrospective analysis.

In alignment with Executive Order 14154 and given requirements under EPCA, DOE requests that commenters give particular consideration to how DOE can most effectively implement the subsections (f) through (h) of Section 2 of E.O. 14154, which relate most directly to DOE's analysis methodologies for appliance and equipment performance standards:

- To safeguard the American people's freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads, and to promote market competition and innovation within the manufacturing and appliance industries;
- To ensure that the global effects of a rule, regulation, or action shall, whenever evaluated, be reported separately from its domestic costs and benefits, in order to promote sound regulatory decision making and prioritize the interests of the American people; [and]
- To guarantee that all executive departments and agencies (agencies) provide opportunity for public comment and rigorous, peer-reviewed scientific analysis.

In alignment with Executive Order 14303, DOE requests that commenters give particular consideration to providing data, analysis, and suggestions for updating analytic methodologies that are consistent with the definition of "Gold Standard Science" included in Section 3 of the Order: reproducible; transparent; communicative of error and uncertainty; collaborative and interdisciplinary; skeptical of findings and assumptions; structured for falsifiability of hypotheses; subject to unbiased peer review; accepting of negative results as positive outcomes; and without conflicts of interest. More detail about each of these characteristics is available in the guidance issued by OSTP on June 23, 2025.⁴⁸

DOE will review comments from this RFI, as well as the Process Rule RFI, alongside the NASEM recommendations. With this information, DOE will begin developing analytical methods and processes that are transparent, accessible, objective, credible, and prevent suboptimal outcomes for industry and consumers.

E. Methodological Support of 42 U.S.C. 6295(o) Analysis

DOE is interested in comments about methodological approaches and associated data that have not been specifically mentioned that would be beneficial for consideration in addressing the NASEM recommendations and in support of analysis to meeting the requirements of EPCA set forth at 42 U.S.C. 6295(o).

VI. Submission of Comments

DOE invites all interested parties to submit in writing by the date specified in the **DATES** section of this document, comments and information on matters addressed in this document. After the close of the comment period, DOE will review the public comments received and consider next steps.

Submitting comments via www.regulations.gov. The www.regulations.gov web page requires you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies Office staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to www.regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information ("CBI")). Comments submitted through www.regulations.gov cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through www.regulations.gov before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that www.regulations.gov provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to www.regulations.gov. If you do not want your personal contact information to be publicly viewable, do not include it in your comments or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles ("faxes") will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: one copy of the document marked "confidential" including all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information

⁴⁸ www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf.

believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing energy conservation standards. DOE actively encourages the participation and interaction of the public during the comment period in this process. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE.

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this request for information and request for comment.

Signing Authority

This document of the Department of Energy was signed on June 30, 2026, by Audrey Robertson, Assistant Secretary (EERE) for Critical Minerals and Energy Innovation, U.S. Department of Energy, 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 July 2, 2026.

Treana V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2026–13673 Filed 7–6–26; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 141, 260, 357, and 369

[Docket No. RM26–12–000]

Revisions to Financial Forms Reporting and Filing Requirements; Correction

AGENCY: Federal Energy Regulatory Commission

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The Federal Energy Regulatory Commission published a document in the **Federal Register** of June 24, 2026, concerning a notice of proposed rulemaking seeking comment on the Commission's proposal to amend certain annual and quarterly financial forms, and its current regulations governing certain FERC financial forms. The document contained an error.

DATES: This correction is effective July 7, 2026, and applicable as of June 24, 2026.

FOR FURTHER INFORMATION CONTACT:

Laura Farkas (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6060. Laura.Farkas@ferc.gov.

Jessica Hunt (Technical Information), Office of Enforcement and Regulatory Accounting, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–6536. Jessica.Hunt@ferc.gov.

Shanee Sibblies (Technical Information), Office of Enforcement and Regulatory Accounting, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, (202) 502–8858. Shanee.Sibblies@ferc.gov.

SUPPLEMENTARY INFORMATION:

Correction

In FR Doc. 2026–12712 (195 FERC ¶ 61,206) beginning on page 37881 in the issue of June 24, 2026, make the following corrections:

1. On page 37881, in the third column, in the **DATES** section, correct “Reply Comments are due July 24, 2026.” to read “Reply Comments are due September 22, 2026.”
2. On page 37888, in the second column, in paragraph 61 of section VI, correct “Reply Comments are due July 24, 2026.” to read “Reply Comments are due September 22, 2026.”

Issued: July 2, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–13726 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[EPA–HQ–OAR–2025–1212; FRL–9632–03–OAR]

RIN 2060–AV67

Minor New Source Review Program Air Permitting Public Participation Requirements for State Implementation Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing to revise the public participation regulatory requirements for sources subject to Clean Air Act (CAA) New Source Review (NSR) programs approved into State Implementation Plans (SIPs). Specifically, the EPA is proposing to recognize in regulation that State and local air quality regulatory authorities (“air agencies”) determine, pursuant to the CAA, whether, when, and to what extent public participation in minor NSR programs is necessary to assure the National Ambient Air Quality Standards (NAAQS) are achieved. If finalized, the changes effected by this rulemaking would provide State and local air agencies with greater discretion to identify the requisite level of public participation that is appropriate in their minor NSR programs, which regulate individual authorizations to construct minor stationary sources and minor modifications to existing stationary sources.

DATES: *Comments.* Comments must be received on or before August 21, 2026.

Public hearing: If anyone contacts us requesting a public hearing on or before July 12, 2026, the EPA will hold a virtual public hearing on July 22, 2026. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2025–1212, by any of the following methods:

- *Federal e-Rulemaking Portal:* <https://www.regulations.gov> (our preferred method). Follow the online instructions for submitting comments.

You can also find a plain language summary of the proposed rule on the Federal eRulemaking Portal.

- *Email:* a-and-r-docket@epa.gov. Include Docket ID No. EPA-HQ-OAR-2025-1212 in the subject line of the message.

- *Fax:* (202) 566-9744. Attention Docket ID No. EPA-HQ-OAR-2025-1212.

- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA-HQ-OAR-2025-1212, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

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

Instructions: All submissions received must include the Docket ID No. EPA-HQ-OAR-2025-1212 for this proposed rulemaking. Comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. For further information on EPA Docket Center services and the current status, please visit the EPA Docket Center online at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For information about this proposed rule, contact Richard Bowen, U.S. EPA, Office of State Air Partnerships, Permitting & Program Support Division, C504-03, Research Triangle Park, NC 27711; telephone number: (919) 541-4436; email address: bowen.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. To request a virtual public hearing, contact the public hearing team at (844) 901-0246 or by email at OSAPpublichearing@epa.gov. If requested, the hearing will be held via virtual platform on July 22, 2026. The hearing will convene at 10 a.m. Eastern Time (ET) and will conclude at 4 p.m. ET; additional hearing hours may be added at the discretion of the EPA. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details on the virtual public hearing at <https://www.epa.gov/nsr/nsr-regulatory-actions>.

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing no later than one business day after a request has been received. To register to speak at the virtual hearing, please use the online registration form available at <https://www.epa.gov/nsr/nsr-regulatory-actions> or contact the public hearing team at (844) 901-0246 or by email at OSAPpublichearing@epa.gov. The last day to pre-register to speak at the hearing will be July 19, 2026. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers at: <https://www.epa.gov/nsr/nsr-regulatory-actions>.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have approximately four minutes to provide oral testimony. The EPA recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

During the hearing, the EPA may ask clarifying questions but will not respond to comments made during oral testimonies. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at <https://www.epa.gov/nsr/nsr-regulatory-actions>. While the EPA expects the hearing to be conducted as set forth earlier, please monitor our website to determine if there are any updates. The EPA reserves the right to delay the date of the public hearing for any reason including scheduling conflicts. If this occurs, the comment period will be extended by the delayed number of days. The EPA does not intend to publish a document in the **Federal Register** announcing updates. All updates and announcements will be communicated on the web page listed above.

If you require the services of a translator or special accommodations, please pre-register for the hearing with the public hearing team and describe your needs by July 14, 2026. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA established a docket for this rulemaking under Docket ID No. EPA-HQ-OAR-2025-1212. All documents in the docket are listed in <https://www.regulations.gov>. Although

listed, some information is not publicly available, *e.g.*, Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only as PDF versions that can only be accessed on the EPA computers in the docket office reading room. Certain databases and physical items cannot be downloaded from the docket but may be requested by contacting the docket office at (202) 566-1744. With the exception of such material, publicly available docket materials are available electronically in <https://www.regulations.gov>.

Instructions. Direct your comments to Docket ID No. EPA-HQ-OAR-2025-1212. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <https://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be CBI or other information the disclosure of which is restricted by statute. Do not submit electronically to <https://www.regulations.gov> any information that you consider to be CBI or other information the disclosure of which is restricted by statute. This type of information should be submitted as discussed below.

The EPA may publish any comment received to the Agency's public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

The <https://www.regulations.gov> website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through <https://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA

recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the Agency may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>.

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

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (e.g., Dropbox, OneDrive, Google Drive). Electronic submissions must be transmitted directly to the CBI Office at the email address osapcbi@epa.gov and, as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email osapcbi@epa.gov to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OSAP Document Control Officer (C404-02), U.S. Environmental Protection Agency, 4930 Old Page Rd., C404-02, Durham, NC 27703, Attention Docket ID No. EPA-HQ-OAR-2025-

1212. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

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

CAA Clean Air Act
CBI Confidential Business Information
CFR Code of Federal Regulations
EPA Environmental Protection Agency
ET Eastern Time
FESOP Federally Enforceable State Operating Permit
FIP Federal Implementation Plan
FR Federal Register
FTP File Transfer Protocol
GP General Permit
NAAQS National Ambient Air Quality Standard or Standards
NNSR Nonattainment New Source Review
NSR New Source Review
OMB Office of Management and Budget
OSAP Office of State Air Partnerships, U.S. EPA
PAL Plantwide Applicability Limit
PBR Permit-by-Rule
PSD Prevention of Significant Deterioration
PTE Potential to Emit
RFP Reasonable Further Progress
SER Significant Emission Rate
SIP State Implementation Plan
TIP Tribal Implementation Plan
U.S.C. United States Code

Table of Contents

- I. Background
 - A. New Source Review Program and State Implementation Plans
 - B. Regulatory Requirements for New Source Review Programs
 - C. Existing Public Participation Requirements for New Source Review Programs
- II. Proposed Rule Revisions
 - A. Summary of the Major Provisions of this Proposal
 - B. Requirements Not Affected by this Proposal and Further Discussion
 - C. Rationale for this Proposal
 - 1. Applicable Legal Framework, Clean Air Act section 110(a)(2)(C), and New Source Review Preconstruction Air Permit Programs
 - 2. Minor New Source Review Public Participation Early Outreach Workgroup Outcome
- III. Considerations for Minor New Source Review Public Participation Practices in Specific Contexts
 - A. Minor New Source Review Public Participation and Clean Air Act Title V Oversight
 - B. Public Participation in State and Local Minor New Source Review Programs and Public Participation in the Tribal Minor New Source Review Program

- IV. State Implementation Plan Submittal Guidelines for the Proposed New Source Review Public Participation Provisions
 - A. State Implementation Plan Submittal Process
 - B. Applicable Statutory and Regulatory Requirements for Approval of State Implementation Plan Submissions
- V. List of Topics for Public Comment
- VI. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Executive Order 14192: Unleashing Prosperity Through Deregulation
 - C. Paperwork Reduction Act (PRA)
 - D. Regulatory Flexibility Act (RFA)
 - E. Unfunded Mandates Reform Act (UMRA)
 - F. Executive Order 13132: Federalism
 - G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
 - I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
 - J. National Technology Transfer Advancement Act (NTTAA)

I. Background

A. New Source Review Program and State Implementation Plans

CAA sections 110(a)(1) and 110(a)(2) direct each State to develop and submit to the EPA a plan that provides for the implementation, maintenance, and enforcement of the NAAQS. This plan is called a SIP. The programs in each SIP are developed by the State air agency and any local air agencies within the State. State and local air agencies have discretion regarding the provisions they adopt and include as part of a SIP's air quality regulatory programs, so long as those programs and their provisions meet the applicable statutory and regulatory requirements. SIP submissions can include a wide variety of provisions, such as: emissions limitations for specific sources of air pollution and associated monitoring, recordkeeping, and reporting requirements; more broadly applicable State or local rules (or State laws) regarding emissions controls for sources of air pollution or categories of sources; other local or State commitments to undertake certain activities; and non-regulatory supporting information.¹ SIPs reflect the principle of cooperative federalism by providing that air agencies may design the air quality

¹ U.S. Environmental Protection Agency. (Last updated Jan. 20, 2023). Basic Information About Air Quality SIPs, <https://www.epa.gov/air-quality-implementation-plans/basic-information-about-air-quality-sips>.

programs for their respective jurisdictions in accordance with the requirements of CAA section 110(a) and corresponding regulations. The EPA then reviews such submissions and shall approve, disapprove, or partially approve and partially disapprove the submission based on the Agency's determination of whether all applicable statutory requirements have been met per CAA section 110(k)(3).² The existing EPA-approved SIP provisions for each State are found in 40 CFR part 52.

CAA section 110(a)(2) includes a list of specific requirements for all SIP submissions, as applicable, including the requirement that States include a stationary source preconstruction permitting program in their SIPs as described in CAA section 110(a)(2)(C).³ This program is known as the NSR program. The goals of this preconstruction review process include seeking to ensure that Federal air quality standards are met, maximizing opportunities for economic development consistent with the preservation of clean air, and ensuring that any decision to increase air pollution is made after full public consideration of the consequences of such a decision. The Supreme Court has recognized that, in enacting the NSR program, "Congress sought to accommodate the conflict between the economic interest in permitting capital improvements to continue and the environmental interest in improving air quality."⁴ In other words, NSR intends to "balance environmental concerns with economic and administrative concerns, at least to a point."⁵ Specifically, CAA section 110(a)(2)(C) requires each SIP to provide for "regulation of the modification and construction of any stationary source . . . as necessary to assure that [the NAAQS] are achieved, including a permit program as required in parts C and D [of CAA title I]."⁶ Parts C and D of CAA title I require SIPs to also include permit programs with additional requirements regulating the modification and construction of "major" stationary sources; as such, parts C and D of CAA title I are often referred to as the "major NSR program." The major NSR program encompasses two core types of preconstruction

permit⁷ requirements for major stationary sources. CAA title I, part C establishes the Prevention of Significant Deterioration (PSD) program, which applies to new major stationary sources⁸ and major modifications⁹ of existing major stationary sources for pollutants for which an area is designated as attainment or unclassifiable for the relevant NAAQS (i.e., pollutants for which there are established NAAQS) and for other pollutants regulated under the CAA.¹⁰ CAA title I, part D establishes the major nonattainment NSR (NNSR) program, which applies to new major stationary sources and major modifications¹¹ of existing major stationary sources for those NAAQS for which an area is designated as nonattainment.¹² The EPA has two sets of regulations implementing the PSD program. One set, found at 40 CFR 51.166, contains the requirements that State and local air agencies' PSD programs must satisfy to be approved by the EPA as part of a SIP. The other set of regulations, found at 40 CFR 52.21, contains the requirements for the EPA's Federal PSD program, which applies in areas that are not subject to a SIP-approved¹³ PSD program. 40 CFR 51.165 contains the EPA's regulatory requirements that State and local air agencies' NNSR programs must satisfy to be approved by the Agency as part of a SIP.

While parts C and D of CAA title I address the major NSR program for

major sources, CAA section 110(a)(2)(C) applies to "the modification or construction of any stationary source" and thus also encompasses the construction of new minor, or non-major, stationary sources and minor modifications to existing stationary sources. Thus, SIPs must also include programs to regulate construction of new minor sources and minor modifications, along with the major source programs, as necessary to assure the NAAQS are achieved. The EPA commonly refers to the minor source program as the "minor NSR" program. As currently written, the Federal requirements for approval of State and local minor NSR programs into a SIP are outlined in 40 CFR 51.160–51.164. These requirements currently apply to both major NSR programs and minor NSR programs but are supplemented by the more detailed regulatory requirements described in the previous paragraph for major NSR programs. Federal requirements for minor NSR programs are less prescriptive than those for major sources and, as a result, there is a larger variation of requirements across State and local minor NSR programs in EPA-approved SIPs than across State and local major NSR programs in EPA-approved SIPs. For example, while major NSR programs apply to "major sources" and "major modifications" as defined within 40 CFR 51.165 and 51.166, the general NSR program regulations at 40 CFR 51.160–51.164 do not define what constitutes a "minor source" or a "minor modification."

Because CAA section 110(a)(2)(C) requires that State and local minor NSR programs regulate minor sources and minor modifications "as necessary to assure that [the NAAQS] are achieved," the statute provides State and local air agencies with discretion to establish their own applicability criteria for their minor NSR programs as needed to assure achievement of the NAAQS in their jurisdictions. While parts C and D of CAA title I require that SIPs include "permit programs" for regulating major sources and major modifications, CAA section 110(a)(2)(C) does not prescribe the use of permits or any other specific mechanism for authorizing the construction of minor sources and minor modifications. Air agencies are free to use permits in their minor NSR programs and frequently do so, but air agencies can also include other preconstruction authorization mechanisms in their minor NSR programs, such as general permits (GPs) and permits-by-rule (PBRs); this

² 42 U.S.C. 7410(k)(3).

³ See 42 U.S.C. 7410(a)(2)(C).

⁴ *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 851 (1984).

⁵ *New York v. EPA*, 413 F.3d 3, 23 (D.C. Cir. 2005) (per curiam).

⁶ See 42 U.S.C. 7410(a)(2)(C), 7470; 67 FR 80186, 80187/2–3 (Dec. 31, 2002).

⁷ An air quality preconstruction permit is a form of preconstruction "authorization," which is the term used in this proposal to refer to all regulatory mechanisms used to authorize proposed preconstruction decisions with qualifying air quality impacts. This preamble uses the term "authorization" in particular to refer to regulatory mechanisms used in the context of air agencies' minor NSR programs because, unlike the CAA's requirements for major NSR "permit programs" established by parts C and D of CAA title I, the CAA's requirements in CAA section 110(a)(2)(C) do not specifically require minor NSR programs to use permits as the mechanism for authorizing the construction or modification of minor stationary sources.

⁸ The term "major stationary source" is defined in the context of State PSD programs at 40 CFR 51.166(b)(1)(i) and in the context of the Federal PSD program at 40 CFR 52.21(b)(1)(i).

⁹ The term "major modification" is defined in the context of State PSD programs at 40 CFR 51.166(b)(2)(i) and in the context of the Federal PSD program at 40 CFR 52.21(b)(2)(i).

¹⁰ 42 U.S.C. 7470–79.

¹¹ The terms "major stationary source" and "major modification" are defined with respect to the NNSR program at 40 CFR 51.165(a)(1)(iv) and at 40 CFR 51.165(a)(1)(v), respectively.

¹² 42 U.S.C. 7501–15.

¹³ A State or local air quality regulatory program or provision becomes "SIP-approved" once the EPA approves a SIP submission containing that program or provision, at which point the program or provision becomes a part of the EPA-approved SIP for that State.

proposed rule further describes these mechanisms later in this section.

This proposed rule relates specifically to the EPA's minimum requirements for approving State and local minor NSR programs to become part of a SIP; these programs apply to proposed new "minor" stationary sources and "minor" modifications to existing stationary sources ("minor NSR preconstruction activities"), and to proposed decisions to authorize their construction ("minor NSR authorizations"). New stationary sources are considered "minor" if they do not have the potential to emit air pollutants in amounts equal to or exceeding the "major source" statutory thresholds within parts C and D of CAA title I.¹⁴ Modifications at existing major stationary sources are considered "minor" if they do not increase emissions by amounts equal to or exceeding the significant emissions rates (SERs) in NSR regulations.¹⁵ Modifications at existing minor stationary sources are considered "minor" if they do not increase emissions by amounts equal to or exceeding the "major source" statutory thresholds within parts C and D of CAA title I.¹⁶

Minor NSR programs also apply to "synthetic minor" sources and modifications, which are new facilities and/or modifications to existing sources that would ordinarily increase emissions of regulated pollutants by amounts equal to or exceeding the applicable "major source" thresholds, but which voluntarily accept one or more enforceable limitation(s) that keep their emissions below the "major source" thresholds. In doing so, new sources and modifications that would otherwise constitute "major" sources and modifications become "synthetic minor" sources and modifications by constraining their emissions to levels that make them minor sources and minor modifications. In contrast, "true

minor" sources and modifications do not require enforceable limitations to keep their emissions below major source thresholds as their emissions are below the "major NSR" thresholds without the application of an enforceable limitation. Both "synthetic minor" and "true minor" sources and modifications are subject to minor NSR program requirements.

In addition, minor NSR programs frequently allow for GPs and PBRs, which may describe preconstruction authorization mechanisms that apply standardized eligibility criteria and pollution control requirements to categories of similar new and modified sources of air pollution. The term GP generally describes a preconstruction permit issued by a reviewing authority that applies to a number of similar emissions units or sources. It establishes a category of covered sources or modifications by creating a permit document that specifies the category, eligibility criteria for sources or modifications to qualify for coverage, and the set of standardized requirements applicable to all similar sources or modifications to be covered.¹⁷ Similarly, the term PBR can be used to describe a preconstruction permit issued by a reviewing authority that may be applied to a number of similar emissions units or sources within a designated category. It establishes this category through a formal rulemaking or similar process, which results in codification of the proposed category, its eligibility requirements, and the standardized requirements for covered sources and modifications into the applicable code of regulations or the SIP.¹⁸ Although each reviewing authority has its own procedures for new and modified sources to confirm coverage under a GP or PBR in its program, the process of confirming coverage typically requires the new or modified source to communicate with the reviewing authority to demonstrate that it qualifies for coverage under the GP or PBR. Because the reviewing authority has already predetermined the eligibility requirements for coverage under each GP or PBR, the reviewing authority's process for confirming GP or PBR coverage is typically streamlined compared to, and different in kind from, the process for authorizing construction of new sources and modifications that

fall outside the category established by a GP or PBR and, therefore, require a specific authorization.

Upon EPA approval of a SIP submission that satisfies minimum requirements for an NSR program, the State or local air agency¹⁹ becomes the reviewing authority for proposed major NSR permits and minor NSR authorizations for sources within its boundaries and issues federally enforceable preconstruction authorizations under State law. Currently, State and local air agencies issue the vast majority of major NSR permits and minor NSR authorizations each year. If a State or local air agency's SIP does not have an EPA-approved PSD or minor NSR program, the EPA promulgates a Federal Implementation Plan (FIP) to satisfy the unfulfilled NSR requirements for the area.²⁰ In that scenario, either the EPA issues the associated NSR authorizations, or an air agency issues the associated NSR authorizations under the FIP on behalf of the Agency by way of a delegation agreement. For the majority of sources located in Indian country,²¹ the EPA is the permitting authority for both major NSR and minor NSR. Tribes may elect to submit a Tribal Implementation Plan (TIP) or participate in a delegation agreement with the EPA to implement major NSR or minor NSR preconstruction authorization decisions on Tribal lands.

The applicability of the preconstruction PSD and NNSR permitting program and/or minor NSR program to a stationary source is a pollutant-specific determination. Thus, a stationary source or modification may be subject to the PSD program for certain pollutants, NNSR for some pollutants, minor NSR for others, and/or not require an NSR authorization below certain thresholds for others.

¹⁴ 42 U.S.C. 7479(1), 7491(g)(7), 7511(b)(4), 7511a(b)(1)(A)(ii)(I), 7511a(c), 7511a(d), 7511a(e), 7511a(f), 7511c(b)(2), 7512a(c)(1), 7513a(b)(3), and 7513a(e). Stationary sources that do not meet the definitional characteristics in these sections are considered "non-major" or "minor" stationary sources.

¹⁵ 40 CFR 51.165(a)(1)(v), 51.165(f)(2)(viii), 51.166(b)(2), and 51.166(w)(2)(viii). Modifications at existing major stationary sources that do not meet the definitional characteristics in these sections are considered "non-major" or "minor" modifications to existing major stationary sources.

¹⁶ 42 U.S.C. 7479(1), 7491(g)(7), 7511(b)(4), 7511a(b)(1)(A)(ii)(I), 7511a(c), 7511a(d), 7511a(e), 7511a(f), 7511c(b)(2), 7512a(c)(1), 7513a(b)(3), and 7513a(e). Modifications at existing minor stationary sources that do not meet the definitional characteristics in these sections are considered "non-major" or "minor" modifications at existing minor stationary sources. *See also* 40 CFR 51.165(a)(1)(iv)(A)(3) and 51.166(b)(1)(i)(C).

¹⁷ *See* 80 FR 25068 (May 1, 2015).

¹⁸ GPs and PBRs are not limited to CAA title I programs; CAA section 504(d) provides that air agencies may also issue CAA title V general permits covering numerous similar sources, after notice and opportunity for public hearing. 42 U.S.C. 7661c(d); *see* 40 CFR 70.6(d).

¹⁹ This preamble uses the terms "air agency," "reviewing authority," and "permitting authority" interchangeably to refer to the regulatory authority responsible for reviewing and approving/disapproving proposed activities that could potentially impact air quality within a specific airshed. In most cases, this regulatory authority is a State or local air quality regulatory agency.

²⁰ The EPA does not issue FIPs if a State or local air agency does not have an EPA-approved NNSR program in the associated SIP; in such cases, the Agency instead directs the State or local air agency to apply the regulatory requirements in 40 CFR part 51, appendix S.

²¹ *See* definition of "Indian country" within 18 U.S.C. 1151. *See also* 42 U.S.C. 7601(d)(1)(A), which authorizes the EPA Administrator to treat Indian Tribes as States under the CAA subject to the provisions of 42 U.S.C. 7601(d)(2).

B. Regulatory Requirements for New Source Review Programs

The provisions codified in 40 CFR 51.160–51.164 contain requirements that air agencies' NSR programs must satisfy to be approved by the EPA as part of a SIP; these SIP approval requirements also apply to air agencies' minor NSR programs. The regulations at 40 CFR 51.160 establish requirements for legally enforceable procedures for major and minor NSR, and the requirements at 40 CFR 51.160(a), (b), and (e) relate most closely to the statutory requirement that NSR programs “provide for . . . regulation of the modification and construction of any stationary source . . . as necessary to assure that [the NAAQS] are achieved.”²² First, 40 CFR 51.160(a) requires SIPs to “set forth legally enforceable procedures that enable the State or local agency to determine whether the construction or modification of a facility, building, structure or installation, or combination of these” would interfere with attainment or maintenance of the NAAQS in the State where the source is located or in a neighboring State, or would violate applicable portions of the SIP's control strategy. Second, 40 CFR 51.160(b) requires the procedures established under 40 CFR 51.160(a) to allow the air agency to prevent construction or modification that would interfere with attainment or maintenance of the NAAQS or violate applicable portions of the SIP's control strategy. Finally, 40 CFR 51.160(e) requires SIPs to “identify [the] types and sizes of facilities, buildings, structures, or installations which will be subject to review” and “discuss the basis for determining which facilities will be subject to review.” Together, these requirements establish minimum elements for air agencies' NSR programs that define the regulatory scope of the programs, *i.e.*, which new sources and modifications will be regulated and how they will be regulated to assure achievement and maintenance of the NAAQS. The requirements under 40 CFR 51.160 provide air agencies a degree of flexibility in establishing State and local NSR programs that include these legally enforceable procedures and can be approved by the EPA as part of a SIP. This flexibility is limited for air agencies' major source NSR programs by the additional regulations at 40 CFR 51.165–51.166.

C. Existing Public Participation Requirements for New Source Review Programs

The CAA requires an opportunity for members of the public to participate both in the SIP development, review, and approval processes,²³ and in some of the programs that are incorporated into SIPs, including major source NSR preconstruction permitting programs.²⁴ The EPA's NSR preconstruction permitting regulations provide additional specificity regarding the methods of meeting the public notice obligations for NSR programs. The regulations establish minimum requirements for an opportunity to submit comments as part of the preconstruction review process for proposed new sources and modifications.²⁵ These regulatory requirements are found at 40 CFR 51.161 and currently do not distinguish between major NSR and minor NSR in terms of applicability. In other words, notwithstanding the statutory distinctions between major NSR (for which the statute requires certain public participation) and minor NSR (for which the statute does not require public participation), the existing regulations currently do not reflect such distinctions and treat both contexts the same.

40 CFR 51.161(a) establishes the basic requirement that State and local air agencies must provide an “opportunity for public comment on information submitted by owners and operators” on the new construction or modification of any stationary source. Specifically, it provides that the public must have access to and opportunity to comment on “the [air] agency's analysis of the effect of construction or modification on ambient air quality, including the [air] agency's proposed approval or disapproval [of the proposed new source or modification].”

40 CFR 51.161(b) provides that an “opportunity for public comment” consists of three required elements: (1) “Availability for public inspection”²⁶ in at least one location in the area affected of the information submitted by the owner or operator and of the State or local [air] agency's analysis of the effect on air quality,” (2) “A 30-day period for submittal of public comment,” and (3)

“A notice by prominent advertisement in the area affected of the location of the source information and analysis specified in paragraph (b)(1) of this section.”

Regarding the third required element of an “opportunity for public comment,” *i.e.*, public notice, such notices typically contain basic information about the draft permit or other preconstruction authorization, such as the permit number, the name and physical address of the facility, and the name and contact information of a person from whom interested persons may obtain additional information on the draft authorization. Depending on the air agency's public notice practices, a public notice may include more detailed information on the draft preconstruction authorization, such as the draft permit and technical support document. The public notice also informs interested parties about how to request and/or attend a public hearing and how to access additional information relevant to the draft preconstruction authorization.

Because some State and local air agencies had already established NSR programs before June 18, 1973, when the EPA promulgated²⁷ the requirements now found at 40 CFR 51.161, some pre-existing State and local minor NSR programs had rules providing an “opportunity for public comment” that conflicted with the requirement for a “30-day period for submittal of public comment.”²⁸ Acknowledging this fact, the EPA provided an exception at 40 CFR 51.161(c) allowing States to “submit for [EPA] approval a comment period which is consistent with such existing requirements” as part of a SIP submission.

Finally, 40 CFR 51.161(d) requires air agencies to submit a copy of the notice required by 40 CFR 51.161(b) to the appropriate EPA Regional office, any other State and local air agencies with jurisdiction in the area where the proposed new or modified source would be located, and any other agency in the area with responsibility for implementing the applicable requirements of 40 CFR 51.160–51.166.

²³ See, *e.g.*, 42 U.S.C. 7410(a)(1) and 7410(a)(2).

²⁴ 42 U.S.C. 7470(5) and 7475(a)(2).

²⁵ See 40 CFR 51.161.

²⁶ In a final rule published on Oct. 18, 2016 (81 FR 71613), the EPA revised the 40 CFR 51.161(b)(1) public-inspection requirement to add language explaining that “[t]his requirement may be met by making these materials available at a physical location or on a public website identified by the State or local agency.”

²⁷ See 38 FR 15834, 15836 (June 18, 1973) (locating these requirements at 40 CFR 51.18); 51 FR 40656, 40669 (Nov. 7, 1986) (moving language from 40 CFR 51.18 to its current location in the Code of Federal Regulations).

²⁸ See 40 CFR 51.161(b)(2).

²² 42 U.S.C. 7410(a)(2)(C).

II. Proposed Rule Revisions

A. Summary of the Major Provisions of This Proposal

The EPA is proposing to revise the Federal public participation requirements under 40 CFR 51.161 for State and local minor NSR programs to be approved by the Agency as part of a SIP. If finalized, this proposal would remove minor NSR public participation as a minimum requirement for SIP submissions, thereby leaving decisions regarding public participation requirements in State and local minor NSR programs to the discretion of the air agencies. These decisions would include whether, when, and for how long to provide opportunities for public participation on preconstruction review of proposed new minor sources and modifications. The EPA does not believe that minor source public participation is generally “necessary to assure that [the NAAQS] are achieved” in the context of developing a program for the “regulation of” minor source construction and modification. The approach proposed in this action would enable air agencies to retain or establish public participation requirements for review of regulated minor source construction and minor modifications when they believe public participation is desirable, consistent with the CAA and Federal regulations. In reviewing SIP submissions, the EPA would not expect, whether informally on a case-by-case basis or formally as a minimum requirement set out in regulation, that States include minor NSR public participation for the SIP to be approved as containing sufficient regulatory provisions “as necessary to assure that [the NAAQS] are achieved.” Rather, States may include such elements at their discretion and tailor them to particular circumstances so long as these elements are consistent with the CAA and applicable Federal regulations. Considering this, the EPA is proposing to revise the Agency’s Federal minimum regulatory requirements for State and local minor NSR programs to reflect the statutory discretion afforded to air agencies to change their minor NSR programs’ public participation requirements through the SIP submission and approval process, including reducing or eliminating those requirements.

CAA section 110(a)(2)(C) requires SIPs to include NSR programs to provide for “regulation of the modification and construction of any stationary source . . . as necessary to assure that national ambient air quality standards are achieved.” The approach proposed in this rulemaking more

closely adheres to this statutory language as it applies to minor NSR. While all SIPs must regulate minor sources and minor modifications within the areas covered by the SIP as necessary to assure that the NAAQS are achieved, air agencies have discretion to include and adjust a broad variety of substantive regulatory tools in their minor NSR programs to fulfill this requirement. Although the EPA believes that procedures for minor NSR public participation typically will not be “necessary,” as compared to substantive regulatory requirements, State and local air agencies may determine that public participation requirements are among these features or otherwise desirable. The EPA also observes that the utility of public participation in the context of minor NSR programs varies depending on a number of factors, and CAA section 110(a)(2)(C) gives air agencies the discretion to consider relevant factors and decide whether and when public participation is most effectively deployed as part of their minor NSR programs’ regulation of new minor sources and minor modifications to assure achievement of the NAAQS. Additionally, in light of the proposed changes described in this action, the transitional regulatory provision at 40 CFR 51.161(c) is no longer necessary or appropriate, and the EPA proposes to delete it. If this rule is finalized as proposed, this transitional provision would be rendered obsolete as public participation would be discretionary for minor NSR programs.

The EPA solicits comment on how a final version of this rule may affect how State and local air agencies analyze, publish, and act upon applications to construct new minor sources and minor modifications under State and local minor NSR programs approved by the Agency as part of their SIPs (question #1 in section V. of this preamble), including how a final version would impact State and local air agencies’ administrative burdens and their estimates of the anticipated burden reduction, should air agencies choose to revise their minor NSR public participation requirements to the maximum extent described in this proposed rule (question #1 in section V. of this preamble). The EPA also solicits comment on regulatory alternatives to the action presented in this proposed rule (question #2 in section V. of this preamble).

The EPA has long exercised the Agency’s authority under the CAA to establish regulations governing the development and submission of SIPs pursuant to CAA section 110, and has the authority to reconsider and revise

these regulations so long as it acknowledges the change in position, offers a reasonable explanation for the change, and considers legitimate reliance interests, where relevant.²⁹ As discussed below, the EPA understands that this action would, if finalized, change minimum requirements applicable by regulation to minor NSR programs and differ from prior representations that minor NSR public participation is required to satisfy the standard in CAA section 110(a)(2)(C). Because this action would not, if finalized, require States to amend their existing SIPs with respect to minor NSR public participation or otherwise, the EPA does not believe that this change impacts legitimate reliance interests on the part of States, regulated parties, or the general public. The EPA further notes that any amendments to SIPs pursued as a result of this action would, if finalized, involve mandatory opportunities for public participation both at the State and local level and during the Agency review process and that any amendments to SIPs would be subject to EPA review on a holistic basis and, ultimately, judicial review in the appropriate venue. Nevertheless, the EPA solicits comment on any reliance interests that may be impacted by this action that should be considered and how such reliance interests should be addressed (question #3 in section V. of this preamble).

B. Requirements Not Affected by This Proposal and Further Discussion

If this rule is finalized as proposed, State and local air agencies would be allowed to, but would not be required to, revise their existing SIP-approved minor NSR program public participation requirements through the SIP submission and approval process (SIP process). The SIP process, and its procedural steps for developing and sending SIP submissions for EPA review and approval, are discussed further in section IV. of this preamble. If an air agency chooses to revise its existing SIP-approved minor NSR public participation requirements in response to a final version of this proposed rule, such actions must be consistent with Federal and State law. If an air agency chooses not to revise its minor NSR program’s existing public participation requirements in response to a final version of this proposed rule, those existing minor NSR public participation requirements would remain in the SIP

²⁹ See *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 568–70 (2025); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009); *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

and continue to apply to minor sources and minor modifications regulated by the air agency within its jurisdiction.

Notably, the EPA is not proposing to revise the public participation requirements that apply to the development and submittal of SIP submissions to the Agency; these requirements are found in 40 CFR part 51, appendix V. Thus, the EPA is not proposing to revise the public participation requirements applicable to the initial development, revision, and approval of State and local minor NSR program elements in SIPs through the SIP process. In all events, the EPA would review whether a SIP submission seeking to revise or establish minor NSR public participation elements satisfies, as a whole and in light of regulatory requirements included in the submission, the statutory requirement to provide for regulation of minor source construction and modification “as necessary to assure” that the NAAQS are achieved.

The EPA is not proposing to revise the minimum Federal public participation requirements that apply to the permitting of new major sources or major modifications to existing sources under air agencies’ major NSR programs, *i.e.*, State and local programs that implement the Federal PSD and NNSR programs.³⁰ The EPA is not proposing to revise the public participation requirements for plantwide applicability limits (PALs) applied to existing major stationary sources.³¹ However, if this proposed rule is finalized, each air agency’s minor NSR program public participation requirements would continue to apply

to the issuance of PALs at existing minor stationary sources and PALs establishing minor modifications at existing stationary sources, and any revisions to a State or local minor NSR program’s public participation requirements that are approved by the EPA into the SIP would also apply to the issuance of such PALs.

Similarly, this proposed rule does not address and would not affect Federal public participation requirements for air agencies’ operating permit programs that implement the statutory requirements of CAA title V,³² the regulatory requirements of 40 CFR 70.7(h), or federally enforceable State operating permit (FESOP) programs.

Finally, this proposed rule does not address the existing public participation requirements associated with preconstruction authorizations issued in Indian country as PSD permits, NNSR permits, or minor NSR authorizations. These requirements are contained in 40 CFR part 52 and in 40 CFR part 49.³³ Because the existing Tribal minor NSR public participation regulations at 40 CFR 49.157 currently require public participation on all draft permits for minor sources and minor modifications locating within Indian country, the EPA solicits comment on whether to pursue a separate rulemaking to amend the Tribal minor NSR public participation requirements and, if so, how the Agency should propose to amend the minor NSR public participation requirements in Indian country (*see* section III.B. of this preamble).

C. Rationale for This Proposal

1. Applicable Legal Framework, Clean Air Act section 110(a)(2)(C), and New Source Review Preconstruction Air Permit Programs

CAA section 110(a)(2)(C) provides the only statutory requirement for minor NSR, which is that SIPs must include a program “to provide for . . . regulation of the modification and construction of any stationary source within the areas covered by the plan *as necessary to assure* that [the NAAQS] are achieved.”³⁴ This language provides that each SIP must contain sufficient elements as a whole to assure achievement of the NAAQS and does not, with respect to minor NSR, specify what air agencies must include for the SIP to be approvable. Given the lack of

other statutory requirements for minor NSR, the EPA has historically interpreted the statute to offer State and local air agencies a broad degree of discretion in developing programs to regulate the construction of new minor stationary sources and minor modifications to existing stationary sources.³⁵

However, the EPA’s general regulatory requirements for preconstruction review programs at 40 CFR 51.160–51.164 have not kept pace with statutory amendments made after the initial promulgation of these regulations. The EPA-promulgated NSR program did not distinguish between “major” and “minor” NSR until after the 1977 CAA amendments, which added detailed requirements in parts C and D of CAA title I for “major” new and modified sources. The language in the NSR regulations at 40 CFR 51.160–51.161 remains substantively unchanged since its original promulgation in 1973. These regulations do not distinguish between “major” new sources and modifications and “minor” new sources and modifications.³⁶ These regulatory requirements were initially adopted in response to a court order requiring the EPA to review SIPs that were previously approved to ensure that they would assure achievement and maintenance of the NAAQS.³⁷ At the time these regulatory requirements were adopted, the primary concern of the court and the EPA was the most heavily polluting major sources, which were the focus of the major NSR program requirements established by Congress in 1977. The establishment of major NSR in the 1977 CAA amendments fundamentally changed how NSR programs operate, enacting more specific requirements for major sources with greater environmental impacts, while leaving State and local air agencies with discretion to regulate all other sources, *i.e.*, minor sources, as necessary to assure achievement and maintenance of the NAAQS. The regulations at 40 CFR 51.160–51.161 are in part a historical remnant from before the existence of the detailed statutory program to regulate

³⁰ See general public participation requirements for major NSR programs at 40 CFR 51.165(i) and 51.166(q).

³¹ As discussed in the preamble to the PAL regulations, “[t]he reviewing authority must establish a PAL in a federally enforceable permit (for example, a “minor” NSR construction permit, a major NSR permit, or a SIP-approved operating permit program).” 67 FR 80186, 80208 (Dec. 31, 2002). In addition, the PAL preamble explains “[w]here the PAL is established in a major NSR permit, major NSR public participation procedures apply.” *Id.* PALs can be established for both existing major sources and existing minor sources, using either a federally enforceable major NSR permit or a federally enforceable minor NSR permit. The public participation requirements for PALs at existing major sources are reflected in 40 CFR 51.165(f)(5), 40 CFR 51.166(w)(5), 40 CFR 52.21(aa)(5), and appendix S to part 51, section IV.K.5; these regulatory sections require that “PALs for existing major stationary sources shall be established, renewed, or increased through a procedure that is consistent with §§ 51.160 and 51.161 of this chapter. This includes the requirement that the reviewing authority provide the public with notice of the proposed approval of a PAL permit and at least a 30-day period for submittal of public comment. . . .” (emphases added).

³² See 42 U.S.C. 7661a(b)(6).

³³ See 40 CFR 49.157 (Federal requirements for public participation on minor NSR and synthetic minor NSR permits issued in Indian country) and 49.171 (Federal requirements for public participation on NNSR permits issued in Indian country).

³⁴ 42 U.S.C. 7410(a)(2)(C) (emphases added).

³⁵ See, e.g., 71 FR 48696, 48700 (Aug. 21, 2006); *Luminant Generation Co., LLC v. EPA*, 675 F.3d 917, 923 (5th Cir. 2012) (“In stark contrast [to major NSR], the CAA prescribes only the barest of requirements for ‘minor’ NSR, which governs the construction or modification of stationary sources that do not meet the emissions thresholds for major NSR.”).

³⁶ The language in these provisions was originally located at 40 CFR 51.18. See 38 FR 15834, 15836 (June 18, 1973). In a 1986 regulation, the EPA moved these provisions into their present location in the Code of Federal Regulations. See 51 FR 40656, 40669 (Nov. 7, 1986).

³⁷ See 38 FR 6279 (Mar. 8, 1973); *NRDC, Inc. v. EPA*, 475 F.2d 968, 970–72 (D.C. Cir. 1973).

major sources and modifications. When the EPA added regulations to implement the more stringent requirements for construction of major sources and major modifications of these sources, the regulations at 40 CFR 51.160–51.161 were largely superseded for major sources and modifications, but they remained the only regulations governing minor sources and modifications. It is thus appropriate to assess whether these regulations and their requirements as applicable to minor sources and modifications are appropriate in light of the CAA's language providing States with discretion to regulate such sources and modifications as necessary to achieve the NAAQS. This proposed rule seeks to address the historical inconsistency in a manner supporting the historical CAA effect of allowing State and local air agencies to manage their respective airsheds in the “minor” NSR context while meeting the statutory obligation of CAA section 110(a)(2)(C).

Applying the Supreme Court's framework under *Loper Bright v. Raimondo*,³⁸ the best reading of CAA section 110(a)(2)(C) is that it delegates discretionary authority to the EPA with regard to determining whether a State or local air agency's program for regulating stationary source construction and modification that is not subject to the major source requirements in parts C and D of title I of the CAA is sufficient to assure maintenance and attainment of the NAAQS. Because of its lack of specificity and use of the term “as necessary,” which leaves flexibility, CAA section 110(a)(2)(C) is best read to limit the EPA's authority to impose specific regulatory requirements in determining what is “necessary” for a minor NSR program to satisfy statutory requirements such that it is approvable under CAA section 110(k)(3). Therefore, consistent with the statute, the EPA provides State and local air agencies significant discretion in developing SIP-approvable programs to regulate minor NSR preconstruction activities.³⁹ Extending this discretion to the degree of public participation that State and local air agencies determine to be effective to achieve the objective of such programs is consistent with this reading. There is no explicit requirement for public participation in preconstruction review of minor sources in CAA section 110(a)(2)(C). Thus, the best reading of this provision of the CAA is that it does not require a Federal minimum standard

for public participation in minor NSR programs. Consistent with statutory requirements, the EPA therefore leaves it to State and local air agencies to determine whether and to what extent public participation should be required in their respective minor NSR programs.

This reading is further supported by the remaining language of CAA section 110(a)(2)(C) and the surrounding provisions of CAA section 110(a)(2). In setting out what must be included in a SIP, CAA section 110(a)(2) begins by specifying that each plan “shall be adopted by the State after reasonable notice and a public hearing”⁴⁰ and concludes by requiring that plans must “provide for consultation and participation by local political subdivisions affected by the plan.”⁴¹ Congress understood that all SIP elements would be subject to procedural requirements for public participation when being developed by the State and did not provide, except where expressly stated, that additional procedural requirements for public participation are a part of any of the substantive elements that follow. The subsections of CAA section 110(a)(2) go on to set out substantive content that must be included in the SIP, as applicable, including enforceable emission limitations and other control measures, means, or techniques (CAA section 110(a)(2)(A)), monitoring capabilities (CAA section 110(a)(2)(B)), prohibitions on emissions that interfere with compliance by other States (CAA section 110(a)(2)(D)), and necessary assurances that the air agency has adequate resources and authority to implement the plan and can do so without violating State or Federal law (CAA section 110(a)(2)(E)). The language of CAA section 110(a)(2)(C) sets out additional substantive requirements in this context, providing that States must include programs for enforcing the emission limitations and other measures provided in CAA section (a)(2)(A) and regulation of the modification and construction of any stationary source as necessary to assure the NAAQS are achieved.

As a matter of statutory structure, the lack of specificity in CAA section 110(a)(2)(C) contrasts with the detail provided in the CAA provisions that establish NSR permitting requirements for major sources and major modifications. The more specific regulatory requirements for major NSR in parts C and D of CAA title I show that Congress considered the construction of new major sources and major

modifications to be of greater concern and therefore warranting more specific regulation compared to “non-major” or “minor” modification and construction. This choice by Congress to prescribe specific requirements for major NSR limits the discretion available to State and local air agencies to determine how to regulate the construction of new major sources and major modifications to existing sources. Conversely, the absence of similar language in CAA section 110(a)(2)(C) with respect to minor NSR, as well as the omission of public participation from the local political subdivision consultation and participation requirement for plans in CAA section 110(a)(2)(M), suggests that air agency discretion is not so limited with respect to minor NSR and that public participation is not a necessary element of minor NSR SIP programs.⁴²

Further, as part of these detailed statutory requirements for major NSR programs, the CAA establishes specific public participation requirements for major NSR, specifically for PSD programs. CAA section 165(a)(2) states that permits proposed under PSD programs for new major sources and major modifications may only be issued after an “opportunity for interested persons including representatives of the Administrator to appear and submit written or oral presentations on the air quality impact of such source, alternatives thereto, control technology requirements, and other appropriate considerations.”⁴³

The language and surrounding context of CAA section 110(a)(2)(C) further suggest that procedural elements such as public participation requirements are typically not forms of “regulation of the modification and construction of any stationary source . . . as necessary to assure that [the NAAQS] are achieved.” The plain meaning of the term “regulation” involves “to direct by rule or

⁴² See, e.g., *City & Cnty. of San Francisco v. EPA*, 604 U.S. 334, 344 (2025) (“[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983) (internal quotation marks omitted)).

⁴³ 42 U.S.C. 7475(a)(2). Although the statutory requirements at CAA title I, part C expressly include a public participation provision and the statutory requirements at CAA title I, part D do not, the EPA has provided by regulation for a uniform approach based on the parallel structure and purpose of the two major source NSR programs (i.e., PSD and NNSR). The EPA is not reopening or revisiting this issue in this rulemaking, which construes the statutory text in CAA section 110(a)(2)(C) and not the statutory text in parts C and D of CAA title I.

³⁸ 603 U.S. 369 (2024).

³⁹ See, e.g., 71 FR 48696, 48700 (Aug. 21, 2006); *Luminant Generation Co. v. EPA*, 675 F.3d 917, 922; see also *La. Env'tl Action Network v. EPA*, 955 F.3d 1088, 1097–98 (D.C. Cir. 2020).

⁴⁰ 42 U.S.C. 7410(a)(2).

⁴¹ 42 U.S.C. 7410(a)(2)(M) (emphasis added).

restriction.”⁴⁴ As applied to “the modification and construction of any stationary source,” the term is most naturally read as referring to substantive restrictions, such as permitting requirements and limitations. Such restrictions may include procedural aspects as a practical matter, but the key element is the restriction itself rather than the ancillary processes involved in carrying out the restriction. For this reason, reading procedural elements like minor NSR public participation into the term “regulation” would be in tension with the breadth of the term “necessary” and the significant discretion afforded to States in crafting minor NSR programs. That conclusion is reinforced by the specific and separate treatment of public participation as to SIP development in CAA section 110(a)(2) and of local political subdivision consultation and participation in CAA section 110(a)(2)(M). While the statute does not prevent State or local air agencies from exercising discretion to adopt public participation requirements for minor NSR, it does not appear to allow the EPA to require minor NSR public participation by regulation or to insist on minor NSR public participation as a condition of approving an otherwise valid SIP submission.

Based on this reading of the CAA, the EPA proposes to revise the Agency’s regulations at 40 CFR 51.161 to remove the requirement for public notice and comment as a minimum feature of State and local minor source NSR programs. If this action is finalized as proposed, the EPA would not expect, whether implicitly in the course of reviewing SIP submissions or explicitly as a minimum requirement enumerated in regulation, that SIPs contain minor NSR public participation. Rather, State and local air agencies would retain the discretion to determine whether, and the extent to which, it is appropriate and reasonable to include public participation elements in their minor NSR programs. As noted above, the EPA is not proposing any changes to the application of 40 CFR 51.161 public participation requirements to the “major” NNSR or PSD preconstruction programs, and any State seeking to amend its SIP would be required to follow the existing regulations for development and submission to the Agency for approval. Should air agencies decide to revise the

public participation requirements in their existing minor source NSR programs in light of any final action the EPA takes on this proposed action, such revisions must be consistent with Federal and State law.

2. Minor New Source Review Public Participation Early Outreach Workgroup Outcome

The EPA conducted a series of outreach sessions from 2022 to 2023 on minor NSR public participation and considered the resulting information to determine how to address the regulatory framework for this proposed action. During these sessions, many State and local air agencies indicated that their minor NSR programs did not require a 30-day opportunity for public comment on all types of minor NSR preconstruction activities regulated under their minor NSR programs.⁴⁵ Air agencies’ NSR programs varied in how widely their minor NSR public participation requirements applied, ranging from requiring an opportunity for public comment for all proposed minor NSR preconstruction activities, to requiring public notice and comment opportunity only for specific types and sizes of new minor sources and modifications (e.g., only to minor sources and modifications that are “synthetic minor” or have other specific characteristics, only to minor sources and modifications locating near sensitive receptors or with confirmed public interest, etc.), to not requiring any public notice or comment opportunity for any minor NSR preconstruction activities.⁴⁶ In some cases, air agencies’ minor NSR programs also provided an opportunity for public comment of less than 30 days.⁴⁷

Many air agencies were surprised to hear the EPA express the view that the existing regulations at 40 CFR 51.161 require minor NSR programs to provide a 30-day opportunity for public comment on all proposed new minor sources and minor modifications regulated under such programs.⁴⁸ Some air agencies questioned whether their air permit programs’ limited budgets, time, and personnel could actually fulfill the existing requirement at 40 CFR 51.161(b)(2) to provide a 30-day “opportunity for public comment” on all regulated minor NSR preconstruction activities due to the high volume of

minor NSR applications.⁴⁹ Recent research also suggests that many State governments presently face budget shortfalls,⁵⁰ which in turn further restrict the resources available to State and local air agencies. Air agencies further asserted that providing public participation on all minor source preconstruction activities would be an ineffective use of their limited resources compared to reviewing proposed preconstruction activities with greater air quality impacts and of greater public interest.⁵¹ To support these arguments, some air agencies noted that many of the proposed minor source preconstruction activities they reviewed were so small in terms of their air quality impacts and public interest that in cases in which the air agency did provide an opportunity for public comment, they received very few comments, most of which were either insubstantial or non-actionable.⁵² These air agencies further argued that subjecting all such activities to public participation requirements risked overwhelming the public with inconsequential information about minimal-impact minor sources and modifications, which could discourage public participation in the overall NSR decision-making process instead of promoting it.⁵³ For these reasons, most air agencies concluded that their minor source public participation practices were already well-tailored to the unique characteristics of their respective jurisdictions and stakeholder bases, allowing them to focus their limited resources on the preconstruction activities that piqued genuine public interest and posed the most consequential air quality impacts, such as authorizing the construction and modification of major sources or issuing operating permits under their CAA title V programs.⁵⁴

⁴⁹ *Id.*

⁵⁰ See, e.g., Goodman, J. (2025). Lawmakers Face Budget Crunches, Tough Decisions to Close Expected Shortfalls. *Pew Charitable Trusts*: <https://www.pew.org/en/research-and-analysis/articles/2025/01/13/lawmakers-face-budget-crunches-tough-decisions-to-close-expected-shortfalls>; Farmer, L. (2025). States Tread Carefully With Budgets as Gaps and Revenue Uncertainty Loom, *Pew Charitable Trusts*: <https://www.pew.org/en/research-and-analysis/articles/2025/07/10/states-tread-carefully-with-budgets-as-gaps-and-revenue-uncertainty-loom>.

⁵¹ See “EPA Summary Observations from 2022–2023 Minor NSR Stakeholder Input from State and Local Air Agencies” in Docket ID No. EPA–HQ–OAR–2025–1212.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁴⁴ Black’s Law Dictionary 1451 (4th ed. 1968); see, e.g., *Kennecott Utah Copper Corp. v. U.S. Dept. of the Interior*, 88 F.3d 1191, 1207 (D.C. Cir. 1996) (interpreting “regulation” to mean a statement that has general applicability and that has the legal effect of binding the agency or other parties” (quotation marks and citation omitted)).

⁴⁵ See “EPA Summary Observations from 2022–2023 Minor NSR Stakeholder Input from State and Local Air Agencies” in Docket ID No. EPA–HQ–OAR–2025–1212.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

III. Considerations for Minor New Source Review Public Participation Practices in Specific Contexts

In the sections that follow, the EPA further discusses factors for consideration related to minor NSR programs' public participation requirements in the contexts of the CAA title V and Tribal minor NSR programs.

A. Minor New Source Review Public Participation and Clean Air Act Title V Oversight

State and local air agencies considering the discretion afforded by this proposed rule should be aware of the potential consequences of decisions to issue minor NSR authorizations without notice and the opportunity for public comment. One potential consequence involves additional oversight through the title V operating permit program.

A key function of the operating permit program established by title V of the CAA is to consolidate "applicable requirements" established under other CAA programs into a single permit document.⁵⁵ Title V permits generally do not impose new pollution control requirements on sources or provide a vehicle to modify applicable requirements established under other CAA programs. The EPA's title V-focused regulatory definition of "applicable requirements" includes, among other requirements, requirements of a SIP and requirements of NSR preconstruction permits.⁵⁶

In many cases, the title V process includes an opportunity for public comment, the EPA's authority to review and, if necessary, object to title V permits that do not assure compliance with the SIP, and the ability for any person to petition the Agency to issue such an objection.⁵⁷ Since 2017, the EPA has issued numerous title V petition responses on this topic. In January 2024, the EPA issued a proposed rulemaking⁵⁸ explaining the situations in which requirements under the NSR preconstruction permitting program would be reviewed using the Agency's title V oversight authorities. In summary, the EPA's position is that NSR preconstruction authorization decisions that have been subject to public notice and the opportunity for comment and judicial review conclusively establish the applicable

requirements of the SIP for construction and modification of individual stationary sources, thereby foreclosing further substantive review of those source-specific NSR permit requirements during the title V permitting process.⁵⁹ By contrast, in situations in which an NSR permit or other NSR authorization was not issued following public notice and the opportunity for comment and judicial review, the title V permitting process may be used to evaluate the substance of such underlying NSR authorization decisions to ensure that the title V permit assures compliance with applicable requirements of the SIP for construction and modification of stationary sources of air pollution.⁶⁰

These underlying principles remain unchanged and unaffected by this proposed rule, and the EPA is not soliciting comment on these principles, which are addressed in a separate rulemaking, Docket ID EPA-HQ-OAR-2023-0401. However, the EPA is including this information to articulate the potential consequences, in the context of title V, of decisions to issue minor NSR authorizations without public participation.

This proposed rule offers State and local air agencies the discretion to determine the appropriate degree of public participation for their minor NSR programs. However, the EPA observes that changes to air agencies' minor NSR public participation requirements could affect the extent to which such air agencies' minor NSR authorization decisions are open to further review in the title V permitting process. For example, if an air agency revises its existing minor NSR public participation requirements such that it can authorize new minor sources and/or minor modifications without public notice and the opportunity for comment, and such sources are subject to the title V permitting program, the EPA may not have grounds to decline to review the substance of the associated minor NSR authorization decisions during the title V permitting process. In such situations, the reduction in public participation requirements for the air agency's minor NSR program may result in an increase in the number of minor NSR authorizations subject to CAA title V challenges and petitions.

B. Public Participation in State and Local Minor New Source Review Programs and Public Participation in the Tribal Minor New Source Review Program

The national Tribal minor NSR preconstruction program for Indian country was established in 2011 in 40 CFR part 49.⁶¹ In addition to establishing general regulations for the Tribal minor NSR program in 40 CFR part 49, the 2011 rule created provisions at 40 CFR 49.156 that addressed the development and implementation of a GP for use in Indian country under a national FIP. Some Tribes have accepted partial or full delegation of NSR preconstruction permitting, including Tribal minor NSR provisions as codified under 40 CFR part 49, while others have developed EPA-approved TIPs for full or portions of an NSR preconstruction permitting program.⁶² Tribal PSD permits, Tribal NNSR permits, Tribal synthetic minor source permits, Tribal true minor source permits, and Tribal permits for minor modifications at existing minor and major sources are all subject to public participation requirements.⁶³

Specific source categories for GPs and PBRs were established by rulemaking on May 1, 2015, and October 14, 2016.⁶⁴ Much like how State and local air agencies often provide public participation when proposing specific categories of similar sources or emissions units for new proposed GPs and PBRs,⁶⁵ the EPA's rulemakings proposing initial issuance of these categories of GPs and PBRs for use in Indian country were subject to public participation via notice and comment (similar to the public participation requirements for creating categories of title V operating GPs).⁶⁶ The EPA's

⁶¹ 76 FR 38748 (July 1, 2011).

⁶² See, e.g., 72 FR 69618 (Dec. 10, 2007); 76 FR 17028 (Mar. 28, 2011); 79 FR 69763 (Nov. 24, 2014); 80 FR 18120 (Apr. 3, 2015); 86 FR 11674 (Feb. 26, 2021); 86 FR 12260 (Apr. 3, 2021).

⁶³ See 40 CFR 49.157.

⁶⁴ See 80 FR 25068 (May 1, 2015) and 81 FR 70944 (Oct. 14, 2016).

⁶⁵ See "EPA Summary Observations from 2022–2023 Minor NSR Stakeholder Input from State and Local Air Agencies" in Docket ID No. EPA-HQ-OAR-2025–1212.

⁶⁶ See EPA Guidance from Stein, Kathie A. (Jan. 25, 1995), "Guidance on Enforceability Requirements for Limiting Potential to Emit through SIP and 112 Rules and General Permits." U.S. Environmental Protection Agency, Office of Enforcement and Compliance Assurance, page 4, <https://www.epa.gov/sites/default/files/2015-07/documents/potoem.pdf>. Similar to Tribal GP programs and Tribal PBR programs, the Oil and Gas Form Registrations (Part 1 and Part 2 Form Registrations) as part of the Tribal National FIP were developed through a national rulemaking process subject to public participation with the

⁵⁵ See 42 U.S.C. 7661c(a); 40 CFR 70.6(a)(1), 71.6(a)(1).

⁵⁶ See 40 CFR 70.2, 71.2. See also *Eng v. EPA*, No. 25–138, U.S. App. 2026 LEXIS 10142, at *12 (9th Cir. Apr. 8, 2026).

⁵⁷ See 42 U.S.C. 7661d(b); 40 CFR 70.8(c), (d).

⁵⁸ 89 FR 1150 (Jan. 9, 2024).

⁵⁹ 89 FR 1150, 1163–64, 1174–83 (Jan. 9, 2024) (discussing the rationale for this position and identifying title V petition responses addressing this issue).

⁶⁰ 89 FR 1150, 1169–71 (Jan. 9, 2024).

regulations for GPs and PBRs also mirror the practices of many air agencies with respect to defining categories of sources and/or emissions units that are “similar in nature.”⁶⁷ Also, similar to many air agencies’ public participation requirements for GPs and PBRs,⁶⁸ the EPA’s public participation requirements for Tribal minor NSR GPs and PBRs do not require that a draft final authorization document be developed and subject to public participation; however, the Agency’s Tribal minor NSR regulations do require that a copy of each Request for Coverage (for GPs)⁶⁹ or Notification of Coverage (for PBRs) be sent to the reviewing authority prior to commencing construction,⁷⁰ and to the Tribe in the area where the source is locating.⁷¹ In addition, owners and operators of sources that receive an approved Request for Coverage must post the approval letter at the site where the source is locating,⁷² and reviewing authorities must post final Notifications of Coverage on the reviewing authority’s website.⁷³

The EPA solicits comment on whether to pursue a separate rulemaking that would propose to revise the Agency’s public participation requirements for authorizing new minor sources and minor modifications locating in Indian country in light of the reading of CAA section 110(a)(2)(C) in this proposed

individual source-specific registration forms not subject to public participation. See 81 FR 35944 (June 3, 2016); 85 FR 15729 (Mar. 19, 2020).

⁶⁷ The EPA’s Tribal minor NSR regulations explain at 40 CFR 49.156(b)(1) that “[a] general permit may be issued for a category of emissions units or sources that are similar in nature, have substantially similar emissions and would be subject to the same or substantially similar requirements governing operations, emissions, monitoring, reporting and recordkeeping. ‘Similar in nature’ refers to size, processes and operating conditions.” Similarly, the EPA’s Tribal minor NSR regulations for PBRs at 40 CFR 49.156(f)(1) note that “[a] permit by rule may be written to address a single emissions unit, a group of the same type of emissions units or an entire minor source.”

⁶⁸ See “EPA Summary Observations from 2022–2023 Minor NSR Stakeholder Input from State and Local Air Agencies” in Docket ID No. EPA–HQ–OAR–2025–1212.

⁶⁹ For a particular source that submits a GP Request for Coverage to the appropriate reviewing authority, the information that must be made publicly available includes the reviewing authority’s analysis of whether the emissions unit or source to be covered by the GP falls within the category of emissions units or sources to which the GP applies, including whether the emissions unit or source to be covered meets any criteria to be eligible for coverage under the GP. See 40 CFR 49.157(a)(5).

⁷⁰ See 40 CFR 49.156(e)(1) and 40 CFR 49.156(f)(1).

⁷¹ See 40 CFR 49.156(e)(2) and 40 CFR 49.156(f)(2).

⁷² See 40 CFR 49.156(e)(6).

⁷³ See 40 CFR 49.156(f)(6)(v).

rule, and, if so, how the Agency should propose to amend the minor NSR public participation requirements in Indian country (question #4 in section V. of this preamble). For example, if pursued, a separate future rulemaking could address public participation requirements in the EPA’s FIP for minor sources in areas with partial or full delegation for minor NSR, as well as discretion regarding public participation requirements in TIPs submitted for EPA approval by federally recognized Tribes. Similarly, a separate future rulemaking could consider issues of public participation regarding authorization of minor source preconstruction activities, including site-specific true minor sources, GPs, PBRs, synthetic minor sources, synthetic minor sources established by GPs, and minor modifications at major sources. The EPA is not soliciting comment on, or proposing any changes to, public participation requirements for major PSD and NNSR permits on Tribal lands in this action.

IV. State Implementation Plan Submittal Guidelines for the Proposed New Source Review Public Participation Provisions

A. State Implementation Plan Submittal Process

If this action is finalized as proposed, the EPA does not intend to require State and local air agencies to take any action to revise their minor NSR programs’ public participation requirements as they already exist within SIPs approved by the Agency. Rather, each air agency would have the discretion to do so if they determine a revision is reasonable given the existing public participation provisions already approved into the SIP for their minor NSR program. If finalized as proposed, State and local air agencies may also elect to keep the existing level of public participation in their SIP-approved minor NSR programs without change.

Should a State or local air agency elect to revise the existing minor NSR public participation requirements within its EPA-approved SIP, it would do so through the SIP process. To revise existing EPA-approved SIP provisions using the SIP process, the air agency would first need to develop a SIP submission containing the proposed revisions, after providing both reasonable notice and public hearings on a draft version of the SIP submission.⁷⁴ The Governor’s designee for the associated State would then need to submit the revised provisions in a SIP

submission to the EPA for review. This SIP submission should also include any supporting information necessary to explain how the revised provisions are consistent with Federal and State law, as applicable. If the EPA fully approves the SIP submission, the proposed changes would be approved into the SIP and the revised minor NSR public participation requirements would become EPA-approved SIP provisions for the associated State or local minor NSR program.

B. Applicable Statutory and Regulatory Requirements for Approval of State Implementation Plan Submissions

As noted previously in this preamble, the provisions included for consideration in a SIP submission must be consistent with applicable Federal and State law. The EPA would not expect, whether implicitly when reviewing SIP submissions or expressly as a matter of minimum requirements stated in regulations, that States include minor NSR public participation as a “necessary” form of regulation to assure achievement of the NAAQS. Rather, with respect to applicable CAA provisions, any SIP submission proposing to revise existing SIP-approved public participation elements for a State or local minor NSR program would need to demonstrate that the proposed revisions meet the requirements of CAA section 110(a)(2)(C) and 40 CFR 51.160 to be approved by the EPA. In addition, CAA section 110(l) precludes approval of any revision to an existing SIP that “would interfere with any applicable requirement concerning attainment and reasonable further progress” (RFP) toward attainment of the NAAQS, “or any other applicable requirement” of the CAA.⁷⁵ The following paragraphs further explain how each of these requirements would apply to SIP submissions developed in response to a final version of this proposed rule.

In its totality, a minor NSR program must assure that the NAAQS are achieved in accordance with CAA section 110(a)(2)(C) before it can be approved as part of a SIP. As noted in section II.C.1. of this preamble, CAA section 110(a)(2)(C) requires that SIPs include State and local minor NSR programs to regulate modification and construction “as necessary” to assure that the NAAQS are achieved in the areas covered by a SIP, and this direction delegates discretion to State and local air agencies to determine whether and to what extent public participation should be required as part

⁷⁴ See 42 U.S.C. 7410(l).

⁷⁵ See *id.*

of their minor NSR programs to serve this purpose. The intent of this proposed rule, and any corresponding final action, is to allow air agencies to propose changes as appropriate to their minor NSR programs' public participation requirements in accordance with this discretion using the SIP process. State and local minor NSR programs that are revised through a SIP submission must still allow the SIP as a whole to assure that the NAAQS are achieved and maintained, which should not allow greater air pollution compared to any minor NSR program regulatory requirements that existed prior to revision of the SIP.

With regard to CAA section 110(l), a SIP submission proposing to alter existing SIP-approved public participation requirements for a State or local minor NSR program should include an explanation of the relationship, if any, between those requirements and the minor NSR program's ability to assure achievement and maintenance of the NAAQS. In general, SIP provisions such as public participation requirements may be viewed as administrative or procedural, such that SIP submissions proposing changes to these requirements are not expected to affect emissions and are, therefore, not expected to be inconsistent with the requirements of CAA section 110(l). For SIP submissions of this nature, so long as they meet the minimum requirements of the CAA and any applicable EPA regulations, a satisfactory CAA section 110(l) explanation might only require a written analysis to explain that the proposed SIP revisions: (a) are administrative or procedural in nature; (b) will not affect emissions; and (c) will not interfere with requirements of the CAA related to such administrative or procedural provisions.

To the extent an air agency would take the position that their program's public participation requirements are not administrative or procedural, the air agency would need to determine the nature of an appropriate CAA section 110(l) analysis for its SIP submission. Factors that may be relevant to such an analysis may include, but are not limited to, the characteristics of minor sources and minor modifications that would be affected by the change to the public participation requirements (e.g., pollutants emitted, resulting emissions increases, and emissions control technologies or practices used by sources and modifications) and the characteristics of the air agency's airshed (e.g., overall emissions profile, meteorology and topography, industrial density and composition, volume of

applications, and level of public interest in those applications). The EPA solicits comment on which factors, if any, the Agency should describe for air agencies to consider in such CAA section 110(l) analyses (question #5 in section V. of this preamble).

With respect to demonstrating that a SIP submission satisfies the requirements of 40 CFR 51.160, the EPA anticipates that the demonstrations and analyses to address these Federal requirements would be similar to those presented with respect to CAA sections 110(a)(2)(C) and 110(l). In particular, 40 CFR 51.160(a)(2) and 51.160(b)(2) derive from CAA section 110(a)(2)(C) but include similar language to that found in CAA section 110(l). If the SIP submission adequately explains how the State or local minor NSR program's revised public participation requirements would not interfere with attainment and RFP toward attainment of the NAAQS or any other applicable CAA requirement, the SIP submission should also be able to explain how the revised minor NSR program requirements would regulate new minor sources and minor modifications as necessary to assure achievement and maintenance of the NAAQS, which is only possible if the legally enforceable procedures in the revised minor NSR program allow the air agency to identify and prevent minor source construction and modification that would interfere with the attainment and maintenance of the NAAQS.

Federal requirements in 40 CFR part 51, appendix V stipulate that the provisions contained within a SIP submission must be subject to public notice, public hearings, and an opportunity for the submission and consideration of public comments at the State level before the EPA can act on the SIP submission. In addition, because the EPA proposes action on SIP submissions through the notice-and-comment rulemaking process, the public participation process required for such rulemakings allows the public to comment on the SIP submission during the Agency's review of the submission.

V. List of Topics for Public Comment

The EPA solicits comments on all aspects of this proposed action. A summary of questions for which the EPA invites specific comment is listed below. The EPA requests that commenters number their responses with the question number when responding to each question.

Question #1: How would a final version of this rule affect how State and local air agencies analyze, publish, and act upon applications requesting

permission to construct new minor sources and minor modifications under State and local minor NSR programs approved by the EPA as part of their SIPs, including potential reductions in administrative burdens (costs or hours) associated with this type of permitting?

Question #2: What regulatory alternatives, if any, should the EPA consider instead of the action presented in this proposed rule?

Question #3: Are there any relevant reliance interests that might be impacted by this proposed action? If so, how should such reliance interests be addressed?

Question #4: In light of the reading of CAA section 110(a)(2)(C) that is presented in this proposed rule, should the EPA pursue a separate rulemaking that would propose to make regulatory changes to the Federal public participation requirements for authorizing new minor sources and minor modifications locating within Indian country? If so, how should the EPA propose to amend the minor NSR public participation requirements in Indian country?

Question #5: What factors, if any, should the EPA describe in situations in which an air agency does not find that a revision to its minor NSR program's public participation requirements is administrative or procedural in nature, for purposes of evaluating whether the SIP submission is consistent with CAA section 110(l)?

VI. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to Executive Order 12866 review are documented in the docket.

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is expected to be an Executive Order 14192 deregulatory action. This proposed rule is expected to provide burden reduction by reducing the minimum Federal requirements for public participation that State and local air agencies' minor NSR programs must meet in order for the EPA to approve such programs into SIPs. The regulatory changes effected by

a final version of this rulemaking would allow air agencies the discretion and flexibility to determine the level of public participation that is appropriate for each type or size of minor NSR preconstruction activity regulated under their minor NSR programs, consistent with Federal and State law as applicable.

C. Paperwork Reduction Act (PRA)

This proposed action, if finalized, would not impose any new information collection burden under the PRA. OMB has previously approved information collection activities for State and local NSR programs and has assigned OMB control number 2060–0003. The regulatory amendments proposed in this action would not directly change any of the information collection activities previously approved by OMB.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Instead, the revisions proposed in this action, if finalized, would better recognize the full scope of discretion afforded to State and local air agencies in determining whether and when the provision of public participation is appropriate for decisions regarding the authorization of new minor sources of air pollution and minor modifications to existing sources. Because the EPA has interpreted the existing Federal NSR public participation regulations as requiring air agencies' minor NSR programs to provide public participation on all decisions involving whether to authorize proposed new minor sources and minor modifications, the discretion provided to air agencies under a final version of this rule may result in fewer proposed minor sources and minor modifications undergoing the time and expense of complying with public participation requirements, which would likely reduce regulatory burdens on small entities proposing new minor sources and minor modifications.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any State, local, or Tribal governments or the private sector. This action would make the provision of public participation discretionary for authorization of proposed new minor

sources and minor modifications to existing sources regulated under air agencies' minor NSR programs.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

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

This action does not have Tribal implications as specified in Executive Order 13175. This action would make the provision of public participation discretionary for authorization of proposed new minor sources and minor modifications to existing sources regulated under air agencies' minor NSR programs. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the Agency has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, the EPA's Policy on Children's Health also does not apply to this action.

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

This action is not a “significant energy action” because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. If finalized, the proposed rule would provide State and local air agencies with the discretion to decide when provision of public participation is appropriate for decisions whether to authorize new minor sources of air pollution and minor modifications to existing stationary sources. The EPA does not expect that these proposed changes would affect energy suppliers, distributors, or users.

J. National Technology Transfer Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

List of Subjects in 40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Lee Zeldin,

Administrator.

[FR Doc. 2026–13667 Filed 7–6–26; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 52d

[Docket No. NIH–2025–0034]

RIN 0925–AA74

Recission of the National Cancer Institute Clinical Cancer Education Program Regulation

AGENCY: National Institutes of Health, Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS), in consultation with the National Institutes of Health (NIH), is proposing to rescind the existing regulation concerning grants under the National Cancer Institute (NCI) Clinical Cancer Education Program because the regulation is obsolete and no longer necessary.

DATES: Comments must be received on or before September 8, 2026.

ADDRESSES: Comments must be submitted in one of the following two ways (please choose only one of the two ways listed):

- Electronically at <https://www.regulations.gov>. Follow the “Submit a comment” instructions. If you are reading this document on www.federalregister.gov, you may use the green “SUBMIT A PUBLIC COMMENT” button beneath this rulemaking's title to submit a comment to the www.regulations.gov docket.

- You may mail comments to the following address: Kelly Daughtridge, NIH Regulations Officer, National Institutes of Health, Office of Management Assessment, Rockledge 1, 6701 Rockledge Drive, Suite 601, Bethesda, Maryland 20817—MSC 7901. Mailed comments must be received by the end of the comment period.

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.

Follow the search instructions <https://www.regulations.gov> to view public comments.

FOR FURTHER INFORMATION CONTACT:

Kelly Daughtridge, NIH Regulations Officer, Office of Management Assessment, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 601, Bethesda, MD 20817—MSC 7901, by email at Kelly.Daughtridge@nih.gov, or by telephone at 301-451-8081 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

1. Background

Deregulation is a central objective of the Trump administration. To achieve this objective, the President has issued several executive orders (E.O.s) to reduce the amount of rulemaking undertaken by Federal agencies and identify and eliminate regulations that are unlawful, anti-competitive, or obsolete and unnecessary, for example E.O. 14219, Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative, February 19, 2025, and E.O. 14192, Unleashing Prosperity Through Deregulation, January 31, 2025. In response to these and other deregulatory initiatives announced by the Trump administration, NIH conducted a comprehensive review of 23 HHS regulations that NIH historically has authored for approval and signature by the Secretary, HHS, and/or assisted in maintaining on behalf of the Secretary, HHS. This review identified the HHS regulation codified at 42 CFR part 52d, National Cancer Institute Clinical Cancer Education Program, as likely obsolete and unnecessary.

Subsequently, NIH Regulations officials and National Cancer Institute (NCI) senior management executives knowledgeable about the scope, history, and intent of the regulation, completed a follow-up review and determined that the regulation had not been updated significantly since 1980. Based on this review, NIH and NCI determined that the program to which the regulation applied has changed over the years and no longer exists in the same form as it did in 1980. Notably, the regulation states at 42 CFR 52d.1 that it applies "to

grants under the Clinical Cancer Education Program authorized by section 404(a)(4) of the Public Health Service Act" (PHSA), but section 404 of the PHSA no longer exists. Thus, NIH and NCI concluded the regulation is outdated, no longer necessary, and should be rescinded. Additionally, NIH and NCI concluded that other existing regulations, including 42 CFR part 52 (Grants for Research Projects) and 2 CFR part 200 (Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards), would continue to apply to NCI Cancer Education grant programs if the regulation at 42 CFR part 52d were rescinded. Neither HHS nor NIH anticipate any adverse impact on stakeholders resulting from the rescission of the regulation.

Thus, HHS, in consultation with NIH, is issuing this proposed rule to rescind the regulation at 42 CFR part 52d, National Cancer Institute Clinical Cancer Education Program, because the regulation is obsolete and unnecessary. While it is anticipated that no measurable cost savings will result from this deregulatory action, the rescission of the regulation codified at 42 CFR part 52d aligns with the administration's deregulation objectives and the goals of E.O.s 14192 and 14219 and other deregulatory initiatives of the President.

Regulatory Impact Analysis

We examined the impact of this proposed rule under Executive Order (E.O.) 12866, Regulatory Planning and Review; E.O. 13563, Improving Regulations and Regulatory Review; E.O. 14192, Unleashing Prosperity Through Deregulation; E.O. 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601–612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563

E.O. 12866, Regulatory Planning and Review, and E.O. 13563, Improving Regulations and Regulatory Review, direct Federal agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity) for all significant regulatory actions. Under E.O. 12866 Section 3(f)(1), rules are "economically significant" if they "[h]ave an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment,

public health or safety, or State, local, or tribal governments or communities." A regulatory impact analysis (RIA) must be prepared for major rules with economic significant effects (\$100 million or more in any one year). We believe this proposed rule is not a significant or economically significant regulatory action under Executive Order 12866.

Executive Order 14192

E.O. 14192, Unleashing Prosperity Through Deregulation, requires that any new incremental costs associated with certain significant regulatory actions "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an Executive Order 14192 deregulatory action.

Executive Order 13132

E.O. 13132, Federalism, requires Federal agencies to consult with State and local government officials in the development of regulatory policies with federalism implications. We reviewed this rule as required under this Order and determined that it will not have a significant potential negative impact on 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 and does not have any federalism implications. The Secretary, HHS, certifies that this rule will not have effect on the States or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. The Secretary certifies that this rule will not create a significant impact on a substantial number of small entities, and therefore a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) generally requires that each agency conduct a cost-benefit analysis; identify and consider a reasonable number of regulatory alternatives; and select the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule before promulgating any proposed or final rule that includes a Federal mandate that may result in

expenditures of more than \$100 million (adjusted for inflation) in at least one year by State, local, and tribal governments, in the aggregate, or by the private sector. Each agency issuing a rule with relevant effects over that threshold must also seek input from State, local, and tribal governments. The current threshold after adjustment for inflation using the Implicit Price Deflator for the Gross Domestic Product is \$193 million. This rule does not meet or exceed that amount.

Paperwork Reduction Act

This proposed rule does not contain any information collection requirements. Therefore, clearance by the Office of Management and Budget is not required.

Financial Assistance Listings

There is no current Financial Assistance Listings program affected by this rule.

List of Subjects in 42 CFR Part 52d

Cancer, Educational study programs, Grant programs-health, Health professions.

PART 52d—[REMOVED AND RESERVED]

■ For the reasons stated in the preamble, under the authority of sections 215, 301, 402, 405, and 410 of the Public Health Service Act (42 U.S.C. 216, 241, 282, 284, and 285), HHS proposes to amend Subchapter D of Chapter 1 of Title 42 of the Code of Federal Regulations by removing part 52d.

Robert F. Kennedy, Jr.

Secretary, Department of Health and Human Services.

[FR Doc. 2026-13711 Filed 7-6-26; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R8-ES-2022-0081; FXES111090FEDR-267-FF09E21000]

RIN 1018-BF83

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for the Kern Canyon Slender Salamander and Endangered Species Status for the Relictual Slender Salamander; Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; revisions and reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are reopening the comment period on our October 18, 2022, proposed rule (2022 proposed rule), and November 21, 2023, revised proposed rule (2023 revised proposed rule) to list the Kern Canyon slender salamander (*Batrachoseps simatus*) and the relictual slender salamander (*Batrachoseps relictus*) under the Endangered Species Act of 1973, as amended (Act), to designate critical habitat for both species, and to issue a rule under section 4(d) of the Act for the Kern Canyon slender salamander. This action will allow all interested parties an additional opportunity to comment on the proposed rule, as well as the opportunity to comment on a new provision for the 4(d) rule in response to previously submitted public comments and our necessary and advisable determination (including consideration of conservation and economic impacts) of the proposed 4(d) rule. Comments previously submitted need not be resubmitted as they are already incorporated into the public record and will be fully considered in the final rule.

DATES: The comment period on the proposed rule that published October 18, 2022 (87 FR 63150), is reopened. We will accept comments received or postmarked on or before August 6, 2026.

To ensure your comment is received and considered, you must submit it using one of the methods identified in the **ADDRESSES** section of this document. Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered.

ADDRESSES: *Comment submission:* All submissions must include the docket number [FWS-R8-ES-2022-0081]. You must submit comments using one of the following methods:

(1) *Electronic submission:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter FWS-R8-ES-2022-0081, which is the docket number for this action. Then, click the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on “Comment.” Please ensure that you have found the correct document before submitting your comments.

(2) *U.S. mail:* Public Comments Processing, Attn: FWS-R8-ES-2022-0081, Policy and Regulations Branch, U.S. Fish and Wildlife Service, MS: PRB

(JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041-3803.

Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered. We will not accept comments via email, fax, or hand delivery. We are not required to consider comments that are submitted after the comment period ends or that are submitted via a method outside of these instructions. Comments containing profanity, vulgarity, threats, or other inappropriate content will not be considered.

We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: This document and supporting materials (including the species status assessment report, comments and information received on the 2022 proposed rule (87 FR 63150) and 2023 revised proposed rule (88 FR 81028), our consideration of economic impacts of the proposed 4(d) rule, and references cited) are available at <https://www.regulations.gov> at Docket No. FWS-R8-ES-2022-0081.

FOR FURTHER INFORMATION CONTACT: Kim S. Turner, Acting Field Supervisor, Sacramento Fish and Wildlife Office; email: fw8sfwocomments@fws.gov; telephone: 916-414-6700. 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. Please see Docket No. FWS-R8-ES-2022-0081 on <https://www.regulations.gov> for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Information Requested

We will accept written comments and information during this reopened comment period on our proposed rule to list the Kern Canyon slender salamander and the relictual slender salamander and designate critical habitat for both species. We will consider information and recommendations from all interested parties. We intend that any final action resulting from the proposal will be based on the best scientific and commercial data available. Our final determination will take into

consideration all comments and any additional information we receive during the reopened comment period on the 2022 proposed rule and 2023 revised proposed rule. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

Information to assist us with issuing protective regulations under section 4(d) of the Act (“4(d) rule”) that may be necessary and advisable to provide for the conservation of the Kern Canyon slender salamander. In particular, we seek information concerning:

(1) The extent to which we should include any of the Act’s section 9 prohibitions in the 4(d) rule;

(2) Whether we should consider any additional or different exceptions from the prohibitions in the 4(d) rule;

(3) Impacts (conservation and economic) associated with implementing the 4(d) rule;

(4) How frequently and in what geographical areas are activities that we propose to regulate under the 4(d) rule (e.g., sale, “take”) currently occurring;

(5) Whether there are other laws currently in place beyond what we describe in the economic considerations document that regulate the activities or “take” prohibited in the proposed 4(d) rule;

(6) The entities likely to request section 10(a)(1)(A) permits for conducting activities that would involve “take” that we propose to prohibit such as capture or handling of the Kern Canyon slender salamander;

(7) Data available on the time and economic costs of obtaining section 10(a)(1)(A) permits for these activities in accordance with our regulations at title 50 Code of Federal Regulations (CFR) § 17.32;

(8) The entities likely to develop habitat conservation plans and request section 10(a)(1)(B) permits for conducting activities that would involve incidental “take” of the Kern Canyon slender salamander that we propose to prohibit;

(9) Data available on the time and economic costs of obtaining section 10(a)(1)(B) permits in accordance with 50 CFR 17.32; and

(10) Any other entities not addressed in this revised proposed rule that may be affected by the 4(d) rule.

Please include any supplemental information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information

you include. Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made solely on the basis of the best scientific and commercial data available, and section 4(b)(2) of the Act directs that the Secretary of the Interior (Secretary) shall designate critical habitat on the basis of the best scientific data available.

You must submit your comments and materials concerning this proposed rule by one of the methods listed in

ADDRESSES.

If you submit information via <https://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <https://www.regulations.gov>.

Because we will consider all comments and information received during all comment periods, our final determination may differ from our October 18, 2022 (87 FR 63150), proposed rule, or from the revised critical habitat boundaries and physical or biological features described in the November 21, 2023, comment period reopening (88 FR 81028). Based on the new information we received during the two prior comment periods, including comments on that information, and information received during this reopening of the comment period, we may conclude that the Kern Canyon slender salamander is endangered instead of threatened, that the relictual slender salamander is threatened instead of endangered, or we may conclude that either or both species do not warrant listing as either endangered species or threatened species. For critical habitat, our final designation may not include all areas proposed, may include some additional areas that meet the definition of critical habitat, and may exclude some additional areas if we find the benefits of exclusion outweigh the benefits of inclusion and will not lead to the extinction of the species.

In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the proposed 4(d) rule for the Kern Canyon

slender salamander if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the species. In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

If you already submitted comments or information on the October 18, 2022, proposed rule (87 FR 63150) or the November 21, 2023, revised critical habitat and comment period reopening (88 FR 81028), please do not resubmit them. Any such comments are incorporated as part of the public record of the rulemaking proceeding, and we will fully consider them in the preparation of our final determination.

Comments and materials we receive, as well as supporting documentation we used in preparing the proposed rule and its revisions, are available for public inspection on <https://www.regulations.gov> at Docket No. FWS-R8-ES-2022-0081.

Background

On October 18, 2022, we published a proposed rule in the **Federal Register** (87 FR 63150) to list the Kern Canyon slender salamander as a threatened species with a 4(d) rule and a critical habitat designation of approximately 2,051 acres (ac) (830 hectares (ha)), and to list the relictual slender salamander as an endangered species with a critical habitat designation of approximately 2,685 ac (1,087 ha). Both species are found in the southern Sierra Nevada mountains. The Kern Canyon slender salamander is known from 19 sites, spread across areas of the Sequoia National Forest and other privately owned land within the Erskine Creek and Bodfish Creek Canyons in Kern County, California. Currently, habitat supporting the Kern Canyon slender salamander is primarily affected by habitat degradation from roads (Factor A), recreation (Factor A), inappropriate grazing (Factor A), fire (Factor A), and effects of climate change (Factor E). These threats continue to degrade the seep and spring habitat, and in some rare cases may result in direct mortality of individual Kern Canyon slender salamanders.

On November 21, 2023 (88 FR 81028), based on feedback from species experts, we proposed revisions to the critical habitat designation and the physical or biological features for both species. We reopened the comment period from November 23, 2023, to December 6, 2023, to allow all interested parties an opportunity to comment on the proposed changes.

During the initial comment period on the 2022 proposed rule, we also received comments from the public related to livestock grazing. The commenters stated that we inaccurately characterized the impacts of current grazing practices on both the relictual slender salamander and the Kern Canyon slender salamander in the proposed rule. They requested that we except any take from managed livestock grazing by including this activity under our 4(d) exception for fuels management activities, as research has shown managed livestock grazing can reduce fuel loads and the risk of catastrophic fire. In addition, one of these commenters emphasized that managed grazing is compatible with healthy wetlands and amphibian conservation goals. In consideration of these comments, we now propose modifying the 4(d) rule to except otherwise prohibited take of the Kern Canyon slender salamander that occurs during grazing activities that results in negligible impacts to the Kern Canyon slender salamander. We also modified the wording of the proposed exception for fuels management activities in order to more clearly explain which activities would be covered by the 4(d) rule and to emphasize that the focus of the provision is on reducing effects to Kern Canyon slender salamander habitat. We are also adding more language to the preamble to clarify which activities and conservation measures would be covered under these exceptions.

After determining that the listing of the Kern Canyon slender salamander as a threatened species is warranted, in response to *Kansas Natural Resources Coalition, et al. v. USFWS, et al.* 780 F.Supp.3d 650 (W.D. Tex. 2025), our necessary and advisable determination under section 4(d) of the Act includes consideration of conservation and economic impacts of the proposed 4(d) rule for the Kern Canyon slender salamander.

Thus, we prepared a supplemental document considering the economic impacts of the 4(d) rule for the Kern Canyon slender salamander. Evaluating economic costs and benefits (economic impacts) of a 4(d) rule requires identifying the changes in regulatory requirements and behavior triggered

specifically by the protections provided by the 4(d) rule beyond the determination to list the species. That is, we must consider the economic impacts of the world with the 4(d) rule and the world without the 4(d) rule. The world without the 4(d) rule includes the protections attributable to the listing of the species (*i.e.*, baseline) as well as existing regulatory protections from the California Endangered Species Act (CA Fish & Game Code Section 2050 *et seq.*) and the Lacey Act, as amended (16 U.S.C. 3371–3378). Our analysis of the incremental impacts (*i.e.*, world with the 4(d) rule) includes individuals applying for research permits to study the Kern Canyon slender salamander, any section 7 analysis for activities that may result in incidental take not excepted under the 4(d) rule, or any section 10 analysis that would be needed on non-Federal lands where there is no overlap with other listed species.

In addition, we do not anticipate many new permits for incidental take will be required. A majority of the species' range is on Federal land, and the 4(d) rule excepts incidental take associated with activities related to fuels management and appropriate livestock grazing activities. For activities other than fuels management and appropriate livestock grazing activities, where there is no Federal nexus for section 7, there will be a new permit requirement which will replace the permitting currently required by California State law if certain standards are met. However, based on the available information at this time, we anticipate this to occur infrequently and in only limited circumstances. This is because only a small portion of the species' range is on private lands and the number of activities occurring on these lands that are expected to require a permit are minimal. Where there is a Federal nexus, the 4(d) rule does not change the obligations to consult under section 7 of the Act. Thus, we concluded that there will likely be limited change to the regulated community as a result of this rule.

In summary, we now reopen the public comment period for an additional 30 days to allow interested parties to comment on the new exception in the 4(d) rule, our consideration of economic impacts of the 4(d) rule, and our Regulatory Flexibility Act (RFA) analysis. Our April 2026 "Consideration of Economic Impacts for the 4(d) Rule for the Kern Canyon slender salamander" is available under supporting materials at <https://www.regulations.gov> at Docket No. FWS–R8–ES–2022–0081.

Proposed 4(d) Rule

Exercising the Secretary's authority under section 4(d) of the Act, we have developed a revised proposed 4(d) rule that is designed to address the Kern Canyon slender salamander's conservation needs. Section 4(d) requires the Secretary to issue such regulations as he deems necessary and advisable to provide for the conservation of each threatened species and authorizes the Secretary to include among those protective regulations any of the prohibitions that section 9(a)(1) of the Act prescribes for endangered species (In re: *Polar Bear Endangered Species Act Listing and 4(d) Rule Litigation*, 818 F. Supp. 2d 214, 228 (D.D.C. 2011), citing *Sweet Home Chapter of Cmty. for a Great Or. v. Babbitt*, 1 F.3d 1, 8 (D.C. Cir. 1993), reviewed on other grounds, 515 U.S. 687 (1995)). As mentioned above, our necessary and advisable determination includes consideration of conservation and economic impacts. We explain below why we find that, if finalized, the prohibitions and exceptions in this proposed rule as a whole satisfy the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Kern Canyon slender salamander.

The protective regulations we are proposing for the Kern Canyon slender salamander incorporate prohibitions from section 9(a)(1) to address the threats to the species. We propose to include the following prohibitions of section 9(a)(1) of the Act and implementing regulations codified at 50 CFR 17.21 which make it illegal for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit or to cause to be committed any of the following acts with regard to any endangered wildlife: (1) import into, or export from, the United States; (2) take (which includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect) within the United States, within the territorial sea of the United States, or on the high seas; (3) possess, sell, deliver, carry, transport, or ship, by any means whatsoever, any such wildlife that has been taken illegally; (4) deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of commercial activity; or (5) sell or offer for sale in interstate or foreign commerce. This proposed protective regulation includes these prohibitions because the Kern Canyon slender salamander is likely to become in danger of extinction within the

foreseeable future, and putting these prohibitions in place is intended to prevent further declines, preserve the species' remaining populations, slow its rate of decline, and decrease synergistic, negative effects from other ongoing or future threats.

As discussed in the 2022 proposed rule to list the relictual slender salamander and the Kern Canyon slender salamander (87 FR 63150; pp. 63172–63173), we have concluded that the Kern Canyon slender salamander is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss and degradation from roads, recreation, inappropriate grazing, fire, and climate change (increased temperatures and decreased snowpack). These threats are impacting population resiliency and species redundancy and representation, thereby affecting the overall status of the Kern Canyon slender salamander. Therefore, regulating activities associated with impacts to Kern Canyon slender salamander from habitat loss and degradation is essential for the species' conservation. Although collection and commercial trade of the Kern Canyon slender salamander is not a threat driving the status of the species, the section 9 prohibitions related to trade and commerce through our application of 50 CFR 17.21(b), (e), and (f) will help limit any loss of individuals and assist in maintaining population dynamics for the species.

Under the Act, “take” means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating take is intended to help preserve the species' remaining populations and slow their rate of decline. Therefore, we propose to prohibit take of the Kern Canyon slender salamander, except for take resulting from those actions and activities specifically excepted by the 4(d) rule.

The revised proposed 4(d) rule would also provide for the conservation of the species by allowing exceptions that are intended to incentivize conservation actions or actions that are not expected to rise to the level that would have a negative impact (*i.e.*, would have only de minimis impacts) on the species' conservation. Exceptions to the prohibitions include the exceptions to the prohibition for endangered wildlife, as set forth in 50 CFR 17.21(c)(2)–(4), (d)(2) and exceptions for threatened

wildlife at 50 CFR 17.31(c). This includes allowing law enforcement to possess and conduct other acts with illegally taken Kern Canyon slender salamander as necessary in performing their official duties.

To further the conservation of the species, any employee or agent of the Service, any other Federal land management agency, the National Marine Fisheries Service, a State conservation agency, or a federally recognized Tribe, who is designated by their agency or Tribe for such purposes, may, when acting in the course of their official duties, take threatened wildlife without a permit if such action is necessary to: (i) aid a sick, injured, or orphaned specimen; or (ii) dispose of a dead specimen; or (iii) salvage a dead specimen that may be useful for scientific study; or (iv) remove specimens that constitute a demonstrable but nonimmediate threat to human safety, provided that the taking is done in a humane manner. Such taking may involve killing or injuring only if it has not been reasonably possible to eliminate such threat by live capturing and releasing the specimen unharmed, in an appropriate area. Any taking must be reported in writing to the Office of Law Enforcement, via contact methods listed at <https://www.fws.gov>, within 5 calendar days. The specimen may only be retained, disposed of, or salvaged under directions from the Office of Law Enforcement.

We recognize the special and unique relationship that we have with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist us in implementing all aspects of the Act. In this regard, section 6 of the Act provides that we must cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with us in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve the Kern Canyon slender salamander that may result in otherwise prohibited take without additional authorization.

In addition, any employee or agent of the Service or of the National Marine Fisheries Service, who is designated by their agency for such purposes, may, when acting in the course of their official duties, take the Kern Canyon slender salamander.

The revised proposed 4(d) rule would also provide for the conservation of the species by allowing exceptions that incentivize conservation actions or that, while they may have some minimal level of take of the Kern Canyon slender salamander, are not expected to rise to the level that would have a negative impact (would have only de minimis impacts) on the species' conservation. The proposed exceptions to these prohibitions include fuels management and grazing activities that are expected to have negligible impacts to the Kern Canyon slender salamander and its habitat.

Wildfire is one of the primary threats to the Kern Canyon slender salamander, and the implementation of fuels management activities will assist in protecting and maintaining habitat for the species. Prescribed fire and fuel reduction activities (such as vegetation removal), when conducted in accordance with established fuels management plans, can reduce excessive vegetation and lower the risk of high-severity wildfire, thereby providing a conservation benefit to the species. Standards and guidelines for fuels management activities that support the conservation of the Kern Canyon slender salamander and its habitat are presented in established and recognized fuels or land management plans such as the Land Management Plan for the Sequoia National Forest (U.S. Forest Service (USFS) 2023, pp. 76–79) and the California Statewide Fuels Reduction Environmental Protection Plan (California Natural Resources Agency (CNRA) and California Environmental Protection Agency (CEPA) 2025, entire). Best management practices include using naturally ignited and prescribed fires to reduce fuels and meet resource management objectives; allowing fire to burn within riparian ecosystems when anticipated fire effects fall within the ecosystem's natural range of variation; conducting fuel reduction activities outside of the species' active period; establishing no-work buffers around sensitive habitat features within project areas; minimizing ground disturbance and discharge of sediment into water sources; avoiding the use of heavy machinery; using hand or small engine tools instead of large equipment; and monitoring occupied habitat during fuel reduction activities (USFS 2023, pp. 76–79; CNRA and CEPA 2025, pp. 3–6).

Thus, we propose to except take of the Kern Canyon slender salamander related to fuels management activities:

(1) That are conducted or authorized by the Federal agency with jurisdiction over the land where the activities occur. This exception includes fuels management activities developed by a Federal, State, county, or other entity to reduce the risk or severity of fire to protect and maintain habitat that supports the Kern Canyon slender salamander. These activities should be in accordance with established and recognized fuels management plans that include measures to minimize impacts to Kern Canyon slender salamander habitat.

(2) That occur on lands where there is no Federal nexus. This exception applies to those situations, whether currently existing or that may develop in the future, where fuels management activities are essential to reduce the risk of catastrophic wildfire, and when such activities will be carried out in accordance with an established and recognized fuels or land management plan that includes measures to minimize impacts to Kern Canyon slender salamander habitat.

Finally, we may under certain circumstances issue permits to carry out one or more otherwise-prohibited activities, including those described above. The regulations that govern permits for threatened wildlife state that the Director may issue a permit authorizing any activity otherwise prohibited with regard to threatened species. These include permits issued for the following purposes: for scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act (50 CFR 17.32). The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

All of the above prohibitions and exceptions were included in the 2022 proposed rule, although we have made some changes to the language of the exceptions in response to public comments. We now also propose to include an exception covering take of Kern Canyon slender salamander that occurs during managed livestock grazing activities that are expected to have negligible impacts on the Kern Canyon slender salamander.

Incompatible livestock grazing is a threat to the Kern Canyon slender salamander when it results in the direct or indirect destruction of riparian habitat. However, managed livestock grazing activities, such as those

conducted within the range of the Kern Canyon slender salamander, can provide a conservation benefit to the species. The conservation benefits provided by managed grazing activities include the maintenance of habitats that are used to support the species' life history. Grazing operations maintain grass and shrubland habitat from becoming overgrown and eventually fuel for wildfire, and appropriate grazing management can reduce fuel loads and the risk of catastrophic fire. Grazing operations that do not follow standard best management practices to avoid overgrazing, especially within riparian areas, would not be part of this exception.

Standards and guidelines for grazing operations that are beneficial to the Kern Canyon slender salamander and its habitat are outlined in the Land Management Plan for the Sequoia National Forest (USFS 2023, pp. 91–94) and the Central California Standards for Rangeland Health and Guidelines for Livestock Grazing Management (Bureau of Land Management (BLM) 2000, entire). Best management practices include limiting livestock utilization of willows and other woody riparian species and deep-rooted plants within riparian areas; limiting annual disturbance to streambanks; fencing of water sources, wetlands, and riparian areas; developing water sources to maintain ecologic and hydrologic function and processes; and locating salt blocks, supplemental feed, and livestock handling or management facilities away from wetland and riparian areas (BLM 2000, p. 9; USFS 2023, p. 93).

Specifically, we propose to except take of the Kern Canyon slender salamander associated with grazing activities:

(1) On Federal lands, as long as the grazing activities comply with the standards and guidelines of the Federal agency with jurisdiction over the land where the activities occur.

(2) On lands where there is no Federal nexus. Such activities will be carried out in accordance with best management practices that include appropriate grazing standards and guidelines and measures to minimize impacts to Kern Canyon slender salamander habitat (especially riparian areas).

The revised proposed 4(d) rule provides for the conservation of the Kern Canyon slender salamander because it will regulate activities that pose a threat to the species or that may become a threat in the future. However, it also provides flexibilities in management and permitting requirements for several activities that

are expected to have negligible impacts to the Kern Canyon slender salamander, as discussed above. Where there is a Federal nexus, the 4(d) rule does not change the consultation obligations under section 7 of the Act, although it may except the need for incidental take authorization. Please see our April 2026 “Consideration of Economic Impacts for the 4(d) Rule for the Kern Canyon slender salamander” on <https://www.regulations.gov> for our consideration of economic impacts. After considering the conservation needs of the species and the economic costs of the 4(d) rule, we have determined that the 4(d) rule is necessary and advisable to provide for the conservation of the species. We appreciate any public comment on the potential impacts (conservation and economic) of the proposed 4(d) rule.

Required Determinations

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; title II of Public Law 104–121, March 29, 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

While we do not conduct RFA analyses on our classification determinations under the Act, in accordance with recent caselaw (*Kansas Natural Resources Coalition, et al. v. USFWS, et al.* 780 F.Supp.3d 650 (W.D. Tex. 2025)), we comply with RFA through consideration of conservation and economic impacts when promulgating 4(d) rules. Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require

agencies to evaluate the potential impacts to indirectly regulated entities.

Some of the actions regulated by the proposed 4(d) rule are likely to involve Federal action agencies. 4(d) rules do not alter any obligations for Federal agencies under section 7 of the Act. Federal agencies, in consultation with the Service, are required to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirements. Consequently, it is our position that only Federal action agencies would be directly regulated during section 7 consultations (regardless of what is prohibited in 4(d) rules). The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Please see our April 2026 “Consideration of Economic Impacts for the 4(d) Rule for the Kern Canyon slender salamander” on <https://www.regulations.gov> for our consideration of impacts to small entities. We certify that, if adopted as proposed, this proposed rule would not have a significant economic impact on a substantial number of small entities. We request information (see Information Requested) to ensure we fully understand the potential impacts of this proposed rule.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose further to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as proposed to be amended at 87 FR 63150 (October 18, 2022) and 88 FR 81028 (November 21, 2023) as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Further amend § 17.43, as proposed to be amended at 87 FR 63150, by revising paragraph (h) to read as follows:

§ 17.43 Special rules—amphibians.

* * * * *

(h) Kern Canyon slender salamander (*Batrachoseps simatus*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Kern Canyon slender salamander. Except as provided under paragraph (v)(2) of this section and §§ 17.4, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of a commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *Exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(iii) Take, as set forth at § 17.31(b).

(iv) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

(v) Take incidental to:

(A) Fuels management activities:

(1) That are conducted or authorized by the Federal agency with jurisdiction over the land where the activities occur. This exception includes fuels management activities developed by a Federal, State, county, or other entity to reduce the risk or severity of fire to protect and maintain habitat that supports the Kern Canyon slender salamander. These activities should be in accordance with established and recognized fuels management plans that include measures to minimize impacts to Kern Canyon slender salamander habitat.

(2) That occur on lands where there is no Federal nexus. This exception applies to those situations, whether currently existing or that may develop in the future, where fuels management activities are essential to reduce the risk of catastrophic wildfire, and when such activities will be carried out in accordance with an established and recognized fuels or land management plan that includes measures to minimize impacts to Kern Canyon slender salamander habitat, and

(B) Grazing activities:

(1) On Federal lands, as long as the grazing activities comply with the

standards and guidelines of the Federal agency with jurisdiction over the land where the activities occur.

(2) On lands where there is no Federal nexus. Such activities will be carried out in accordance with best management practices that include appropriate grazing standards and guidelines and measures to minimize impacts to Kern Canyon slender salamander habitat (especially riparian areas).

Brian R. Nesvik,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2026–13719 Filed 7–6–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 260630–0157]

RIN 0648–BO10

Reef Fish Fishery of the Gulf of America; Amendment 62

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Amendment 62 to the Fishery Management Plan for the Reef Fish Resources of the Gulf (FMP) (Amendment 62), as prepared and submitted by the Gulf Council (Council). This proposed rule and Amendment 62 would revise the catch limits and sector allocations for Gulf of America (Gulf) red grouper, based on the best scientific information available. Additionally, this proposed rule would remove the shallow-water grouper (SWG) recreational seasonal closure, from February 1 through March 31, in Gulf Federal waters seaward of the 20-fathom boundary.

DATES: Written comments on the proposed rule must be received on or before August 6, 2026.

ADDRESSES: A plain language summary of this proposed rule is available at <https://www.regulations.gov/docket/NOAA-NMFS-2026-0991>. You may submit comments on this document, identified by [NOAA–NMFS–2026–0991], by either of the following methods:

Electronic Submission: Submit comments electronically via the Federal

e-Rulemaking Portal. Visit <https://www.regulations.gov> and type [NOAA–NMFS–2026–0991] in the Search box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Mail: Send written comments to Daniel Luers, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period may not be considered by NMFS. All comments received are part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address) 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.

An electronic copy of Amendment 62 is available from <https://www.regulations.gov> or from the Southeast Regional Office website at: <https://www.fisheries.noaa.gov/action/amendment-62-gulf-red-grouper-management-measures>. Amendment 62 includes an environmental assessment, a Regulatory Flexibility Act (RFA) analysis, regulatory impact review, and fishery impact statement.

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

SUPPLEMENTARY INFORMATION: The Gulf reef fish fishery, which includes red grouper, is managed under the FMP. The FMP was prepared by the Council and NMFS, approved by the Secretary of Commerce, and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*).

Background

The Magnuson-Stevens Act requires NMFS, with advice from the regional fishery management councils, to prevent overfishing and achieve, on a continuing basis, the optimum yield from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the Nation, particularly with respect to providing food production, recreational opportunities, and protecting marine ecosystems.

This action is taken under the statutory authority of Magnuson-Stevens Act section 303(a)(15), which requires fishery management plans to establish annual catch limits and accountability measures to prevent overfishing, and section 303(b)(2), which allows the designation of zones where, and periods when, fishing may be limited or not permitted.

Unless otherwise noted, all weights in this proposed rule are in pounds (lb) gutted weight.

The current catch limits for red grouper were set in 2022 (87 FR 40742, July 8, 2022). The current Gulf red grouper overfishing limit (OFL) and acceptable biological catch (ABC) are 5.99 million lb (2.72 million kilogram (kg)) and 4.96 million lb (2.25 million kg), respectively. The total annual catch limit (ACL) is set equal to the ABC, and is allocated 59.3 percent to the commercial sector and 40.7 percent to the recreational sector. This allocation was specified in Amendment 53 to the FMP and is informed, in part, by Marine Recreation Information Program—Fishing Effort Survey (MRIP–FES) recreational data (84 FR 25573, May 2, 2022). The current maximum sustainable yield (MSY) proxy for red grouper is based on the yield associated with a fishing mortality rate (F) that would result in a spawning stock biomass (SSB) of 30 percent of the spawning potential ratio (SPR) ($F_{30\%SPR}$), where SPR is the ratio of the SSB to its unfished state. A proxy for MSY is used when there is insufficient data to directly determine the MSY.

The most recent stock assessment for red grouper (Southeast Data, Assessment, and Review (SEDAR) 88) was completed in 2025. SEDAR 88 used updated recreational catch and effort data produced by the Florida State Reef Fish Survey (SRFS). To obtain complete estimates of recreational catch for the stock assessment, SRFS combined private recreational landings and discard estimates with charter vessel catch informed by estimates from MRIP–FES, as well as headboat catch informed by the Southeast Region Headboat Survey. Thus, when “SRFS” is referred to in this proposed rule with respect to management of the red grouper stock and SEDAR 88, it encompasses all of these sources of recreational data combined. The stock assessment results indicated an increase in the red grouper stock size relative to the previous assessment (SEDAR 61, 2019). Based on its review of SEDAR 88, the Council’s Scientific and Statistical Committee (SSC) determined that the Gulf red grouper stock was not overfished or undergoing overfishing

and recommended increases to the OFL and ABC. However, because SEDAR 88 used different recreational data than the previous assessment, the current and proposed OFL and ABC are not directly comparable.

Based on the results of SEDAR 88 indicating the stock size has increased, the Council requested that NMFS take emergency action (based on social and economic justification) to increase the red grouper catch limits for the 2025 fishing season (90 FR 37804, August 6, 2025). Because initial projections from SEDAR 88 assumed that any management action initiated by the Council would begin in 2027, the assessment projections required updating to reflect management actions that would begin in 2025. Using these updated projections, the Council’s SSC recommended an OFL of 10.64 million lb (4.83 million kg) and an ABC of 8.28 million lb (3.76 million kg).

The SSC’s OFL recommendation is consistent with its recommendation to change the current MSY proxy to a more conservative value. As explained above, the current MSY proxy is the yield at $F_{30\%SPR}$. The SSC recommended a more conservative MSY proxy of the yield at $F_{40\%SPR}$. An SPR of 40 percent is more conservative than an SPR of 30 percent because it means that the spawning biomass is closer to the level of an unfished population (40 percent of the level of the unfished population as opposed to 30 percent). The SSC concluded that certain biological and ecological characteristics of red grouper support more conservative management. For example, red grouper undergoes ontogenetic spatial shifts from nearshore shallow habitats to offshore deep-water habitats; large females transition to male based on environmental and social cues that are not completely understood; and its propensity to create unique habitats in the benthic substrate and territorial behavior may generate a carrying capacity issue that limits available space for other red grouper. The SSC determined that accounting for the complex life history of red grouper is imperative when recommending the revised F_{msy} proxy and thus the OFL. The SSC has, in recent years, recommended setting an MSY proxy of $F_{40\%SPR}$ for hermaphroditic groupers like gag, scamp and yellowmouth grouper, and also yellowedge grouper. Based on their recent management advice to the Council for grouper species with similar life history characteristics to red grouper, the SSC concluded that an $F_{40\%SPR}$ as the proxy for F_{MSY} was appropriate.

Commercial harvest of Gulf red grouper has been managed under the

Grouper-Tilefish Individual Fishing Quota (IFQ) Program since the program was implemented by Amendment 29 to the FMP in 2010 (74 FR 44732, August 31, 2009). The IFQ program serves as the commercial accountability measure (AM) for red grouper. The commercial quota for red grouper is set 5 percent less than the commercial ACL to allow for multi-use allocation with gag to reduce discards and allow commercial fishermen to better use the allocation they have in a given fishing year. Red grouper multi-use allocation can be used to possess, land, or sell red grouper after an IFQ account holder's (shareholder or associated vessel accounts) red grouper allocation has been landed and sold, or transferred; and to possess, land, or sell gag, only after both gag and gag multi-use allocation have been landed and sold, or transferred from all of the IFQ account holder's accounts. However, if gag is under a rebuilding plan, the percentage of red grouper multi-use allocation is equal to zero. Gag is currently under a rebuilding plan, and thus red grouper multi-use allocation is currently set to zero.

The recreational sector is managed using an ACL and ACT, and both in-season and post-season AMs. The in-season AM for red grouper requires NMFS to close the recreational sector when red grouper landings reach or are projected to reach the recreational ACL. If landings exceed the red grouper recreational ACL in a fishing year, the post-season AM requires NMFS to maintain the recreational ACT and shorten the duration of the following fishing year by the amount necessary to ensure landings do not exceed the recreational ACT, unless NMFS determines that managing to the ACT in the following year is unnecessary. If red grouper is overfished and landings exceed the recreational ACL, then both the recreational ACL and ACT must be reduced in the following year by the amount of the previous year's recreational overage. This proposed rule and Amendment 62 would not revise the recreational AMs.

Recreational harvest triggered in-season closures of the red grouper recreational season in each year from 2021 through 2024. In each of those 4 years, both the recreational ACT and ACL were exceeded, resulting in implementation of the post-season AM in 3 of the 4 following years to shorten the red grouper season as required. The post-season AM for the 2025 recreational season, which was triggered by the 2024 overage of the recreational ACL, was not implemented because the

emergency action increased the red grouper catch limits.

For the commercial sector, the 5 percent buffer between the commercial ACL and ACT would be retained in this proposed rule to account for the gag multi-use allocation of the IFQ program. For the recreational sector, this proposed rule would maintain the current 9 percent buffer between the recreational ACL and ACT that was set in Amendment 53. This recreational buffer would be maintained because the use of more precise SRFS data to monitor recreational landings and the substantial increase in the recreational ACL are expected to prevent future recreational ACL overages.

In 2013, NMFS implemented a framework action under the FMP that established the current SWG recreational seasonal closure (78 FR 33259, June 4, 2013). The seasonal closure is effective from February 1 through and March 31, annually, in Gulf Federal waters seaward of a line approximating the 20-fathom boundary (50 CFR 622.34(d)). In the Gulf, the SWG species are gag, red grouper, black grouper, scamp, yellowfin grouper, and yellowmouth grouper. The closure was established to provide protection for spawning SWG species in deeper Gulf waters while allowing recreational harvest to occur shoreward of the 20-fathom boundary. Although this proposed rule would eliminate this closure, all SWG species except red grouper have other seasonal closure regulations in effect, or in development, which are expected to prohibit their recreational harvest during February and March beginning in 2027. Gulf gag has a recreational seasonal closure in effect from January through August (50 CFR 622.34(e)). On March 18, 2026, NMFS published a proposed rule that would create recreational seasonal closure for black grouper, yellowfin grouper, scamp, and yellowmouth grouper from January through June (91 FR 12989). If that proposed rule is finalized, red grouper would be the only SWG species affected by the removal of the current SWG recreational seasonal closure. However, as described in Amendment 62, the current seasonal closure may be redirecting red grouper recreational effort inshore and therefore reducing the overall benefit of the closure to the red grouper stock. Additionally, red grouper that are shoreward of the current closure boundary are generally smaller in size and therefore discards may be increased due to the red grouper minimum size limit. The Council determined that it was appropriate to recommend removal of the February through March

recreational closure given the increase to the stock size as indicated by SEDAR 88 and the increased catch limits in this proposed rule.

Management Measures Contained in This Proposed Rule

This proposed rule would revise the Gulf red grouper commercial and recreational ACLs, the commercial quota, and the recreational ACT. In addition, this proposed rule would remove the SWG recreational seasonal closure of February through March seaward of the 20-fathom boundary.

Catch Limits

The proposed rule would increase the commercial ACL from 2.94 million lb (1.33 million kg) to 4.51 million lb (2.05 million kg) for 2026, 5.08 million lb (2.30 million kg) for 2027, and 5.65 million lb (2.56 million kg) for 2028 and subsequent years. The commercial quota would increase from 2.79 million lb (1.27 million kg) to 4.28 million lb (1.94 million kg) for 2026, 4.83 million lb (2.19 million kg) for 2027, and 5.37 million lb (2.44 million kg) for 2028 and subsequent years.

The proposed rule would increase the recreational ACL from 2.02 million lb (0.92 million kg) to 2.11 million lb (0.96 million kg) for 2026, 2.37 million lb (1.08 million kg) for 2027, and 2.63 million lb (1.19 million kg) for 2028 and subsequent years. The recreational ACT would increase from 1.84 million lb (0.83 million kg) to 1.92 million lb (0.87 million kg) for 2026, 2.16 million lb (0.98 million kg) for 2027, and 2.39 million lb (1.08 million kg) for 2028 and subsequent years. The current and proposed recreational catch limits are not directly comparable because of the recreational datasets used in the prior and current assessments, but the proposed catch limits are increases from the current values.

SWG Recreational Seasonal Closure

This proposed rule would remove the recreational seasonal closure from February through March for SWG species in Gulf Federal waters seaward of a line approximating the 20-fathom boundary. Although this proposed rule would eliminate this closure, as previously noted, all SWG species except red grouper have other seasonal closure regulations in effect, or in development, which prohibit their recreational harvest during this time period.

Management Measures in Amendment 62 That Would Not Be Codified by This Proposed Rule

In addition to the measures that would be codified through this proposed rule, Amendment 62 would update the MSY proxy, the OFL, the ABC and the sector allocations for Gulf red grouper. NMFS published a notice of availability of Amendment 62 on April 2, 2026, (91 FR 16623) and will approve, partially approve, or disapprove the amendment within 30 days after the public comment period ends (July 1, 2026).

MSY Proxy, OFL and ABC

Amendment 62 would revise the MSY proxy, OFL, and ABC for red grouper based on the Council's SSC recommendations and consistent with SEDAR 88. The MSY proxy would be defined as the yield at $F_{40\%SPR}$. The OFL would be 10.64 million lb (4.83 million kg), and the ABC would be 8.28 million lb (3.76 million kg). The total ACL would be 6.62 million lb (3.00 million kg) in 2026 (80 percent of the ABC), 7.45 million lb (3.38 million kg) in 2027 (90 percent of the ABC), and 8.28 million lb (3.76 million kg) in 2028 and subsequent years (100 percent of the ABC). The Council determined that a phase-in approach to increasing the total catch limits over several years would be appropriate, as the SSC receives an annual interim stock analysis for red grouper and could advise the Council if the increases to the total ACL were no longer warranted.

Sector Allocations

Currently, the commercial sector is allocated 59.3 percent and the recreational sector is allocated 40.7 percent of the total ACL based on each sector's average landings from 1986 through 2005 (including MRIP-FES recreational harvest estimates). Amendment 53 set this allocation to maintain historical fishing practices. The allocation was based on the original reference years (1986 through 2005) for red grouper landings but with updated recreational landings using the MRIP-FES dataset, which was used in the stock assessment that informed the catch levels in Amendment 53. Amendment 62 would update the commercial-recreational allocation using the same reference period (1986–2005), but based on SRFS estimated recreational harvest. This results in a commercial allocation of 68.2 percent and a recreational allocation of 31.8 percent of the total ACL. SRFS recreational landings estimates are lower than those produced by MRIP-

FES. Continuing with the current allocation without accounting for the decrease in estimated catch and effort associated with the change to SRFS from MRIP-FES would result in a *de facto* reallocation from the commercial sector to the recreational sector.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with Amendment 62, the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This proposed rule is not an Executive Order 14192 regulatory action because this rule is not significant under Executive Order 12866.

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

The Senior Lead Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. A description of the factual basis for this determination follows. A copy of the full analysis is available from NMFS (see **ADDRESSES**). All monetary estimates in the following analysis are in 2024 dollars.

A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections of this proposed rule.

Amendment 62 and this proposed rule would revise the Gulf red grouper OFL, ABC, and total ACL. This proposed rule would also revise the Gulf red grouper sector allocations from 59.3 percent allocated to the commercial sector and 40.7 percent recreational sector to 68.2 percent allocated to the commercial sector and 31.8 percent recreational sector. Additionally, this proposed rule would eliminate the February 1 through March 31 recreational closed season for SWG in

Federal waters seaward of the 20-fathom boundary.

This proposed rule would apply to all commercial fishing businesses, charter vessel and headboat (for-hire) fishing businesses, and recreational fishers (anglers) that fish for Gulf red grouper in Federal waters. The proposed rule would also apply to red grouper IFQ shareholders. None of the proposed changes would directly apply to federally-permitted dealers. Any change in the supply of Gulf red grouper available for purchase by dealers as a result of this proposed rule, and associated economic effects, would be an indirect effect of the proposed rule and would therefore fall outside the scope of the RFA.

The RFA requires NMFS to describe the impact of the proposed rule on small entities (5 U.S.C. 603). Small entities include small businesses, small organizations, and small governmental jurisdictions (5 U.S.C. 601(3)–(6)). Recreational anglers are not businesses, organizations, or governmental jurisdictions, so they are outside the scope of this analysis.

As of July 8, 2021, there were 825 limited access valid or renewable Federal commercial Gulf reef fish permits. In order to commercially harvest Gulf red grouper, a vessel permit must also be linked to an IFQ account and possess sufficient allocation for this species. IFQ accounts can be opened, and valid permits can be linked to IFQ accounts, at any time during the year. Eligible vessels can receive red grouper allocation from other IFQ participants. On average from 2020 through 2024, there were 671 IFQ accounts that held red grouper allocation and 68 percent of those held red grouper shares. During the same period, there were 324 federally-permitted commercial reef fish vessels, on average each year, with reported landings of red grouper in the Gulf. Their average annual vessel-level gross revenue from all species for 2020 through 2024 was approximately \$137,779 and Gulf red grouper landings accounted for approximately 34 percent of this revenue. From 2020 through 2024, the maximum annual revenue from all species reported by a single one of the commercial vessels that landed Gulf red grouper was approximately \$1.24 million in 2022. Economic profits for these commercial vessels are estimated to be 28.1 percent of their annual gross revenue, on average, or \$38,716 per vessel during this period. Although many fishing businesses own only one permitted vessel, some hold or own multiple permits and vessels. Since comprehensive ownership data are currently unavailable for vessels

harvesting Gulf red grouper, this analysis assumes that each of the 324 vessels is independently owned by a single business. This assumption is expected to result in an overestimate of the actual number of businesses directly regulated by this proposed rule. Additionally, 150 IFQ shareholder accounts, on average from 2020 through 2024, possessed red grouper shares but did not report any landings of red grouper. The account holders either transferred red grouper allocation only or were inactive. It is assumed that each of these accounts is independently owned by a single business as well. Revenue and cost data are not collected directly from IFQ shareholders; therefore, estimates of economic profits for the Gulf red grouper IFQ commercial fishing businesses that did not report landings are unavailable.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (North American Industry Classification System [NAICS] code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of \$11 million for all its affiliated operations worldwide. All the commercial fishing businesses directly regulated by this proposed rule are believed to be small entities based on the NMFS size standard.

This proposed rule would also apply to for-hire businesses. For-hire businesses sell fishing services to recreational anglers. As of August 26, 2021, there were 1,273 valid or renewable Gulf reef fish charter vessel/headboat permits. NMFS estimates that the average charter vessel operating in the Gulf receives approximately \$107,000 in gross revenue and \$32,000 in net income annually. The average headboat receives approximately \$325,000 in gross revenue and \$95,000 in net income annually. In the Gulf, headboats cater to large, diverse groups of individual anglers and typically market multi-species trips rather than targeting a single stock. Therefore, NMFS assumes that no headboat trips would be gained or lost due to the proposed rule and headboats would not experience any direct economic impacts.

For other industries, the Small Business Administration has established size standards for all major industry sectors in the U.S., including for-hire businesses (NAICS code 487210). A

business primarily involved in for-hire fishing is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates) and has annual receipts (*i.e.*, revenue) not in excess of \$14.0 million for all its affiliated operations worldwide. Based on this information, all for-hire fishing businesses regulated by this proposed rule are determined to be small businesses for the purpose of this analysis.

This proposed rule would revise the total ACL for Gulf red grouper. Specifically, the proposed rule sets the total ACL for Gulf red grouper at 6.62 million lb (3.00 million kg) in 2026, 7.45 million lb (3.38 million kg) in 2027, and 8.28 million lb (3.76 million kg) in 2028 and subsequent years. This proposed rule would also revise the Gulf red grouper sector allocations to be 68.2 percent of the total ACL for the commercial sector and 31.8 percent of the total ACL for the recreational sector. The proposed rule would increase the commercial ACL from 2.94 million lb (1.33 million kg) to 4.51 million lb (2.05 million kg) for 2026, 5.08 million lb (2.30 million kg) for 2027, and 5.65 million lb (2.56 million kg) for 2028 and subsequent years. This proposed rule would increase the commercial quota from 2.79 million lb (1.27 million kg) to 4.28 million lb (1.94 million kg) in 2026, 4.83 million lb (2.19 million kg) in 2027, and 5.37 million lb (2.44 million kg) in 2028 and subsequent years. Relative to the status quo, NMFS expects the commercial sector would see an increase in red grouper landings and revenue. NMFS anticipates that if the overall supply of red grouper commercial landings increases, the average price per lb would likely decrease. When accounting for potential ex-vessel price changes, the overall change in ex-vessel revenue and profits is positive. NMFS estimates the expected change in ex-vessel revenue resulting from the proposed changes to the total red grouper ACL to be \$2,768,089 in 2026, \$2,906,092 in 2027, and \$2,495,524 in 2028 and subsequent years. The average vessel would experience an increase in revenue of \$8,543 in 2026, \$8,969 in 2027, and \$7,702 in 2028 and subsequent years. This would result in an increase to annual economic profits of \$2,401 per vessel in 2026, \$2,520 per vessel in 2027, and \$2,164 per vessel in 2028 and subsequent years. These changes in net benefits equate to approximately a 6 percent increase in baseline annual revenue and profits per active vessel. However, substantial uncertainty exists

regarding the commercial sector's actual capacity to harvest the increased amount of the red grouper commercial quota. In recent years, the commercial sector has consistently underutilized the commercial quota. Because of this historical underutilization, the increases to annual revenue and profits, as described above, should be interpreted as an upper bound of potential economic benefits. Therefore, NMFS does not anticipate that this proposed rule would have a significant positive or negative economic impact on any small commercial entities.

This proposed rule could potentially affect prices for red grouper IFQ shares and annual allocations by expanding the available commercial supply. While these precise fluctuations cannot be quantified with current data, annual allocation transfer prices are anticipated to decrease. This would directly lower operating costs for the estimated 30 percent of commercial fishing accounts that rely entirely on transferred allocation to harvest red grouper.

Because the estimated red grouper ex-vessel own-price flexibility is relatively inflexible (-0.533), the market price has historically shown resilience to supply increases. Consequently, the downward pressure on allocation prices might be limited, allowing a realized increase in transfer volume to offset lower per-pound prices and yield higher overall proceeds for IFQ shareholders. However, these revenue projections depend heavily on the fleet's capacity to actually harvest the expanded quota; if the new quota is significantly underutilized, allocation transfer prices could experience a downward trend without the offsetting financial benefit of increased transfer volumes. With respect to long-term IFQ share values, prices would be expected to increase if prospective buyers anticipate higher future earnings from these expanded quotas. If low utilization rates persist or if buyers remain skeptical about future market stability, permanent share values may stabilize or decrease. Regardless of the market-driven indirect effects on allocation and share prices, the proposed rule would directly increase the volume of quota pounds, a marketable asset, distributed to IFQ shareholder accounts.

This proposed rule would set the Gulf red grouper recreational ACL at 2.11 million lb (0.96 million kg) for 2026, 2.37 million lb (1.08 million kg) for 2027, and 2.63 million lb (1.19 million kg) for 2028 and subsequent years. The recreational ACT would be set at 1.92 million lb (0.87 million kg) for 2026, 2.16 million lb (0.98 million kg) for 2027, and 2.39 million lb (1.08 million

kg) for 2028 and subsequent years. NMFS expects that under the proposed recreational catch limits, annual target trips of charter vessels for Gulf red grouper would increase during the months of July through December. In 2026, under the proposed red grouper recreational ACL, a short recreational in-season closure is anticipated to occur on December 28, as a result of the recreational ACL being projected to be reached, but in subsequent years, no closure would be expected. Overall, this proposed rule is expected to increase charter vessels' target trips of red grouper by 33,779 in 2026 and 34,359 in 2027, 2028 and subsequent years. In the long-term, because factors of production, such as labor and capital, can be used elsewhere in the economy, NMFS expects only short-term changes to economic profits. NMFS expects the increase of 33,779 additional directed red grouper recreational angler trips in 2026 to increase annual net revenue for charter vessels by approximately \$5,776,209. NMFS expects the 34,359 additional directed angler trips in 2027, 2028, and subsequent years to increase net revenue for charter vessels by approximately \$5,875,389. Divided by the number of Gulf reef fish charter vessel/headboat permits, this results in an average per vessel increase in annual net revenue of approximately \$4,537 in 2026 and \$4,615 in 2027, 2028, and subsequent years. Because the count of Gulf reef fish charter vessel/headboat permits includes for-hire vessels that function primarily as headboats, and not all permitted vessels may be active, the estimated average increase in annual net revenue per charter business may be an underestimation.

While the proposed increase to the red grouper recreational ACL is expected to increase charter vessel revenues, there is uncertainty regarding the effort response of these charter vessels and the actual generation of new distinct red grouper trips. Rather than resulting in entirely new red grouper target effort, the increase in the red grouper recreational ACL and longer fishing season may instead result in joint targeting of multiple reef fish species simultaneously, or merely a shift in existing effort away from other grouper species. Because of these confounding targeting dynamics and data limitations, the projected increases in charter vessels' net benefits should be considered an upper bound of potential economic effects and actual benefits are likely to be much smaller. Therefore,

NMFS does not anticipate that this proposed rule would have a significant positive or negative economic impact on any small for-hire entities.

This proposed rule also eliminates the February 1 through March 31 recreational closed season for SWG in Gulf Federal waters seaward of a line approximating the 20-fathom boundary. In the short-term, this would be expected to have positive effects on the recreational sector by providing additional access to fishing grounds, which could result in increased for-hire fishing business revenues. As explained in the Background section above, all SWG species except red grouper have other seasonal closure regulations in effect, or in development, which prohibit their recreational harvest during this time period. Thus, NMFS expects only the private angling component and the for-hire component specifically targeting and/or catching red grouper would be affected by this change. The extent to which this may increase catch rates and landings for red grouper by the recreational sector and associated economic effects cannot be quantitatively estimated.

Based on the above analysis, this proposed rule, if implemented, would not be expected to impose direct costs or other regulatory burdens on the small entities it would apply to. Although the proposed rule is projected to result in an increase in net benefits for both the commercial sector and for-hire component of the recreational sector, these net benefits are not economically significant in terms of altering overall vessel profitability or changing operational structures, particularly when accounting for baseline catch uncertainties. As such, this proposed rule would not have a significant economic impact on a substantial number of small entities. As a result, an initial regulatory flexibility analysis is not required, and none has been prepared.

List of Subjects in 50 CFR Part 622

Commercial, Fisheries, Fishing, Gulf, Recreational, Red grouper, Reef fish.

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

Dated: June 30, 2026.

Kelly Denit,

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

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

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

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

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

§ 622.34 [Amended]

■ 2. In § 622.34, remove and reserve paragraph (d).

■ 3. In § 622.39, revise paragraph (a)(1)(iii)(C) to read as follows:

§ 622.39 Quotas.

* * * * *

(a) * * *

(1) * * *

(iii) * * *

(C) *Red grouper.*

(1) For fishing year 2026—4.28 million lb (1.94 million kg).

(2) For fishing year 2027—4.83 million lb (2.19 million kg).

(3) For fishing year 2028 and subsequent years—5.37 million lb (2.44 million kg).

* * * * *

■ 4. In § 622.41, revise paragraph (e)(1) and (e)(2)(iv) to read as follows:

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

* * * * *

(e) * * *

(1) *Commercial sector.* The IFQ program for groupers and tilefishes in the Gulf of America serves as the accountability measure for commercial red grouper. The commercial ACT for red grouper is equal to the applicable quota specified in § 622.39(a)(1)(iii)(C). The commercial ACL for red grouper, in gutted weight, is 4.51 million lb (2.05 million kg) for 2026, 5.08 million lb (2.30 million kg) for 2027, and 5.65 million lb (2.56 million kg) for 2028 and subsequent years.

(2) * * *

(iv) The recreational ACL for red grouper, in gutted weight, is 2.11 million lb (0.96 million kg) for 2026, 2.37 million lb (1.08 million kg) for 2027, and 2.63 million lb (1.19 million kg) for 2028 and subsequent years. The recreational ACT for red grouper, in gutted weight, is 1.92 million lb (0.87 million kg) for 2026, 2.16 million lb (0.98 million kg) for 2027, and 2.39 million lb (1.08 million kg) for 2028 and subsequent years.

* * * * *

[FR Doc. 2026–13682 Filed 7–6–26; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 91, No. 128

Tuesday, July 7, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2026–0100]

General Conference Committee of the National Poultry Improvement Plan and 47th Biennial Conference

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice, pursuant to the provisions of the rules and regulations of the Department of Agriculture and the Federal Advisory Committee Act (FACA), of a meeting of the General Conference Committee (GCC or the Committee) of the National Poultry Improvement Plan (NPIP) and the NPIP's 47th Biennial Conference.

DATES: The General Conference Committee meeting will be held on August 11, 2026, from 1:30 p.m. to 6:00 p.m. MST. The General Session of the Biennial Conference will begin on August 12, 2026, at 8:00 a.m. and end no later than August 14, 2026, at 2:00 p.m. MST.

ADDRESSES: The meeting and conference will be held at the Hilton Salt Lake City Center Hotel, 255 South West Temple, Salt Lake City, UT 84101.

FOR FURTHER INFORMATION CONTACT: Dr. Savannah Busby, Acting Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 301, Conyers, GA 30094; (770) 922–3496, savannah.busby@usda.gov.

SUPPLEMENTARY INFORMATION: The General Conference Committee (the Committee) of the National Poultry Improvement Plan (NPIP), representing cooperating State agencies and poultry industry members, serves an essential function by acting as liaison between the poultry industry and the Department in matters pertaining to poultry health.

Topics for discussion at the upcoming meeting include:

1. New diagnostic tests seeking NPIP approval.
2. Salmonella update.
3. Avian Influenza update.
4. Mycoplasma update.

The meeting will be open to the public; however, public participation in discussions during the sessions will only be allowed if time permits. Written statements may be filed at the meeting or filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to Docket No. APHIS–2026–0100 when submitting your statements.

Reasonable Accommodations

If needed, please request reasonable accommodations no later than July 29, 2026, by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. Requests made after that date may be considered, but it may not be possible to fulfill them.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act (5 U.S.C. 10).

Equal opportunity practices, in accordance with USDA policies, will be followed in all membership appointments to the Committee.

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (e.g., Braille, large print, audiotope, American Sign Language, etc.) should contact the State or local Agency that administers the program or contact USDA through the Telecommunications Relay Service at 711 (voice and TTY). Additionally, program information may be made

available in languages other than English.

Dated: July 2, 2026.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2026–13717 Filed 7–6–26; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Data Security Requirements for Accessing Confidential Data

AGENCY: U.S. Census Bureau and U.S. Bureau of Economic Analysis, Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act (PRA) of 1995, invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment on the proposed extension of the Data Security Requirements for Accessing Confidential Data collection, prior to the submission of the information collection request (ICR) to OMB for approval.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before September 8, 2026.

ADDRESSES: Interested persons are invited to submit written comments by email to adrm.pra@census.gov. Please reference Data Security Requirements for Accessing Confidential Data in the subject line of your comments. You may also submit comments, identified by Docket Number USBC–2026–0199, to the Federal e-Rulemaking Portal: <http://www.regulations.gov>. All comments received are part of the public record. No comments will be posted to <http://www.regulations.gov> for public viewing until after the comment period has closed. Comments will generally be

posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Tiffany S Tayman, Supervisory Program Analyst, 301-763-1675, and Tiffany.S.Tayman@census.gov at Census Bureau, or Thomas Anderson, Research Data Center Administrator, (301) 278-9117, and thomas.anderson@bea.gov at Bureau of Economic Analysis.

SUPPLEMENTARY INFORMATION:

I. Abstract

Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (hereafter referred to as the Evidence Act) mandated that OMB establish a Standard Application Process (SAP) for requesting access to certain confidential data assets. Specifically, the Evidence Act requires OMB to establish a common application process through which agencies, the Congressional Budget Office, State, local, and Tribal governments, researchers, and other individuals, as appropriate, may apply for access to certain confidential data assets collected, accessed, or acquired by a statistical agency or unit. This process maintains stringent controls to protect confidentiality and privacy, as required by the law governing the data-owning agency.

Data collected, accessed, or acquired by statistical agencies and units is vital for developing evidence of conditions, characteristics, and behaviors of the public and on the operations and outcomes of public programs and policies. This evidence can benefit the stakeholders in the programs, the broader public, as well as policymakers and program managers at the local, State, Tribal, and National levels. The many potential benefits of access to data for evidence building notwithstanding, the U.S. Census Bureau and the U.S. Bureau of Economic Analysis (BEA) are required by the law governing their activities to maintain controls to protect the confidentiality and privacy of the data they collect.

The SAP Portal is a web-based application for the public to request access to confidential data assets from

federal statistical agencies and units. The objective of the SAP Portal is to increase public access to confidential data for the purposes of evidence building and reduce the burden of applying for such access. Once an individual's application in the SAP Portal has received a positive determination by the data-owning agency, the data-owning agency(ies) or unit(s) will begin the process of collecting information to fulfill their data security requirements.

The paragraphs below outline the process for BEA and Census to collect information fulfilling their data security requirements, consistent with their statutory requirements.

Collection of Information for Data Security Requirements

In the instance of a positive determination for an application requesting access to a U.S. Census Bureau and/or a U.S. Bureau of Economic Analysis confidential data asset through the SAP process, the U.S. Census Bureau and/or the U.S. Bureau of Economic Analysis will contact the applicant(s) to initiate the process of collecting information to fulfill their security requirements. These requirements include additional information necessary for the statistical agency or unit to place the applicant(s) in a trusted category that may include the applicant's successful completion of a background investigation, confidentiality training, nondisclosure, and data use agreements.

The U.S. Census Bureau and the U.S. Bureau of Economic Analysis's data security requirements include the completion of trainings on topics such as data stewardship, controlled unclassified information (CUI), records management, safety, and IT Security. Requirements also include the completion of forms:

- Form BC-1759, Special Sworn Status—U.S. Census Bureau
- OF-306 Declaration for Federal Employment
- Fair Credit Release—U.S. Census Bureau
- Selective Service Form—U.S. Census Bureau
- BC-4002 Foreign National Residence History—U.S. Census Bureau
- BC-4003 Initial Information Sheet—U.S. Census Bureau
- BC-4004 Researcher Semi-Annual Contact Information and Travel History Update—U.S. Census Bureau
- Sworn Statement (Affirmation) of Nondisclosure for Consultant to BEA—U.S. Bureau of Economic Analysis

- Annual Census Bureau Data Handling University Training, including:
 - Data Stewardship & Controlled Unclassified Information (CUI)
 - Title 13 Awareness Course
 - Title 26 Awareness Training
 - Cybersecurity Awareness & Protection Course
- Annual Census Bureau Records Management Training
- Annual Bureau of Economic Analysis Title 26 Awareness Training
- Annual Bureau of Economic Analysis Data Stewardship and IT Security Training
- Annual Bureau of Economic Analysis Records Management 101 Training
- Annual Bureau of Economic Analysis Active Shooter Training
- Annual Bureau of Economic Analysis Employees Safety Training

II. Method of Collection

Electronically (internet).

III. Data

OMB Control Number: 0607-1026.

Form Number(s): Various.

Type of Review: Regular submission, Request for an Extension, without Change, of a Currently Approved Collection.

Affected Public: Individuals who are seeking a security clearance with either the U.S. Census Bureau or the U.S. Bureau of Economic Analysis.

Estimated Number of Respondents: 900.

Estimated Time per Response: On average, 57 minutes for the U.S. Bureau of Economic Analysis and 433 minutes for the U.S. Census Bureau. This estimate includes completion of paperwork and training requirements. The amount of time to complete the agreements and other paperwork that comprise the U.S. Census Bureau and the U.S. Bureau of Economic Analysis's security requirements will vary based on the confidential data assets requested and the access modality. This estimate does not include the time needed to complete and submit an application within the SAP Portal. All efforts related to SAP Portal applications occur prior to and separate from the U.S. Census Bureau and the U.S. Bureau of Economic Analysis's effort to collect information related to data security requirements.

Estimated Total Annual Burden Hours: Overall, per year, the U.S. Census Bureau and the U.S. Bureau of Economic Analysis estimate they will collect data security information for a total of 300 application submissions that received a positive determination within the SAP Portal. The U.S. Census Bureau and the U.S. Bureau of

Economic Analysis estimate that the total burden for the collection of information for data security requirements and completion of training over the course of the three-year OMB clearance will be about 7,350 hours and, as a result, an average annual burden of 2,450 hours.

Estimated Total Annual Cost to Public: \$0. There is no cost to the respondent other than time to answer the information request.

Respondent's Obligation: Mandatory.

Legal Authority: Data collection for this project is authorized under 13 U.S.C. 9 and 23(c) for the Census Bureau and 22 U.S.C. 3104 and 15 CFR part 80 for BEA.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include, or summarize, each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Departmental PRA Compliance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2026-13665 Filed 7-6-26; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 260701-0158]

XRIN 0694-XC165

Notice of Request for Public Comments on Section 232 National Security Investigation of Anthracite Coal

AGENCY: Bureau of Industry and Security, Office of Strategic Industries and Economic Security, U.S. Department of Commerce.

ACTION: Notice of request for public comments.

SUMMARY: On June 29, 2026, the Secretary of Commerce initiated an investigation to determine the effects on the national security of imports of anthracite coal. This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended (Section 232). Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's (Department) Bureau of Industry and Security (BIS), Office of Strategic Industries and Economic Security. This notice identifies issues on which the Department is especially interested in obtaining the public's views.

DATES: Comments may be submitted at any time but must be received by July 21, 2026.

ADDRESSES: Comments on this notice may be submitted to the Federal rulemaking portal at: www.regulations.gov. The www.regulations.gov ID for this notice is BIS-2026-0298. Please refer to XRIN 0694-XC165 in all comments.

All filers using the portal should use the name of the person or entity submitting the comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC." Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL"

on the top of that page. The required corresponding non-confidential version of those comments must be clearly marked "PUBLIC." The file name of the non-confidential version should begin with the character "P." Any submissions with file names that do not begin with either a "BC" or a "P" will be assumed to be public and will be made publicly available at: <https://www.regulations.gov>. Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: Stephen Astle, Director, Defense Industrial Base Division, Office of Strategic Industries and Economic Security, Bureau of Industry and Security, U.S. Department of Commerce, (202) 482-4506, anthracite232@bis.doc.gov. For more information about the Section 232 program, including the regulations and the text of previous investigations, see www.bis.doc.gov/232.

SUPPLEMENTARY INFORMATION:

Background

On June 29, 2026, the Secretary of Commerce initiated an investigation under Section 232 (19 U.S.C. 1862) to determine the effects on national security of imports of anthracite coal. For the purposes of this investigation, anthracite coal encompasses products classified under HTSUS code 2701.11.0000 (Anthracite Coal) and 2701.12.0010 (Metallurgical Bituminous Coal). The scope of this investigation is primarily focused on anthracite coal and metallurgical bituminous coal products that are considered critical materials for domestic steel production and industrial processes, including their role as derivative articles of steel for potential coverage under Section 232 tariffs.

For the purpose of this investigation, "anthracite coal" refers to the highest rank of coal, characterized by its high carbon content (86–97 percent), low volatile matter, and superior heating value. Steelmakers use anthracite coal for electric arc furnace (EAF) steelmaking due to its purity and role as a foaming agent and charge ingredient, supporting mission-critical operations across industrial, defense, and infrastructure sectors.

Request for Public Comments

This investigation is being undertaken in accordance with part 705 of the

National Security Industrial Base Regulations (15 CFR parts 700 to 709) (NSIBR). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to BIS's Office of Strategic Industries and Economic Security no later than July 21, 2026. The Department is particularly interested in comments and information directed at the criteria listed in § 705.4 of the regulations as they affect national security, including the following:

- (i) the current and projected demand for anthracite coal in the United States;
- (ii) the extent to which domestic production of anthracite coal can meet domestic demand;
- (iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for anthracite coal;
- (iv) the concentration of U.S. imports of anthracite from a small number of suppliers or foreign nations and the associated risks;
- (v) the impact of foreign government subsidies and predatory trade practices on the competitiveness of anthracite producers in the United States;
- (vi) the economic impact of artificially suppressed prices of anthracite due to unfair foreign trade practices and state-sponsored overproduction;
- (vii) the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over supplies of anthracite coal;
- (viii) the feasibility of increasing domestic capacity for anthracite coal production to reduce import reliance;
- (ix) the impact of current trade policies on domestic production of anthracite coal, and whether additional measures, including tariffs or quotas, are necessary to protect national security;
- (x) the impact of the use or lack of use of anthracite coal on U.S. manufacturing employment;
- (xi) the potential for foreign control or exploitation of the anthracite coal supply chain;
- (xii) the future role of anthracite coal production of items essential to national security or in activities related to national security; and
- (xiii) any other relevant factors.

Material submitted by members of the public that is business confidential information will be exempted from public disclosure as provided for by § 705.6 of the regulations (see the **ADDRESSES** section of this notice). Communications from agencies of the United States Government will not be made available for public inspection. BIS does not maintain a separate public inspection facility. Requesters should

first view the Bureau's web page, which can be found at: <https://efoia.bis.doc.gov/> (see "Electronic FOIA" heading). If requesters cannot access the website, they may call (202) 482-0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published at 15 CFR 4.1, *et seq.*

Jessica Curyto,

Deputy Assistant Secretary for Strategic Trade.

[FR Doc. 2026-13663 Filed 7-2-26; 11:15 am]

BILLING CODE 3510-33-P

DEPARTMENT OF COMMERCE

International Trade Administration

Notice of Scope Ruling Applications Filed in Antidumping and Countervailing Duty Proceedings

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

SUMMARY: The U.S. Department of Commerce (Commerce) received scope ruling applications, requesting that scope inquiries be conducted to determine whether identified products are covered by the scope of antidumping duty (AD) and/or countervailing duty (CVD) orders and that Commerce issue scope rulings pursuant to those inquiries. In accordance with Commerce's regulations, we are notifying the public of the filing of the scope ruling applications listed below in the month of May 2026.

DATES: Applicable July 7, 2026.

FOR FURTHER INFORMATION CONTACT: Yasmin Bordas, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482-3813.

SUPPLEMENTARY INFORMATION:

Notice of Scope Ruling Applications

In accordance with 19 CFR 351.225(d)(3), we are notifying the public of the following scope ruling applications related to AD and CVD orders and findings filed in or around the month of May 2026. This notification includes, for each scope application: (1) identification of the AD and/or CVD orders at issue (19 CFR 351.225(c)(1)); (2) concise public descriptions of the products at issue, including the physical characteristics (including chemical, dimensional and technical characteristics) of the products

(19 CFR 351.225(c)(2)(ii)); (3) the countries where the products are produced and the countries from where the products are exported (19 CFR 351.225(c)(2)(i)(B)); (4) the full names of the applicants; and (5) the dates that the scope applications were filed with Commerce and the name of the ACCESS scope segment where the scope applications can be found.¹ This notice does not include applications which have been rejected and not properly resubmitted. The scope ruling applications listed below are available on Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), at <https://access.trade.gov>.

Scope Ruling Applications

Certain Freight Rail Couplers and Parts Thereof from the People's Republic of China (China) (A-201-857/A-570-145/C-570-146); Coupler Bodies and Knuckles;² produced in China and exported from Mexico; submitted by McConway & Torley LLC ("M&T"); March 10, 2026;³ ACCESS scope segment "SCO—Greenbrier"

Mattresses from Mexico (A-201-859); Therapeutic Air Mattress Support Surfaces and Related Mattress System Kits;⁴ produced in and exported from

¹ See *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 86 FR 52300, 52316 (September 20, 2021) (*Final Rule*) ("It is our expectation that the **Federal Register** list will include, where appropriate, for each scope application the following data: (1) identification of the AD and/or CVD orders at issue; (2) a concise public summary of the product's description, including the physical characteristics (including chemical, dimensional and technical characteristics) of the product; (3) the country(ies) where the product is produced and the country from where the product is exported; (4) the full name of the applicant; and (5) the date that the scope application was filed with Commerce.").

² The product is a ferrous alloy steel component manufactured in standard Association of American Railroads (AAR) configurations (E, E/F, and F), produced by casting, heat treatment, and machining, with optional surface finishing (e.g., shot blasting, coating, priming, or painting); it is supplied in finished or unfinished form, individual or joined as an assembly, and may be presented mounted or unmounted, with dimensions and tolerances conforming to AAR M-211 and/or AAR M-215 specifications.

³ This scope application was inadvertently omitted from the *Notice of Scope Ruling Applications Filed in Antidumping and Countervailing Duty Proceedings* **Federal Register** notice, 91 FR 25336 (May 8, 2026).

⁴ The products are therapeutic air mattress replacement support surfaces produced in common patient-care bed sizes (for example, 36 × 80 inches, 36 × 84 inches, 35 × 88 inches, 42 × 80 inches, 42 × 82 inches, and 48 × 82 inches), as well as other sizes depending on the intended application, including bariatric and pediatric dimensions. Each subject mattress surface consists primarily of an array of inflatable air cells/bladders that provides the core or main support system of the surface. The air cell core is enclosed by a removable cover

Mexico; submitted by Joerns Healthcare LLC (“Joerns”); May 2, 2026; ACCESS scope segment “SCO—Joerns Healthcare—Air mattress support surfaces”

Mobile Access Equipment and Subassemblies Thereof from the China (A–570–139/C–570–140); Certain Steel Components for Mobile Access Equipment;⁵ produced in China and exported from China; submitted by Hunan Sinoboom Machinery Equipment Co., Ltd. (“Sinoboom Machinery”); May 13, 2026; ACCESS scope segment “SCO—Boom Lift Components”

Notification to Interested Parties

This list of scope ruling applications is not an identification of scope inquiries that have been initiated. In accordance with 19 CFR 351.225(d)(1), if Commerce has not rejected a scope ruling application nor initiated the scope inquiry within 30 days after the filing of the application, the application will be deemed accepted and a scope inquiry will be deemed initiated the following day—day 31.⁶ Commerce’s practice generally dictates that where a deadline falls on a weekend, Federal holiday, or other non-business day, the appropriate deadline is the next business day.⁷ Accordingly, if the 30th

(ticking), and the surface is designed to be placed on a hospital-style bed frame or similar patient-care bed frame.

⁵ The products are an array of steel components for mobile access equipment (MAE), including axles which are composed of a front and rear axle. The front and the rear axles are attached to the front and the rear ends of the chassis frame, respectively, through a fixed shaft in the middle. The wheel assemblies, including brakes and wheels, are installed on both ends of the axle, enabling the MAE to move. Additionally, the front axle connects to each wheel with a steering module. The links include the upper link and the lower link, both of which are steel components that connect the boom assembly in a telescopic boom lift to the chassis. One end of the links connects to the boom assembly, and the other end of the links connects to the chassis. All the connections are done by holes in the links and pins that go through the holes. The connection brackets are steel components that connect sections of the articulating boom. The lower connection bracket connects the first (bottom) section and the second (middle) section of the boom. The upper connection bracket connects the second (middle) section and the third (upper) section of the boom. The last bracket connects the third (upper) section and the jib or the platform. The connection brackets are made by welding together cut-to-shape and drilled steel plates, and other smaller steel parts.

⁶ In accordance with 19 CFR 351.225(d)(2), within 30 days after the filing of a scope ruling application, if Commerce determines that it intends to address the scope issue raised in the application in another segment of the proceeding (such as a circumvention inquiry under 19 CFR 351.226 or a covered merchandise inquiry under 19 CFR 351.227), it will notify the applicant that it will not initiate a scope inquiry, but will instead determine if the product is covered by the scope at issue in that alternative segment.

⁷ See *Notice of Clarification: Application of “Next Business Day” Rule for Administrative*

day after the filing of the application falls on a non-business day, the next business day will be considered the “updated” 30th day, and if the application is not rejected or a scope inquiry initiated by or on that particular business day, the application will be deemed accepted and a scope inquiry will be deemed initiated on the next business day which follows the “updated” 30th day.⁸

In accordance with 19 CFR 351.225(m)(2), if there are companion AD and CVD orders covering the same merchandise from the same country of origin, the scope inquiry will be conducted on the record of the AD proceeding. Further, please note that pursuant to 19 CFR 351.225(m)(1), Commerce may either apply a scope ruling to all products from the same country with the same relevant physical characteristics, (including chemical, dimensional, and technical characteristics) as the product at issue, on a country-wide basis, regardless of the producer, exporter, or importer of those products, or on a company-specific basis.

For further information on procedures for filing information with Commerce through ACCESS and participating in scope inquiries, please refer to the Filing Instructions section of the Scope Ruling Application Guide, at https://access.trade.gov/help/Scope_Ruling_Guidance.pdf. Interested parties, apart from the scope ruling applicant, who wish to participate in a scope inquiry and be added to the public service list for that segment of the proceeding must file an entry of appearance in accordance with 19 CFR 351.103(d)(1) and 19 CFR 351.225(n)(4). Interested parties are advised to refer to the case segment in ACCESS as well as 19 CFR 351.225(f) for further information on the scope inquiry procedures, including the timelines for the submission of comments.

Please note that this notice of scope ruling applications filed in AD and CVD proceedings may be published before any potential initiation, or after the initiation, of a given scope inquiry based on a scope ruling application identified in this notice. Therefore, please refer to the case segment on ACCESS to determine whether a scope ruling application has been accepted or rejected and whether a scope inquiry has been initiated.

Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended, 70 FR 24533 (May 10, 2005).

⁸ This structure maintains the intent of the applicable regulation, 19 CFR 351.225(d)(1), to allow day 30 and day 31 to be separate business days.

Interested parties who wish to be served scope ruling applications for a particular AD or CVD order may file a request to be included on the annual inquiry service list during the anniversary month of the publication of the AD or CVD order in accordance with 19 CFR 351.225(n) and Commerce’s procedures.⁹

Interested parties are invited to comment on the completeness of this monthly list of scope ruling applications received by Commerce. Any comments should be submitted to Scot Fullerton, Acting Deputy Assistant Secretary for AD/CVD Operations, Enforcement and Compliance, International Trade Administration, via email to CommerceCLU@trade.gov.

This notice of scope ruling applications filed in AD and CVD proceedings is published in accordance with 19 CFR 351.225(d)(3).

Dated: July 1, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–13645 Filed 7–6–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF847]

Endangered Species Act; Taking of Endangered and Threatened Species; Permit Modification; Permit No. 23861

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

ACTION: Notice; receipt of modification request for an Endangered Species Act Incidental Take Permit; request for comments and information.

SUMMARY: Notice is hereby given that the Midwest Biodiversity Institute (MBI) has applied in due form for a permit modification pursuant to the Endangered Species Act of 1973, as amended (ESA). The permit application is for the incidental take of ESA-listed shortnose sturgeon (*Acipenser brevirostrum*), Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*) from the Gulf of Maine (GOM) and New York Bight (NYB) Distinct Population Segments (DPSs), and Atlantic salmon (*Salmo salar*) from the GOM DPS

⁹ See *Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*, 86 FR 53205 (September 27, 2021).

associated with the otherwise lawful sampling of non-ESA listed fish in the Lower Kennebec, Middle Kennebec, and Sebasticook Rivers in Maine. NMFS is furnishing this notice in order to allow other agencies and the public an opportunity to review and comment on the application materials. All comments received will become part of the public record and will be available for review.

DATES: Comments and information must be received no later than August 6, 2026.

ADDRESSES: The application is available for download and review at <https://www.fisheries.noaa.gov/national/endangered-species-conservation/incidental-take-permits> and at <http://www.regulations.gov>. The application is also available upon request (see **FOR FURTHER INFORMATION CONTACT**).

You may submit comments, identified by NOAA–NMFS–2026–1717, by Electronic Submission: Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov> and enter NOAA–NMFS–2026–1717 in the Search box. Click on the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

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 <http://www.regulations.gov> without change. All Personal Identifying Information (e.g., name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. We will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Celeste Stout, Office of Protected Resources, NMFS, (301) 427–8436, celeste.Stout@noaa.gov.

SUPPLEMENTARY INFORMATION: Section 9 of the ESA and Federal regulations prohibit the “taking” of a species listed as endangered or threatened. The ESA defines “take” to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may issue permits, under limited circumstances, to take listed species incidental to, and not the purpose of, otherwise lawful activities. Section 10(a)(1)(B) of the ESA provides for authorizing incidental take of listed

species. NMFS regulations governing permits for threatened and endangered species are promulgated at 50 CFR 222.307.

Species Covered in This Notice

The following species are included in the conservation plan and permit application: Atlantic salmon (*Salmo salar*)—Gulf of Maine DPS, Atlantic sturgeon (*Acipenser oxyrinchus oxyrinchus*)—Gulf of Maine DPS and New York Bight DPS, and shortnose sturgeon (*Acipenser brevirostrum*).

Background

MBI has conducted annual fish assemblage sampling in the Lower Kennebec River since 2002 and the Lower Sebasticook River since 2008 under ESA coverage initially provided through section 7 incidental take statements and, since December 15, 2020, through ESA section 10 Incidental Take Permit (ITP) No. 23861. The permit authorized incidental take of ESA-listed shortnose sturgeon, Atlantic sturgeon, and Atlantic salmon associated with electrofishing surveys targeting non ESA-listed fish species in the Kennebec River drainage. On September 9, 2022, NMFS modified the ITP to expand the study area into the Middle Kennebec River to support collection of baseline fisheries data associated with anticipated dam removal and fish passage restoration activities. MBI now requests a modification to the existing ITP to increase the annual incidental take limits for shortnose sturgeon and Atlantic salmon based on increased encounters during ongoing monitoring, expanded study area coverage, and increased occurrence of juvenile and adult Atlantic salmon in the Kennebec River system. Specifically, MBI requests an increase in the annual authorized take limit for shortnose sturgeon by two, adult Atlantic salmon by one, and is requesting take of 10 juvenile Atlantic salmon annually. MBI requests that the take for the remainder of the permit duration be in 2-year rolling takes. MBI proposes to continue long-term electrofishing surveys to assess fish assemblage health and monitor resident and diadromous fish populations in the Kennebec River drainage.

Conservation Plan

Section 10 of the ESA specifies that no permit may be issued unless an applicant submits an adequate conservation plan. The conservation plan prepared by MBI describes measures designed to minimize and mitigate the impacts of incidental take of ESA-listed shortnose sturgeon,

Atlantic sturgeon, and Atlantic salmon associated with electrofishing surveys conducted in the Kennebec River drainage. MBI proposes to continue implementing measures to avoid and minimize take, including: (1) limiting sampling to mid-September through mid-October to reduce the likelihood of encounters with early life stages and periods of peak species presence; (2) coordinating with NOAA and Maine Department of Marine Resources (DMR) prior to sampling activities regarding recent detections and stocking locations of ESA-listed species; (3) ensuring all personnel are trained in electrofishing procedures, listed species identification, and species handling protocols; and (4) operating electrofishing equipment in a manner that minimizes injury or mortality, including reducing pulse frequency in areas with prior listed species encounters, suspending electrofishing immediately upon observation of a listed species affected by the electric field, and ceasing sampling activities for at least five minutes or until fish have departed the area. Additionally, sampling will not occur when water temperatures exceed 22 °C. MBI will continue reporting all listed species encounters to NOAA within 24 hours and submit annual monitoring reports summarizing sampling activities and incidental takes.

MBI states that boat-mounted pulsed DC electrofishing remains the most effective and least harmful method for conducting large-river fish assemblage surveys. Alternative sampling methods were considered but rejected because they are less effective, more resource intensive, and may require greater handling of listed species; thereby, increasing the risk of injury or mortality. MBI further proposes adaptive management measures, including monitoring incidental take levels throughout the sampling season and modifying, reducing, or ceasing sampling activities if authorized take limits are approached. Based on more than two decades of sampling with no documented mortality of ESA-listed species, MBI concludes that the proposed conservation measures minimize the potential for adverse effects to listed species while supporting long-term monitoring of fish assemblages in the Kennebec River system.

MBI also proposes several supplemental conservation and outreach measures intended to support broader ESA-listed species recovery efforts and public awareness. These measures include collaboration with the NOAA Fisheries Office of Habitat Conservation Restoration Center in

Maine to conduct fish assemblage sampling upstream of the Lemon Stream Dam in Starks, Maine. Sampling at this location is intended to provide state and federal agency personnel with direct exposure to electrofishing procedures, habitat conditions, and associated native and non-native fish assemblages to inform future recovery planning for ESA-listed species. No additional ESA take authorization would be required for activities at this site because ESA-listed species are not expected to occur there.

As an additional conservation-related measure, MBI will continue presenting research findings and monitoring results at regional technical conferences and outreach events to increase awareness of the ecological importance of the middle and lower Kennebec River for ESA-listed species. MBI currently presents annually at the Northeast Aquatic Biologists Conference and, with support from The Nature Conservancy, is considering additional presentations at the Maine Atlantic Salmon Forum, Maine Water Conference, and Northeast Fish and Wildlife Conference, as well as presentations to donors and stakeholders associated with the Kennebec River Trust. MBI states that these outreach efforts are intended to build support for restoration of Atlantic salmon access to historic spawning habitat within the Sandy River watershed.

National Environmental Policy Act

Issuing an ESA section 10(a)(1)(B) permit constitutes a Federal action requiring NMFS to comply with the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) as implemented by 40 CFR parts 1500–1508 and NOAA Administrative Order 216–6A, Environmental Review Procedures for Implementing the National Policy Act (1999). NMFS has preliminarily determined that the proposed action falls within a category of actions that are categorically excluded from the requirement to prepare an Environmental Assessment or Environmental Impact Statement, as the action does not individually or cumulatively have a significant effect on the human environment.

Next Steps

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the application, associated documents, and comments received during the comment period to determine whether the application meets the requirements of section 10(a) of the ESA. If NMFS determines that the requirements are met, a permit will be issued for incidental takes of ESA-listed

sturgeon. The final NEPA and permit determinations will not be made until after the end of the comment period. NMFS will publish a record of its final action in the **Federal Register**.

Dated: July 1, 2026.

Larissa Plants,

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

[FR Doc. 2026–13706 Filed 7–6–26; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2013–0022]

Agency Information Collection Activities; Extension of Collection; Safety Standard for Adult Portable Bed Rails

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Information Collection; Request for Comment.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission (CPSC or Commission) announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval of information collection requirements associated with the Safety Standard for Adult Portable Bed Rails. OMB previously approved the collection of information under control number 3041–0192. OMB's most recent extension of approval will expire on August 31, 2026. On April 24, 2026, CPSC published a notice in the **Federal Register** to announce the agency's intention to seek extension of approval of the collection of information. The Commission did not receive any public comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to OMB a request for extension of approval of that collection of information.

DATES: Submit comments on the collection of information by August 6, 2026.

ADDRESSES: Submit comments about this request by email: OIRA_submission@omb.eop.gov or fax: 202–395–3888. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. Written comments that are sent to OMB also should be submitted electronically at [http://](http://www.regulations.gov)

www.regulations.gov, under Docket No. CPSC–2013–0022.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Safety Standard for Adult Portable Bedrails.

OMB Number: 3041–0192.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of adult portable bed rails.

General Description of Collection: The Safety Standard for Adult Portable Bed Rails (16 CFR part 1270) addresses the unreasonable risk of injury and death associated with entrapment and other hazards from adult portable bed rails (APBRs). The standard incorporates by reference ASTM F3186–17, *Standard Specification for Adult Portable Bed Rails and Related Products*, with modifications. 16 CFR 1270.2. Sections 9, 10, and 11 of ASTM F3186–17 contain requirements for labels, warnings and instructional literature.

Estimated Number of Respondents: CPSC is aware of 12 known entities supplying APBRs to the U.S. market.

Estimated Time per Response: On average, each entity will respond approximately six times to accommodate the CPSC required labeling and instructional literature for various APBR models each year. The estimated time for required labeling is about eight hours per model. Therefore, the estimated burden associated with labels is 576 hours (12 entities × 6 models per entity × 8 hours per model = 576 hours). The estimated time for required instructional material is 24 hours per model. Each entity responds for an average of six different APBR models. Therefore, the estimated burden associated with instructional literature is 1,728 hours (12 entities × 6 models per entity × 24 hours per model).

Total Estimated Annual Burden: Based on the estimated time response for labeling (576 hours) and instructional literature (1,728 hours), CPSC expects the estimated burden for this collection of information is approximately 2,304 hours.

Total Estimated Annual Cost to Respondents: CPSC estimates the hourly compensation for the time to create required labels is \$42.03 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” June 2025), total compensation for all sales and

office workers in goods producing private industries: https://www.bls.gov/news.release/archives/ecec_09122025.htm. Therefore, the estimated annual cost to industry associated with the labeling requirements is approximately \$24,209 (\$42.03 per hour × 576 hours = \$24,209.28) and, the estimated annual cost to industry associated with the instructional material requirements is approximately \$72,628 (\$42.03 per hour × 1,728 hours = \$72,627.84).

Accordingly, CPSC estimates that the total burden cost for firms to comply with labeling and instructional material requirements to be \$96,837 annually (\$24,209 + \$72,628).

Alberta E. Mills,
Secretary, Consumer Product Safety Commission.

[FR Doc. 2026–13643 Filed 7–6–26; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2026–SCC–1387]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; William D Ford Federal Direct Loan Program Repayment Plan Selection Form

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 August 6, 2026.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. Reginfo.gov provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting

documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carolyn Rose, (202) 453–5967.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: William D Ford Federal Direct Loan Program Repayment Plan Selection Form.

OMB Control Number: 1845–0014.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 660,000.

Total Estimated Number of Annual Burden Hours: 110,220.

Abstract: The Fixed Payment Repayment Plan Request form serves as the means by which Direct Loan borrowers notify the Department of their choice of an initial fixed payment repayment plan as described in 34 CFR 685.208 before their loans enter repayment. The form may also be used by borrowers to request a change to one of these plans after their loans have entered repayment. If a borrower does not select an initial repayment plan, the borrower is placed on the Standard Repayment Plan or the Tiered Standard Repayment Plan in accordance with 34 CFR 685.210(a)(2).

The One Big Beautiful Bill Act (OBBBA) signed into law on July 4, 2025, made statutory changes to the Higher Education Act of 1965 as amended (the HEA) regarding Direct Loans that impact regulatory requirements related to this information collection.

This is a request for a revision of the current information collection to include the new regulatory

requirements in order to comply with the OBBBA.

Ross Santy,

Chief Data Officer Office of Planning, Evaluation and Policy Development.

[FR Doc. 2026–13647 Filed 7–6–26; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator and Foreign Utility Company Status

	Docket Nos.
Canyon Peak Power LLC	EG26–198–000
Hillsboro Solar Project LLC	EG26–199–000
Bexar ProjectCo 4, LLC	EG26–200–000
Bexar ProjectCo 3, LLC	EG26–201–000
Bexar ProjectCo 2, LLC	EG26–202–000
Bexar ProjectCo 1, LLC	EG26–203–000
Arroyo ProjectCo 7, LLC	EG26–204–000
Arroyo ProjectCo 6, LLC	EG26–205–000
Arroyo ProjectCo 5, LLC	EG26–206–000
Arroyo ProjectCo 4, LLC	EG26–207–000
Arroyo ProjectCo 3, LLC	EG26–208–000
Arroyo ProjectCo 2, LLC	EG26–209–000
Arroyo ProjectCo 1, LLC	EG26–210–000
Snapdragon Solar, LLC	EG26–211–000
E South Hero Co. LLC	EG26–212–000
Honey Mesquite Wind Farm, LLC	EG26–213–000
Yellow Cat Wind LLC	EG26–214–000
Grant Solar, LLC	EG26–215–000
Crockett Cogeneration, LLC	EG26–216–000
Chicopee Energy BESS LLC	EG26–217–000
Framingham BESS LLC	EG26–218–000
Soltage Maspeth ESS, LLC	EG26–219–000
RE Cobalt LLC	EG26–220–000
Tehuacana Creek Solar LLC	EG26–221–000
Alliance NYGT, LLC	EG26–222–000
EdSan 2C Solar, LLC	EG26–223–000
EdSan 2C Storage, LLC	EG26–224–000
EdSan 5 Solar, LLC	EG26–225–000
Edwards Sanborn Reserve, LLC ..	EG26–226–000
Sundance Solar, LLC	EG26–227–000
I Squared Capital	FC26–15–000

Take notice that during the month of June 2026, the status of the above-captioned entities as Exempt Wholesale Generators or Foreign Utility Companies became effective by operation of the Commission’s regulations. 18 CFR 366.7(a) (2025).

Dated: July 1, 2026

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–13679 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Project No. 15249–002]

Lewis Ridge Pumped Storage, LLC; Notice of Reasonable Period of Time for Water Quality Certification Application

On June 24, 2026, Lewis Ridge Pumped Storage, LLC (Lewis Ridge LLC), submitted to the Federal Energy Regulatory Commission (Commission) documentation from the Kentucky Department of Environmental Protection (Kentucky DEP) that it received a complete request for a Clean Water Act section 401(a)(1) water quality certification as defined in 40 CFR 121.5, from Lewis Ridge LLC, in conjunction with the above captioned project on June 12, 2026. Pursuant to the Commission's regulations,¹ we hereby notify the Kentucky DEP of the following:

Date of Receipt of the Certification Request: June 12, 2026.

Reasonable Period of Time to Act on the Certification Request: One year, June 12, 2027.

If Kentucky DEP fails or refuses to act on the water quality certification request on or before the above date, then the certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

(Authority: 18 CFR 2.1)

Dated: July 1, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–13696 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission**

[Docket No. IC26–39–000]

Commission Information Collection Activities (FERC–556); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–556 (OMB Control No. 1902–0075) Certification of Qualifying Facility (QF) Status for a Small Power Production or Cogeneration Facility.

DATES: Comments on collections of information are due September 8, 2026.

ADDRESSES: You may submit your comments (identified by Docket No. IC26–39–000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov and telephone at (202) 502–6468.

SUPPLEMENTARY INFORMATION:

Title: FERC–556, Certification of Qualifying Facility (QF) Status for a Small Power Production or Cogeneration Facility

OMB Control No.: 1902–0075

Type of Request: Three-year extension of the FERC–556 information collection requirements with no changes to the current reporting requirements.

Abstract: Form No. 556 is required to implement sections 201 and 210 of the Public Utility Regulatory Policies Act of 1978¹ (PURPA). FERC is authorized, under those sections, to encourage cogeneration and small power production and to prescribe such rules as necessary to carry out the statutory directives.

A primary statutory objective is efficient use of energy resources and facilities by electric utilities. One means of achieving this goal is to encourage production of electric power by cogeneration facilities, which make use of reject heat associated with commercial or industrial processes, and by small power production facilities, which use renewable resources and other wastes. PURPA encourages the development of small power production facilities and cogeneration facilities that meet certain technical and corporate criteria through establishment of various regulatory benefits. Facilities that meet these criteria are called Qualifying Facilities (QFs).

FERC's regulations in 18 CFR part 292, as relevant here, specify: (a) the certification procedures which must be followed by owners or operators of small power production and cogeneration facilities; (b) the criteria which must be met; (c) the information which must be submitted to FERC in order to obtain qualifying status; and (d) the PURPA benefits which are available to QFs to encourage small power production and cogeneration.

18 CFR part 292 also exempts some QFs from certain corporate, accounting, reporting, and rate regulation requirements of the Federal Power Act,² certain state laws, and the Public Utility Holding Company Act of 2005.³

Type of Respondents: Facilities that are self-certifying their status as a cogenerator or small power producer or that are submitting an application for FERC certification of their status as a cogenerator or small power producer.

Estimate of Annual Burden: The Commission estimates the burden and cost for this information collection as follows:

¹ 16 U.S.C. 796 and 824i.

² 16 U.S.C. 791a, *et seq.*

³ 42 U.S.C. 16451 through 165463.

¹ 18 CFR 4.34(b)(5).

FERC-556—CERTIFICATION OF QUALIFYING FACILITY STATUS FOR A SMALL POWER PRODUCTION OR COGENERATION FACILITY

Facility type	Filing type	Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & cost per response ⁴	Total annual burden hours & total annual cost (rounded)	Cost per respondent (\$)(rounded)
		(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
Cogeneration Facility >1 MW ⁵ .	Self-certification	50	2.14	107	3.54 hrs; \$361.08	378.78 hrs; \$38,635.56 ...	\$772.71
Cogeneration Facility >1 MW.	Application for FERC certification.	0	2.14	0	50 hrs; \$5,100	0 hrs; \$0	0
Small Power Production Facility >1 MW.	Self-certification	2,924	2.14	6,257.36	3.54 hrs; \$361.08	22,151.05 hrs; \$2,259,407.55.	772.71
Small Power Production Facility >1 MW.	Application for FERC certification.	0	2.14	0	50 hrs; \$5,100	0 hrs; \$0	0
Cogeneration and Small Power Production Facility ≤1 MW ⁶ .	Self-certification	1,422	2.14	3,043.08	3.54 hrs; \$361.08	10,772.50 hrs; \$1,098,795.33.	772.71
Total		4,396		9,407.44		33,302 hrs; \$3,396,837.66	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 1, 2026.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2026-13692 Filed 7-6-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP26-546-000]

Wyoming Interstate Company, L.L.C., Fort Union Gas Gathering, L.L.C.; Notice of Application and Establishing Intervention Deadline

Take notice that on June 23, 2026, Wyoming Interstate Company, L.L.C. (WIC), Post Office Box 1087, Colorado Springs, Colorado 80944, and Fort Union Gas Gathering, L.L.C. (FUGG), Two North Nevada Avenue, Colorado Springs, Colorado 80903, (collectively, the Applicants), filed a joint application under section 7 of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations requesting authorization for FUGG Capacity Lease Project (Project). The Project consists of the lease of capacity on FUGG's system by WIC of 50,000 dekatherms per day of natural gas transportation capacity, from a new receipt point on FUGG system located in Campbell County, Wyoming, to an existing interconnection between FUGG and WIC in Converse County, Wyoming. Also, FUGG is requesting a limited jurisdiction certificate authorizing FUGG to operate the leased capacity to allow WIC to transport interstate natural gas on FUGG's gathering system without subjecting FUGG's gathering operations to the Commission's NGA jurisdiction. The Project will allow WIC to provide interstate natural gas transportation requested by ONEOK Rockies Midstream LLC, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all

interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

Any questions regarding the proposed project should be directed to Francisco Tarin, Director of Regulatory, Post Office Box 1087, Colorado Springs, Colorado 80944, by phone at (719) 667-7517, or by email at Francisco_Tarin@kindermorgan.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,¹ within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS)

⁴ The Commission staff believes that industry is similarly situated in terms of wages and benefits. Therefore, cost estimates are based on FERC's 2026 average annual wage (and benefits) for a full-time employee of \$213,003 (or \$102.00/hour).

⁵ MW = megawatt.

⁶ The regulation at 18 CFR 292.203(d) exempts small power production facilities and cogeneration facilities from self-certification if they have a net power production capacity of 1 MW or less. However, we are disclosing burdens for these filings because some facilities seek status as qualifying facilities regardless of their capacity.

¹ 18 CFR 157.9.

or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on July 22, 2026. How to file protests, motions to intervene, and comments is explained below.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation (OPP) at (202) 502-6595 or OPP@ferc.gov.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)² and 385.211³ of the Commission's regulations under the NGA, any person⁴ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁵ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before 5:00 p.m. Eastern Time on July 22, 2026.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please

reference the Project docket number CP26-546-000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP26-546-000).

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁶ has

the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁷ and the regulations under the NGA⁸ by the intervention deadline for the project, which is 5:00 p.m. Eastern Time on July 22, 2026. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP26-546-000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP26-546-000.

To file via USPS: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE Washington, DC 20426.

To file via any other courier: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

The Commission encourages electronic filing of motions to intervene

² 18 CFR 157.10(a)(4).

³ 18 CFR 385.211.

⁴ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁵ 18 CFR 385.2001.

⁶ 18 CFR 385.102(d).

⁷ 18 CFR 385.214.

⁸ 18 CFR 157.10.

(option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail at: Francisco Tarin, Director of Regulatory, Post Office Box 1087, Colorado Springs, Colorado 80944, or by email (with a link to the document) at Francisco_Tarin@kindermorgan.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed⁹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹⁰ Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.¹¹ A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from OPP at (202) 502–6595 or on the FERC website at www.ferc.gov using the “eLibrary” link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Intervention Deadline: 5:00 p.m. Eastern Time on July 22, 2026.

(Authority: 18 CFR 2.1)

Dated: July 1, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026–13695 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC26–37–000]

Commission Information Collection Activities (FERC–561); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–561 (OMB Control No. 1902–0099), Annual Report of Interlocking Directorates.

DATES: Comments on collections of information are due September 8, 2026.

ADDRESSES: You may submit your comments (identified by Docket No. IC26–37–000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- **Electronic Filing:** Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- **Mail via U.S. Postal Service Only:** Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE, Washington, DC 20426.

- **Hand (including courier) delivery:** Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email

at ferconlinesupport@ferc.gov, or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov and telephone at (202) 502–6468.

SUPPLEMENTARY INFORMATION:

Title: FERC–561, Interlocking Directorates.

OMB Control No.: 1902–0099.

Abstract: The FERC Form 561 responds to the Federal Power Act (FPA) requirements for annual reporting of similar types of positions which public utility officers and directors hold with financial institutions, insurance companies, utility equipment and fuel providers, and with any of an electric utility's 20 largest purchasers of electric energy (*i.e.*, the 20 entities with high expenditures of electricity). The FPA specifically defines most of the information elements in the Form 561 including the information that must be filed, the required filers, the directive to make the information available to the public, and the filing deadline.

The Commission uses the information required by 18 CFR 131.31 and collected by the Form 561 to implement the FPA requirement that those who are authorized to hold interlocked directorates annually disclose all the interlocked positions held within the prior year. The Form 561 data identifies persons holding interlocking positions between public utilities and other entities, allows the Commission to review these interlocking positions, and allows identification of possible conflicts of interest.

Type of Respondents: Each officer or director of a public utility also holding the position of officer, director, partner, appointee, or representative of any other entity listed in section 305(c)(2) of the FPA (including but not limited to organizations primarily engaged in the business of providing financial services or credit, insurance companies, security underwriters, electrical equipment suppliers, fuel provider, and any entity which is controlled by one or more of these entities).

Estimate of Annual Burden: The Commission estimates the total annual burden and cost¹ for this information collection as follows:

⁹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹⁰ 18 CFR 385.214(c)(1).

¹¹ 18 CFR 385.214(b)(3) and (d).

¹ Commission staff estimates that the industry's skill set and cost (for wages and benefits) for FERC–561 are approximately the same as the

Commission's average cost. The FERC 2026 average salary plus benefits for one FERC full-time equivalent (FTE) is \$213,003/year (or \$102.00/hour).

FERC FORM 561, ANNUAL REPORT OF INTERLOCKING DIRECTORATES

Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden & cost per response	Total annual burden hours & total annual cost	Cost per respondent (\$)
(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5) ÷ (1)
2,700	1	2,700	0.25 hrs.; \$25.50	675 hrs.; \$68.850	\$25.50

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 1, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-13694 Filed 7-6-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC26-41-000]

Commission Information Collection Activities (FERC-549D); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC-549D (OMB Control No. 1902-0253), Quarterly Transportation and Storage Report For Intrastate Natural Gas and Hinshaw Pipelines.

DATES: Comments on collections of information are due September 8, 2026.

ADDRESSES: You may submit your comments (identified by Docket No. IC26-41-000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208-3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov and telephone at (202) 502-6468.

SUPPLEMENTARY INFORMATION:

Title: FERC-549D, Quarterly Transportation and Storage Report for Intrastate Natural Gas and Hinshaw Pipelines.

OMB Control No.: 1902-0253

Type of Request: Three-year extension of the FERC-549D information collection requirements with no changes to the current reporting requirements.

Abstract: The reporting requirements under FERC-549D are required to carry out the Commission's policies in accordance with the general authority in Section 1(c) of the Natural Gas Act (NGA)¹ and Section 311 of the Natural Gas Policy Act of 1978 (NGPA).² This collection promotes transparency by making available intrastate and Hinshaw pipeline transactional information. The Commission collects the data on a standardized form with all requirements outlined in 18 CFR 284.126.

The FERC-549D collects the following information:

- Full legal name and identification number of the shipper receiving service, including whether the pipeline and the shipper are affiliated;

- Type of service performed;
- The rate charged under each contract;

- The primary receipt and delivery points for each contract;

- The quantity of natural gas the shipper is entitled to transport, store, or deliver for each transaction;

- The duration of the contract, specifying the beginning and (for firm contracts only) ending month and year of current agreement;

- Total volumes transported, stored, injected or withdrawn for the shipper; and

- Annual revenues received for each shipper, excluding revenues from storage services.

Filers submit the Form-549D on a quarterly basis.

Type of Respondents: Intrastate natural gas pipelines under NGPA Section 311 authority and Hinshaw pipelines.

Estimate of Annual Burden:³ The Commission estimates the annual public reporting burden and cost⁴ for FERC-549D as shown in the following table: FERC-549D (Quarterly Transportation and Storage Report for Intrastate Natural Gas and Hinshaw Pipelines).

¹ 15 U.S.C.. 717(c).

² 15 U.S.C.. 3371.

³ The Commission defines burden as the total time, effort, or financial resources expended by

persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

⁴ The Commission staff estimates that the industry's hourly cost for wages plus benefits is similar to the Commission's \$102.00 FY 2026 average hourly cost for wages and benefits.

FERC-549D—QUARTERLY TRANSPORTATION AND STORAGE REPORT FOR INTRASTATE NATURAL GAS AND HINSHAW PIPELINES

	Average annual number of respondents	Average annual number of responses per respondent	Average annual total number of responses	Average burden hrs. & Cost (\$) per response	Total annual burden hours & total annual cost (\$) (rounded)	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) *(4) = (5)	(5) ÷ (1)
PDF filings	134	2	268	12.5 hrs.; \$1,275	3,350 hrs.; \$341,700 ...	\$2,550
Total			268		3,350 hrs.; \$341,700 ...	

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 1, 2026.
Debbie-Anne A. Reese,
Secretary.
[FR Doc. 2026-13698 Filed 7-6-26; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2221-041]

The Empire District Electric Company;
Notice of Programmatic Agreement
Consultation Meeting

- a. *Project Name and Number:* Ozark Beach Hydroelectric Project No. 2221-041.
- b. *Applicant:* The Empire District Electric Company.
- c. *Date and Time of Meeting:* Wednesday, August 5, 2026, at 11:00 a.m. Eastern Daylight Time.
- d. *Meeting Location:* Teleconference.
- e. *FERC Contact:* Michael Davis, (202) 502-8339, michael.davis@ferc.gov.
- f. *Purpose of Meeting:* Commission staff will hold a meeting with representatives from the Advisory Council on Historic Preservation (Advisory Council), Missouri State Historic Preservation Office (Missouri SHPO), Osage Nation, Delaware Nation, and The Empire District Electric Company to discuss the Programmatic

Agreement for the Ozark Beach Hydroelectric Project, which was issued on February 2, 2025 and February 10, 2026.
g. Intervenor in the referenced proceeding may attend the meeting; however, participation will be limited to representatives of the Advisory Council, Missouri SHPO, Osage Nation, Delaware Nation, The Empire District Electric Company, and Commission staff. A summary of the meeting will be placed in the public record of this proceeding. Intervenor planning to attend the meeting should notify Michael Davis at (202) 502-8339 or michael.davis@ferc.gov by 5 p.m. Eastern Time, Wednesday, July 29, 2026.
(Authority: 18 CFR 2.1)
Dated: July 1, 2026.
Debbie-Anne A. Reese,
Secretary.
[FR Doc. 2026-13697 Filed 7-6-26; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:
Filings Instituting Proceedings
Docket Numbers: PR26-67-000.
Applicants: Banquete Hub LLC.
Description: 284.123 Rate Filing: MBR Info Filing GCX Expansion to be effective N/A.
Filed Date: 6/30/26.
Accession Number: 20260630-5136.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: PR26-68-000.
Applicants: Kinder Morgan Keystone Gas Storage LLC.
Description: 284.123 Rate Filing: MBR Information Filing (GCX Acquisition) to be effective N/A.
Filed Date: 6/30/26.
Accession Number: 20260630-5138.

Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: PR26-69-000.
Applicants: Kinder Morgan Texas Pipeline LLC.
Description: 284.123 Rate Filing: MBR Informational Filing (GCX Expansion) to be effective N/A.
Filed Date: 6/30/26.
Accession Number: 20260630-5139.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: RP26-948-000.
Applicants: Northern Natural Gas Company.
Description: 4(d) Rate Filing: 20260630 Negotiated Rate Filing to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630-5152.
Comment Date: 5 p.m. ET 7/13/26.
Docket Numbers: RP26-949-000.
Applicants: NEXUS Gas Transmission, LLC.
Description: 4(d) Rate Filing: Negotiated Rates Castleton 860652 eff 7-01-2026 to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630-5217.
Comment Date: 5 p.m. ET 7/13/26.
Docket Numbers: RP26-950-000.
Applicants: HE&D Offshore, L.P., DCOR Shelf, LLC.
Description: Joint Petition for Limited Waiver of Capacity Release Regulations, et al. of HE&D Offshore, L.P., et al.
Filed Date: 6/30/26.
Accession Number: 20260630-5279.
Comment Date: 5 p.m. ET 7/13/26.
Docket Numbers: RP26-951-000.
Applicants: Scout V Hugoton Gathering, LP.
Description: 4(d) Rate Filing: Annual Filing of Fuel Retention Percentages to be effective 8/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701-5028.
Comment Date: 5 p.m. ET 7/13/26.
Docket Numbers: RP26-952-000.
Applicants: Mountain Valley Pipeline, LLC.
Description: 4(d) Rate Filing: Negotiated Rate Capacity Release Agreements—7/1/2026 to be effective 7/1/2026.

Filed Date: 7/1/26.

Accession Number: 20260701–5030.

Comment Date: 5 p.m. ET 7/13/26.

Docket Numbers: RP26–953–000.

Applicants: Equitrans, L.P.

Description: 4(d) Rate Filing;

Negotiated Rate Capacity Release Agreements—7/1/2026 to be effective 7/1/2026.

Filed Date: 7/1/26.

Accession Number: 20260701–5042.

Comment Date: 5 p.m. ET 7/13/26.

Docket Numbers: RP26–954–000.

Applicants: Northern Border Pipeline Company.

Description: 4(d) Rate Filing; 2026 Agreement Clean-Up to be effective 8/1/2026.

Filed Date: 7/1/26.

Accession Number: 20260701–5076.

Comment Date: 5 p.m. ET 7/13/26.

Docket Numbers: RP26–955–000.

Applicants: Rover Pipeline LLC.

Description: 4(d) Rate Filing;

Summary of Negotiated Rate Capacity Release Agreements 7–1–2026 to be effective 7/1/2026.

Filed Date: 7/1/26.

Accession Number: 20260701–5103.

Comment Date: 5 p.m. ET 7/13/26.

Docket Numbers: RP26–956–000.

Applicants: Mountain Valley Pipeline, LLC.

Description: 4(d) Rate Filing; Remove Expired Negotiated Rate Agreement—8/1/2026 to be effective 8/1/2026.

Filed Date: 7/1/26.

Accession Number: 20260701–5233.

Comment Date: 5 p.m. ET 7/13/26.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: July 1, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–13680 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC26–28–000; EL26–24–000.

Applicants: PacifiCorp, PacifiCorp.

Description: Response to 05/21/2026, Deficiency Letter of PacifiCorp.

Filed Date: 6/29/26.

Accession Number: 20260629–5274.

Comment Date: 5 p.m. ET 7/20/26.

Docket Numbers: EC26–120–000.

Applicants: Cleco Power LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Cleco Power LLC.

Filed Date: 6/29/26.

Accession Number: 20260629–5280.

Comment Date: 5 p.m. ET 7/20/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2654–002; ER26–149–001; ER25–205–001.

Applicants: Swiftwater Solar, LLC, Medway Grid, LLC, Vitol Inc.

Description: Updated Market Power Analysis for Northeast Region of Vitol Inc., et al.

Filed Date: 6/29/26.

Accession Number: 20260629–5275.

Comment Date: 5 p.m. ET 8/28/26.

Docket Numbers: ER16–700–010.

Applicants: CPV Towantic, LLC.

Description: Triennial Market Power Analysis for Northeast Region and Notice of Change in Status of CPV Towantic, LLC.

Filed Date: 6/29/26.

Accession Number: 20260629–5279.

Comment Date: 5 p.m. ET 8/28/26.

Docket Numbers: ER21–445–007; ER17–1821–015.

Applicants: Panda Stonewall LLC, Hill Top Energy Center LLC.

Description: Triennial Market Power Analysis for Northeast Region of Hill Top Energy Center LLC, et al.

Filed Date: 6/26/26.

Accession Number: 20260626–5289.

Comment Date: 5 p.m. ET 8/25/26.

Docket Numbers: ER21–2128–005; ER21–2129–005; ER22–529–006; ER21–1923–006; ER19–1200–017; ER16–355–

013; ER16–141–016; ER24–3059–004; ER10–2346–016; ER10–2353–016; ER25–2977–002; ER11–4351–018; ER17–2336–013.

Applicants: Shoreham Solar Commons LLC, Pinnacle Wind, LLC, Mount Storm Wind LLC, Lookout WindPower LLC, Forward WindPower LLC, Dan's Mountain Wind Force, LLC, Conetoe II Solar, LLC, Colonial Eagle Solar, LLC, Clearway Power Marketing LLC, Black Rock Wind Force, LLC, 299F2M WHAM8 SOLAR, LLC, 276FED WHAM8 SOLAR, LLC, 0HAM WHAM8 SOLAR, LLC.

Description: Updated Market Power Analysis for Northeast Region of 0HAM WHAM8 SOLAR, LLC, et al.

Filed Date: 6/29/26.

Accession Number: 20260629–5278.

Comment Date: 5 p.m. ET 8/28/26.

Docket Numbers: ER22–2643–004; ER23–1967–003.

Applicants: Three Corners Prime Tenant, LLC, Three Corners Solar, LLC.

Description: Triennial Market Power Analysis for Northeast Region of Three Corners Solar, LLC, et al.

Filed Date: 6/29/26.

Accession Number: 20260629–5284.

Comment Date: 5 p.m. ET 8/28/26.

Docket Numbers: ER24–116–008; ER14–1140–013.

Applicants: Inspire Energy Holdings, LLC, Rhythm Ops, LLC.

Description: Triennial Market Power Analysis for Northeast Region of Rhythm Ops, LLC, et al.

Filed Date: 6/26/26.

Accession Number: 20260626–5288.

Comment Date: 5 p.m. ET 8/25/26.

Docket Numbers: ER24–1163–004; ER17–1840–003; ER22–784–008; ER25–1407–002; ER15–2534–003.

Applicants: Saddleback Ridge Wind, LLC, CPV Rogue's Wind, LLC, CPV Maple Hill Solar, LLC, Canton Mountain Wind, LLC, CPV Backbone Solar, LLC.

Description: Updated Market Power Analysis for Northeast Region of CPV Backbone Solar, LLC, et al.

Filed Date: 6/29/26.

Accession Number: 20260629–5282.

Comment Date: 5 p.m. ET 8/28/26.

Docket Numbers: ER25–1407–003.

Applicants: CPV Rogue's Wind, LLC.

Description: Notice of Change in Status of CPV Rogue's Wind, LLC.

Filed Date: 6/29/26.

Accession Number: 20260629–5283.

Comment Date: 5 p.m. ET 7/20/26.

Docket Numbers: ER26–3079–000.

Applicants: NorthWestern Corporation.

Description: Tariff Amendment: Cancellation of SA 1032—Puget Sound Energy to be effective 6/1/2026.

Filed Date: 7/1/26.

Accession Number: 20260701–5336.

Comment Date: 5 p.m. ET 7/22/26.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: July 1, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–13677 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC26–38–000]

Commission Information Collection Activities (FERC–912); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently

approved information collection, FERC–912 (OMB Control No. 1902–0237), PURPA Section 210(m) Notification Requirements Applicable to Cogeneration and Small Power Production Facilities.

DATES: Comments on collections of information are due September 8, 2026.

ADDRESSES: You may submit your comments (identified by Docket No. IC26–38–000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov and telephone at (202) 502–6468.

SUPPLEMENTARY INFORMATION:

Title: FERC–912, PURPA Section 210(m) Notification Requirements Applicable to Cogeneration and Small Power Production Facilities.

OMB Control No.: 1902–0237.

Type of Request: Three-year extension of the FERC–912 information collection requirements with no changes to the current reporting requirements.

Abstract: On August 8, 2005, the Energy Policy Act of 2005 (EPAct

2005)¹ was signed into law. Section 1253(a) of EPAct 2005 amends Section 210 of the Public Utility Regulatory Policies Act of 1978 (PURPA) by adding subsection “(m),” which provides, based on a specified showing, for the termination and subsequent reinstatement of an electric utility's obligation to purchase from, and sell energy and capacity to, qualifying facilities (QFs). In 2019, the Commission revised its regulations in 18 CFR 292.309–292.313 in Docket No. RM19–15–000 to account for industry changes. These industry changes include: the decrease in reliance on oil and natural gas, the increase of natural gas supply due to access of shale reserves, and the decreasing costs of renewable energy sources. Due to the modifications in the rulemaking, the Commission revised its information collection requirements. The Commission now collects the following information on FERC Form 912:

- *§ 292.310:* an electric utility's application for the *termination of its obligation* to purchase energy from a QF,

- *§ 292.311:* an affected entity or person's application to the Commission for an order *reinstating the electric utility's obligation* to purchase energy from a QF,

- *§ 292.312:* an electric utility's application for the *termination of its obligation* to sell energy and capacity to QFs, and

- *§ 292.313:* an affected entity or person's application to the Commission for an order *reinstating the electric utility's obligation* to sell energy and capacity to QFs.²

Type of Respondents: Electric utilities.

Estimate of Annual Burden:³ The Commission estimates the total Public Reporting Burden and cost for this information collection as follows:

¹ Public Law 109–58, 119 Stat. 594 (2005).

² 18 CFR 292.311 and 292.313.

³ Burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

**FERC-912 (IC22-9-000)—COGENERATION AND SMALL POWER PRODUCTION, PURPA SECTION 210(m) REGULATIONS
FOR TERMINATION OR REINSTATEMENT OF OBLIGATION TO PURCHASE OR SELL**

	Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours & average cost per response (\$) ⁴	Total annual burden hours & total annual cost (\$)	Cost per respondent (\$)
	(1)	(2)	(1) × (2) = (3)	(4)	(3) × (4) = (5)	(5) ÷ (1) = (6)
Termination of obligation to purchase.	4	1.5	6	12; \$1,224	72; \$7,344	\$1,836
Reinstatement of obligations to purchase.	0	0	0	0; \$0	0; \$0	0
Termination of obligation to sell.	2	1	2	8; \$816	16; \$1,632	816
Reinstatement of obligation to sell.	0	0	0	0; \$0	0; \$0	0
Total					88 hours; \$8,976	2,652

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 1, 2026.

Debbie-Anne A. Reese,
Secretary.

[FR Doc. 2026-13693 Filed 7-6-26; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC26-40-000]

Commission Information Collection Activities (FERC-549C); Comment Request; Extension

AGENCY: Federal Energy Regulatory
Commission.

ACTION: Notice of information
collections and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC-549C OMB Control No. 1902-0174), Standards for Business Practices of Interstate Natural Gas Pipelines.

DATES: Comments on collections of information are due September 8, 2026.

ADDRESSES: You may submit your comments (identified by Docket No. IC26-40-000) by one of the following methods:

Electronic filing through <https://www.ferc.gov>, is preferred.

- *Electronic Filing:* Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

- For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery:

- *Mail via U.S. Postal Service Only:* Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

- *Hand (including courier) delivery:* Deliver to: Federal Energy Regulatory Commission, Office of the Secretary, 12225 Wilkins Avenue, Rockville, MD 20852.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <https://www.ferc.gov>. For user assistance, contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at (866) 208-3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading

comments and issuances in this docket may do so at <https://www.ferc.gov>.

FOR FURTHER INFORMATION CONTACT:

Kayla Williams may be reached by email at DataClearance@FERC.gov and telephone at (202) 502-6468.

SUPPLEMENTARY INFORMATION:

Title: FERC-549C, Standards for Business Practices of Interstate Natural Gas Pipelines.

OMB Control No.: 1902-0174.

Type of Request: Three-year extension of the FERC-549C information collection requirements with no changes to the current reporting requirements.

Abstract: The business practice standards under FERC-549C are required to carry out the Commission's policies in accordance with the general authority in sections 4, 5, 7, 8, 10, 14, 16, and 20 of the Natural Gas Act (NGA),¹ and sections 311, 501, and 504 of the Natural Gas Policy Act of 1978 (NGPA).² The Commission adopted these business practice standards in order to update and standardize the natural gas industry's business practices and procedures in addition to improving the efficiency of the gas market and the means by which the gas industry conducts business across the interstate pipeline grid. Since 1996, the Commission has incorporated by reference in its regulations the North American Energy Standards Board (NAESB) business practice standards and communication methodologies of interstate natural gas pipelines to create a more integrated and efficient pipeline network system. These regulations have been promulgated in the Order No. 587 series of orders,³ wherein the

⁴ The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * \$102.00 per Hour = Average Cost per Response. The hourly cost figure comes from the FERC average salary (\$213,003/year).

Commission staff believes the 2026 FERC average salary to be a representative wage for industry respondents.

¹ 15 U.S.C. 717c-717w.

² 15 U.S.C. 3301-3432.

³ This series of orders began with the Commission's issuance of Order No. 587, *Standards*
Continued

Commission has incorporated by reference the standards for interstate natural gas pipeline business practices and electronic communications developed by NAESB’s Wholesale Gas Quadrant (WGQ). Upon incorporation by reference, the revisions to three sets of version 4.0 standards will add two new standards and revise one standard in the currently incorporated version of NAESB’s business practice standards.⁴

NAESB is an American National Standards Institute-accredited, non-profit standards development organization formed for the purpose of developing voluntary standards and model business practices that promote more competitive and efficient natural gas and electric markets. NAESB has divided its efforts among four quadrants including two retail quadrants, a wholesale electric quadrant, and the WGQ. The NAESB WGQ standards are a product of this effort. Industry participants seeking additional or amended standards (to include principles, definitions, standards, data elements, process descriptions, and technical implementation instructions) must submit a request to the NAESB office, detailing the change, so that the appropriate process may take place to amend the standards.

Failure to collect the FERC–549C data would prevent the Commission from monitoring and properly evaluating pipeline transactions and/or meeting statutory obligations under both the NGA and NGPA.

On December 4, 2024, NAESB filed a report informing the Commission that it had modified Version 4.0 of the business practice standards (Informational Report).⁵ These revisions to the standards would improve the reliability of the interstate natural gas infrastructure to support the bulk electric system and improve communication among gas and electric market participants to enhance situational awareness during extreme cold weather events.⁶ Notably, the Informational Report identifies revisions to three sets of standards which include two new standards and one revised standard. One new standard facilitates the posting of applicable scheduled quantity information for power plants that are directly connected to the pipeline as part of the new “Gas Electric Coordination” posting category. The one revised standard includes a new “Gas Electric Coordination” posting category. The second new standard supports the inclusion of the geographic information of impacted area(s), location(s), and/or pipeline facility(ies) by a transportation service provider when issuing a critical notice. Pipelines are currently required to make this information available through computer-to-computer electronic data interchange in addition to other batch file downloadable formats they may provide.⁷

Type of Respondents: Natural gas pipelines under the jurisdiction of NGA and NGPA.

*Estimate of Annual Burden.*⁸ The Commission estimates the total annual burden and cost for this information collection as follows:⁹

FERC–549C—STANDARDS FOR BUSINESS PRACTICES OF INTERSTATE NATURAL GAS PIPELINES

	Number of respondents ¹⁰	Number of responses per respondent	Total number of responses	Average burden hrs. per response	Total burden hours & total cost ¹¹	Cost per respondent (\$)
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(5)/(1) = (6)
Standards for Business Practices of Interstate Natural Gas Pipelines.	165	1	165	33.33 hrs.; \$3,266.34 ..	5,932.74 hrs.; \$581,408.52.	\$3,266.34

Comments: Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency’s estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

for *Bus. Pracs. of Interstate Nat. Gas Pipelines*, 61 FR 39053 (July 26, 1996), FERC Stats. & Regs. ¶ 31,038 (1996) (cross-referenced at 76 FERC ¶ 61,042).

⁴ *Standards for Bus. Pracs. of Interstate Nat. Gas Pipelines*, Order No. 587–AB, 91 FR 31651 (May 28, 2026), 195 FERC ¶ 61,135, (2026).

⁵ See NAESB WGQ Business Practice Standards Version 4.0 Report, Docket No. RM96–1–044 (Dec. 4, 2024).

⁶ As explained below, NAESB has adopted two new standards and revisions to one existing standard in response to Recommendation 5 of the report that the staffs of the Commission, North American Electric Reliability Corporation (NERC), and Regional Entities issued November 7, 2023: FERC et al., *FERC, NERC & Reg’l Entity Staff Rep.: Inquiry into Bulk-Power Sys. Operations During Dec. 2022 Winter Storm Elliott*, Docket No. AD23–8–000, at 143 (Nov. 7, 2023) (Recommendation 5), <https://elibrary.ferc.gov/eLibrary/filedownload?fileid=00F8FAAC-A049-C84B-8784-8BB5FEC00000> (as updated Feb. 28, 2024, <https://elibrary.ferc.gov/eLibrary/>).

⁷ 18 CFR 284.12 (a)(1)(v), (b)(3)(i)(A). See *Standards for Bus. Pracs. of Interstate Nat. Gas Pipelines*, Order No. 587–G, 83 FERC ¶ 61,029, at text accompanying note 58 (1998), 63 FR 20072 (April 23, 1998).

⁸ The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

⁹ Commission staff estimates that the industry’s skill set and cost (for wages and benefits) for FERC–549C are approximately the same as the Commission’s average cost. The FERC 2026 average salary plus benefits for one FERC full-time equivalent (FTE) is \$213,003/year (or \$102.00/hour) posted by the Bureau of Labor Statistics for the Utilities sector (available at https://www.bls.gov/oes/current/naics3_221000.htm).

¹⁰ The number of respondents is the number of entities in which a change in burden from the current standards to the proposed exists, not the total number of entities from the current or proposed standards that are applicable.

¹¹ The estimated hourly cost (salary plus benefits) provided in this section is based on the salary figures for May 2024 posted on April 2, 2025 by the Bureau of Labor Statistics for the Utilities sector (available at https://www.bls.gov/oes/current/naics2_22.htm) and scaled to reflect benefits using the relative importance of employer costs for employee compensation (available at <https://www.bls.gov/news.release/ecec.nr0.htm>). The hourly estimates for salary plus benefits are: Computer and Information Systems Manager (Occupation Code: 11–3021), \$110.62. Computer and Information Analysts (Occupation Code: 15–1210), \$68.34. Electrical Engineer (Occupation Code: 17–2071), \$71.19. Legal (Occupation Code: 23–0000), \$140.76. The average hourly cost (salary plus benefits), weighting these skill sets evenly, is \$97,728. We round it to \$98/hour.

Dated: July 1, 2026.
Debbie-Anne A. Reese,
 Secretary.
 [FR Doc. 2026–13699 Filed 7–6–26; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

ACTION: Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–1531–013.
Applicants: CPV Fairview, LLC.
Description: Triennial Market Power Analysis for Northeast Region of CPV Fairview, LLC.
Filed Date: 6/29/26.
Accession Number: 2026062–5269.
Comment Date: 5 p.m. ET 8/28/26.
Docket Numbers: ER25–1275–000; ER25–1275–001.
Applicants: BHS Solar, LLC.
Description: Supplement to 12/19/2025, and Response to 05/28/2026, Deficiency Letter, BHS Solar, LLC tariff filing.
Filed Date: 6/29/26.
Accession Number: 20260629–5271.
Comment Date: 5 p.m. ET 7/20/26.
Docket Numbers: ER25–1845–004.
Applicants: Orange and Rockland Utilities, Inc.
Description: Compliance filing: Orange and Rockland’s Compliance Filing to be effective 3/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5137.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER26–3051–000.
Applicants: Bayou Cove Peaking Power, LLC.
Description: 205(d) Rate Filing: Normal filing 2026 change in status to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630–5253.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: ER26–3052–000.
Applicants: Big Cajun I Peaking Power, LLC.
Description: 205(d) Rate Filing: Normal filing 2026 change in status to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630–5257.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: ER26–3053–000.
Applicants: Big Cajun I Units I and II, LLC.
Description: 205(d) Rate Filing: Normal filing 2026 change in status to be effective 7/1/2026.

Filed Date: 6/30/26.
Accession Number: 20260630–5263.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: ER26–3054–000.
Applicants: Cottonwood Energy Company LP.
Description: 205(d) Rate Filing: Normal filing 2026 change in status to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630–5268.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: ER26–3055–000.
Applicants: Louisiana Generating, LLC.
Description: 205(d) Rate Filing: Normal filing 2026 change in status to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630–5275.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: ER26–3056–000.
Applicants: New England Power Pool Participants Committee.
Description: 205(d) Rate Filing: July 2026 Membership Filing to be effective 7/1/2026.
Filed Date: 6/30/26.
Accession Number: 20260630–5277.
Comment Date: 5 p.m. ET 7/21/26.
Docket Numbers: ER26–3057–000.
Applicants: Pacific Gas and Electric Company.
Description: Compliance filing: WDT: WDT4 Settlement, WDT3 RY2024 AU to be effective N/A.
Filed Date: 7/1/26.
Accession Number: 20260701–5002.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER26–3058–000.
Applicants: Pacific Gas and Electric Company.
Description: Compliance filing: WDT: WDT4 Settlement, WDT3 RY2025 AU to be effective N/A.
Filed Date: 7/1/26.
Accession Number: 20260701–5003.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER26–3059–000.
Applicants: Pacific Gas and Electric Company.
Description: Compliance filing: WDT: WDT4 Settlement, WDT4 RY2026 AU to be effective N/A.
Filed Date: 7/1/26.
Accession Number: 20260701–5004.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER26–3060–000.
Applicants: McCallum Enterprises I Limited Partnership.
Description: McCallum Enterprises I Limited Partnership submits Waiver Request for Waiver Section 206 of the ISO-NE OATT.
Filed Date: 6/23/26.
Accession Number: 20260623–5196.
Comment Date: 5 p.m. ET 7/14/26.

Docket Numbers: ER26–3061–000.
Applicants: ISO New England Inc., New England Power Pool Participants Committee.
Description: 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii): ISO-NE; Revisions to Provide for Rate Rollover if New Rates are not Effective to be effective 9/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5047.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER26–3062–000.
Applicants: Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 1518R30 Arkansas Electric Cooperative Corp NITSA NOA to be effective 6/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5053.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3063–000.
Applicants: Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 3869R1 People’s Electric Coop/ Southwestern Attachment AO to be effective 6/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5065.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3064–000.
Applicants: Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 1276R42 Evergy Metro NITSA NOA to be effective 9/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5077.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3065–000.
Applicants: PacifiCorp.
Description: 205(d) Rate Filing: CPEM Const Agt—Casper Wind Decommissioning (RS No. 811) to be effective 8/31/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5082.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3066–000.
Applicants: Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 1628R33 Western Farmers Electric Cooperative NITSA NOAs to be effective 9/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5089.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3067–000.
Applicants: NorthWestern Corporation
Description: 205(d) Rate Filing: RS 188—Revised Colstrip 1 and 2 Transmission Agreement to be effective 9/1/2026.

Filed Date: 7/1/26.
Accession Number: 20260701–5116.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3068–000.
Applicants Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 3474R2 Clarksville Light & Water NITSA NOA to be effective 6/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5120.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3069–000.
Applicants PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Amendment to WMPA SA No. 6915; Queue No. AF2–039/AF2–088 to be effective 8/31/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5128.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3070–000.
Applicants Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 2236R20 Golden Spread Electric Cooperative NITSA NOA to be effective 6/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5146.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3071–000.
Applicants Duke Energy Progress, LLC.
Description: 205(d) Rate Filing: DEP-NCEMC Non-Conforming Amended and Restated LGIA SA No. 464) to be effective 8/31/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5149.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3072–000.
Applicants Oklahoma Gas and Electric Company.
Description: 205(d) Rate Filing: Wholesale Distribution Access Service Tariff to be effective 8/31/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5190.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3073–000.
Applicants PJM Interconnection, L.L.C.
Description: 205(d) Rate Filing: Amendment to GIA SA No. 7461; Project Identifier No. AG1-156 to be effective 8/31/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5207.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3074–000.
Applicants Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 1067R15 East Texas Electric Cooperative NITSA and NOA to be effective 6/1/2026.

Filed Date: 7/1/26.
Accession Number: 20260701–5220.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3075–000.
Applicants Spindle Battery, LLC.
Description: 205(d) Rate Filing: Market-Based Rate Application and Request for Waivers and Blanket Approvals to be effective 8/31/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5235.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3076–000.
Applicants Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 1148R38 American Electric Power NITSA and NOA to be effective 6/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5251.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3077–000.
Applicants Southwest Power Pool, Inc.
Description: 205(d) Rate Filing: 1518R31 Arkansas Electric Cooperative Corp NITSA NOAs to be effective 9/1/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5265.
Comment Date: 5 p.m. ET 7/22/26.
Docket Numbers: ER25–3078–000.
Applicants Arche Energy Project Tenant, LLC.
Description: 205(d) Rate Filing: Arche Energy Project Tenant—Revisions to Market-Based Rate Tariff to be effective 7/2/2026.
Filed Date: 7/1/26.
Accession Number: 20260701–5281.
Comment Date: 5 p.m. ET 7/22/26.
The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.asp>) by querying the docket number.
Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.
eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.
For public inquiries and assistance with making filings such as

interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or OPP@ferc.gov.

Dated: July 1, 2026.

Carlos D. Clay,
Deputy Secretary.

[FR Doc. 2026–13676 Filed 7–6–26; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

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.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of

the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than July 22, 2026.

A. Federal Reserve Bank of Chicago (Christopher Koopmans, Senior Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414.

Comments can also be sent electronically to

Comments.applications@chi.frb.org:

1. *Brookfield Bancshares, Inc., Brookfield, Illinois*; to continue engaging in extending credit and servicing loans, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2026–13691 Filed 7–6–26; 8:45 am]

BILLING CODE:P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments 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, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than July 22, 2026.

A. Federal Reserve Bank of Chicago (Christopher Koopmans, Senior Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414.

Comments can also be sent electronically to

Comments.applications@chi.frb.org:

1. *Rudolph S. Leytze, individually, and in his capacity as trustee of the Leytze Generation Skipping Trust FBO Rudolph S. Leytze, and The Mary Elizabeth Leytze Spousal Limited Access Trust, all of Naples, Florida; Anna L. Basile Wehner, of Iowa City, Iowa; Catherine L. Basile, individually, and in her capacity as trustee of the Leytze Generation Skipping Trust FBO Catherine L. Basile, both of Cedar Rapids, Iowa; Nicholas E. Basile, Burlingame, California; Regina E. Bonsignore, Zachary J. Garber, and Richard S. Garber, all of St. Paul, Minnesota; Adam Faler, Rudolph R. Leytze, Alejandro Urbina, and Laura C. Faler, all of Cedar Rapids, Iowa; Corrine I. Garber, Ely, Minnesota; Jonathan A. Garber, Mapleton, Minnesota; Susan A. Garber, in her capacity as trustee of the Susan A. Garber Revocable Trust, and the Leytze Generation Skipping Trust FBO Susan A. Garber, all of Cedar Rapids, Iowa; Alison L. Urbina, individually, and in her capacity as custodian for one or more minor children, all of Cedar Rapids, Iowa; and Emily L. Yetter, individually, and in her capacity as custodian for one or more minor children, all of Marion, Iowa, and as trustee of The Mary Elizabeth Leytze Spousal Limited Access Trust, of Naples, Florida*; as a group acting in concert, to retain voting shares of Fidelity Ban Corporation, Independence, Iowa, and thereby indirectly retain voting shares of BankIowa, Cedar Rapids, Iowa.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2026–13689 Filed 7–6–26; 8:45 am]

BILLING CODE:P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part

225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 6, 2026.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to *KCAApplicationComments@kc.frb.org:*

1. *Sovereign Bancorp, Inc., Shawnee, Oklahoma*; to acquire Leader First Bancorp, Inc., and thereby indirectly acquire The First National Bank in Marlow, both of Marlow, Oklahoma.

B. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201–2272. Comments can also be sent electronically to *Comments.applications@dal.frb.org:*

1. *The Bank of Nova Scotia, Toronto, Canada*; to acquire Maple Financial Holdings, Inc., Dallas, Texas, and thereby indirectly acquire MapleMark Bank, Tulsa, Oklahoma.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2026-13690 Filed 7-6-26; 8:45 am]

BILLING CODE:P

FEDERAL TRADE COMMISSION

[File No. P264200]

Policy Statement Concerning the Suppression of Accuracy in Artificial Intelligence Systems

AGENCY: Federal Trade Commission.

ACTION: Proposed policy statement; request for comments.

SUMMARY: The Federal Trade Commission (“Commission”) is proposing a policy statement regarding the application of the prohibition on deceptive acts or practices in section 5 of the Federal Trade Commission Act to companies that market artificial intelligence (“AI”) systems.

DATES: Comments must be received on or before Friday, July 31, 2026.

ADDRESSES: Members of the public may file a comment online or on paper by following the instructions in the Comment Submissions part of the **SUPPLEMENTARY INFORMATION** section below. Write “AI Policy Statement; Matter No. P264200” on your comment and file your comment online at <https://www.regulations.gov/docket/FTC-2026-0859>. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H-144 (Annex P), Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Summary

Artificial Intelligence (AI) is reshaping how Americans consume information, educate our children, and perform our jobs.¹ As they have marketed their remarkable breakthroughs to the public, AI companies have spent years representing explicitly and implicitly that their systems aim to produce the best output—output that faithfully and accurately achieves users’ stated

objectives and the built-in objectives that users expect in the AI system—that is possible within their technological and resource constraints. Because of these representations and the inherent nature of the products and services in question, consumers have a reasonable expectation that AI systems aim to give truthful and accurate outputs. Consumers have no basis to believe that AI systems aim to produce outputs that are distorted by undisclosed ideological objectives.

Nonetheless, an AI company might be tempted to alter or steer the output of its systems contrary to consumers’ reasonable expectations for various reasons, including attempted compliance with a State law, such as Colorado’s recently revised Artificial Intelligence Act. But steering an AI system in this manner may deceive consumers in violation of section 5 of the FTC Act. That is true even if the deceptive steering is done in an effort to comply with State laws. Of course, a company may be able to avert potential deception by making truthful, non-misleading representations about the aims of its model. But such representations would need to make clear the AI company is prioritizing objectives different than those consumers requested or would otherwise expect.

II. Background

Artificial intelligence is an umbrella term covering a universe of different tools and systems now used across nearly every sector of the economy and in most people’s daily lives.² Regardless of whether one has in mind modern large language models, AI applications applying large-language models to particular purposes, or a not-yet-developed superintelligence, the hallmark of a successful AI system is an ability to accurately “make predictions, recommendations, or decisions” for its user consistent with a given objective.³ Their utility can then be judged by how well the solution matches consumers’ objectives.

On a fundamental level, these products and services solve problems for people. For many Americans, they are becoming part and parcel of daily life, relied upon for research, analysis, and advice on both personal and business issues. This development reflects consumers’ confidence that AI

companies are bound by the same rules as other American companies: they will deal with consumers in good faith and with no hidden agenda, and they will not work in the shadows to punish those who hold opinions contrary to theirs. In large part, that confidence itself reflects the basic fact that the United States is the global standard-bearer for AI technologies.⁴ That American companies dominate every layer of the AI ecosystem should not be taken for granted. Geopolitical rivals are investing heavily in this sphere, hoping to inject their own companies and values into the marketplace. American dominance is thus about more than winning some abstract race. It is about ensuring Americans can continue to feel their values are being respected as they interact with, and benefit from, an AI-powered economy.

Under the President’s leadership, the Trump-Vance Administration has taken decisive steps to sustain America’s global AI dominance⁵ by removing regulatory barriers that impede AI innovation.⁶ Excessive AI regulation would undermine American AI supremacy by deterring and suppressing the same ingenuity responsible for making American AI great.⁷ At the same time, however, as President Trump’s National Policy Framework for Artificial Intelligence recognizes, responsible AI innovation can co-exist with prudent guardrails. For example, AI technologies should protect children and empower

⁴ See J.D. Vance, Remarks by the Vice President at the Artificial Intelligence Action Summit in Paris, France (Feb. 11, 2025), www.presidency.ucsb.edu/documents/remarks-the-vice-president-the-artificial-intelligence-action-summit-paris-france [hereinafter “Vance AI Summit Remarks”].

⁵ See, e.g., AI Action Plan, *supra* note 1; E.O. 14318, Accelerating Federal Permitting of Data Center Infrastructure, 90 FR 35385, 35385 (July 23, 2025) (prioritizing the rapid and efficient buildout of AI data centers and the infrastructure that power them by easing Federal regulatory burdens); E.O. 14319, 90 FR at 35389 (noting agencies have an “obligation not to procure [AI] models that sacrifice truthfulness and accuracy to ideological agendas”); E.O. 14320, Promoting the Export of the American AI Technology Stack, 90 FR 35393, 35393 (July 23, 2025) (establishing a coordinated national effort to support the American AI industry by promoting the export of full-stack American AI technology packages).

⁶ See, e.g., E.O. 14148, Initial Rescissions of Harmful Executive Orders and Actions, 90 FR 8237, 8240 (Jan. 20, 2025), <https://www.govinfo.gov/content/pkg/FR-2025-01-28/pdf/2025-01901.pdf> (revoking E.O. 14110, Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, 88 FR 75191 (Oct. 30, 2023)); E.O. 14179, Removing Barriers to American Leadership in Artificial Intelligence, 90 FR 8741, 8741–42 (Jan. 23, 2025), www.govinfo.gov/content/pkg/FR-2025-01-31/pdf/2025-02172.pdf.

⁷ E.O. 14179, 90 FR at 8741; Vance AI Summit Remarks, *supra* note 4.

¹ Executive Office of the President, *Winning the Race: America’s AI Action Plan* at 1 (July 2025), <https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf> [hereinafter “AI Action Plan”]; The Council of Economic Advisors, Executive Office of the President, *Artificial Intelligence and the Great Divergence* at 1 (Jan. 2026), <https://www.whitehouse.gov/wp-content/uploads/2026/01/Artificial-Intelligence-and-the-Great-Divergence-5.pdf>.

² See, e.g., E.O. 14319, Preventing Woke AI in the Federal Government, at sec. 1, 90 FR 35389, 35389 (July 23, 2025) (“Artificial intelligence . . . will play a critical role in how Americans of all ages learn new skills, consume information, and navigate their daily lives.”).

³ 15 U.S.C. 9401(3).

parents.⁸ And most relevant to this statement, AI technologies should not be used to silence or censor lawful expression or dissent.⁹ Importantly, President Trump's proposed approach is a national AI framework, protecting innovation and competition by providing national regulatory clarity and certainty and avoiding a balkanized or patchwork regulatory approach driven by the States—or, most dangerously, imposed by certain anti-innovation State governments on the rest of the country.

America's AI Action Plan and other critical executive actions strike that balance between accelerating innovation and protecting Americans,¹⁰ but anti-innovation States' recent efforts to regulate AI are concerning. The growing number of enacted and proposed State AI laws threatens to create a patchwork of regulatory regimes and compliance challenges for American companies.¹¹ For example, some States have enacted laws regulating the outputs of various AI models, ultimately requiring American companies to embed "ideological bias within [their AI] models."¹²

On December 11, 2025, President Trump signed Executive Order 14365, "Ensuring a National Policy Framework for Artificial Intelligence."¹³ The Executive Order builds on the Administration's prior work to encourage adoption of AI and remove regulatory barriers, aiming to "sustain and enhance the United States' global AI dominance" by establishing a "minimally burdensome national policy framework for AI—not 50 discordant State ones."¹⁴ The Executive Order

directs the Commission to issue this enforcement policy statement clarifying the application of section 5 of the Federal Trade Commission Act ("FTC Act") to AI models, and in particular, address how State laws requiring alterations to the accurate outputs of AI models can conflict with the requirements of the FTC Act.¹⁵

III. The Commission's Authority Under Section 5 of the FTC Act

Nearly ninety years ago, Congress gave the Commission the authority to protect consumers from "unfair or deceptive acts or practices in or affecting commerce."¹⁶ Importantly, Congress did not provide State-law safe harbors—even where a State's laws shape the provision of those products or services, companies must comply with section 5.

Section 5 of the FTC Act's prohibition on deceptive acts or practices secures consumers' right to truth in the marketplace.¹⁷ In our 1983 Policy Statement on Deception, we said "the Commission will find deception if there is a representation, omission or practice that is likely to mislead the consumer acting reasonably in the circumstances, to the consumer's detriment."¹⁸ This test, which "undergird[s] all deception cases," consists of three elements.¹⁹ "First, there must be a representation, omission or practice that is likely to mislead the consumer."²⁰ "Second, we examine the practice from the perspective of a consumer acting reasonably in the circumstances."²¹ And "[t]hird, the representation, omission or practice must be a material one," such that it is "likely to affect the consumer's conduct or decision with regard to a product or service."²²

Federal courts have adopted the same principles in assessing whether an act or practice is deceptive.²³ Courts have also held the Commission's deception

authority covers implied misrepresentations, half-truths,²⁴ and instances where only a "significant minority" of consumers are misled.²⁵ Moreover, courts have recognized the Commission's deception authority requires the entity to substantiate the representation it makes about its products or services with sufficient evidence.²⁶ At its core, the Commission's deception authority is based on "well-established principles of advertising law and common sense."²⁷

The Commission has applied the principles underlying its section 5 deception authority to address false or misleading claims in a multitude of factual circumstances and across a wide variety of products and services,²⁸ including new and evolving technologies.²⁹ And we have taken aim at companies that failed to provide adequate disclosures,³⁰ as well as

²⁴ See, e.g., *Novartis Corp. v. FTC*, 223 F.3d 783, 787 (D.C. Cir. 2000); *Fanning v. FTC*, 821 F.3d 164, 170–72 (1st Cir. 2016); *Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992).

²⁵ *ECM Biofilms, Inc. v. FTC*, 851 F.3d 599, 610 (6th Cir. 2017) (quoting *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015)). A small proportion of consumers, such as 10%, can constitute a "significant minority." See, e.g., *Telebrands Corp.*, 140 F.T.C. 278, 325 (2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006) (10.5% is significant); *Firestone Tire & Rubber Co. v. FTC*, 481 F.2d 246, 249 (6th Cir. 1973) (10–15% is significant).

²⁶ See, e.g., *POM Wonderful*, 777 F.3d at 490–91; *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010); *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009).

²⁷ *FTC v. Com. Planet, Inc.*, 878 F. Supp. 2d 1048, 1083 (C.D. Cal. 2012), *aff'd in part*, 642 F. App'x 680 (9th Cir. 2016); see also *FTC v. Johnson*, 96 F. Supp. 3d 1110, 1142 (D. Nev. 2015) (rejecting "fair notice" argument as to section 5(a) liability and noting there is "extensive case law and guidance on what constitutes a deceptive act or practice under Section 5(a)").

²⁸ See, e.g., *FTC v. Fleetcor Techs., Inc.*, 620 F. Supp. 3d 1268, 1289–1313 (N.D. Ga. 2022) (fuel cards and discounts), *aff'd sub nom FTC v. Corpay, Inc.*, 164 F.4th 807 (11th Cir. 2026); *FTC v. D-Link Sys., Inc.*, No. 3:17–CV–00039–JD, 2017 WL 4150873, at *2 (N.D. Cal. Sept. 19, 2017) (data security and protections for IoT devices); *Pom Wonderful*, 777 F.3d at 490–500 (dietary supplements); *Com. Planet, Inc.*, 878 F. Supp. 2d at 1083 (online web pages and negative option plans).

²⁹ See, e.g., *Stipulated Order, FTC v. Amazon.com, Inc.*, No. 2:23–CV–00932–JHC (W.D. Wash. Sept. 25, 2025), Dkt. No. 535 (enrolling consumers into online shopping memberships without consumers' express informed consent); *Compl., United States v. Facebook*, No. 19–cv–2184 (D.D.C. July 24, 2019), Dkt. No. 1 (misrepresenting that users would have to "turn[] on" facial-recognition technology); *Compl., FTC v. New Consumer Sols., LLC*, No. 1:15–cv–01614 (N.D. Ill. Feb. 23, 2015), Dkt. No. 1 (misrepresenting ability to detect melanoma by analyzing pictures of consumers' skin); *Compl., In re Sears Holdings Mgmt. Corp.*, FTC Docket No. C–4264 (Sept. 9, 2009) (tracking consumers' "online browsing").

³⁰ See, e.g., *FTC v. LendingClub Corp.*, No. 18–CV–02454–JSC, 2020 WL 2838827, at *6 (N.D. Cal. June 1, 2020) (inadequate disclosures of loan

⁸ The White House, National Policy Framework for Artificial Intelligence (Mar. 20, 2026).

⁹ *Id.*

¹⁰ See *supra* note 6.

¹¹ See The White House, Fact Sheet: President Donald J. Trump Ensures a National Policy Framework for Artificial Intelligence (Dec. 11, 2025), <https://www.whitehouse.gov/fact-sheets/2025/12/fact-sheet-president-donald-j-trump-ensures-a-national-policy-framework-for-artificial-intelligence/> [hereinafter "AI National Policy Fact Sheet"] ("State legislatures have introduced over 1,000 different AI bills[.]"; E.O. 14319, 90 FR at 35389).

¹² See, e.g., E.O. 14365, Ensuring a National Policy Framework for Artificial Intelligence, 90 FR 58499, 58499 (Dec. 11, 2025) ("For example, a new Colorado law banning 'algorithmic discrimination' may even force AI models to produce false results in order to avoid a 'differential treatment or impact' on protected groups."); AI National Policy Fact Sheet, *supra* note 11 ("States such as California and Colorado are considering requiring AI companies to censor outputs and insert left-wing ideology in their programming."). Colorado has since materially revised the law referred to by this Executive Order, but the new version poses many of the same concerns. See *infra* note 43.

¹³ E.O. 14365, 90 FR at 58499.

¹⁴ *Id.*

¹⁵ *Id.* at 58500 (Section 7).

¹⁶ Wheeler-Lea Act, Public Law 75–447, 52 Stat. 111 (1938) (codified in relevant part at 15 U.S.C. 45(a)(1)).

¹⁷ *In re Int'l Harvester Co.*, 104 F.T.C. 949, 1056 (1984).

¹⁸ FTC Policy Statement on Deception ("Deception Policy Statement"), 103 F.T.C. 174, 183 (1984), (appended to *In re Clifdale Assocs., Inc.*, 103 F.T.C. 110 (1984)), <https://www.ftc.gov/legal-library/browse/ftc-policy-statement-deception>.

¹⁹ *Id.* at 175.

²⁰ *Id.*

²¹ *Id.*

²² *Id.* Material information affects a consumer's decision to purchase a product but may also affect other kinds of consumer conduct. *Id.* at 182 n.45 (citing the Commission's complaint in *Volkswagen of America*, 99 F.T.C. 446 (1982)).

²³ See, e.g., *FTC v. Pukke*, 53 F.4th 80, 104 (4th Cir. 2022); *FTC v. Moses*, 913 F.3d 297, 306 (2d Cir. 2019); *FTC v. E.M.A. Nationwide, Inc.*, 767 F.3d 611, 631 (6th Cir. 2014).

governmental and private standard-setting entities that sought to restrict truthful advertising.³¹

IV. Deceiving Consumers as to the Objectives of an AI System Is a Section 5 Violation

AI products and services are not exempt from section 5's long-established, and generally applicable reach. The Commission has already brought a number of recent enforcement actions to combat deceptive claims in connection with AI-powered scams, as well as material misrepresentations about the performance, efficacy, and characteristics of AI products.³² For instance, the Commission recently invoked well-established section 5 principles to address an AI company's misleading claims about the ability of its conversational AI tool to replace human customer service representatives.³³ Although the Commission is careful to avoid unduly burdening innovation in the AI industry,³⁴ the Commission will

origination fees); see also *FTC v. Cyberspace.Com LLC*, 453 F.3d 1196, 1200 (9th Cir. 2006) ("A solicitation may be likely to mislead by virtue of the net impression it creates even though the solicitation also contains truthful disclosures.").

³¹ See, e.g., *In re Am. Med. Ass'n*, 94 F.T.C. 701, 235 (1979) (restricting physician advertising).

³² See, e.g., Consent Order, *In re Workado, LLC*, No. C-4822 (F.T.C. Aug. 21, 2025) (deceptive claims regarding accuracy or efficacy of its AI-content detection products), https://www.ftc.gov/system/files/ftc_gov/pdf/ContentatScaleAI-DecisionandOrder.pdf; Stipulated Order, *FTC v. TheFBAMachine Inc.*, No. 24-cv-6635-JXN-LDW (D.N.J. July 31, 2025), Dkt. No. 162 (falsely guaranteeing consumers could make money operating online storefronts using AI-powered software); Consent Order, *In re DoNotPay, Inc.*, FTC Docket No. C-4812 (Jan. 14, 2025) (deceptive claims about the ability of its AI chatbot to replace the services of a human lawyer), https://www.ftc.gov/system/files/ftc_gov/pdf/2323042_donotpay_decision_and_order_o.pdf; Consent Order, *In re IntelliVision Techs. Corp.*, No. C-4809 (F.T.C. Jan. 8, 2025) (deceptive claims regarding accuracy or efficacy of its AI-powered facial recognition software), https://www.ftc.gov/system/files/ftc_gov/pdf/2323023c4809intellivisionfinalorder.pdf; Stipulated Order, *FTC v. Evolv Techs. Holdings, Inc.*, No. 1:24-cv-12940-PGL (D. Mass. Nov. 26, 2024), Dkt. No. 2 (false claims about the efficacy of its AI-powered security screening system for detecting weapons).

³³ See Compl., *FTC v. Air Ai Techs., Inc.*, No. 2:25-cv-03068-SMB (D. Ariz. Aug. 25, 2025), Dkt. No. 1 (deceptive claims regarding efficacy and profitability related to the company's "conversational AI" product).

³⁴ In fact, the Commission has already taken steps to address these unnecessary burdens, for example, by setting aside the previous Commission's order against a generative AI company. See Order Reopening and Setting Aside Order at 5, *In re Rytr LLC*, FTC Docket C-4806 (Dec. 22, 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/Rytr-Order.pdf ("Where actors use AI to violate the law or deceive consumers about the capabilities of their generative AI, they should be held accountable, as the FTC has done and will continue to do. But that is not the case here. Rushing in to impose aggressive law enforcement unsupported by facts or law is improper and is not in the public interest.").

continue to protect consumers and the market from deceptive or unfair business practices, including those relying on AI systems or technologies, by using well-established section 5 principles.

In marketing their products as problem-solving tools, AI companies have represented explicitly and implicitly that their AI systems aim to produce the best output possible given technological and resource constraints.³⁵ AI companies aggressively market themselves as building products and services that distill all of human knowledge to solve problems, large and small, in furtherance of users' given objectives.³⁶ This is because companies know their success depends on their

³⁵ See, e.g., OpenAI, *Why Language Models Hallucinate* (Sept. 5, 2025) ("At OpenAI, we're working hard to make AI systems more useful and reliable. Even as language models become more capable, one challenge remains stubbornly hard to fully solve: hallucinations."), <https://openai.com/index/why-language-models-hallucinate/>; Anthropic, *Claude Product Overview*, <https://claude.com/product/overview> (last visited May 22, 2026) ("Meet your thinking partner . . . Tackle any big, bold, bewildering challenge with Claude . . . The AI for problem solvers . . . Tackle your toughest work . . . Like an expert in your pocket . . . There's never been a worse time to be a problem, or a better time to be a problem solver . . . What problem are you up against?"); Anthropic, *How People Ask Claude for Personal Guidance*, <https://www.anthropic.com/research/claude-personal-guidance> <https://www.anthropic.com/research/claude-personal-guidance> (Apr. 30, 2026) ("Helpfulness is one of Claude's most important traits. Speaking with Claude should be akin to a conversation with a brilliant friend, one who will speak frankly to a person about their situation, providing information grounded in evidence."); X.ai, *Chat With Grok*, <https://x.ai/grok> (last accessed May 20, 2026) ("Grok is your truth-seeking AI companion for unfiltered answers with advanced capabilities in reasoning, coding, and visual processing.").

³⁶ See, e.g., Anthropic, *Claude*, <https://claude.com> (last visited May 22, 2026) ("What is Claude and how does it work? Claude is an artificial intelligence, trained by Anthropic using Constitutional AI to be safe, accurate, and secure—the trusted assistant for you to do your best work. . . . What should I use Claude for? If you can dream it, Claude can help you do it. Claude can process large amounts of information, brainstorm ideas, generate text and code, help you understand subjects, coach you through difficult situations, simplify your busywork so you can focus on what matters most, and so much more."); OpenAI, *ChatGPT Capabilities Overview* <https://help.openai.com/en/articles/9260256-chatgpt-capabilities-overview> (last visited Mar. 17, 2026) (touting ChatGPT's ability to solve problems); OpenAI, *Extracting Insights with ChatGPT Data Analysis*, <https://help.openai.com/en/articles/9213685-extracting-insights-with-chatgpt-data-analysis> (last visited Mar. 17, 2026) (claiming ChatGPT can identify missing or outlier data); OpenAI, *ChatGPT for Healthcare*, <https://help.openai.com/en/articles/20001046-chatgpt-for-healthcare> (last visited Mar. 17, 2026) ("ChatGPT for Healthcare can pull from millions of peer-reviewed studies, clinical guidelines, and public health sources" to "[g]et clinical answers with citations" that "perform[] better than human baselines across every role measured").

products' utility, and an AI system's utility is a function of its ability to accomplish the objectives users ask it to accomplish.³⁷

Consumers share this understanding of the purpose of AI systems and have learned to trust these systems across a broad swath of applications, from education to health, finance, relationships or a myriad of other uses.³⁸ In fact, according to one major AI developer, consumers accept AI system outputs without conducting any further fact checking over 90% of the time, even though these systems purport to only strive for, rather than guarantee, complete accuracy.³⁹ In other words, consumers ask AI systems for help answering deeply personal and important questions, and they overwhelmingly trust that the system is designed to provide an answer tailored specifically to their objectives.⁴⁰ And because of both the companies' marketing and the inherent value proposition of an AI system, this widely

³⁷ Similarly, an ability to make accurate predictions, correctly solve problems, or make good decisions hinges on AI systems operating without undisclosed ideological biases that contradict explicit and implicit claims of accuracy and neutrality. Though the exact line of what constitutes bias may be difficult to draw, forcing an AI system to prioritize a singular ideological objective over all else is on the wrong side. See Concurring Statement of Comm'r Andrew N. Ferguson, *In re IntelliVision Techs. Corp.*, Matter No. 2323023, at 1 (F.T.C. Dec. 3, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/intellivision-ferguson-concurrence.pdf.

³⁸ Paulo Vargas, *Your Teen Is Probably Using AI for Homework*, Digital Trends (Mar. 2, 2026) ("More than half of U.S. teens ages 13 to 17 say they have turned to chatbots . . . for school tasks."), <https://www.digitaltrends.com/computing/your-teen-is-probably-using-ai-for-homework/>; Walt Williams, *Survey: Consumers Increasingly Turn to AI for Financial Advice*, ABA Banking Journal (Sept. 2, 2025) ("A majority of consumers are turning to artificial intelligence for financial advice . . ."), <https://bankingjournal.aba.com/2025/09/survey-consumers-increasingly-turn-to-ai-for-financial-advice/>; Theo Burman, *Americans Are Using AI To Diagnose Their Health Issues*, Newsweek (July 20, 2025) ("Both clinicians and patients are using artificial intelligence more and more to help diagnose illness and injuries . . ."), <https://www.newsweek.com/ai-healthcare-diagnosis-chatgpt-doctor-2100091>; *How People Ask Claude for Personal Guidance*, Anthropic (Apr. 30, 2026) (finding 12% of all conversations with the Claude program concerned relationship navigation, 6% concerned personal development, and 4% concerned spirituality), <https://www.anthropic.com/research/claude-personal-guidance>.

³⁹ Ted Ladd, *Anthropic: 91% of Users Do Not Fact-Check AI. Let's Fix That*, Forbes (Mar. 5, 2026), <https://www.forbes.com/sites/tedladd/2026/03/05/anthropic-91-of-users-do-not-fact-check-ai-lets-fix-that/>.

⁴⁰ Reasonable consumers would not expect, of course, that an AI system would output content that is clearly and unequivocally not protected by the First Amendment, such as child pornography. And nothing in this statement shall be construed to prohibit companies from imposing limits on model use to prevent cybersecurity attacks.

held consumer expectation is eminently reasonable.

Of course, AI systems are likely to simultaneously pursue multiple objectives, some explicit and some implicit. This will often be consistent with consumers' reasonable expectations. Users of an AI chatbot might, for example, reasonably expect the system to balance succinctness, clarity, relevance, accuracy, and other objectives in its attempt to produce the best output. And while truth and accuracy are in many cases implicit objectives in requests to AI systems, a user could request output that is intentionally inaccurate or that deprioritizes accuracy in favor of some other objective like entertainment.

These representations and baseline consumer expectations notwithstanding, AI companies might steer their systems' outputs toward objectives other than those that consumers ask for or expect. A company could be tempted, for example, to abuse consumer trust by training a model surreptitiously to produce ideologically motivated distortions in a response to a factual question, such as to correct what the developer believes are "historical injustices" in the facts.⁴¹ Or a company could be pressured by a State law to alter its technology's outputs. The original version of Colorado's Artificial Intelligence Act,⁴² for example, imposed a broad duty on AI companies to avoid output that might lead to disparate impacts in various contexts, including when a customer's foreseeable use of that output could itself create a disparate impact. And the revised version of that law explicitly provides AI companies can be held liable for discriminatory outcomes caused by their customers' use of their products.⁴³ It is predictable that an AI company might suppress accuracy and interpose other objectives, such as so-called "equity," to avoid liability under this law, but fail to disclose these ulterior objectives in order to hide the loss of accuracy they necessitate.⁴⁴ AI

companies may also be subject to public pressure to surreptitiously avoid politically inflammatory outputs, as well as the temptation to clandestinely modify their AI systems to further their own or their employees' political agendas.

In light of the above, the Commission believes AI companies that steer the outputs of their AI systems toward unexpected objectives, and away from the objectives set by or reasonably expected by users, are likely to deceive⁴⁵ consumers in violation of section 5 of the FTC Act.⁴⁶ AI companies have made both explicit and implicit representations that their systems aim to produce outputs that achieve users' objectives as faithfully and accurately as they can.⁴⁷ Those representations, absent adequate disclaimers or qualifications, are material as consumers rely on them and are likely to consider, in their decision as to which AI system to use or pay for, whether a particular system is designed to produce output accomplishing their objectives or to intentionally produce a worse output in service of another objective. Consumers may be induced to pay for a service that does not behave as advertised. Consumers may also be deceived into relying on a technology that, by design, produces worse outputs and may recommend suboptimal courses of action, not because of any technological or resource limitations, but because the AI developer's hidden agenda subverted consumers' objectives.

As is always the case, a company's motives for deceiving consumers are irrelevant to the application of section

from making hiring and other employment decisions based on merit and skill, their needs, or the needs of their customers because of the specter that such a process might lead to disparate outcomes, and thus disparate-impact lawsuits. . . . Disparate-impact liability imperils the effectiveness of civil rights laws by mandating, rather than proscribing, discrimination."'). Indeed, it seems likely a law restricting truthful speech because it might lead another person to commit disparate impact discrimination would not survive First Amendment scrutiny, but that is orthogonal to the FTC Act issues we address here.

⁴⁵ The Commission at this time takes no position on whether the practices discussed in this statement may also be unfair under the FTC Act.

⁴⁶ This conduct is distinct from the problem of incorrect output from AI systems, frequently called "hallucinations," that stem not from a design decision to prioritize objectives contrary to users' reasonable expectations, but from the technological and resource limitations AI systems necessarily reflect. While a company may, for example, unlawfully deceive consumers if it misrepresents the likelihood of such hallucinations, the Commission does not believe such hallucinations in and of themselves raise issues under section 5 or any other law the Commission enforces.

⁴⁷ See *supra* notes 35 & 36.

⁴⁸ Whether motivated by profit, shaping public opinion, or anything else, section 5 prohibits deceiving consumers. These prohibitions apply even when a company engages in a deceptive act or practice in order to comply with a State law. Although the FTC Act does not expressly preempt State law, State law is impliedly preempted to the extent it conflicts with a Federal regulatory scheme.⁴⁹ A State law that requires an AI firm to deceive its consumers obviously conflicts with section 5's express purpose of protecting consumers from such conduct.

An AI company can, of course, take actions that shape consumer expectations in ways that make it unreasonable for consumers to believe the AI system is designed to achieve the objectives that consumers would otherwise expect. A company can, for example, clearly and conspicuously disclose that its systems are designed to produce outputs that prioritize certain objectives over what users request and otherwise expect. But such a disclaimer would have to be adequate to shift consumer expectations that would be based otherwise both on companies' explicit representations and on the inherent value proposition of AI systems as tools to solve human problems. An adequate disclaimer could not be buried in terms of service, for instance. It would have to clearly and conspicuously dispel the notion that the system is designed to give the best answer possible. Such a disclaimer would need to be prominent, and it is doubtful a one-time disclosure subsequently hidden away in fine print would suffice. The more the disclosure cuts against the reasonable expectations users would take away from other contexts, the more persistent and prominent it would need to be.⁵⁰ A prominent misrepresentation is unlikely to be remedied by a less prominent,

⁴⁸ *FTC v. Bay Area Bus. Council*, 423 F.3d 627, 635 (7th Cir. 2005) (deception); *In re Kraft, Inc.*, 114 F.T.C. 40, 122 (1991) (deception).

⁴⁹ *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 300 (1988) ("[S]tate law is pre-empted when it actually conflicts with federal law. Such conflict will be found when it is impossible to comply with both state and federal law, or where the state law stands as an obstacle of the full purposes and objectives of Congress." (internal quotations omitted)).

⁵⁰ *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 12 (1st Cir. 2010) (explaining disclaimers "are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression."); *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir.1989) ("[d]isclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression.").

⁴¹ See, e.g., Leo Briceno, *Anthropic's Moral Compass Architect Suggested AI Overcorrection Could Address Historical Injustices*, Fox News (Apr. 22, 2026), <https://www.foxnews.com/politics/anthropics-moral-compass-architect-suggested-ai-overcorrection-could-address-historical-injustices>.

⁴² Colo. Sen. Bill 24–205 (enacted May 17, 2024), *repealed and reenacted, as amended*, by Colo. Sen. Bill 26–189 (enacted May 14, 2026).

⁴³ Colo. Sen. Bill 26–189, 6–1–1707 (enacted May 14, 2026).

⁴⁴ See E.O. 14281, *Restoring Equality of Opportunity and Meritocracy*, at sec. 1, 90 FR 17537 (Apr. 23, 2025) ("Disparate-impact liability all but requires individuals and businesses to consider race and engage in racial balancing to avoid potentially crippling legal liability. . . . On a practical level, disparate-impact liability has hindered businesses

subsequent disclosure.⁵¹ Ultimately, it is the company’s responsibility to ensure compliance with section 5.

V. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before Friday, July 31, 2026. Write “AI Policy Statement; Matter No. P264200” on your comment. Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the <https://www.regulations.gov> website.

We encourage you to submit comments through the <https://www.regulations.gov> website. Postal mail addressed to the Commission will be subject to delay because of heightened security screening. If you prefer to file your comment on paper, write “AI Policy Statement; Matter No. P264200” on your comment and on the envelope, and send it via overnight service to: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H-144 (Annex P), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive

health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the <https://www.regulations.gov> website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before Friday, July 31, 2026. For information

on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

By direction of the Commission.

April J. Tabor,
Secretary.

[FR Doc. 2026–13628 Filed 7–6–26; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

Granting of Requests for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination—on the dates indicated—of the waiting period provided by law and the premerger notification rules. The listing for each transaction includes the transaction number and the parties to the transaction. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

EARLY TERMINATIONS GRANTED
[05/01/2026, 05/31/2026]

05/01/2026		
20251510		Garage Topco, LP; Cantaloupe, Inc.; Garage Topco, LP.
05/05/2026		
20261221	G	Bending Spoons S.p.A.; tractive GmbH; Bending Spoons S.p.A.
20261233	G	Quad-C Partners X, L.P.; Norwest Equity Partners X, LP; Quad-C Partners X, L.P.
20261245	G	Brookfield Oaktree Wealth Solutions Alternative Funds S.A.; Brookfield NERH Aggregator LLC; Brookfield Oaktree Wealth Solutions Alternative Funds S.A.
20261249	G	KKR North America XIV (Bloom) Blocker; Roark Capital Partners VI (T) LP; KKR North America XIV (Bloom) Blocker.
20261262	G	Peak Rock Capital Fund IV LP; BioRidge Pharma Holdco, LLC; Peak Rock Capital Fund IV LP.

⁵¹ See, e.g., Deception Policy Statement at *48, *supra* note 18 (“Depending on the circumstances, accurate information in the text may not remedy a false headline because reasonable consumer may glance only at the headline.”); see also *FTC v. Corpay, Inc.*, 164 F.4th 807, 836 (11th Cir. Jan. 6, 2026) (disclaimers or qualifying language may not correct a misleading impression when the

disclaimer “is small, ambiguous, or contradicted by the body of the ad”) (citing *FTC v. Cyberspace.com LLC*, 453 F.3d 1198, 1200–01 (9th Cir. 2006); *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 12 (1st Cir. 2010) (explaining disclaimers “are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an

accurate impression”); *Removatron Int’l Corp. v. FTC*, 884 F.2d 1489, 1497 (1st Cir.1989) (“[d]isclaimers or qualifications in any particular ad are not adequate to avoid liability unless they are sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression.”).

EARLY TERMINATIONS GRANTED—Continued

[05/01/2026, 05/31/2026]

20261273	G	Clean Harbors, Inc.; Terra Nova Solutions, Inc.; Clean Harbors, Inc.
20261288	G	Cox Family Voting Trust; Fullpath Ltd.; Cox Family Voting Trust.
20261304	G	Martin Marietta Materials, Inc.; New Frontier Materials LLC; Martin Marietta Materials, Inc.
20261310	G	Watsco, Inc.; James J. Durrett, Jr.; Watsco, Inc.
20261311	G	James J. Durrett, Jr.; Watsco, Inc.; James J. Durrett, Jr.
20261313	G	GFL Environmental Inc.; SECURE Waste Infrastructure Corp.; GFL Environmental Inc.
20261319	G	Olympus Growth Fund VIII, L.P.; ORIX Corporation; Olympus Growth Fund VIII, L.P.
05/08/2026		
20261218	G	Prestige Consumer Healthcare Inc.; Breathe Consumer Healthcare Topco, LLC; Prestige Consumer Healthcare Inc.
20261231	G	Genstar BI Gen Holdings (Cayman) LP; Med II S.L.P.; Genstar BI Gen Holdings (Cayman) LP.
20261281	G	Harvest Partners IX (Parallel), L.P.; LF Parent Co, Inc.; Harvest Partners IX (Parallel), L.P.
05/11/2026		
20261064	G	The Brink's Company; NCR Atleos Corporation; The Brink's Company.
05/14/2026		
20261278	G	Repay Holdings Corporation; The Hearst Family Trust; Repay Holdings Corporation.
20261305	G	Zurich Insurance Group Ltd; Beazley plc; Zurich Insurance Group Ltd.
20261329	G	Sun Life Financial Inc.; Bell Partners Inc.; Sun Life Financial Inc.
20261338	G	ESCO Technologies Inc.; TB Continuity II Trust; ESCO Technologies Inc.
20261339	G	TB Continuity II Trust; ESCO Technologies Inc.; TB Continuity II Trust.
20261343	G	Nexans S.A.; Ronald H. Rosenbeck; Nexans S.A.
20261344	G	Quantum Energy Partners VIII, LP; Energy Spectrum Partners VIII LP; Quantum Energy Partners VIII, LP.
20261349	G	ECP VI-D, LP; TriArtisan ES Partners II LP; ECP VI-D, LP.
20261350	G	Elon Musk; CF APR Super Holdings LLC; Elon Musk.
05/21/2026		
20261291	G	Ron Leonhardt; Two Harbors Investment Corp.; Ron Leonhardt.
20261294	G	Infinx Technology Solutions Private Limited; TTCP Fund II, L.P.; Infinx Technology Solutions Private Limited.
20261303	G	TPG Partners X, L.P.; Learfield Holdco, LLC; TPG Partners X, L.P.
20261346	G	Littlejohn Fund VI, L.P.; Southfield Freeze LP; Littlejohn Fund VI, L.P.
05/26/2026		
20261325	G	National HealthCare Corporation; National Health Investors, Inc.; National HealthCare Corporation.
20261326	G	AIPCF VIII Indirect Investor AIV LP; Avanos Medical, Inc.; AIPCF VIII Indirect Investor AIV LP.
20261327	G	AP Gem Holdings, L.P.; McKesson Corporation; AP Gem Holdings, L.P.
20261336	G	Underwriters Laboratories Inc.; Dr. Gilles Martin; Underwriters Laboratories Inc.
20261361	G	Novo Nordisk Foundation; Bain Capital Tech Opportunities Fund, L.P.; Novo Nordisk Foundation.
20261411	G	Hexagon AB; Baker Hughes Company; Hexagon AB.
20261420	G	Republic Services, Inc.; Gregg Meyers; Republic Services, Inc.

FOR FURTHER INFORMATION CONTACT:

Theresa Kingsberry (phone: 202–326–3100), Program Support Specialist, Federal Trade Commission, Bureau of Competition, Premerger Notification Office, Washington, DC 20024.

By direction of the Commission.

Joel Christie,

Acting Secretary.

[FR Doc. 2026–13661 Filed 7–6–26; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Privacy Act of 1974; Matching Program

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for

Medicare & Medicaid Services (CMS) is providing notice of a re-established matching program between CMS and the Department of Veterans Affairs (VA), Veterans Health Administration (VHA), titled, “Verification of Eligibility for Minimum Essential Coverage Under the Patient Protection and Affordable Care Act”. Under this Matching Program, CMS will share data with the VA to verify if an applicant is enrolled in Minimum Essential Coverage in a Veterans Health Administration Health Care Program. This information from the VA will be used to assist CMS to determine if an individual is eligible for Insurance Affordability Programs.

DATES: The deadline for comments on this notice is August 6, 2026. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately June 15, 2026 to December 15, 2027) and within 3 months of expiration may be renewed for one additional year if the parties make no change to the matching

program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit written comments on this notice, by mail or email, to the CMS Privacy Officer, Division of Security, Privacy Policy & Oversight, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850, to barbara.demopulos@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact Terence Kane, Director, Division of Automated Verifications and SEP Policy, Marketplace Eligibility and Enrollment Group, Center for Consumer Information and Insurance Oversight, CMS, at (301) 492–4449 or by email at Terence.kane@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a) provides certain protections for individuals applying for and receiving federal benefits. The law governs the use of computer matching

by federal agencies when records in a system of records (meaning, federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other federal or non-federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the OMB, in advance and annually, as required by 5 U.S.C. 552a(o) (2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopoulos,

CMS Privacy Act Officer, Division of Security, Privacy Policy & Oversight, Information Security and Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services.

Participating Agencies

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is the recipient agency, and the Department of Veterans Affairs (VA), Veterans Health Administration (VHA) is the source agency.

Authority for Conducting the Matching Program

The matching program is authorized under 42 U.S.C. 18001.

Purpose(s)

The purpose of the matching program is to assist CMS in determining individuals' eligibility for financial assistance in paying for private health insurance coverage. In this matching program, VHA provides CMS with data when an Administering Entity (AE) requests it and VHA is authorized to

release it, verifying whether an individual who is applying for or is enrolled in private health insurance coverage under a qualified health plan through a federally-facilitated health insurance exchange is eligible for coverage under a VHA health plan. CMS makes the data provided by VHA available to the requesting AE through a data services hub to use in determining the applicant's or enrollee's eligibility for financial assistance (including an advance tax credit and cost-sharing reduction, which are types of insurance affordability programs) in paying for private health insurance coverage. VHA health plans provide minimum essential coverage, and eligibility for such plans usually precludes eligibility for financial assistance in paying for private coverage. The data provided by VHA under this matching program will be used by CMS and AEs to authenticate identity, determine eligibility for financial assistance, and determine the amount of the financial assistance.

Categories of Individuals

The categories of individuals whose information is involved in the matching program are:

- Veterans whose records at VHA match data provided to VHA by CMS (submitted by AEs) about individuals who are applying for or are enrolled in private insurance coverage through a federally-facilitated health insurance exchange.

Categories of Records

The categories of records used in this matching program are identity records and minimum essential coverage period records consisting of the following data elements:

Data provided by CMS to VHA:

- a. First Name (required)
- b. Middle Name/Initial (if provided by applicant)
- c. Surname (Applicant's Last Name) (required)
- d. Date of Birth (required)
- e. Sex (required)
- f. SSN (required)
- g. Requested Qualified Health Plan (QHP) Coverage Effective Date (required)
- h. Requested QHP Coverage End Date (required)
- i. State Identification (required)
- j. Transaction ID (required)

Data provided by VHA to CMS:

- a. SSN (required)
- b. Start/End Date(s) of enrollment period(s) (when match occurs)
- c. A blank date response when a non-match occurs, or if the VA's records contain a Date of Death.

System(s) of Records

The data used in this matching program will be disclosed from the following systems of records, based on the routine uses identified:

- Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018).

- “Veterans and Beneficiaries Purchased Care Community Health Care Claims, Correspondence, Eligibility, Inquiry and Payment Files-VA,” System No. 54VA10; last fully published at 90 FR 4447354 (September 15, 2025).

- “Compensation, Pension, Education, and Veteran Readiness and Employment Records, VA (58VA21/22/28), last published at 90 FR 44464.

[FR Doc. 2026–13671 Filed 7–6–26; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Health Care Services Outreach Program Measures, OMB No. 0906–0009—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than August 6, 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 Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Rural Health Care Services Outreach Program Measures, OMB No. 0906-0009—Revision.

Abstract: The Rural Health Care Services Outreach (Outreach) Program is authorized by section 330A(e) of the Public Health Service Act (42 U.S.C. 254c(e)) to “promote rural health care services outreach by improving and expanding the delivery of health care services to include new and enhanced services in rural areas.” HRSA currently collects information about Outreach grants using an OMB-approved set of performance measures and seeks to revise that approved collection. The proposed changes are a result of keeping this instrument relevant, responsive to the Outreach Program needs and to improve clarity and ease of reporting for respondents.

A 60-day notice published in the **Federal Register** on April 7, 2026, vol. 91, No. 66; pp. 17660–61. There were no public comments.

Need and Proposed Use of the Information: HRSA has revised the performance measures which Outreach awardees will submit to HRSA on an annual basis. The purpose of the revised data collection is to assess Outreach awardees’ progress in meeting the program goals and how well each awardee meets their community needs. Additionally, HRSA will be able to monitor and assess the impact of the Outreach program and ensure that funds are effectively used to provide services that meet the target population’s needs.

The proposed changes include the consolidation of three sub-sections (Consortium/Network, Access to Care, and Population Demographics) into two new sub-sections (Capacity/Organizational Information and Access/Population Demographics); addition of nine new maternal health measures (four required measures; five optional measures) for the 11 award recipients in the Healthy Rural Hometown Initiative track only; and adding one new question and revising the response selection list related to sustainability. Additionally, there is an increase in the

estimated total burden hours compared to the previous ICR package. The increase in burden is to account for a new cohort of recipients new to this data collection. This includes 40 recipients funded under the Regular Outreach Track and 18 recipients funded under the Healthy Rural Hometown Initiative Track awarded under HRSA-25-038.

Likely Respondents: Respondents include all 58 Outreach award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Care Services Outreach Performance Measures	58	1	58	8.75	507.50
Total	58	1	58	8.75	507.50

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2026-13636 Filed 7-6-26; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC or Committee) meeting.

The purpose of the IACC meeting is to discuss committee business, agency updates, and issues related to autism research and services activities. The meeting will be open to the public to attend in person or virtually. Virtual viewing will be accessible via NIH Videocast. Advanced registration is required for in-person attendance. Individuals wishing to participate in

person or virtually and in need of special assistance or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least seven (7) business days prior to the meeting.

The open session can be accessed from the NIH Videocast website (<https://videocast.nih.gov/>).

Name of Committee: Interagency Autism Coordinating Committee.

Date: July 31, 2026.

Time: 9:00 a.m. to 5:00 p.m. ET.

Agenda: To discuss committee business, updates, and issues related to autism research and services activities.

Address: National Institutes of Mental Health (NIMH), Neuroscience Center (NSC), First Floor Conference Rooms, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Open Meeting. Hybrid.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (iacc.hhs.gov) prior to the meeting. Pre-registration is required for in-person attendance.

Deadlines: Public Comment Due Date: Friday, July 17, by 5:00 p.m. ET, Public Comment Guidelines, For public comment instructions, see below.

Contact Person: Ms. Rebecca Martin, Office of National Autism Coordination, National Institute of Mental Health, NIH, Phone: 301-435-0886, Email: IACCPublicInquiries@mail.nih.gov.

Public Comments

The IACC welcomes written and oral/virtual public comments from members of the autism community and asks the community to review and adhere to its Public Comment Guidelines. In the 2021–2023 IACC Strategic Plan, the IACC lists the “Spirit of Collaboration” as one of its core values, stating that, “We will treat others with respect, listen with open minds to the diverse lived experiences of people on the autism spectrum and their families, consider multiple solutions, and foster discussions where participants can comfortably share different opinions.” In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also adhere to this core value.

A limited number of slots are available for individuals to provide a ~3-minute summary or excerpt of their written comment to the Committee during the meeting either in person or via videoconference. For those interested in that opportunity, please indicate “Interested in providing oral/virtual comment” in your written submission, along with your name, address, email, phone number, and professional/organizational affiliation so that OARC staff can contact you if a slot is available.

For any given meeting, priority for comment slots will be assigned to individuals and organizations that have not previously provided comments in the current calendar year. This will help ensure that as many individuals and organizations as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately in order to allow other comments and the rest of the meeting to proceed on schedule.

Public comment submissions received by 5:00 p.m. ET on Friday, July 17,

2026, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, Friday, July 17, 2026, may be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. The Committee is not able to respond individually to comments. All public comments become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided. For public comment guidelines, see: <https://iacc.hhs.gov/meetings/public-comments/guidelines/>.

Technical issues: If you experience any technical problems with the webcast, please email IACCPublicInquiries@mail.nih.gov.

Disability Accommodations: All IACC Full Committee Meetings provide Closed Captioning through the NIH videocast website. Individuals whose full participation in the meeting will require special accommodations (e.g., sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last-minute requests may be made but may not be possible to accommodate.

Security: Pre-registration is required for in-person attendance. Upon arrival, all attendees will be required to complete the check-in process. Visitors should be prepared to state the purpose of their visit and present a valid form of identification, such as a REAL ID-compliant identification, U.S. passport, or proof of legal U.S. residency. Non-U.S. persons must pre-register at least 10 business days in advance and wait for approval to attend. Seating will be available on a first-come, first-served basis.

Meeting schedule is subject to change.

More Information: Information about the IACC is available on the website: <https://iacc.hhs.gov>.

Dated: July 2, 2026.

Rosalind M. Niamke,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–13714 Filed 7–6–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, September 17, 2026, 08:30 a.m. to September 18, 2026, 04:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, M, 20892 which was published in the **Federal Register** on July 24, 2025, 90 FR 34872.

This notice is being amended to reflect the change in date from September 17–18, 2026, to October 28, 2026. The time will change from 8:30 a.m. to 4:00 p.m. to 8:30 a.m. to 3:00 p.m. The meeting format will adjust from in-person/virtual to virtual only. The meeting is partially closed to the public.

Dated: July 1, 2026.

Margaret N. Vardanian,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–13635 Filed 7–6–26; 8:45 am]

BILLING CODE 4167–05–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; Cognitive

and Language Habilitation and Rehabilitation.

Date: July 29, 2026.

Time: 9:00 a.m. to 5:00 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: Devon Rene Oskvig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-9088, devon.oskvig@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Training and Career Development: Healthcare, Health Promotion & Implementation.

Date: July 30–31, 2026.

Time: 9:30 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: Helen Huang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594 8934, helen.huang@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

Date: July 30, 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: Yuanyi Feng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594-1180, fengy7@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: International Research Scientist Development Awards.

Date: July 30, 2026.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rockville, MD 20892, (301) 594-4377, shiv.prasad@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Clinical Care and Interventions for Substance Use Disorder, Prevention, and Treatment of Addiction.

Date: July 30–31, 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: Cristina Lyn Reitz-Krueger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-2060, cristina.reitz-krueger@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: SEP for R01 and R21 applications.

Date: July 30, 2026.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Lee Warren Slice, MS, BA, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402 9286, slicelw@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Contracts: Development of Radiological/Nuclear Medical Countermeasures (MCMs) And Biodosimetry Devices.

Date: July 30–31, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Hailey P. Weerts, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594 3506, hailey.weerts@nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Aging, Injury, Musculoskeletal, and Rheumatologic Disorders Study Section.

Date: July 30–31, 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: Nketi I. Forbang, MD, MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006K1, Bethesda, MD 20892, (301) 594-0357, forbangni@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Early Development of Vaccines Against Infectious Diseases.

Date: July 30, 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: Vanitha Sundaresa Raman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-594-3950, vanitha.raman@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Pregnancy, Reproduction and Metabolism.

Date: July 30, 2026.

Time: 10:30 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: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435-5947, banerjees5@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Motivated Behavior, Alcohol, and Addictive Substances.

Date: July 30, 2026.

Time: 11:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mamatha Garige, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 443-1706, mamatha.garige@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Alzheimer's and Neurodegeneration II.

Date: July 30, 2026.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Patricia Manos Kraemer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 827-2551, manospa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-24-129: Specific Pathogen Free Macaque Colonies.

Date: July 30, 2026.

Time: 2:00 p.m. to 5:00 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: Tori Stone, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-7549, tori.stone@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Basic Neuroscience.

Date: July 30, 2026.

Time: 12:00 p.m. to 3:00 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: Marta Veronica Hamity, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 451-1664, marta.hamity@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in drug development, toxicology, and delivery.

Date: July 30, 2026.

Time: 12:00 p.m. to 5:00 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: Heidi B. Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 907-H, Bethesda, MD 20892, (301) 827 3055, hfriedman@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 1, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-13686 Filed 7-6-26; 8:45 am]

BILLING CODE 4167-05-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0114]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Civil Surgeon Designation

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information

collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until August 6, 2026.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at <http://www.regulations.gov> under e-Docket ID number USCIS-2013-0002. All submissions received must include the OMB Control Number 1615-0114 in the body of the letter, the agency name and Docket ID USCIS-2013-0002.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, John R. Pfirrmann-Powell, Acting Deputy Chief, telephone number (240) 721-3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <http://www.uscis.gov>, or call the USCIS Contact Center at 800-375-5283 (TTY 800-767-1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on April 20, 2026, at 91 FR 21012, allowing for a 60-day public comment period. USCIS did receive one comment in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS-2013-0002 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5 CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information

makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Civil Surgeon Designation.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-910; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. This information collection is required to determine whether a physician meets the statutory and regulatory requirement for civil surgeon designation. For example, all documents are reviewed to determine whether the physician has a currently valid medical license and whether the physician has had any action taken against him or her by the medical licensing authority of the U.S. state(s) or U.S. territories in which he or she practices. If the Application for Civil Surgeon Designation (Form I-910) is approved, the physician is included in USCIS's public Civil

Surgeon locator and is authorized to complete Form I-693 (OMB Control Number 1615-0033) for an applicant's adjustment of status.

(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 annual respondents for the information collection I-910 is 470 and the estimated hour burden per response is 2 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total annual hour burden associated with this collection is 2 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 \$24,205.

Dated: July 1, 2026.

John R. Pfirrmann-Powell,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2026-13640 Filed 7-6-26; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7106-N-29]

Privacy Act of 1974; System of Records

AGENCY: Office of Housing, HUD.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Housing and Urban Development (HUD), Office of Housing, is issuing public notice of its intent to modify the Office of Single-Family Housing, Privacy Act system of records, Single-Family Mortgage Asset Recovery Technology (SMART) system. The purpose of the Smart System is to provide various loan servicing functions including generating payoffs and processing payments for HUD FHA Insured Title II Secretary held loans. The modification will expand the categories of records in the system and incorporate the "Do Not Pay" routine use to support payment integrity and compliance with applicable federal requirements.

DATES: Comments will be accepted on or before August 6, 2026. This proposed action will be effective on the date following the end of the comment period unless comments are received

which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number or by one of the following methods:

Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions provided on that site to submit comments electronically.

Fax: 202-619-8365.

Email: privacy@hud.gov.

Mail: Attention: Privacy Office, Kimberly Morton, Acting Chief Privacy Officer; The Executive Secretariat; 451 7th Street SW, Room 10139; Washington, DC 20410-0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Kimberly Morton, Acting Chief Privacy Officer, 451 7th Street SW, Room 10139; Washington, DC 20410-0001; telephone number (804) 822-4801 (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: HUD, Office of Single-Family Housing maintains the SMART System. HUD is publishing this notice to include these changes reflecting the modified items below:

1. *Category of Records:* Updated this revise notice to add Taxpayer Identification number (TIN) on Automated Clearing House (ACH) deposits for refunds/overages on Secretary held loans.

2. *Routine Uses for Records Maintained in the System:* This Notice incorporates the "Do Not Pay" routine use required by OMB M-25-32, which was added to this System of Records Notice by FR-7106-N-12, 91 FR 2137, January 16, 2026.

SYSTEM NAME AND NUMBER:

Single-Family Mortgage Asset Recovery Technology (SMART), HUD/HOU-58.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Digital records are maintained at the Amazon Web Services (AWS) Simple Technology Solutions Inc, 1775 I Street NW, Suite 1150, Washington, DC 2006-2402. Active paper records are kept at ISN Corporation, 2000 N Classen Blvd., Suite 3200, Oklahoma City, OK 73106.

SYSTEM MANAGER(S):

Office of Single-Family Housing, Elissa Saunders, Director, Office of Single Family Asset Management, 100 S Charles Street, 5th Floor, Baltimore, MD 21201, Telephone Number (202) 402-2378.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Housing and Community Development Act of 1987, 42 U.S.C. 3543(a); Sec. 204, National Housing Act, 12 U.S.C. 1710(a).

PURPOSES OF THE SYSTEM:

The Single Family Mortgage Asset Recovery Technology (SMART) System is a specialized servicing web-application that is used to service and track servicing activities for the Secretary Held portfolio including 235 insured, Asset Control Area Program (ACA), Emergency Home Loan Program (EHL), Good Neighbor Next Door Program (GNND), Hope for Homeowners (H4H), Nehemiah Program, Partial Claim (PC), Purchase Money Mortgage (PMM). SMART provides automated business processes to perform comprehensive loan servicing for loan programs that are under the jurisdiction of the Office of Single Family Asset Management.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Mortgagors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Mortgagor's Full Name, Social Security Number, Date of Birth, Email, Work Address, Financial Information, Taxpayer Identification Number (TIN), home address, Phone Number, Spouse Name, Lender Loan Number, FHA Case Number.

RECORD SOURCE CATEGORIES:

Records are initiated by HUD employees and their contractors. Information is also received from Single Family Insurance System (CLAIMS Subsystem), HUD FHA Resource Center Customer Relationship Management System (CRM), Department of Treasury and it also collects and maintains information entered by authorized personnel based on loan data received from Asset Disposition and Management System (ADAMS).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(1) To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

(2) To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(3) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, cooperative agreement, or other agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function.

(4) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for the purpose of: (1) detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs; or (4) for the purpose of establishing or verifying the eligibility of, or continuing compliance with statutory and regulatory requirements by, applicants for, recipients or beneficiaries of, participants in, or providers of services with respect to, cash or in-kind assistance or payments under Federal benefits programs or recouping payments or delinquent debts under such Federal benefits programs. Records under this routine use may be disclosed only to the extent that the information shared is necessary and relevant to verify pre-award and prepayment requirements prior to the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(5) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or other agreement for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, to otherwise support the Department's mission, or for other research and statistical purposes not otherwise prohibited by law or regulation. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The entity receiving information under this routine use may not further disclose the records in an identifiable form.

(6) To contractors, experts, and consultants with whom HUD has a contract, service agreement, assignment, or other agreement, when necessary, to utilize relevant data for the purpose of testing new technology and systems designed to enhance program operations and performance.

(7) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed that there has been a breach of the system of records; (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed breach to prevent, minimize, or remedy such harm.

(8) To another Federal agency or Federal entity, when HUD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(9) To appropriate Federal, State, local, tribal, or other governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the

violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws and when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(10) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(11) To the U.S. Treasury for disbursements and adjustments.

(12) To the IRS for reporting discharge of indebtedness.

(13) To the U.S. Department of the Treasury when disclosure of the information is relevant to review payment and award eligibility through the Do Not Pay Working System for the purposes of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds, including funds disbursed by a state (meaning a state of the United States, the District of Columbia, a territory or possession of the United States, or a federally recognized Indian tribe) in a state-administered, federally funded program.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are retrieved by Electronic and paper records. Electronic records are maintained within HUD-authorized systems using encryption and restricted-access directories. Paper records are stored in secured offices or file cabinets with physical access controls.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by mortgagor name, FHA Case Number, or home address.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

In accordance with HUD records disposition schedule 2225.6, Appendix

20. records are destroyed upon successful creation of the final document or file, or when no longer needed for business use, whichever is later. Backup and recovery digital media will be destroyed or otherwise rendered irrecoverable per NIST SP 800–88 “Guidelines for Media Sanitization.” GRS 5.2, Item 20, DAA–GRS2017–0003–0002. Temporary. Destroy upon verification of successful creation of the final document or file, or when no longer needed for business use, whichever is later.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Administrative Safeguards: When first gaining access to SMART and annually, all users must agree to the systems “Rules of Behavior” which specify handling of personal information and any physical records.

Technical Safeguards: Controls for the system include, but are not limited to, username identification, password protection, multi-factor authentication, firewalls, virtual private network, encryption, and is limited to authorized users.

Physical Safeguards: Controls to secure the data and protect paper records are maintained and locked in file cabinets. The original collateral documents (hard copy) are stored at the contractor’s office site for all open loans, and the closed documents are stored at a secured offsite document storage facility. All hard copy files are stored within a secured room within the contractor’s secured office suite when not in use. Background screening, limited authorizations, and access, with access limited to authorized personnel and technical restraints employed regarding accessing the records, access to automated systems by authorized users by username and passwords.

RECORD ACCESS PROCEDURES:

Individuals requesting records of themselves should address written inquiries to the Department of Housing and Urban Development 451 7th Street SW, Washington, DC 20410–0001. For verification, individuals should provide their full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

CONTESTING RECORD PROCEDURES:

The HUD rule for contesting the content of any record pertaining to the individual by the individual concerned is published in 24 CFR 16.8 or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals requesting notification of records of themselves should address written inquiries to the Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide their full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Docket No. FR–7092–N–20, 89 FR 12865, February 20, 2024, as modified by FR–7106–N–12, 91 FR 2137, January 16, 2026.

Kimberly Morton,

Acting Chief Privacy Officer.

[FR Doc. 2026–13660 Filed 7–6–26; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7107–N–13; OMB Control No.: 2577–0216]

30-Day Notice of Proposed Information Collection: Annual Moving To Work (MTW) Plan and Report Elements, MTW Plan-Expansion

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comments from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* August 6, 2026.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Anna Guido, PRA Compliance Officer,

Paperwork Reduction Act Division, PRAD, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email at PaperworkReductionActOffice@hud.gov, ATTN: Anna Guido, telephone (202) 402–5535. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 4, 2025 at 90 FR 42772.

A. Overview of Information Collection

Title of Information Collection: Annual MTW Plan and Report Elements, MTW Plan-Expansion.

OMB Approval Number: 2577–0216.

Type of Request: Revision of a currently approved collection.

Form Number: HUD Form –50900; HUD Form–50900–EXPANSION.

Description of the need for the information and proposed use: The Moving to Work (MTW) demonstration was first established under Section 204 of Title II of section 101(e) of the Omnibus Consolidated Rescissions and Appropriations Act of 1996, Public Law 104–134, 110 Stat. 1321–281; 42 U.S.C. 1437f note (1996 MTW Statute). In 2016, the MTW demonstration program was expanded pursuant to Section 239 of the Fiscal Year 2016 Appropriations Act, Public Law 114–113 (2016 MTW Expansion Statute).

All public housing agencies (PHAs) are required to submit a five (5) year plan and annual plans as stated in Section 5A of the 1937 Act, as amended. MTW PHAs designated prior to 2016 (Initial MTW PHAs) that are subject to the Standard MTW Agreement, are required to submit the Annual MTW Plan and Annual MTW Report Elements (also known as the HUD Form 50900) in lieu of the standard annual and 5-year PHA plans. MTW PHAs designated after 2016 (Expansion MTW PHAs) that are subject to the MTW Operations Notice, are required to submit the MTW Plan-Expansion (also known as the HUD Form 50900–EXPANSION) in addition

to the standard annual and 5-year PHA plans.

The HUD Form 50900 and the HUD Form 50900–EXPANSION contain important information regarding the MTW PHA’s upcoming MTW activities and a retrospective look back at the MTW PHA’s preceding fiscal year (FY). HUD collects the information in these forms in order to track the prevalence of MTW activities, accurately and timely respond to congressional and other inquiries, and identify promising practices learned through the MTW demonstration.

Discussion of Revisions

The HUD Form 50900–EXPANSION was previously called the “MTW Supplement to the Annual PHA Plan” (HUD Form 50075–MTW under OMB No. 2577–0226). In order to streamline administration of this collection, it is being renamed and moved under OMB No. 2577–0216. Revisions are also being made to the HUD Form 50900–EXPANSION to reduce the reporting and administrative burden on Expansion MTW PHAs. Many core questions and all custom questions within the HUD Form 50900–Expansion that were previously required for MTW activities will be eliminated. In addition to eliminating these previously required questions, other sections will be streamlined where information is already verified through existing certifications and HUD systems. This will reduce burden on Expansion MTW PHAs.

Through the MTW Plan-Expansion, each Expansion MTW PHA will continue to inform HUD, its residents and the public of the PHA’s mission for serving the needs of low-income and very low-income families, and the PHA’s strategy for addressing those needs. In conjunction with the regular PHA Plan, the MTW Plan-Expansion, provides an easily identifiable source by which residents, participants in tenant-based programs, and other members of the public may locate policies, rules, and requirements concerning the Expansion MTW PHA’s operations, programs, and services.

No revisions are being made to the HUD Form 50900 for Initial MTW PHAs.

The 2016 MTW Expansion Statute authorized an additional 100 MTW slots and additional slots may be added through future appropriations acts. Eligible applicants interested in obtaining MTW designation are required to submit applications to HUD, as explained in the applicable HUD Notice. The information collection covers the information needed from applicants to

determine which applicants should be selected. The information provided demonstrates the applicants’ plans to implement a local MTW program and includes related applicant history. The application includes such information as narrative exhibits, certifications, data forms, and supporting documentation. The information will be used by HUD staff to evaluate threshold requirements and review applications.

General Comments

On the Need To Increase Data Collection and Transparency for the MTW Plan Expansion: The commenter urges that additional data be collected by MTW Expansion PHAs. Specifically, the commenter requests narrative information for each waiver and associated activity.

HUD Response: Descriptions of MTW waivers and associated activities and their applicable safe harbors are described in the MTW Operations Notice, which is linked in the Form. HUD seeks to cease requiring these additional descriptions to prevent redundancy. To the extent an MTW Expansion PHA seeks to go beyond applicable safe harbors, they would be required to provide additional description.

On the Need To Collect Information on Public Comments for the MTW Plan Expansion: The commenter urges HUD to maintain required information on public comments.

HUD Response: MTW Expansion PHAs certify in the “Certifications of Compliance” section that public process requirements have been met. To further ensure the extent to which this occurs, additional entries have been added on public comments and the required public process to ensure these requirements are met.

On Marinating the Evaluations Section for the MTW Plan Expansion: The commenter urges HUD to maintain the evaluations section of the MTW Plan Expansion.

HUD Response: For MTW Expansion PHAs, all required evaluation is conducted through HUD’s Office of Policy Development and Research (PD&R). PD&R provides the public with information on the evaluations it conducts, so to require that MTW Expansion PHAs also provide information was determined to be redundant.

Positive Comment on the MTW Funding Flexibility Section of the MTW Plan Expansion: The commenter supports the “Planned Application of MTW Funding Flexibilities” Section.

HUD Response: Thank you for your comment.

On Allowing MTW Expansion PHAs an Additional Option for Safe Harbor Waivers in the MTW Plan Expansion: The commenter requests a third option beyond “yes/no” to the question of whether the PHA “meets all fo the associated Safe Harbors . . . for which the MTW Expansion Agency does not have a proposed or approved Safe Harbor Waiver” for PHAs seeking a Safe Harbor Waiver.

HUD Response: Per the information request, if the MTW Expansion PHA is seeking a Safe Harbor Waiver, they would be proposing a Safe Harbor Waiver. They would then input “no.”

On Allowing MTW Expansion PHAs To Skip the Entire Local-Non Traditional (LNT) Section of the MTW Plan Expansion if It Is Not Applicable: The commenter requests that MTW Expansion PHAs that do not have applicable LNT waivers and associated activities be able to skip the section in its entirety.

HUD Response: MTW Expansion PHAs may input “0” or “N/A” for fields as appropriate. This is explained in the instructions section.

On Capturing LNT Substantially the Same (STS) Information in the MTW Plan Expansion: The commenter requests that additional unit information be collected for LNT development units in order to ensure proper calculation of the STS requirement.

HUD Response: LNT development units under waiver and associated activity 17.c are calculated by approximating a number of units compared to the investment of MTW funds. This process is explained in the MTW Operations Notice. The information collected in the LNT STS section collects the information necessary for this exercise.

On Capturing LNT Data in the MTW Plan Expansion: The commenter believes information in Section F and Section G on LNT development is redundant.

HUD Response: The information in Section F represents planned information and information on all completed projects, which is important to the analysis of that particular activity. The information in Section G represents actual information for the applicable calendar year that is necessary to conduct the STS analysis. This is clearly described in the instructions section. An additional qualifier was added to the table.

On the Certifications of Compliance: The commenter requests that HUD review the Certifications of Compliance to ensure they are consistent with MTW flexibility.

HUD Response: HUD has reviewed the Certifications of Compliance to

ensure they are consistent with MTW flexibility.

Information collection	Number of respondents	Frequency of responses	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Application	0	0	0	0	0	\$0	\$0
HUD Form 50900: "Annual MTW Plan and Report Elements"	39	2	78	115	8,970	62.44	560,087
HUD Form 50900-EX-PANSION: "MTW Plan-Expansion"	100	1	100	6	600	62.44	37,464
Totals	139	3	178	121	4,578	62.44	597,551

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Anna Guido,

Department PRA Compliance Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2026-13672 Filed 7-6-26; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-R7-ES-2026-1255; FXES11607MRG01-267-FF07CMM00]

Marine Mammal Protection Act; Permit Applications and Issuances

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), invite public comment on applications for permits to conduct certain activities involving marine mammals for which the Service has jurisdiction under the Marine Mammal Protection Act. In addition, we announce permits that we have issued recently in response to prior applications.

DATES: We must receive comments on the new permit applications by August 6, 2026. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date.

To ensure your comment is received and considered, you must submit it using one of the methods identified in the **ADDRESSES** section of this document. Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered.

ADDRESSES:

Obtaining Documents:

- *Application Materials:* The applications, application supporting materials, and any comments and other materials that we receive are available for public inspection at <https://www.regulations.gov> in Docket No. FWS-R7-ES-2026-1255.

- *Issued Permits:* To access materials pertaining to the permits we have issued, see Permits Issued by the Service under **SUPPLEMENTARY INFORMATION**.

Comment submission: All submissions must include the docket number [FWS-R7-ES-2026-1255] for this document. You must submit comments using one of the following methods:

- *Electronic submission:* Federal eRulemaking Portal at: <https://www.regulations.gov>. In the Search box, enter FWS-R7-ES-2026-1255, which is

the docket number for this action. Then click the Search button. On the resulting page, you may submit a comment by clicking on "Comment." Please ensure that you have found the correct document before submitting your comments.

- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS-R7-ES-2026-1255, Policy and Regulations Branch, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041-3803.

Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered. We will not accept comments via email, fax, or hand delivery. We are not required to consider comments that are submitted after the comment period ends or that are submitted via a method outside of these instructions. Comments containing profanity, vulgarity, threats, or other inappropriate content will not be considered.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

Katrina Liebhich, via email at r7mmmregulatory@fws.gov or by telephone at 907-786-3800. 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:

I. Background

With some exceptions, the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), prohibits the take and importation of marine mammals and marine mammal products absent Federal

authorization. In carrying out our responsibilities under the MMPA, we, the U.S. Fish and Wildlife Service (Service), may authorize such activities via permits after receipt of an application and verification that MMPA statutory and regulatory requirements are met.

Section 104(c) of the MMPA specifies the conditions for authorizing the taking or importation of a marine mammal for purposes of scientific research, public display, or enhancing the survival or recovery of a species or stock under the MMPA.

This notice provides information about two aspects of the MMPA permitting process: application and issuance. In section II, we provide the public with notice of and the opportunity to comment on applications that we have received from entities or individuals to conduct certain activities with marine mammals for which the Service has jurisdiction under the MMPA. In section III, we announce recently issued MMPA permits to entities or individuals in response to prior applications.

II. Applications Available for Public Review

To help us carry out our conservation responsibilities for affected species, and in consideration of section 104(c) of the MMPA, we invite the public and local, State, Tribal, and Federal agencies to comment on the applications listed below before final action is taken. Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of these marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

A. Permit Applications Received

We invite comments on the following applications:

Applicant: U.S. Fish and Wildlife Service, Anchorage, AK; Permit No. PER10641535 [CSTASK5815578]

The applicant requests a modification to their scientific research permit to

collect blood and skin samples from 11 captive Pacific walruses (*Odobenus rosmarus divergens*) to improve aging methods. This information will add to a body of knowledge that can inform population estimates and improve understanding of demographic parameters essential for assessing conservation needs, such as age-specific survival and reproduction.

B. Public Comment Procedures

1. How do I comment on permit applications?

Before issuing any requested permit, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments that we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (a) Those supported by quantitative information or studies; and (b) those that include citations to, and analyses of, the applicable laws and regulations.

2. May I review comments submitted by others?

You may view public comments at <https://www.regulations.gov> unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or other Federal law.

3. Who will see my comments?

If you submit a comment at <https://www.regulations.gov>, your entire comment, including any personal identifying information, will be posted on the website. If you submit a

hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

C. Next Steps for Submitted Applications

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed above in this notice, we will publish a subsequent notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching <https://www.regulations.gov> for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to <https://www.regulations.gov> and search for “12345A”.

III. Permits Issued by the Service

We have issued permits to conduct certain activities involving marine mammals and marine mammal products in response to prior permit applications that we received. This notice informs the public that the Service has issued the permits listed in table 1 below.

The permittees’ original permit application materials, along with public comments we received during public comment periods for the applications, are available for review.

To locate the application materials and received comments, go to <https://www.regulations.gov> and search for the appropriate permit number (e.g., PER12345) or docket number (e.g., FWS–R7–ES–2026–1255) provided in table 1.

TABLE 1—MMPA PERMITS RECENTLY ISSUED

Permit number	Applicant	Permit issuance date	Docket number
PER19222522	U.S. Geological Survey	12/02/25	FWS–R7–ES–2025–0037
PER14048379	University of Memphis	03/12/26	FWS–R7–ES–2025–0037

IV. Authority

We issue this notice under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and its implementing regulations.

Drew Crane,

Acting Assistant Regional Director, Fisheries and Ecological Services, Alaska Region.

[FR Doc. 2026–13707 Filed 7–6–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs**

[267A2100DD/AAKP300000/
AOA501010.000000; OMB Control Number
1076–0152]

**Agency Information Collection
Activities; Tribal Revenue Allocation
Plans**

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice of information collection;
request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary—Indian Affairs (AS–IA) is proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before September 8, 2026.

ADDRESSES: To submit comments, please visit <https://www.regulations.gov/docket/BIA-2022-0005/document> or use the search field on <https://www.regulations.gov> to find the “BIA–2022–0005” docket. Please follow the instructions on *Regulations.gov* for submitting a comment; and reference the “OMB Control Number 1076–0152” within your comment submission. You may also mail comments to Indian Affairs, RACA, 1001 Indian School Road NW, Suite 229, Albuquerque, NM 87104.

FOR FURTHER INFORMATION CONTACT: Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; comments@bia.gov; (202) 208–5403. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. You may also view the ICR at <https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=1076-0152>.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501) 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.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: An Indian tribe must ask the Secretary to approve a Tribal revenue allocation plan. In order for Indian Tribes to distribute net gaming revenues in the form of per capita payments, information is needed by the AS–IA to ensure that Tribal revenue allocation plans include: (1) Assurances that certain statutory requirements are met, (2) a breakdown of the specific uses to

which net gaming revenues will be allocated, (3) eligibility requirements for participation, (4) tax liability notification, and (5) the assurance of the protection and preservation of the per capita share of minors and legal incompetents. Sections 290.12, 290.17, 290.24 and 290.26 of 25 CFR part 290, Tribal Revenue Allocation Plans, specify the information collection requirement. The information to be collected includes: The name of the Tribe, Tribal documents, the allocation plan, and other documents deemed necessary.

Title of Collection: Tribal Revenue Allocation Plans, 25 CFR 290.

OMB Control Number: 1076–0152.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Federally recognized Indian Tribes.

Total Estimated Number of Annual Respondents: 20.

Total Estimated Number of Annual Responses: 20.

Estimated Completion Time per Response: 100 hours.

Total Estimated Number of Annual Burden Hours: 2,000 hours.

Respondent’s Obligation: Required to obtain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: \$0.

Authority

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501).

Steven Mullen,

*Information Collection Clearance Officer,
Office of Regulatory Affairs and Collaborative
Action—Indian Affairs.*

[FR Doc. 2026–13718 Filed 7–6–26; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs**

[267A2100DD AAKE200000/
AOA501010.000000]

**Indian Gaming; Extension of Tribal-
State Class III Gaming Compact
Between the Yurok Tribe of the Yurok
Reservation, California, and the State
of California**

AGENCY: Bureau of Indian Affairs,
Interior.

ACTION: Notice.

SUMMARY: This notice announces the extension of the Class III gaming compact between the Yurok Tribe of the Yurok Reservation, California, and the State of California.

DATES: The extension takes effect on July 7, 2026.

FOR FURTHER INFORMATION CONTACT: Mr. Troy Woodward, Acting Director, Office of Indian Gaming, Office of the Assistant Secretary—Indian Affairs, Washington, DC 20240, IndianGaming@bia.gov; (202) 219-4066.

SUPPLEMENTARY INFORMATION: An extension to an existing Tribal-State Class III gaming compact does not require approval by the Secretary if the extension does not modify any other terms of the compact. *See* 25 CFR 293.5. The Yurok Tribe of the Yurok Reservation, California, and the State of California have reached an agreement to extend the expiration date of their existing Tribal-State Class III gaming compact to December 31, 2026. This publication provides notice of the new expiration date of the compact.

William Henry Kirkland III,
Assistant Secretary—Indian Affairs.

[FR Doc. 2026-13701 Filed 7-6-26; 8:45 am]

BILLING CODE 4337-15-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-608]

USMCA Automotive Rules of Origin: Economic Impact and Operation, 2027 Report; Submission of Questionnaire and Information Collection Plan for Office of Management and Budget Review

AGENCY: U.S. International Trade Commission.

ACTION: Notice of submission of request for approval of a questionnaire and information collection to the Office of Management and Budget (OMB).

SUMMARY: The information requested by the questionnaire is for use by the Commission in connection with Investigation No. 332-608, *USMCA Automotive Rules of Origin: Economic Impact and Operation, 2027 Report*.

ADDRESSES: All Commission offices are located in the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. 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.

FOR FURTHER INFORMATION CONTACT: Please direct all questions to the project

team via email at USMCAAutoROO@usitc.gov or via phone to Conor Hargrove at 202-708-5409.

Comments about the proposal should be provided to the OMB Office of Information and Regulatory Affairs, through the Information Collection Review Dashboard at <https://www.reginfo.gov>. All comments should be specific, indicating whether any part of the questionnaire is objectionable, describing the concern in detail, and including specific suggested revisions or language changes. Please send electronic copies of any comments to the Commission's survey team via email to USMCAAutoROO@usitc.gov.

The public record for this investigation is viewable on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. General information concerning the Commission is available on its website (<https://www.usitc.gov>). Hearing-impaired individuals can obtain information on this matter by contacting the TDD terminal at 202-205-1810.

SUPPLEMENTARY INFORMATION: The information requested by the questionnaire is for use by the U.S. International Trade Commission in connection with Investigation No. 332-608, *USMCA Automotive Rules of Origin: Economic Impact and Operation, 2027 Report*, instituted under section 202A(g)(2) of the United States-Mexico-Canada Agreement (USMCA) Implementation Act (19 U.S.C. 4532(g)(2)) (the Act). The Act requires that the Commission prepare a series of five biennial reports on the USMCA automotive rules of origin (ROOs) and their impact on the U.S. economy, effect on U.S. competitiveness, and relevancy in light of technological changes, and to provide those reports to the President, the House Committee on Ways and Means, and the Senate Committee on Finance. The second of the five reports was delivered on July 1, 2025, with three additional reports due in 2027, 2029, and 2031.

This investigation was instituted on February 11, 2026, and the notice of investigation was published in the **Federal Register** on February 23, 2026 (91 FR 8521), and corrected in a notice published February 26, 2026 (91 FR 9640). The Commission will deliver the third of its five reports to the President and Congress by July 1, 2027. The Commission indicated in its notice of investigation that it will need to obtain data and information through a survey. The survey will assist the Commission in gathering responses and data from motor vehicle producers in the United States to determine the direct impacts of

the ROOs on the aforementioned factors. Such data are not publicly available, and without this information collection, certain aspects of the Commission's analysis of the impact of the ROOs will be less robust in, or absent from, its report to be submitted in compliance with the requirements under the Act.

The Commission intends to submit the following draft information collection plan to the OMB:

- (1) *Number of forms submitted:* 1.
- (2) *Title of form:* The USMCA Automotive Rules of Origin Motor Vehicle Producer Questionnaire.
- (3) *Type of request:* New.
- (4) *Frequency of use:* Industry questionnaire, single data gathering, scheduled for 2026.
- (5) *Description of respondents:* North American motor vehicle producers with U.S. production operations.
- (6) *Estimated number of questionnaire requests to be emailed:* 25.
- (7) *Estimated total number of hours to complete the questionnaire per respondent:* 25 hours.
- (8) Information obtained from the questionnaire that qualifies as confidential business information will be so treated by the Commission and not disclosed in a manner that would reveal the individual operations of a business.

Information about the investigation and other supplementary documents may be downloaded from the Commission's website at <https://www.usitc.gov/USMCAAutoROO>.

By order of the Commission.

Issued: July 1, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-13658 Filed 7-6-26; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1466]

Certain Antibody Drug Conjugates and Components Thereof and Products Containing the Same; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission ("Commission") has determined not to review an initial determination ("ID") (Order No. 17) of the presiding administrative law judge

(“ALJ”), terminating this investigation in its entirety based on withdrawal of the complaint.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on December 22, 2025, based on a complaint filed by AbbVie Inc. of North Chicago, Illinois; ImmunoGen, Inc. of Waltham, Massachusetts; and ImmunoGen Switzerland GmbH (collectively, “AbbVie”). 90 FR 59867 (Dec. 22, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States of certain antibody drug conjugates and components thereof and products containing the same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States or to prevent the establishment of an industry in the United States. *Id.* The Commission’s notice of investigation named as respondents ProfoundBio US Co. of Seattle, Washington; ProfoundBio (Suzhou) Co., Ltd. of Suzhou, China; Genmab A/S of Valby, Denmark; Genmab B.V. of Utrecht, Netherlands; and Genmab US, Inc. of Plainsboro, New Jersey (collectively, “Respondents”). *Id.* The Office of Unfair Import Investigations (“OUII”) is participating in the investigation. *Id.*

On June 8, 2026, AbbVie filed an unopposed motion under Commission Rule 210.21(a) (19 CFR 210.21(a)) to terminate this investigation in its entirety based on withdrawal of the complaint. On June 15, 2026, OUII filed a response supporting the motion. Respondents did not file a response.

On June 16, 2026, the ALJ issued Order No. 17 (the subject ID), which granted the motion. The ID found that no extraordinary circumstances counsel

against termination of this investigation and that the motion complies with the requirements of Commission Rule 210.21(a)(1). No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID. The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on July 1, 2026.

The authority for the Commission’s determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission’s Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 2, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–13700 Filed 7–6–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1509]

Certain Vehicle Space Guards; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 1, 2026, under section 337 of the Tariff Act of 1930, as amended, on behalf of Johnathan Black Kotyk of Atlantic Beach, Florida. An amended complaint was filed on June 17, 2026, and a supplement was filed on June 22, 2026. The amended 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 vehicle space guards by reason of the infringement of certain claims of U.S. Patent No. 7,527,314 (“the ‘314 patent”). The amended complaint, as supplemented, 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 amended complaint, except for any confidential information

contained therein, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10 (2025).

Scope of Investigation: Having considered the amended complaint, the U.S. International Trade Commission, on July 1, 2026, *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 1–4, 6, 8–12, 14–16, and 18–19 of the ‘314 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 “vehicle space guards having attachment means for car seats”;

(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:* Jonathan Black Kotyk, 162 Magnolia Street, Atlantic Beach, FL 32233.

(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:

Drop Stop, LLC, 1925 Century Park East
16th Floor, Los Angeles, CA 90067.

The Container Store, Inc., 500 Freeport
Parkway, Coppell, Texas 75019.

Walmart, Inc., 702 SW 8th Street,
Bentonville, AR 72716.

232 Technologies Inc., 1988 Ocean
Pkwy., Brooklyn, NY 11223.

Sportman's Market Inc. (Sporty's),
Clermont County/Sporty's Airport,
2001 Sporty's Drive, Batavia, Ohio
45103-9719.

(c) The Office of Unfair Import
Investigations, U.S. International Trade
Commission, 500 E Street SW, Suite
401, Washington, DC 20436; and

(4) For the investigation so instituted,
the Chief Administrative Law Judge,
U.S. International Trade Commission,
shall designate the presiding
Administrative Law Judge.

Responses to the amended 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 amended complaint
and the notice of investigation.
Extensions of time for submitting
responses to the amended 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
amended complaint and in this notice
may be deemed to constitute a waiver of
the right to appear and contest the
allegations of the amended 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 amended 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: July 1, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-13657 Filed 7-6-26; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1451]

Certain Ink Cartridges and Components Thereof I; Notice of a Commission Determination To Review in Part an Initial Determination Granting a Motion for Summary Determination of Violation; Request for Written Submissions on the Issue Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade
Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that
the U.S. International Trade
Commission ("Commission") has
determined to review in part an initial
determination ("ID") (Order No. 16) of
the presiding administrative law judge
("ALJ") granting a motion for summary
determination of violation. The
Commission requests written
submissions from the parties on the
issue under review and from the parties,
interested government agencies, and
other interested persons on the issues of
remedy, the public interest, and
bonding, under the schedule set forth
below.

FOR FURTHER INFORMATION CONTACT:

Edward S. Jou, Esq., Office of the
General Counsel, U.S. International
Trade Commission, 500 E Street SW,
Washington, DC 20436, telephone (202)
205-3316. Copies of non-confidential
documents filed in connection with this
investigation may be viewed on the
Commission's electronic docket (EDIS)
at <https://edis.usitc.gov>. For help
accessing EDIS, please email
EDIS3Help@usitc.gov. General
information concerning the Commission
may also be obtained by accessing its
internet server at <https://www.usitc.gov>.
Hearing-impaired persons are advised
that information on this matter can be
obtained by contacting the
Commission's TDD terminal, telephone
(202) 205-1810.

SUPPLEMENTARY INFORMATION: The
Commission instituted this investigation
on June 17, 2025, based upon a
complaint filed on behalf of Epson
Portland Inc. of Hillsboro, Oregon,
Epson America, Inc. of Los Alamitos,
California, and Seiko Epson Corporation
of Nagano, Japan (collectively,
"Complainants"). 90 FR 25643-44 (June
17, 2025). The complaint, as
supplemented, alleges violations of
section 337 of the Tariff Act of 1930, as
amended, 19 U.S.C. 1337 ("section
337"), based upon the importation into

the United States, the sale for
importation, and the sale within the
United States after importation of
certain ink cartridges and components
thereof by reason of the infringement of
certain claims of U.S. Patent No.
8,540,347 ("the '347 patent"), U.S.
Patent No. 9,061,508 ("the '508 patent"),
U.S. Patent No. 11,535,037 ("the '037
patent"), U.S. Patent No. 11,820,150
("the '150 patent"), and U.S. Patent No.
12,246,539 ("the '539 patent"). *Id.* at
25643. The complaint, as supplemented,
further alleges that an industry in the
United States exists as required by
subsection (a)(2) of section 337. *Id.*

The Commission's notice of
investigation named as respondents:
Dongguan Ocbestjet Digital Technology
Co., Ltd. d/b/a Ocbestjet of Guangdong,
China ("Dongguan Ocbestjet"); Ocbestjet
Printer Consumables (HK) Co., Ltd.,
d/b/a Ocbestjet of Hong Kong
("Ocbestjet HK"); Tatrix International
China Co., Ltd. of Guangdong, China
("Tatrix"); Luozhi Trading Co., Ltd. of
Guangdong, China ("Luozhi Trading");
Shenzhen Hongxinyuan E-Commerce
Co., Ltd., d/b/a Jianjai, d/b/a Vi-US of
Guangdong, China; Shenzhen Kaizhen
Technology Co., Ltd., d/b/a PayForLess
of Guangdong ("Kaizen Tech."), China;
Zhuhai Zhenyang Electronics Co., Ltd.,
d/b/a Oinkwere of Guangdong, China
("Zhenyang Elec."); Shangrao Shixuan
E-Commerce Co., Ltd., d/b/a Inkgo of
Jiangxi, China; Zhuhai Hengyunda
Electronics Co., Ltd., d/b/a Upriin of
Guangdong, China ("Hengyunda Elec.");
Zhuhai Rongtaida Electronics Co., Ltd.,
d/b/a Hookink of Guangdong, China
("Rongtaida Elec."); Zhuhai Shi Wei Tai
Electronics Co., Ltd., d/b/a Ondula-A of
Guangdong, China ("Shi Wei Tai
Elec."); Zhuhai Yixing Electronics Co.,
Ltd., d/b/a Greenjob USSOP of
Guangdong, China ("Yixing Elec."); Mei
Jin Technology HK Co., Ltd., d/b/a
YBFeir, d/b/a MJing of Hong Kong
("Mei Jin Tech."); ZhuHai MeiJiAn
Trading Co., Ltd., d/b/a HaloFox of
Guangdong, China ("MeiJiAn Trading");
Qiong Wang, d/b/a 7-magic of
Guangdong, China; Shen Zhen Sailing
Technology Limited, d/b/a Triple-Color
of Shenzhen, China; Zhuhai Shuofeng
E-commerce Co., Ltd., d/b/a super-ink-
club of Guangdong, China ("Shuofeng E-
commerce"); Zhuhai Bowang
Technology Co., Ltd., d/b/a office-print-
club of Guangdong, China ("Bowang
Tech."); Mountain Peak, Inc., d/b/a/
Billiontree Technology USA, Inc.
("Mountain Peak"), d/b/a
TonerKingdom of City of Industry,
California; and Straightouttaintk, LP, d/
b/a discountinkllc, d/b/a einkshop2014
of San Jose, California

(“Straightouttaint”). *Id.* at 25643–44. The Office of Unfair Import Investigations (“OUII”) is also a party to this investigation. *Id.* at 25644.

Respondents Shenzhen Hongxinyuan E-Commerce Co., Ltd., Shangrao Shixuan E-Commerce Co., Ltd., Shen Zhen 2 Sailing Technology Limited, and Qiong Wang were terminated from the investigation by withdrawal of the complaint. Order No. 12 (Dec. 16, 2025), *unreviewed by Comm’n Notice* (Jan. 7, 2026).

Respondents Tatrix, Zhenyang Elec., Hengyunda Elec., Rongtaida Elec., Shi Wei Tai Elec., Yixing Elec., Mei Jin Tech., Mountain Peak, Straightouttaint, Dongguan Ocbestjet, Ocbestjet HK, Luozhi Trading, Kaizhen Tech., MeiJiAn Trading, Shuofeng E-commerce, and Bowang Tech. (the “Defaulting Respondents”) have been found in default. Order No. 10 (Sept. 30, 2025), *unreviewed by Comm’n Notice* (Dec. 5, 2025); Order No. 13 (Dec. 16, 2025), *unreviewed by Comm’n Notice* (Jan. 8, 2026).

Complainants have withdrawn their allegations as to claims 1, 4, 14, 16–17, and 23 of the ‘347 patent, claims 1, 3, 9, 12, 14, and 19 of the ‘508 patent, claims 9 and 10 of the ‘037 patent, claims 9–11 and 19–20 of the ‘150 patent, and claims 2, 9, 11, 18, 20, and 27 of the ‘539 patent, and these claims have been terminated from the investigation. Order No. 14 (Dec. 18, 2025), *unreviewed by Comm’n Notice* (Jan. 8, 2026).

On February 3, 2026, Complainants filed a motion for summary determination of a violation by the Defaulting Respondents by reason of infringement of claims 8, 11, and 20 of the ‘037 patent, claims 7 and 17 of the ‘508 patent, claim 1 of the ‘037 patent, claim 1 of the ‘150 patent, and claims 1, 10, and 19 of the ‘539 patent. On February 13, 2026, OUII filed a response in support of Complainants’ motion.

On May 15, 2026, the ALJ issued the subject ID (Order No. 16) granting the motion for summary determination, which included a recommended determination on remedy and bonding. No petitions for review of the ID were filed.

Having reviewed the record of the investigation, including the ID, the pleadings, and the parties’ briefing on summary determination, the Commission has determined to review the ID in part. Specifically, the Commission has determined to review the ID’s findings with respect to indirect infringement and the economic prong of the domestic industry requirement. The Commission has determined not to review the other findings in the ID.

In connection with its review, the Commission requests responses to the following questions:

1. Identify any evidence in the record that can be used to quantify the number of Domestic Industry Products practicing each Asserted Patent that were manufactured in the United States within the context of the worldwide manufacturing of these products or other record information that would support in numerical terms Mr. Ramsey’s statement that “the vast majority of the Domestic Industry Products are manufactured by EPI in the United States”. In particular, discuss whether there is information in the exhibits attached to Mr. Ramsey’s declaration that can be used to compare the number of Domestic Industry Products practicing each Asserted Patent that were packaged in the United States with the number of those products that were manufactured in the United States, and identify whether there is any other numerical information that would support Mr. Ramsey’s statement. How would this information affect the ID’s determination that the domestic industry requirement was satisfied under each of subsection (A) and subsection (B)?

2. Were foreign manufacturing costs for Domestic Industry Products manufactured outside the United States considered as part of the significance analysis addressed in footnote 20 of the ID? In your response, please address whether there is any information in the record that could be used to quantify the manufacturing costs for Domestic Industry Products practicing each Asserted Patent that were manufactured outside of the United States. How would the inclusion or exclusion of such foreign manufacturing costs affect a value-added computation or the overall domestic industry analysis under each of subsection (A) and subsection (B)?

3. Please explain using a holistic analysis of all relevant considerations why based on the record the asserted investments under subsection (A) and separately under subsection (B) are significant, taking into account *inter alia* the amounts invested, the nature and extent of activities in the United States attributable to the amounts invested, the realities of the marketplace at hand, and any quantitative analyses presented to the ALJ that compare the asserted investments to one or more benchmarks and why such benchmarks are relevant or appropriate in establishing the significance of the asserted investments in this investigation under each of subsections (A) and (B).

The parties are requested to brief their positions on the questions above with

reference to the applicable law and the existing evidentiary record. No additional briefing will be considered.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm’n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission’s determination. See Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the

investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. In the initial submission, Complainants are also requested to identify the remedy sought and Complainants and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to state the date that the asserted patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than the close of business on July 15, 2026. All reply submissions must be filed no later than the close of business on July 22, 2026. Opening submissions from the parties are limited to 30 pages. Reply submissions shall be limited to 10 pages. All submissions from third parties and/or interested government agencies are limited to 10 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (Inv. No. 337-TA-1451) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business

days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS

The Commission vote for this determination took place on July 1, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.
Issued: July 1, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-13633 Filed 7-6-26; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-646 and 731-TA-1502-1516 (Review)]

Prestressed Concrete Steel Wire Strand From Argentina, Colombia, Egypt, Indonesia, Italy, Malaysia, Netherlands, Saudi Arabia, South Africa, Spain, Taiwan, Tunisia, Turkey, Ukraine, and the United Arab Emirates; Notice of Commission Determination To Conduct Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it will proceed with full reviews pursuant to the Tariff Act of 1930 to determine whether revocation of the countervailing duty order on prestressed concrete steel wire strand ("PC strand") from Turkey and the revocation of the antidumping duty orders on PC strand from Argentina,

Colombia, Egypt, Indonesia, Italy, Malaysia, the Netherlands, Saudi Arabia, South Africa, Spain, Taiwan, Tunisia, Turkey, Ukraine, and the United Arab Emirates would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. A schedule for the reviews will be established and announced at a later date.

DATES: April 7, 2026.

FOR FURTHER INFORMATION CONTACT:

Caitlyn Costello (202-205-2058), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (<https://www.usitc.gov>). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>.

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 through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

SUPPLEMENTARY INFORMATION: On April 7, 2026, the Commission determined that it should proceed to full reviews in the subject five-year reviews pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). The Commission found that both the domestic and respondent interested party group responses from the United Arab Emirates to its notice of institution (91 FR 156, January 2, 2026) were adequate, and determined to conduct a full review of the order on imports from the United Arab Emirates. The Commission also found that the respondent interested party group responses from Argentina, Colombia, Egypt, Indonesia, Italy, Malaysia, Netherlands, Saudi Arabia, South Africa, Spain, Taiwan, Tunisia, Turkey, and Ukraine were inadequate but determined to conduct full reviews of the orders on imports from those countries in order to promote administrative efficiency in light of its determinations to conduct full review of the orders with respect to the United Arab Emirates. A record of the Commissioners' votes will be available

from the Office of the Secretary and at the Commission's website.

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.

Original Issued: April 20, 2026.

Issued: July 2, 2026.

Susan Orndoff,

Supervisory Attorney.

[FR Doc. 2026–13709 Filed 7–6–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1463]

Certain Microcurrent Facial Toning Devices and Systems Thereof; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on Settlement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (“Commission”) has determined not to review an initial determination (“ID”) (Order No. 12) of the presiding administrative law judge (“ALJ”), terminating this investigation in its entirety based on settlement. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 28, 2025, based on a complaint filed by ZIIP, Inc. of Pleasant Hill, California and The Beauty Tech Group Ltd. of the United Kingdom (together, “Complainants”). 90 FR

54744 (Nov. 28, 2025). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain microcurrent facial toning devices and systems thereof by reason of infringement of claims 1–4, 6, 7, 9, 11, and 12 of U.S. Patent No. 10,967,180 and claims 1–6, 8, 10, 12, 14, 15, and 18–20 U.S. Patent No. 12,042,652. *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as the sole respondent The Carol Cole Co. d/b/a NuFACE of Vista, California (“Respondent”). *Id.* The Office of Unfair Import Investigations is not participating in the investigation. *Id.*

On May 29, 2026, Complainants and Respondent filed a joint motion under Commission Rule 210.21(a)(2) (19 CFR 210.21(a)(2)) to terminate this investigation in its entirety based on a settlement agreement.

On June 11, 2026, the ALJ issued the subject ID (Order No. 12) pursuant to Commission Rule 210.(b) (19 CFR 210.21(b)), granting the motion. The subject ID finds that the motion complies with the Commission's Rules and that terminating the investigation would not be contrary to the public interest. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

The investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on July 1, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 1, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–13632 Filed 7–6–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–522 and 731–TA–1258 (Second Review)]

Passenger Vehicle and Light Truck Tires 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 antidumping and countervailing duty orders on passenger vehicle and light truck tires 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.²

Background

The Commission instituted these reviews on January 2, 2026 (91 FR 159) and determined on April 7, 2026 that it would conduct expedited reviews (91 FR 21310, April 21, 2026).

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 July 2, 2026. The views of the Commission are contained in USITC Publication 5760 (July 2026), entitled *Passenger Vehicle and Light Truck Tires from China: Investigation Nos. 701–TA–522 and 731–TA–1258 (Second Review)*.

By order of the Commission.

Issued: July 2, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–13703 Filed 7–6–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1424]

Certain Flash-Spun Nonwoven Materials and Products Containing Same; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on July 1, 2026, the presiding

¹ The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² Chairman David S. Johanson dissenting.

administrative law judge (“ALJ”) issued an Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public and interested government agencies only.

FOR FURTHER INFORMATION CONTACT:

Richard P. Hadorn, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3179. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. (19 U.S.C. 1337(d)(1)). A similar provision applies to cease and desist orders. (19 U.S.C. 1337(f)(1)).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: (i) a general exclusion order directed to certain flash-spun nonwoven materials and products containing same imported, sold for importation, and/or sold after importation into the United States; (ii) should the Commission not enter a general exclusion order, then a limited exclusion order directed to certain flash-spun nonwoven materials and products containing same imported, sold for importation, and/or sold after importation by respondents Kingwills New Material Technology Co., Ltd. of Nantong, Jiangsu, China; Zhejiang

Qingyun New Material Co., Ltd. of Jiaxing, Zhejiang, China; Jiangsu Qingyun New Materials Co., Ltd. AKA Jiangsu Kingwills New Materials Co., Ltd. of Nantong, Jiangsu, China; Shanghai Qingyun New Material Technology Co., Ltd. of Shanghai, China; Kingwills International Ltd. of Kowloon, Hong Kong, China; Impak Corporation (“Impak”) of Los Angeles, California; Weifang Konzer Safety Protective Equipment Co., Ltd. of Anqiu, Shandong, China; Jiangsu Tubo New Material Co., Ltd. of Kunshan, Jiangsu, China; TOBO Group of Shanghai, China; Hangzhou Several Sets of Electronic Commerce Co., Ltd. of Yuhang, Hangzhou, China; and Hangzhou Qiao Shell Digital Technology Co., Ltd. of Yuhang, Hangzhou, China; and (iii) a cease and desist order directed to Impak. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public and interested government agencies are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ’s Recommended Determination on Remedy and Bonding issued in this investigation on July 1, 2026. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, 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 recommended remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended 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, complainants’ licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and
- (v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on August 3, 2026.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above pursuant to 19 CFR 210.4(f). Submissions should refer to the investigation number (“Inv. No. 337–TA–1424”) in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/secretary/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission’s

Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 2, 2026

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026-13704 Filed 7-6-26; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-1718]

Importer of Controlled Substances

Application: Benuvia Operations, LLC.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Benuvia Operations, LLC. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before August 6, 2026. Such persons may also file a written request for a hearing on the application on or before August 6, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator,

8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on May 7, 2026, Benuvia Operations, LLC., 3950 North Mays Street, Round Rock, Texas 78665-2729, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Psilocybin	7437	I
Psilocyn	7438	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Ecgonine	9180	II
Remifentanyl	9739	II

The company plans to import the listed controlled substances of Active Pharmaceutical Ingredients to support their customers. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026-13705 Filed 7-6-26; 8:45 am]

BILLING CODE:P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)

On July 2, 2026, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Montana in the lawsuit entitled *United States and the State of Montana v. Columbia Falls Aluminum Company, LLC*, Civil Action No. 9:26-cv-00099-KLD. The proposed Consent Decree resolves the United States' and the State of Montana's claims against the Columbia Falls Aluminum Company ("CFAC") under Section 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 ("CERCLA"), 42 U.S.C. 9607(a), and the Montana Comprehensive Environmental Cleanup and Responsibility Act, §§ 75-

10-701, *et seq.*, for the recovery of costs related to the release of hazardous substances at the Anaconda Aluminum Co. Columbia Falls Reduction Plant National Priorities List Site (also known as the Columbia Falls Aluminum Company Site) (the "Site") near Columbia Falls, Montana.

In the proposed Consent Decree, CFAC agrees to reimburse the United States Environmental Protection Agency ("EPA") for \$1,800,000.00 in past response costs, and to pay future response costs that will be incurred at the Site. CFAC also agrees to reimburse any independent State future response costs incurred by the Montana Department of Environmental Quality. CFAC will complete all cleanup work required under the Record of Decision issued by EPA for the Site in January, 2025. EPA estimates the cost of the work required of CFAC under the Consent Decree is \$57,634,528.00.

In return for CFAC's agreement to perform the work required by the Consent Decree and pay EPA's past and future response costs and the State's future response costs, the United States is providing a standard covenant not to sue under Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a). The State is also providing a covenant under sections 711, 715(2)(a), 722, and 726 of CECRA.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the State of Montana v. Columbia Falls Aluminum Company, LLC*, D.J. Ref. No. 90-11-3-12932. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment-ees.enrd@usdoj.gov .
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>. If you require assistance accessing the Consent Decree, you may request assistance by email or by mail to the

addresses provided above for submitting comments.

Jason A. Dunn,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2026-13721 Filed 7-6-26; 8:45 am]

BILLING CODE 4410-15-P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 91 FR 40044, July 1, 2026.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: July 6, 2026, 2:30 p.m. Eastern Time.

CHANGES IN THE MEETING: The time and date for the meeting of the Finance Committee of the Legal Services Corporation Board of Directors has changed. The meeting will now occur on Tuesday, July 7, at 3:30 p.m. Eastern Time. The meeting will be held virtually and be livestreamed for public observation on LSC's YouTube page: www.youtube.com/@LegalServicesCorp/streams.

CONTACT PERSON FOR MORE INFORMATION: Kimberly Little, Board and Executive Coordinator, at (202) 295-1500. Questions may also be sent by electronic mail to the Office of the Corporate Secretary at updates@lsc.gov.

(Authority: 5 U.S.C. 552b.)

Dated: July 2, 2026.

Stefanie Davis,

Deputy General Counsel, Legal Services Corporation.

[FR Doc. 2026-13708 Filed 7-2-26; 4:15 pm]

BILLING CODE 7050-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 05000615; NRC-2024-0146]

Tennessee Valley Authority; Clinch River Nuclear Site, Unit 1; Notice of Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: Construction permit application; notice of uncontested hearing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is providing public notice of an uncontested hearing on a construction permit application from Tennessee Valley Authority for construction of Clinch River Nuclear

Unit 1 at the Clinch River Nuclear Site in Roane County, Tennessee.

DATES: The hearing is scheduled to begin at 5:30 p.m. on August 13, 2026, at the Pollard Technology Conference Center auditorium located at 210 Badger Ave., Oak Ridge, TN 37830. This meeting will be preceded by an open house beginning at 5 p.m. at the same location.

ADDRESSES: Please refer to Docket ID NRC-2024-0146 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0146. Address questions about Docket IDs in [Regulations.gov](https://www.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.

- **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:

Allen Fetter, telephone: 301-415-8556; email: Allen.Fetter@nrc.gov and Ricky Vivanco, telephone: 301-415-0021; email: Ricky.Vivanco@nrc.gov. Both are staff of the Office of Advanced Reactors at the U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

By letter dated April 29, 2026 (ADAMS Accession Package No. ML26119A628), Tennessee Valley Authority (TVA or the applicant) submitted to the NRC revision 1 of a construction permit application under

part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities," for a small modular reactor (SMR) at the Clinch River Nuclear (CRN) site located in Oak Ridge, Roane County, Tennessee. The application is for a single-unit BWRX-300 SMR designated as Clinch River Nuclear Unit 1 (hereinafter also referred to as CRN-1). The BWRX-300 is a small modular boiling water reactor (BWR), designed by GE Vernova Hitachi Nuclear Energy (GVH), with a nominal electrical output of 300 megawatts-electric (MWe) and a thermal power rating of 870 megawatts thermal (MWt). The NRC staff Safety Evaluation Report is available in ADAMS under ML26168A505. The Environmental Report was included in Part 1 of the Clinch River Construction Permit Application and is available in ADAMS under ML25118A209. The NRC staff's Final Supplemental Environmental Impact Statement is available in ADAMS under ML26035A285.

Pursuant to Section 189a. of the Atomic Energy Act of 1954, as amended, and the Commission Policy Statement on Mandatory Hearings for Reactor Licensing (published in the **Federal Register** at 91 FR 34661), notice is hereby given that the uncontested (*i.e.*, mandatory) hearing will be held on August 13, 2026 starting at 5:30 p.m. in the Pollard Technology Conference Center auditorium located at 210 Badger Ave., Oak Ridge, TN 37830. Members of the public are invited to attend the hearing. There will be an opportunity for members of the public to ask questions and provide feedback on the application. This is not an opportunity to request a contested hearing, where petitioners can file intervention requests that contain the contentions they wish to litigate pursuant to 10 CFR 2.309. The opportunity to request a contested hearing and petition for leave to intervene was noticed on July 15, 2025, (90 FR 31709) and no intervention petitions were received.

An open house will be held before the hearing begins, from 5 to 5:30 p.m., to give the public an opportunity to speak with the NRC staff. The hearing will then convene at 5:30 p.m. and begin with a presentation by the NRC staff that will explain the review process and provide a brief overview of the application, followed by a comment period of up to 3 hours. During the comment period, the public will be provided an opportunity to speak on the record. Each member of the public will be allowed to speak for no more than five minutes at a time to ensure that all stakeholders who wish to provide oral

comments or ask questions will have the opportunity to do so. The applicant has been made aware of the hearing and was invited to provide a presentation of no more than 30 minutes following the NRC staff presentation.

The hearing record for comments will remain open until August 27, 2026. Written comments must be submitted to the following email address:

ClinchRiver-CPHearing@nrc.gov. In order to be included in the hearing record, written comments must be received by August 27, 2026. The NRC staff will not consider comments or questions received by other means or after the deadline of August 27, 2026. The NRC staff will treat any comments or questions received consistent with the Commission Policy Statement on Mandatory Hearings for Reactor Licensing.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: July 1, 2026.

For the Nuclear Regulatory Commission.

Michele Sampson,

Deputy Director, Office of Advanced Reactors.

[FR Doc. 2026-13662 Filed 7-6-26; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2026-0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of July 6, 13, 20, 27, and August 3, 10, 2026. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: <https://www.nrc.gov/public-involve/public-meetings/schedule.html>.

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please contact the Reasonable Accommodations Resource by email at *Reasonable_Accommodations.Resource@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC

20555, at 301-415-1969, or by email at *Betty.Thweatt@nrc.gov* or *Samantha.Miklaszewski@nrc.gov*.

MATTERS TO BE CONSIDERED:

Week of July 6, 2026

There are no meetings scheduled for the week of July 6, 2026.

Week of July 13, 2026—Tentative

There are no meetings scheduled for the week of July 13, 2026.

Week of July 20, 2026—Tentative

Tuesday, July 21, 2026

9:00 a.m. Advanced Reactor

Landscape: Current Status and Moving Forward (Public Meeting)
(Contact: Wesley Held: 301-287-3591)

Additional Information: The meeting will be held in the Commissioners' Hearing Room, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting in person or watch live via webcast at the Web address—<https://video.nrc.gov/>.

Week of July 27, 2026—Tentative

There are no meetings scheduled for the week of July 27, 2026.

Week of August 3, 2026—Tentative

There are no meetings scheduled for the week of August 3, 2026.

Week of August 10, 2026—Tentative

There are no meetings scheduled for the week of August 10, 2026.

CONTACT PERSON FOR MORE INFORMATION:

For more information or to verify the status of meetings, contact Wesley Held at 301-287-3591 or via email at *Wesley.Held@nrc.gov*.

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: July 1, 2026.

For the Nuclear Regulatory Commission.

Wesley W. Held,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2026-13644 Filed 7-2-26; 11:15 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2026-3202]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person.

DATES: Comments must be filed by August 6, 2026. A request for a hearing or petitions for leave to intervene must be filed by September 8, 2026. This biweekly notice includes all amendments issued, or proposed to be issued, from June 9, 2026, to June 22, 2026. The last biweekly notice was published on June 23, 2026.

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

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2026-3202. 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 listed in the "For Further Information Contact" section of this document.

- *Mail comments to:* Office of Nuclear Material Safety and Safeguards, Mail Stop: TWFN-5-A85, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Program Management, Announcements and Editing Staff.

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

FOR FURTHER INFORMATION CONTACT: Angela M. Baxter, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-8209; email: *Angela.Baxter@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2026–3202, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website*: Go to <https://www.regulations.gov> and search for Docket ID NRC–2026–3202.
- *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. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

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

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2026–3202, facility name, unit number(s), docket number(s), application date, and subject, in your comment submission.

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

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly

disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown in this notice, the Commission finds that the licensees' analyses provided, consistent with section 50.91 of title 10 of the *Code of Federal Regulations* (10 CFR) "Notice for public comment; State consultation," are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60

days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration, which will serve to establish when the hearing is held. If the final determination is that the license amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the license amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or designated

agency thereof, may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053>) and the NRC's public website (<https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>).

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the "Guidance for Electronic Submissions to the NRC" (ADAMS Accession No. ML13031A056), and on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals.html>).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to: (1) request a digital identification (ID) certificate which allows the participant (or their counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or their counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding

if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals/getting-started.html>). After a digital ID certificate is obtained and a docket is created, the participant must submit adjudicatory documents in the Portable Document Format. Guidance on submissions is available on the NRC's public website (<https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>). A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed in order to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website (<https://www.nrc.gov/site-help/e-submittals.html>), by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting

authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available on the NRC's public website (<https://adams.nrc.gov/ehd>), unless otherwise excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The following table provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensees' proposed NSHC determinations. For further details with respect to these license amendment applications, see the applications for amendment, which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

LICENSE AMENDMENT REQUESTS

DTE Electric Company; Fermi, Unit 2; Monroe County, MI

Docket No	50-341.
Application date	March 20, 2026.
ADAMS Accession No	ML26079A190.
Location in Application of NSHC	Pages 29-31 of the Enclosure.

LICENSE AMENDMENT REQUESTS—Continued

Brief Description of Amendment	The proposed amendment would modify the Fermi, Unit 2 technical specifications by incorporating a license condition to allow implementation of the requirements of 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components [SSCs] for Nuclear Power Reactors." The amendment would permit the use of a risk-informed process to categorize SSCs according to their safety significance, enabling alternative treatment requirements for SSCs of low safety significance while maintaining or enhancing requirements for those of high safety significance.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jon P. Christinidis, DTE Electric Company, Expert Attorney—Regulatory, 1635 WCB, One Energy Plaza, Detroit, MI 48226.
NRC Project Manager, Telephone Number	Luis Cruz Rosado, 301-415-4106.

Energy Northwest; Columbia Generating Station; Benton County, WA

Docket No	50-397.
Application date	May 27, 2026.
ADAMS Accession No	ML26147A259.
Location in Application of NSHC	Pages 1-3 of the Enclosure.
Brief Description of Amendment	The proposed amendment would adopt Technical Specifications Task Force (TSTF) Traveler TSTF-554, "Revise Reactor Coolant Leakage Requirements," which is an approved change to the Standard Technical Specifications (TSs). The proposed changes would revise the TS definition of "Leakage," would clarify the requirements when pressure boundary leakage is detected, and would add a Required Action when pressure boundary leakage is identified. The proposed amendment is requested as part of the Consolidated Line Item Improvement Process.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Ryan Lukson, Assistant General Counsel, Energy Northwest, MD 1020, P.O. Box 968, Richland, WA 99352.
NRC Project Manager, Telephone Number	Mahesh Chawla, 301-415-8371.

Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE

Docket No	50-298.
Application date	June 17, 2026.
ADAMS Accession No	ML26168A419.
Location in Application of NSHC	Pages 3-5 of Attachment 1.
Brief Description of Amendment	The proposed amendment would adopt Technical Specification (TS) Task Force (TSTF) Traveler TSTF-585 (TSTF-585), "Revise LCO 3.0.3 to Require Managing Risk." TSTF-585 would revise Limiting Condition for Operation (LCO) 3.0.3 to require assessing and managing plant risk whenever LCO 3.0.3 is entered. If the risk assessment determines that continuing plant operation is acceptable and other conditions are satisfied, 24-hours from entry into LCO 3.0.3 is permitted to initiate a shutdown. Otherwise, initiation of the shutdown is required immediately. The proposed amendment also would revise or add some TS Required Actions to direct other actions instead of entry into LCO 3.0.3.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	John C. McClure, Executive Vice President External Affairs and General Counsel, Nebraska Public Power District, P.O. Box 499, Columbus, NE 68601.
NRC Project Manager, Telephone Number	Tony Sierra, 301-287-9531.

Pacific Gas and Electric Company; Diablo Canyon Nuclear Power Plant, Units 1 and 2; San Luis Obispo County, CA

Docket Nos	50-275, 50-323.
Application date	June 8, 2026.
ADAMS Accession No	ML26159A390.
Location in Application of NSHC	Pages 2-3 of the Enclosure.
Brief Description of Amendments	The proposed amendments would revise the implementation wording for Amendment Nos. 252 and 254, for Diablo Canyon Nuclear Power Plant, Units 1 and 2, respectively, to provide for a more flexible implementation schedule. Amendment Nos. 252 and 254 modified the technical specifications to allow the use of Optimized ZIRLO™ as an approved fuel rod cladding material.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jennifer Post, Esq., Pacific Gas and Electric Co., 300 Lakeside Drive, Oakland, CA 94612.

LICENSE AMENDMENT REQUESTS—Continued

NRC Project Manager, Telephone Number	Samson Lee, 301-415-3168.
Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL; Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2; Hamilton County, TN; Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2; Rhea County, TN	
Docket Nos	50-259, 50-260, 50-296, 50-327, 50-328, 50-390, 50-391.
Application date	May 26, 2026.
ADAMS Accession No	ML26146A133.
Location in Application of NSHC	Pages E3-E4 of the Enclosure.
Brief Description of Amendments	The proposed amendments would revise the Browns Ferry Nuclear Plant, Units 1, 2, and 3, Sequoyah Nuclear Plant, Units 1 and 2, and Watts Bar Nuclear Plant, Units 1 and 2, technical specifications for the Risk Informed Completion Time (RICT) Program in accordance with Technical Specifications Task Force (TSTF) Traveler TSTF-591, Revision 0, "Revise Risk Informed Completion Time Program." The proposed amendments would revise the RICT program to reference Regulatory Guide 1.200, Revision 3, instead of Revision 2, as well as make other changes to the program consistent with the traveler.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Edward C. Meade, (Interim) Executive VP and General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive WT 6A, Knoxville, TN 37902.
NRC Project Manager, Telephone Number	Kimberly Green, 301-415-1627.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating

license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, were published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that

assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the following table. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

LICENSE AMENDMENT ISSUANCES

Dominion Energy Nuclear Connecticut, Inc.; Millstone Power Station, Unit No. 3; New London County, CT

Docket No	50-423.
Amendment Date	June 12, 2026.
ADAMS Accession No	ML26154A163.
Amendment No	295.
Brief Description of Amendment	The amendment revised Millstone Power Station, Unit No. 3, Technical Specification 3.5.2, "ECCS [Emergency Core Cooling System] Subsystems—Tavg Greater Than or Equal To 350°F [Degrees Fahrenheit]," to provide a one-time allowance to extend the allowed outage time from 72 hours to 168 hours.
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 3 and 4; Burke County, GA

Docket Nos	52-025, 52-026.
Amendment Date	June 7, 2026.
ADAMS Accession No	ML26110A004.
Amendment Nos	215 (Unit 3) and 212 (Unit 4).

LICENSE AMENDMENT ISSUANCES—Continued

Brief Description of Amendments	The amendments revised Technical Specification 3.4.10 to adopt changes similar to those that are described in Technical Specification Task Force (TSTF) Traveler 490, Revision 0, "Deletion of E Bar Definition and Revision to RCS [reactor coolant system] Specific Activity Tech Spec" (ML052630462).
Public Comments Received as to Proposed NSHC (Yes/No)	Yes.
Virginia Electric and Power Company, Dominion Nuclear Company; North Anna Power Station, Units 1 and 2; Louisa County, VA	
Docket Nos	50–338, 50–339.
Amendment Date	June 5, 2026.
ADAMS Accession No	ML26127A342.
Amendment Nos	299 (Unit 1) and 282 (Unit 2).
Brief Description of Amendments	The amendments deleted the technical specification requirement for the Power Range Neutron Flux Rate—High Negative Rate Trip function, as described in the submittal.
Public Comments Received as to Proposed NSHC (Yes/No)	No.
Vistra Operations Company LLC; Beaver Valley Power Station, Units 1 and 2; Beaver County, PA	
Docket Nos	50–334, 50–412.
Amendment Date	June 10, 2026.
ADAMS Accession No	ML26127A277.
Amendment Nos	328 (Unit 1) and 218 (Unit 2).
Brief Description of Amendments	The amendments revised the technical specifications (TS) based on Technical Specifications Task Force (TSTF) Traveler TSTF–599, Revision 1, "Eliminate Periodic Surveillance Test of Simultaneous Start of Redundant Diesel Generators," and TSTF–599, "Eliminate Periodic Surveillance Test of Simultaneous Start of Redundant Diesel Generators." Specifically, TSTF–589 related changes eliminated the TS requirements for the automatic diesel generator (DG) start and loading capability to be operable during shutdown. In addition, the TSTF–589 changes modified which DG surveillance requirements (SRs) are required during shutdown. The TSTF–599 changes deleted an SR requiring verification that, when started simultaneously, DGs achieve a specific frequency and voltage within a specified time period.
Public Comments Received as to Proposed NSHC (Yes/No)	No.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: June 25, 2026.

For the Nuclear Regulatory Commission.

Hipólito González, Acting Director,
Division of Licensing Projects I, Office of
Nuclear Reactor Regulation.

[FR Doc. 2026–13659 Filed 7–6–26; 8:45 am]

BILLING CODE 7590–01–P

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <https://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:
David A. Trissell, General Counsel, at
202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Public Proceeding(s)
- III. Summary Proceeding(s)

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an

existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2026–289 and K2026–286;
MC2026–291 and K2026–288]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 10, 2026.

point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s)*: MC2026–289 and K2026–286; *Filing Title*: USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1502 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: July 1, 2026; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative*: Christopher Mohr; *Comments Due*: July 10, 2026.

III. Summary Proceeding(s)

1. *Docket No(s)*: MC2026–291 and K2026–288; *Filing Title*: USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1028, and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: July 1, 2026; *Filing Authority*: 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,
Legal Assistant.

[FR Doc. 2026–13702 Filed 7–6–26; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105835; File No. SR–PEARL–2026–28]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2900 Regarding Information Circular Requirements

July 1, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² notice is hereby given that on June 22, 2026, MIAX PEARL, LLC (“MIAX Pearl” or “Exchange”) ³, filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to: (1) amend Rule 2900(a) to add express cross-references to Rules 2107 and 2120; (2) delete Rule 2900(b)(1) in its entirety, thereby removing the requirement that the Exchange distribute an information circular prior to the commencement of trading in each UTP Exchange Traded Product ⁴ that generally includes the same information as contained in the information circular approved by the listing exchange; (3) amend Rule 2900(b)(2)(B) to require that any written description be provided in a form approved by the listing exchange or prepared by the open-ended management company issuing such securities, not later than the time a confirmation of the first transaction in

such securities is delivered to such purchaser; and (4) renumber Rules 2900(b)(2) through (5) as Rules 2900(b)(1) through (4), respectively. The proposal is similar to a proposal that Cboe BZX Exchange, Inc. (“Cboe BZX”) filed with the Commission.⁵

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>, and 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 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 delete Rule 2900(b)(1) in its entirety to eliminate the requirement that the Exchange distribute an information circular prior to the commencement of trading in each UTP Exchange Traded Product that generally includes the same information as contained in the information circular provided by the listing exchange as provided in Rule 2900(b)(1). The Exchange also proposes to amend Rule 2900(a) to add express cross-references to Rules 2107 and 2120. The Exchange also proposes to amend Rule 2900(b)(2)(B) to require that any written description be provided in a form approved by the listing exchange or prepared by the open-ended management company issuing such securities, not later than the time a confirmation of the first transaction in such securities is delivered to such purchaser.⁶ Last, the Exchange proposes to renumber Rules 2900(b)(2) through

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ All references to “MIAX Pearl” in this filing are to MIAX Pearl Equities, the equities trading facility of MIAX PEARL, LLC. *See* Exchange Rule 1901.

⁴ *See* Exchange Rule 2622(h)(1)(i) (to be renumbered as Exchange Rule 2622(a)(1)(i) when a separate proposed rule change, SR–PEARL–2026–27, becomes effective). *See* Securities Exchange Act Release No. 105721 (June 17, 2026) (SR–PEARL–2026–27).

⁵ *See* Securities Exchange Act Release No. 105715 (June 17, 2026) (SR–CboeBZX–2026–054).

⁶ As further described below, the Exchange will notify Equity Members of the written description requirement under Rule 2900(b)(2)(B) by means of an information circular. Such written description will only be required when required by the listing exchange.

(5) as Rules 2900(b)(1) through (4), respectively.

Rule 2900(b) governs the trading of UTP Exchange Traded Products on the Exchange—securities listed on another national securities exchange that trade on the Exchange pursuant to unlisted trading privileges (“UTP”). Under current Rule 2900(b)(1), the Exchange must distribute an information circular prior to the commencement of trading in each UTP Exchange Traded Product that generally mirrors the information circular issued by the primary listing exchange, including: (a) the special risks of trading the new Exchange Traded Product; (b) the Exchange Rules that will apply to the new Exchange Traded Product; (c) information about the dissemination of the value of the underlying assets or indexes; and (d) the risk of trading during the Early Trading Session (4:00 a.m.–9:30 a.m. Eastern Time) and the Late Trading Session (4:00 p.m.–8:00 p.m. Eastern Time) due to the lack of calculation or dissemination of the Intraday Indicative Value or a similar value. The Exchange proposes to delete 2900(b)(1) in its entirety.

This information circular requirement is unnecessary because the primary listing exchange’s information circular already provides Equity Members⁷ with the same disclosures the Exchange would otherwise be required to produce. Equity Members have access to the primary listing exchange’s information circular prior to the commencement of UTP trading and may rely upon it for the same purposes.⁸ The Exchange’s issuance of a separate, duplicative circular therefore serves no independent investor protection function.

The Exchange also proposes to amend Rule 2900(a) to add express cross-references to Rule 2107 (Suitability) and Rule 2120 (Customer Disclosures). The Exchange is adding express cross references to those rules in Rule 2900(a) to enhance their visibility in the context of UTP Exchange Traded Product. These rules already apply to Equity Members by operation of the Exchange’s rulebook. The cross-references are intended to make the applicable framework explicit in the context of UTP Exchange Traded Products. Rule 2107 independently requires Equity Members to ensure that any recommendation of a UTP Exchange Traded Product complies with the suitability requirements of FINRA Rules regardless of whether the Exchange has issued a product-specific information

circular. Similarly, Rule 2120 independently requires Equity Members to provide customers with a written disclosure of the risks of trading outside of Regular Trading Hours before accepting any order for execution during such sessions, a standing obligation not contingent on the Exchange’s issuance of a product-specific information circular.

Because Rule 2900(b)(1) has historically served as the mechanism through which the Exchange satisfies the notification obligation under Rule 2900(b)(2)(B), deletion of Rule 2900(b)(1) necessitates a conforming amendment to Rule 2900(b)(2)(B). The Exchange proposes to amend Rule 2900(b)(2)(B) to require that any written description be provided in a form approved by the listing exchange. The Exchange will notify Equity Members by information circular that such written description will only be required when mandated by the listing exchange or prepared by the open-ended management company issuing such securities, not later than the time a confirmation of the first transaction in such securities is delivered to such purchaser. This amendment is consistent with the broader purpose of the proposed rule change: where the listing exchange’s information circular already provides Equity Members with the information necessary to assess a UTP Exchange Traded Product, a duplicative written description obligation serves no independent investor protection function. Equity Members may rely on the listing exchange’s information circular in the same manner and to the same effect.

Finally, the Exchange proposes to renumber existing Rules 2900(b)(2) through (5) as Rules 2900(b)(1) through (4), respectively.

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.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁰ 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)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed deletion of Rule 2900(b)(1) is consistent with the Act because the primary listing exchange’s information circular already provides Equity Members with the same disclosures that the Exchange’s information circular would contain. The investor protection functions historically served by the information circular requirement are independently addressed through the primary listing exchange’s information circular and the Member-level obligations imposed by Rules 2107 and 2120, to which the Exchange proposes to add express cross-references in Rule 2900(a). The investor protection functions historically served by the information circular requirement are independently addressed through the primary listing exchange’s information circular. The proposed amendment to Rule 2900(b)(2)(B) ensures that where a written description is required, it is provided in a form approved by the listing exchange or prepared by the open-ended management company issuing such securities, not later than the time a confirmation of the first transaction in such securities is delivered to such purchaser, thereby aligning the Exchange’s requirements with those of the primary listing exchange. The Exchange will further notify Equity Members by information circular that such written description will only be required when mandated by the listing exchange, ensuring that no duplicative obligation is imposed where the listing exchange has not determined one to be warranted. The renumbering of Rules 2900(b)(2) through (5) as Rules 2900(b)(1) through (4) is ministerial. For these reasons, the Exchange believes the proposed rule change is consistent with 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 proposed rule change eliminates duplicative procedural obligations

⁷ See Exchange Rule 1901.

⁸ Such information circulars are generally available on the primary listing exchange’s website.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

¹¹ *Id.*

applicable to the Exchange in its capacity as a UTP trading venue. It does not alter the terms or conditions under which UTP Exchange Traded Products may be traded on the Exchange, impose any new requirements on Equity Members, or affect the ability of any market participant to access the Exchange's markets. Equity Members will continue to have access to the primary listing exchange's information circular prior to the commencement of UTP trading and may rely upon it for the same purposes as the Exchange's information circular. The proposed amendment to Rule 2900(b)(2)(B) aligns the written description obligation with the primary listing exchange's requirements and does not impose any burden on Equity Members beyond what the primary listing exchange itself requires. Accordingly, the Exchange does not believe the proposed rule change imposes any burden on competition 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

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act¹² and Rule 19b-4(f)(6)¹³ 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; or (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 Act¹⁴ and Rule 19b-4(f)(6)¹⁵ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)¹⁶ normally does not become operative prior to 30 days after the date of the filing. However, pursuant

to Rule 19b-4(f)(6)(iii),¹⁷ 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 rule change eliminates duplicative procedural obligations applicable to the Exchange in its capacity as a UTP trading venue because the primary listing exchange's information circular already provides Members with the same disclosures the Exchange would otherwise be required to produce.¹⁸ The Exchange also notes that the proposed rule change does not alter the terms or conditions under which UTP Derivative Securities may be traded on the Exchange. For these reasons, 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.¹⁹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-PEARL-2026-28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

¹⁷ 17 CFR 240.19b-4(f)(6)(iii).

¹⁸ The Exchange represents that such information circulars are generally available on the primary listing market's website. See *supra* note 8.

¹⁹ 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).

Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-PEARL-2026-28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<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-2026-28 and should be submitted on or before July 28, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-13652 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105829; File No. SR-FINRA-2026-013]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Except Accounts Pursuant to Section 530A of the Internal Revenue Code From the Requirements of FINRA Rule 3210 (Accounts At Other Broker-Dealers and Financial Institutions)

July 1, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on June 17, 2026, the Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a "non-controversial" rule

²⁰ 17 CFR 200.30-3(a)(12) and (59).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

¹² 15 U.S.C. 78s(b)(3)(A).

¹³ 17 CFR 240.19b-4(f)(6).

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁶ 17 CFR 240.19b-4(f)(6).

change under paragraph (f)(6) of Rule 19b-4 under the Act,³ which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 3210 (Accounts At Other Broker-Dealers and Financial Institutions) to except from the requirements of the rule accounts pursuant to Section 530A of the Internal Revenue Code.

The text of the proposed rule change is available on FINRA's website at <http://www.finra.org> and at the principal office of FINRA.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose Background

Section 70204 of Public Law 119-21, 139 Stat. 72 (2025) added new Section 530A to the Internal Revenue Code ("IRC"),⁴ which sets forth provisions governing the establishment of accounts for specified eligible individuals ("Trump Accounts").⁵ Broadly, a Trump Account is a type of traditional individual retirement account that is subject to some special rules.⁶ Pursuant to IRC Section 530A and related guidance, a Trump Account is established for the exclusive benefit of an eligible individual, or such eligible individual's beneficiaries, and

designated at its establishment as a Trump Account. The statute among other things sets forth criteria for the Secretary of the United States Department of the Treasury ("Treasury") to select trustees for the Trump Accounts⁷ and establishes various guardrails for the operation of the accounts.⁸

FINRA Rule 3210, adopted in April 2017,⁹ governs accounts opened or established by associated persons of members at firms other than the firm with which they are employed. In adopting Rule 3210, FINRA noted the rule's role, as a matter of sound supervisory practice, in facilitating the effective oversight of the trading activities of associated persons of member firms.¹⁰ The rule places obligations on associated persons when opening a specified account at another member firm ("executing member") or other financial institution to, (1) obtain prior written consent from their employer member firm ("employer member"),¹¹ and (2) notify in writing

⁷ See, e.g., 26 U.S.C. 530A(g).

⁸ For example, the statute sets forth requirements as to the types of investments that are eligible for such accounts ("eligible investments"). An "eligible investment" as defined by IRC Section 530A(b)(3)(A) means any mutual fund or exchange traded fund ("ETF") which: (i) tracks the returns of a qualified index; (ii) does not use leverage; (iii) does not have annual fees and expenses of more than 0.1 percent of the balance of the investment in the fund; and (iv) meets such other criteria as the Treasury Secretary determines appropriate. A "qualified index" as defined by IRC Section 530A(b)(3)(B) means: (i) the Standard and Poor's 500 stock market index; or (ii) any other index which is comprised of equity investments in primarily United States companies, and for which regulated futures contracts are traded on a qualified board or exchange.

⁹ See Securities Exchange Act Release No. 77550 (April 7, 2016), 81 FR 21924 (April 13, 2016) (Order Approving Proposed Rule Change to Adopt FINRA Rule 3210 (Accounts At Other Broker-Dealers and Financial Institutions), as Modified by Partial Amendment No. 1 and Partial Amendment No. 2; File No. SR-FINRA-2015-029).

¹⁰ See *Regulatory Notice* 16-22 (June 2016) (Accounts At Other Broker-Dealers and Financial Institutions) (announcing the adoption of Rule 3210 and noting in part that sound supervisory practices require that a member firm monitor personal accounts opened or established outside of the firm by its associated persons).

¹¹ See Rule 3210(a), which provides that that no person associated with a member shall, without the prior written consent of the member, open or otherwise establish at a member other than the employer member, or at any other financial institution, any account in which securities transactions can be effected and in which the associated person has a beneficial interest. Supplementary Material .02 ("Related and Other Persons") of the rule provides in part that, for purposes of the rule, the associated person shall be presumed to have a beneficial interest in, and to have established, any account that is held by: (a) the spouse of the associated person; (b) a child of the associated person or of the associated person's spouse, provided that the child resides in the same household as or is financially dependent upon the

the executing member, or other financial institution, of their association with the employer member.¹² The rule also requires an executing member, upon written request by the employer member, to transmit duplicate copies of confirmations and statements, or the transactional data contained therein, with respect to an account subject to the rule.¹³ Further, the rule sets forth specified exceptions from these requirements for transactions in unit investment trusts, municipal fund securities as defined under MSRB Rule D-12, qualified tuition programs pursuant to Section 529 of the IRC ("529 plans") and variable contracts or redeemable securities of companies registered under the Investment Company Act, as amended, or for accounts that are limited to transactions in such securities, or to Monthly Investment Plan type accounts.¹⁴

Proposed Rule Change

Current Rule 3210 does not expressly exclude Trump Accounts from the requirements described above. As such, Trump Accounts established by associated persons on behalf of related persons, or that are established by related persons of associated persons, would be subject to the rule, absent an exception. FINRA is proposing to amend Rule 3210 to add "accounts pursuant to Section 530A of the Internal Revenue Code" (i.e., Trump Accounts) to the specified transactions and accounts under Supplementary Material .03 to Rule 3210 that shall not be subject to the rule's requirements.¹⁵ FINRA believes that amending Rule 3210 to include an exception from the rule's requirements for these Trump Accounts is consistent with the rule's longstanding approach,¹⁶ given such accounts are reasonably classed with the

associated person; (c) any other related individual over whose account the associated person has control; or (d) any other individual over whose account the associated person has control and to whose financial support the associated person materially contributes. As such, for purposes of Rule 3210, the accounts of such related or other persons generally fall within the scope of the rule's requirements.

¹² See Rule 3210(b).

¹³ See Rule 3210(c).

¹⁴ See Supplementary Material .03 to Rule 3210.

¹⁵ See proposed Rule 3210.03 in Exhibit 5. FINRA notes that the proposed exception is specific to Trump Accounts and the transactions in eligible investments that are effected in Trump Accounts.

¹⁶ See, e.g., Securities Exchange Act Release No. 75655 (August 10, 2015), 80 FR 48941 (August 14, 2015) (Notice of Filing of a Proposed Rule Change To Adopt FINRA Rule 3210 (Accounts At Other Broker-Dealers and Financial Institutions) in the Consolidated FINRA Rulebook; File No. SR-FINRA-2015-029), note 30 (noting in part FINRA's intention to avoid imposing burdens that are unnecessary from a supervisory standpoint).

³ 17 CFR 240.19b-4(f)(6).

⁴ 26 U.S.C. 530A (for purposes of this rule filing, hereinafter referred to as "IRC Section 530A").

⁵ The term "eligible individual" is defined under IRC Section 530A(b)(2) to mean an individual who has not attained the age of 18 before the specified election to establish a Trump Account on behalf of such individual is made.

⁶ See, e.g., Internal Revenue Service ("IRS") Notice 2025-68 ("Notice 2025-68").

types of transactions and accounts that are currently excepted from Rule 3210's requirements. For instance, similar to 529 plans—for which current Rule 3210 provides an exception—the extent to which an account owner may direct the underlying investments in a Trump Account is strictly limited.¹⁷ Trump Accounts are structured by statute to function as standardized, passive investment vehicles designed solely to facilitate long-term exposure to broad-based market indices.¹⁸ Accounts of this nature generally do not implicate the supervisory purposes of Rule 3210.

As such, FINRA does not believe it is necessary to impose on members and their associated persons the information collection and compliance burdens of the rule with respect to Trump Accounts. Further, members have requested certainty with regard to the treatment of accounts pursuant to IRC Section 530A under Rule 3210. In response to these requests, FINRA believes it is appropriate to implement the proposed exception immediately given the impending July 4, 2026, implementation date for Trump Accounts.

FINRA has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so FINRA can implement the proposed rule change immediately.¹⁹

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,²⁰ which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable

principles of trade, and, in general, to protect investors and the public interest.

FINRA believes that the proposed rule change will further the purposes of the Act because it will preserve investor protection and serve the public interest by appropriately tailoring supervisory requirements to account type and risk profile. It maintains Rule 3210's core purpose—promoting effective oversight of associated persons' accounts at other members or firms—while recognizing that Trump Accounts already have built-in guardrails that would limit the supervisory concerns the rule is designed to address. By providing an exception for these accounts that operate within a comprehensive statutory framework, the proposed rule change also eliminates unnecessary administrative burdens while ensuring regulatory oversight remains appropriate to actual risk. FINRA believes that immediate implementation of the proposed rule change is appropriate and in the public interest given the July 4, 2026, implementation date for Trump Accounts.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the potential economic impacts of the proposed rule change, including anticipated costs, benefits, and distributional and competitive effects, relative to the current baseline.

Regulatory Need

FINRA is proposing to add an exception to Rule 3210 for associated persons opening Trump Accounts. Trump Accounts are opened automatically by election through the Treasury and are structured to function as standardized, passive investment vehicles. Trading in Trump Accounts would not implicate the supervisory purposes of Rule 3210.

Economic Baseline

The economic baseline includes current Rule 3210, all associated persons who elect to open Trump Accounts, the members that employ them, and any trustees selected by the Treasury. The economic baseline also includes members that later become trustees of Trump Accounts.

Economic Impacts

The proposed rule change would benefit associated persons and members by removing the compliance costs of Rule 3210. Specifically, under the proposed rule change, associated persons who elect to open Trump Accounts at a member other than their employer would not need to obtain prior written consent from the employer member or notify the member holding the Trump Account of the association with the employer member. The employer member would not need to evaluate the associated person's request to open the Trump Account, and the member holding the Trump Account would not need to send duplicate copies of confirmations and statements to the employer member. FINRA anticipates no reduction in investor protection from the proposed rule change given the automatic nature of Trump Account openings and the structure of Trump Accounts as standardized and passive investment vehicles. FINRA anticipates no initial impacts on competition, and potentially some enhancement of competition to open Trump Accounts of associated persons by members that become trustees of Trump Accounts.

Alternatives Considered

The proposed rule change facilitates the implementation of IRC Section 530A. No alternatives were considered.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²¹ and Rule 19b-4(f)(6) thereunder.²²

A proposed rule change filed under Rule 19b-4(f)(6) normally does not

¹⁷ See 26 U.S.C. 530A. See also 26 U.S.C. 529. 529 plans also include limitations on investments. See generally SEC Investor Bulletin: An Introduction to 529 Plans, available at <https://www.investor.gov/introduction-investing/general-resources/news-alerts/alerts-bulletins/investor-bulletins/introduction-529-plans-investor-bulletin>.

¹⁸ For further background, see Notice 2025-68 and the Trump Accounts website at trumpaccounts.gov; see also Letter regarding Request for No-Action Relief from Form CRS Delivery Requirements for Certain Limited-Purpose Retirement Accounts ("Trump Accounts") from John S. Markle, Counsel for Robinhood Financial LLC & Robinhood Securities, LLC, to Emily Westerberg Russell, Chief Counsel, SEC Division of Trading and Markets, 2026 SEC NO-ACT. LEXIS 51 (May 5, 2026).

¹⁹ FINRA notes that the proposed rule change would not impact members that are funding portals or have elected to be treated as capital acquisition brokers ("CABs"), given that neither funding portals nor CABs are subject to Rule 3210.

²⁰ 15 U.S.C. 78o-3(b)(6).

²¹ 15 U.S.C. 78s(b)(3)(A).

²² 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. FINRA has satisfied this requirement.

become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii),²³ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. FINRA has requested that the Commission waive the 30-day delay requirement so that the proposed rule change may become operative immediately upon filing. In its request, FINRA stated that amending FINRA Rule 3210 to except Trump Accounts would be consistent with the rule's longstanding approach, given such accounts are reasonably classed with the types of transactions and accounts that are currently excepted from FINRA Rule 3210's requirements.

Currently, FINRA Rule 3210 excepts transactions in unit investment trusts, municipal fund securities as defined under MSRB Rule D-12, 529 plans and variable contracts or redeemable securities of companies registered under the Investment Company Act, as amended, and accounts that are limited to transactions in such securities, and Monthly Investment Plan type accounts. FINRA stated that Trump Accounts are similar to 529 plans in that the extent to which an account owner may direct the underlying investments in a Trump Account is strictly limited. FINRA further noted that Trump Accounts are structured by statute to function as standardized, passive investment vehicles designed solely to facilitate long-term exposure to broad-based market indices, thereby limiting an account owner directing the underlying investments. As such, FINRA stated that Trump Accounts would not implicate the supervisory purposes of FINRA Rule 3210. In addition, waiving the 30-day operative delay would help ensure that members and associated persons have certainty with regard to the treatment of such accounts prior to the implementation of Trump Accounts on July 4, 2026. For these reasons, the Commission believes that waiving the 30-day operative delay for this proposed rule change is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change 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-FINRA-2026-013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-FINRA-2026-013. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-FINRA-2026-013 and should be submitted on or before July 28, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-13648 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105844; File No. SR-CME-2026-002]

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Adoption of Chicago Mercantile Exchange's Rules Governing Security Futures Product Listing Standards, Adoption of Chicago Mercantile Exchange Inc.'s Rules Governing Security Futures Adjustments, and Adoption of Chicago Mercantile Exchange Inc.'s Rules Governing Cash-Settled Single Stock Security Futures

July 2, 2026.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 ("Act"),¹ notice is hereby given that on June 29, 2026 Chicago Mercantile Exchange, Inc. ("CME" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change 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. CME also has filed this proposed rule change with the Commodity Futures Trading Commission ("CFTC"). The Exchange filed a written certification with the CFTC under Section 5c(c) of the Commodity Exchange Act ("CEA")² and CFTC Regulation 41.24(a)³ on June 29, 2026.

I. CME's Description and Text of the Proposed Rule Change

The Exchange previously offered physically delivered single stock security futures contracts for trading as SFPs pursuant to its registration with the CFTC as a designated contract market and prior notice registration with the SEC as a national securities exchange under the Act but ceased offering such products for trading in March 2011.

Pursuant to its current notice registration, CME is re-adopting Rulebook Chapter 700 to expand the previously adopted Chapter's applicability to cash-settled SFPs to enable the Exchange to list cash-settled futures on individual common stock securities, allowing for an expanded scope of listed products. Proposed Chapter 700 specifies initial and

²³ 17 CFR 240.19b-4(f)(6)(iii).

²⁴ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(7).

² 7 U.S.C. 7a-2(c).

³ 17 CFR 41.24(a).

maintenance listing standards for SFPs including the proposed Cash-Settled Single Stock Security Futures. The Exchange developed Chapter 700 and the proposed amendments to comply with Section 6(h) of the Exchange Act.

The Exchange is also re-adopting Rulebook Chapter 701, Security Futures Product Adjustments. The proposed Chapter 701 specifies the Exchange's response to corporate events and the possible unavailability or inaccuracy of spot values for use as final settlement prices. The proposed Chapter 701 is identical to the previously adopted Chapter 701.

The Exchange is also adopting the new Rulebook Chapter 711, which will govern more specifically the trading of cash-settled futures on individual securities. The revisions to Chapter 700 and the new Chapter 711 are modeled after the Exchange's existing Rulebook Chapter 710, Physically Delivered Single Security Futures, which governs trading of futures on individual equity securities that settle by delivery of the underlying security at expiration.⁴

II. CME'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. CME's Statement of the Purpose of, and Statutory Basis for, Proposed Rule Change

1. Purpose

CME proposes (i) adding definitions of the terms "narrow-based security index" and "security futures products" to CME Rulebook Chapter iii (Definitions); (ii) adopting CME Rulebook Chapter 700 ("Security Futures Product Listing Standards"), (iii) adopting CME Rulebook Chapter 701 ("Security Futures Products Adjustments"), and (iv) adopting CME Rulebook Chapter 711 ("Cash-Settled Single Stock Security Futures") to allow the listing of cash-settled futures on individual equity securities as SFPs (collectively, the "Rule Amendments").

⁴ The Exchange has indicated that it currently has no plans to list any Physically Delivered Single Security Futures for trading.

Rulebook Chapter iii Definitions

CME proposes adding two defined terms to Chapter iii. First, CME proposes to add the term "narrow-based index future," defined as a futures contract based upon a security index that is considered narrow-based as defined in Section 1a(35) of the CEA. Second, CME proposes to add the term "Security Futures Products" to Chapter iii, defined as a contract based on securities products as such term is defined by Section 1a(45) of the CEA. The text of the definition also provides that "Security Futures Products ("SFPs") include futures contracts based upon a single security; futures contracts based upon a narrow-based security index; and options on any security futures as those terms are defined in Sections 1a(35) and 1a(44) of the Commodity Exchange Act."

CME notes that these definitions are identical to the definitions for these terms that it had added to CME Rulebook Chapter iii when it was previously notice-registered with the Commission as a national securities exchange for SFPs.

Rulebook Chapter 700 Security Futures Product Listing Standards

CME proposes adopting Rulebook Chapter 700 to set out listing standards pursuant to which it will list SFPs for trading, including the trading of cash-settled futures on individual equity securities. CME previously adopted Chapter 700 in 2002 in connection with offering physically delivered single security futures contracts for trading as SFPs.⁵ CME proposes to re-adopt this Chapter, subject to certain revisions. The proposed listing standards are generally identical to the previously adopted Chapter 700 with revisions to enable the listing of cash-settled futures on individual equity securities to allow for an expanded scope of the types of SFPs the Exchange may list for trading and with the deletion of two former rules that applied to physically settled contracts alone. The proposed listing standards are also generally identical to the sample listing standards published in Staff Legal Bulletin No. 15 ("SLB 15")⁶ except that they:

- Reflect the modifications to the statutory listing standards requirements adopted by the Commission and the

⁵ Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by the Chicago Mercantile Exchange Relating to Listing Standards for Security Futures Products, Securities Exchange Act Release No. 34-46975 (Dec. 9, 2002), 67 FR 77297 (Dec. 17, 2002).

⁶ SEC Division of Market Regulation; Staff Legal Bulletin No. 15: Listing Standards for Trading Security Futures Products (September 5, 2001).

CFTC governing shares of American Depositary Receipts, exchange-traded funds, trust-issued receipts, and shares of registered closed-end management investment companies;⁷

- Provide for the trading of cash-settled single security futures contracts for trading as SFPs;

- Include more stringent listing standard requirements, including that (1) the underlying security must have an estimated deliverable supply in excess of 20 million shares, (2) the underlying security must have a minimum market capitalization of at least \$100 billion, and (3) the underlying security must have had a minimum average daily value of transactions ("ADVT") of at least \$450 million over the prior six months, except where the underlying security has been listed for trading for less than six months, in which case the requirement would be a minimum ADVT of at least \$1 billion over the prior month; and

- Include more stringent maintenance listing standard requirements, including that (1) the underlying security must have an estimated deliverable supply in excess of 20 million shares, (2) the underlying security must have a minimum market capitalization of at least \$50 billion, and (3) the underlying security must have had a minimum ADVT of at least \$200 million for the prior calendar quarter, except where the underlying security has been listed for trading for less than a quarter, in which case the requirement would be a minimum ADVT of at least \$1 billion over the period traded during the calendar quarter.

This section describes the generalized Rule framework for Rulebook Chapter 700:

Scope of Chapter 700—Chapter 700 applies to initial and maintenance listing standards for SFPs listed on the Exchange.

Initial Listing Standards for Single Security Futures—Rule 70001 provides that for a SFP that is cash settled⁸ or physically settled, to be eligible for initial listing, the security underlying

⁷ See Joint Order Granting the Modification of Listing Standards Requirements (American Depositary Receipts), Securities Exchange Act Release No. 44725 (August 20, 2001) and Joint Order Granting the Modification of Listing Standards Requirements (Exchange Traded Funds, Trust Issued Receipts and shares of Closed-End Funds), Securities Exchange Act Release No. 46090 (June 19, 2002), 67 FR 42760 (June 25, 2002).

⁸ CME has proposed adding the language "cash settled" to the previously adopted Rule 70001 to specify that Chapter 700 will provide for the trading of cash-settled single security futures contracts for trading as SFPs.

the futures contract must meet each of the following thirteen (13) requirements:

Rule 70001.1, or requirement 1, requires that the underlying security “must be a common stock, or in the case of a physically delivered single securities futures contract, an American Depositary Receipt (‘ADR’) representing common stock or ordinary shares, a share of an exchange traded fund (‘ETF Share’), a trust issued receipt (‘TIR’) or a share of a registered closed-end management investment company (‘Closed-End Fund Share’).” Given the proposed addition of cash-settled single security futures contracts for trading as SFPs to the previously adopted Chapter 700, CME proposes adding the clarification that only physically delivered single securities futures contracts must be ADRs representing common stock or ordinary shares, ETFs, TIRs, or Closed-End Fund Shares.

Rule 70001.2, or requirement 2, requires that the underlying security “must be registered under Section 12 of the Securities Exchange Act of 1934 (as amended from time to time, the ‘Exchange Act’), and its issuer must be in compliance with any applicable requirements of the Exchange Act.”

Rule 70001.3, or requirement 3, requires that the underlying security “must be listed on a national securities exchange or traded through the facilities of a national securities association and reported as a ‘national market system’ security as set forth in Rule 11Aa3–1 under the Exchange Act (‘NMS security’).”

Rule 70001.4, or requirement 4, requires that “[t]here must be at least seven million shares or receipts evidencing the underlying security outstanding that are owned by persons other than those required to report their security holdings pursuant to Section 16(a) of the Exchange Act.” Rule 70001 provides an interpretation for requirement 4 as applied to restructure securities. Specifically, “Interpretation of Requirement 4” provides that “[i]n the case of an equity security that a company issues or anticipates issuing as the result of a spin-off, reorganization, recapitalization, restructuring or similar corporate transaction (‘Restructure Security’), the Exchange may assume that this requirement is satisfied if, based on a reasonable investigation, it determines that, on the product’s intended listing date: (A) at least 40 million shares of the Restructure Security will be issued and outstanding; or (B) the Restructure Security will be listed on an exchange or automated quotation system that is subject to an initial listing requirement of no less than seven million publicly owned

shares.” The interpretation also provides that “[i]n the case of a Restructure Security issued or distributed to the holders of the equity security that existed prior to the ex-date of a spin-off, reorganization, recapitalization, restructuring or similar corporate transaction (‘Original Equity Security’), the Exchange may consider the number of outstanding shares of the Original Equity Security prior to the spin-off, reorganization, recapitalization, restructuring or similar corporate transaction (‘Restructuring Transaction’).”

Rule 70001.5, or requirement 5, requires that the underlying security’s “estimated deliverable supply, as reasonably determined by the Exchange consistent with Appendix A to Part 41 of the CFTC Regulations, must exceed 20 million shares.” CME proposes adding this requirement to the previously adopted Rule 70001 to more effectively protect against manipulative trading practices. CME also proposes revising the numbering in Rule 70001 to accommodate this new requirement 5.

Rule 70001.6, or requirement 6, requires that the underlying security “must have a minimum market capitalization of at least \$100 billion.” CME proposes adding this requirement to the previously adopted Rule 70001 to more effectively protect against manipulative trading practices. CME also proposes revising the numbering in Rule 70001 to accommodate this new requirement 6.

Rule 70001.7, or requirement 7, requires that the underlying security “must have had a minimum average daily value of transactions of at least \$450 million over the prior six months, except where the underlying security has been listed for trading for less than six months, in which case the underlying security must have had a minimum average daily value of transactions of at least \$1 billion over the prior month.” CME proposes adding this requirement to the previously adopted Rule 70001 to more effectively protect against manipulative trading practices. This requirement would replace Rule 70001.6 under the previously adopted Rule 70001, which imposed a lower standard for historical trading value. Consequently, CME also proposes removing the interpretation of the previously adopted Rule 70001.6 (“Interpretation of Requirement 6”). CME also proposes revising the numbering in Rule 70001 to accommodate the new requirement 7.

Rule 70001.8, or requirement 8, requires that for an underlying security other than an ETF Share, TIR, or Closed-End Fund Share, “there must be at least

2,000 security holders.” Rule 70001 provides an interpretation of this requirement (“Interpretation of Requirement 8”). Specifically, the interpretation provides that “[i]f the security under consideration is a Restructure Security, the Exchange may assume that this requirement is satisfied if, based on a reasonable investigation, the Exchange determines that, on the product’s intended listing date: (A) at least 40 million shares of the Restructure Security will be issued and outstanding; or (B) the Restructure Security will be listed on an exchange or automated quotation system that is subject to an initial listing requirement of at least 2,000 shareholders.” The interpretation further provides that “[i]n the case of a Restructure Security issued or distributed to the holders of the Original Equity Security, the Exchange may consider the number of shareholders of the Original Equity Security prior to the Restructuring Transaction.”

Rule 70001.9, or requirement 9, requires that for an underlying security that is an ETF Share, TIR, or Closed-End Fund Share, “it must have had a total trading volume (in all markets in which the underlying security has traded) of at least 2,400,000 shares or receipts evidencing the underlying security in the preceding 12 months.”

Rule 70001.10, or requirement 10, requires that “[i]f the underlying security is a ‘covered security’ as defined under Section 18(b)(1)(A) of the Securities Act of 1933, the market price per share of the underlying security has been at least \$3.00 for the previous five consecutive business days preceding the date on which the Exchange commences to list and trade the Security Futures Product on said underlying security.” CME proposes revising the previously adopted Rule 70001.10 to add an end-quotation mark to the term “covered security” for clarification purposes. Requirement 10 further specifies that “the market price of such underlying security is measured by the closing price reported in the primary market in which the underlying security is traded.”

Rule 70001 provides an interpretation of requirement 10 as applied to restructure securities (“Interpretation of Requirement 10”). The interpretation provides for a “Look-Back Test” which specifies that, “[i]n determining whether a Restructure Security that is issued or distributed to the shareholders of an Original Equity Security (but not a Restructure Security that is issued pursuant to a public offering or rights distribution) satisfies this requirement, the Exchange may ‘look back’ to the

market price history of the Original Equity Security prior to the ex-date of the Restructuring Transaction if the following Look-Back Test is satisfied: (a) The Restructure Security has an aggregate market value of at least \$500 million; (b) The aggregate market value of the Restructure Security equals or exceeds the Relevant Percentage (defined below) of the aggregate market value of the Original Equity Security; (c) The aggregate book value of the assets attributed to the business represented by the Restructure Security equals or exceeds both \$50 million and the Relevant Percentage of the aggregate book value of the assets attributed to the business represented by the Original Equity Security; or (d) The revenues attributed to the business represented by the Restructure Security equals or exceeds both \$50 million and the Relevant Percentage of the revenues attributed to the business represented by the Original Equity Security.”

The interpretation of requirement 10 further provides that, “[f]or purposes of determining whether the Look-Back Test is satisfied, the term ‘Relevant Percentage’ means: (i) 25%, when the applicable measure determined with respect to the Original Equity Security or the business it represents includes the business represented by the Restructure Security; and (ii) 33–1/3%, when the applicable measure determined with respect to the Original Equity Security or the business it represents excludes the business represented by the Restructure Security.” The interpretation specifies that “[i]n calculating comparative aggregate market values, the Exchange will use the Restructure Security’s closing price on its primary market on the last business day prior to the Selection Date, or the Restructure Security’s opening price on its primary market on the Selection Date, and will use the corresponding closing or opening price of the related Original Equity Security.” The interpretation further specifies that “in calculating comparative asset values and revenues, the Exchange will use the issuer’s (i) latest annual financial statements or (ii) most recently available interim financial statements (so long as such interim financial statements cover a period of not less than three months), whichever are more recent,” which financial statements “may be audited or unaudited and may be pro forma.”

The interpretation of requirement 10 also provides guidance on “Restructure Securities Issued in Public Offering or Rights Distribution.” Specifically, “[i]n determining whether a Restructure Security that is distributed pursuant to

a public offering or a rights distribution satisfies requirement 10, the Exchange may look back to the market price history of the Original Equity Security if: (i) the foregoing Look-Back Test is satisfied; (ii) the Restructure Security trades ‘regular way’ on an exchange or automatic quotation system for at least five trading days immediately preceding the Selection Date; and (iii) at the close of trading on each trading day on which the Restructure Security trades ‘regular way’ prior to the Selection Date, as well as at the opening of trading on Selection Date, the market price of the Restructure Security was at least \$3.00.”

The interpretation of requirement 10 provides a limitation on the use of the Look-Back Test. In particular, “[e]xcept in the case of a Restructure Security that is distributed pursuant to a public offering or rights distribution, the Exchange will not rely upon the market price history of an Original Equity Security for any trading day unless it also relies upon the trading volume history for that trading day.” An additional limitation is that “once the Exchange commences to rely upon a Restructure Security’s trading volume and market price history for any trading day, the Exchange will not rely upon the trading volume and market price history of the related Original Equity Security for any trading day thereafter.”

Rule 70001.11, or requirement 11, requires that “[i]f the underlying security is not a ‘covered security’ as defined under Section 18(b)(1)(A) of the Securities Act of 1933, the market price per share of the underlying security has been at least \$7.50 for the previous five consecutive business days preceding the date on which the Exchange commences to list and trade the Security Futures Product on said underlying security.” CME proposes revising the previously adopted Rule 70001.11 to add an end-quotation mark to the term “covered security” for clarification purposes. Rule 70001.11 further specifies that “the market price of such underlying security is measured by the closing price reported in the primary market in which the underlying security is traded.” Rule 70001 provides an interpretation of requirement 11 as applied to restructure securities, which is identical to the interpretation provided for requirement 10, except that the relevant market price of the Restructure Security—for purposes of determining whether a Restructure Security that is distributed pursuant to a public offering or a rights distribution satisfies requirement 11—is \$7.50, instead of \$3.00.

Rule 70001.12, or requirement 12, requires that “[i]f the underlying security is an ADR: (a) [t]he Exchange

must have an effective surveillance sharing agreement with the primary exchange in the home country where the stock underlying the ADR is traded; (b) [t]he combined trading volume of the ADR and other related ADRs and securities in the U.S. ADR market, or in markets with which the Exchange has in place an effective surveillance sharing agreement, represents (on a share equivalent basis) at least 50% of the combined worldwide trading volume in the ADR, the security underlying the ADR, other classes of common stock related to the underlying security, and ADRs overlying such other stock over the three-month period preceding the dates of selection of the ADR for futures trading (“Selection Date”); (c)(1) [t]he combined trading volume of the ADR and other related ADRs and securities in the U.S. ADR market, and in markets where the Exchange has in place an effective surveillance sharing agreement, represents (on a share equivalent basis) at least 20% of the combined worldwide trading volume in the ADR and in other related ADRs and securities over the three-month period preceding the Selection Date; [(c)](2) [t]he average daily trading volume for the ADR in the U.S. markets over the three-month period preceding the Selection Date is at least 100,000 receipts; and [(c)](3) [t]he daily trading volume for the ADR is at least 60,000 receipts in the U.S. markets on a majority of the trading days for the three-month period preceding the Selection Date; [o]r (d) [t]he Securities and Exchange Commission and Commodity Futures Trading Commission have otherwise authorized the listing.”

Rule 70001.13, or requirement 13, requires that “[t]he Exchange will not list for trading any SFP where the underlying security is a Restructure Security that is not yet issued and outstanding, regardless of whether the Restructure Security is trading on a ‘when issued’ basis or on another basis that is contingent upon the issuance or distribution of securities.”

Maintenance Listing Standards for Single Security Futures—Rule 70002.1 provides that “[t]he Exchange will not open for trading any SFP that is cash settled or physically settled with a new expiration or delivery month, and may prohibit any opening purchase transactions in the SFP already trading, to the extent it deems such action necessary or appropriate, unless the underlying security meets each of” eight (8) maintenance requirements, “provided that, if the underlying security is an ETF Share, TIR or Closed-End Fund Share, the applicable

requirements for initial listing of the related SFP,” as described in Rule 70001, “shall apply in lieu of” the eight maintenance requirements. CME proposes revising the previously adopted Rule 70002.1 to add the language “cash settled” and “expiration” to specify that Chapter 700 will provide for the trading of cash-settled SFPs that are subject to expiration. CME also proposes removing certain misplaced commas from the previously adopted Rule 70002.1. The eight maintenance requirements are as follows:

Rule 70002.1(a), or requirement 1.a, requires that the underlying security “must be registered under Section 12 of the Exchange Act.”

Rule 70002.1(b), or requirement 1.b, requires that “[t]here must be at least 6,300,000 shares or receipts evidencing the underlying security outstanding that are owned by persons other than those who are required to report their security holdings pursuant to Section 16(a) of the Exchange Act.”

Rule 70002.1(c), or requirement 1.c, requires that “[t]here must be at least 1,600 securityholders.”

Rule 70002.1(d), or requirement 1.d, requires that the underlying security “must have had a minimum average daily value of transactions of at least \$200 million for the prior calendar quarter, except where the underlying security has been listed for trading for less than a quarter, in which case the underlying security must have had a minimum average daily value of transactions of at least \$1 billion over the period traded during the calendar quarter.” CME proposes adding this requirement to the previously adopted Rule 70002.1 to more effectively protect against manipulative trading practices. This requirement would replace Rule 70002.1(d) under the previously adopted Rule 70002, which imposed a lower standard for historical trading value. Consequently, CME also proposes removing the interpretation of the previously adopted Rule 70002.1(d) (“Interpretation of Requirement 1.d”).

Rule 70002.1(e), or requirement 1.e, requires that the underlying security’s estimated deliverable supply, as reasonably determined but the Exchange consistent with Appendix A to Part 41 of the CFTC Regulations, must exceed 20 million shares.” CME proposes adding this requirement to the previously adopted Rule 70002.1 to more effectively protect against manipulative trading practices. CME also proposes revising the numbering in Rule 70002 to accommodate this new requirement 1.e.

Rule 70002.1(f), or requirement 1.f, requires that the underlying security “must have a minimum market capitalization of at least \$50 billion.” CME proposes adding this requirement to the previously adopted Rule 70002.1 to more effectively protect against manipulative trading practices. CME also proposes revising the numbering in Rule 70002 to accommodate this new requirement 1.f.

Rule 70002.1(g), or requirement 1.g, requires that “[t]he market price per share or receipt of the underlying security has not closed below \$3.00 on the previous trading day to the Expiration Day of the nearest expiring Contract on the underlying security.” This requirement specifies that “[t]he market price per share of the underlying security will be measured by the closing price reported in the primary market in which the underlying security traded.” Rule 70002 provides an interpretation of this requirement as applied to restructure securities (“Interpretation of Requirement 1.g”). Specifically, “[i]f a Restructure Security is approved for SFP trading under the initial listing standards per Rule 70001, the market price history of the Original Equity Security prior to the commencement of trading in the Restructure Security, including ‘when-issued’ trading, may be taken into account in determining whether this requirement is satisfied.”

Rule 70002.1(h), or requirement 1.h, requires that, “[i]f the underlying security is an ADR and was initially deemed appropriate for SFP trading per Rule 70001.12.b or Rule 70001.12.c., the Exchange will not open for trading SFPs having additional delivery months on the ADR unless: (1) [t]he percentage of worldwide trading volume in the ADR and other related securities that takes place in the U.S. and in markets with which the Exchange has in place effective surveillance sharing agreements for any consecutive three-month period is . . . at least 30%, without regard to the average daily trading volume in the ADR . . . or at least 15% when the average U.S. daily trading volume in the ADR for the previous three months is at least 70,000 receipts; (2) [t]he Exchange has in place an effective surveillance sharing agreement with the primary exchange in the home country where the security underlying the ADR is traded; or (3) [t]he Securities and Exchange Commission and Commodity Futures Trading Commission have otherwise authorized the listing.”

Rule 70002.2 provides that “[t]he Exchange will not open trading in a SFP with a new delivery month unless: (a) [t]he issuer of the underlying security

satisfies applicable Exchange Act reporting requirements, or corrects any failure within 30 days after the date the report was due to be filed; (b) [t]he underlying security is listed on a national securities exchange or is principally traded through the facilities of a national securities association and is designated as an NMS security; and (c) [t]he underlying security is registered under Section 12 of the [Exchange Act], and its issuer is in compliance with applicable requirements of the Exchange Act.” CME proposes revising the numbering in the previously adopted Rule 70002 to correct an error where the numbering was not continued after Rule 70002.1.

Rule 70002.3 provides that, “[i]f prior to the withdrawal from trading of a SFP covering an underlying security that has been found not to meet the Exchange’s requirements for continued approval, the Exchange determines that the underlying security again meets the Exchange’s requirements, the Exchange may open for trading new delivery months in such SFP and may lift any restriction on opening purchase transactions.”

Rule 70002.4 provides that, “[w]henver the Exchange announces that approval of an underlying security has been withdrawn for any reason or that the Exchange has been informed that the issuer of an underlying security has ceased to be in compliance with Exchange Act reporting requirements, each Clearing Member and Exchange Member (as such terms are defined in the Rules of the Exchange as in effect from time to time) shall, prior to effecting any transaction in SFPs with respect to such underlying security for any customer, inform such customer of such fact and that the Exchange may prohibit further transactions in such SFPs as it determines is necessary and appropriate.”

Rulebook Chapter 701 Security Futures Products Adjustments

CME also proposes adopting Rulebook Chapter 701 to set out Rules that specify CME’s response to corporate events and the possible unavailability or inaccuracy of spot values for use as final settlement prices. CME previously adopted Chapter 701 in 2005.⁹ CME now proposes to re-adopt this Chapter in connection with CME’s proposal to offer cash-settled single security futures contracts for

⁹Notice of Filing and Immediate Effectiveness of a Proposed Rules Governing Security Futures Adjustments, Securities Exchange Act Release No. 34-51958 (June 30, 2005), 70 FR 39814 (July 11, 2005).

trading as SFPs, with some non-substantive modifications.

This section describes the generalized Rule framework for Rulebook Chapter 701:

Scope of Chapter 701—Rule 70101 specifies that Rulebook Chapter 701 shall be “limited in application to [SFPs] traded on [CME] where the underlying interest is a single equity security or a narrow-based index.” This rule further provides that “[t]he procedures for clearing, delivery, settlement and other matters not specifically covered herein shall be governed by the Rules of the Exchange.”

Adjustments to Security Futures Products—Rule 70110.1 provides that “[d]eterminations as to whether and how to adjust the terms of Security Futures Products to reflect events affecting underlying interests shall be made by the Clearing House based on its judgment as to what is appropriate for the protection of investors and the public interest, taking into account such factors as fairness to the buyers and sellers of [SFPs] on the underlying interest, the maintenance of a fair and orderly market in futures on the underlying interest, consistency of interpretation and practice, efficiency of settlement of delivery obligations arising from physically-settled [SFPs], and the coordination with other clearing agencies of the clearance and settlement of transactions in the underlying security.” The rule also provides that “[t]he Clearing House may, in addition to determining adjustments to Security Futures Products on a case-by-case basis, adopt interpretations having general application to specified types of events.” The rule specifies that “[e]very determination by the Clearing House in respect of [SFPs] pursuant to [Rule 70110] shall be within the discretion of the Clearing House and shall be conclusive and binding on all investors and not subject to review.” The rule also clarifies that it applies to SFPs “based on single equity securities only.”

Rule 70110.2 provides that “[w]hen there is a dividend, stock dividend, stock distribution, stock split, reverse stock split, rights offering, distribution, reorganization, recapitalization, reclassification or similar event in respect of any underlying security, or a merger, consolidation, dissolution or liquidation of the issuer of any underlying security, the number of [SFP] contracts, the unit of trading, the settlement price and the underlying security, or any of them, with respect to all outstanding [SFPs] open for trading in the underlying security may be adjusted in accordance with [Rule 70110].” The rule also

provides that “[i]f the Clearing House does not learn, or does not learn in a timely manner, of an event for which the Clearing House would have otherwise made an adjustment, the Clearing House shall not be liable for any failure to make such adjustment or delay in making such adjustment.” The rule further provides that “[i]n making any adjustment determination, the Clearing House shall apply the factors set forth in [Rule 70110] in light of the circumstances known to it at the time such determination is made.”

Rule 70110.3 provides that “[i]t shall be the general rule that there will be no adjustments to reflect ordinary cash dividends or distributions or ordinary stock dividends or distributions (collectively, ‘ordinary distributions’) by the issuer of the underlying security.”

Rule 70110.4 provides that, subject to Rule 70110.3, “it shall be the general rule that in the case of a stock dividend, stock distribution or stock split whereby one or more whole numbers of shares of the underlying security are issued with respect to each outstanding share, each SFP contract covering that underlying security shall be increased by the same number of additional SFP contracts as the number of shares issued with respect to each share of the underlying security, the last settlement price established immediately before such event shall be proportionately reduced, and the unit of trading shall remain the same.”

Rule 70110.5 provides that, subject to Rule 70110.3, “it shall be the general rule that in the case of a stock dividend, stock distribution or stock split whereby other than a whole number of shares of the underlying security is issued in respect of each outstanding share, the last settlement price established immediately before such event shall be proportionately reduced, and conversely, in the case of a reverse stock split or combination of shares, the last settlement price established immediately before such event shall be proportionately increased.” Rule 70110.3 also specifies that “[w]hen the settlement price with respect to a stock future has been reduced or increased in accordance with this paragraph, the unit of trading shall be proportionately increased or reduced, as the case may be.”

Rule 70110.6 provides that “[i]t shall be the general rule that in the case of any distribution made with respect to shares of an underlying security, other than ordinary distributions and other than adjustments for which adjustments are provided in [Rules 70110.4 or 70110.5], if the Clearing House determines that an adjustment to

the terms of [SFPs] on such underlying security is appropriate, (a) the last settlement price established immediately before such event shall be reduced by the value per share of the distributed property, in which event the unit of trading shall not be adjusted, or alternatively, (b) the unit of trading in effect immediately before such event shall be adjusted so as to include the amount of property distributed with respect to the number of shares of the underlying security represented by the unit of trading in effect prior to such adjustment, in which event the settlement price shall not be adjusted.” Under Rule 70110.6, “[t]he Clearing House shall, with respect to adjustments under [Rule 70110], have the authority to determine the value of distributed property.”

Rule 70110.7 provides that “[i]n the case of any event for which adjustment is not provided in any of the foregoing paragraphs of [Rule 70110], the Clearing House may make such adjustments, if any, with respect to the Security Futures Products affected by such event as the Clearing House determines.”

Rule 70110.8 provides that adjustments shall “become effective in respect of outstanding [SFPs] on the ‘ex-date’ established by the primary market for the underlying security.”

Rule 70110.9 provides that “[i]t shall be the general rule that (a) all adjustments of the settlement price of an outstanding stock future shall be rounded to the nearest adjustment increment, (b) when an adjustment causes a settlement price to be equidistant between two adjustment increments, the settlement price shall be rounded up to the next highest adjustment increment, (c) all adjustments of the unit of trading shall be rounded down to eliminate any fraction, and (d) if the unit of trading is rounded down to eliminate a fraction, the adjusted settlement price shall be further adjusted, to the nearest adjustment increment, to reflect any diminution in the value of the stock future resulting from the elimination of the fraction.”

Rule 70110.10 provides that, “[n]otwithstanding the general rules set forth in [Rules 70110.3 through 70110.9] or which may be set forth as interpretations to [Rule 70110], the Clearing House shall have the power to make exceptions in those cases or groups of cases in which, in applying the standards set forth in [Rule 70110.1], the Clearing House shall determine such exceptions to be appropriate.” This provision clarifies, however, that “the general rules [in Rules 70110.3 through 70110.9] shall be applied unless the

Clearing House affirmatively determines to make an exception in a particular case or group of cases.”

Rule 70110 provides an interpretation of the rule (“Interpretation to Rule 70110”). The interpretation specifies that “[c]ash dividends or distributions by the issuer of the underlying security that the Clearing House believes to have been declared pursuant to a policy or practice of paying such dividends or distributions on a quarterly or other regular basis, will, as a general rule, be deemed to be ‘ordinary distributions’ within the meaning of [Rule 70110.3].” The interpretation also provides that “[t]he Clearing House will determine on a case-by-case basis whether other dividends or distributions are ‘ordinary distributions’ or whether they are dividends or distributions for which an adjustment should be made.”

The Interpretation to Rule 70110 further provides that “[s]tock dividends or distributions by the issuer of the underlying security that the Clearing House believes to have been declared pursuant to a policy or practice of paying such dividends or distributions on a quarterly basis will, as a general rule, be deemed to be ‘ordinary distributions’ within the meaning of [Rule 70110.3].” The interpretation also provides that “[t]he Clearing House will ordinarily adjust for other stock dividends and distributions.” The interpretation clarifies that “[w]here the Clearing House determines to adjust for a cash or stock dividend or distribution, the adjustment shall be made in accordance with the applicable provisions of [Rule 70110].”

The Interpretation to Rule 70110 also provides that “[a]djustments will ordinarily be made for rights distributions, except as provided below [in this interpretation] in the case of certain ‘poison pill’ rights.” The interpretation further provides that “[w]hen an adjustment is made for a rights distribution, the unit of trading in effect immediately prior to the distribution will ordinarily be adjusted to include the number of rights distributed with respect to the number of shares or other units of the underlying security comprising the unit of trading.” The interpretation clarifies that if “the Clearing House determines that the rights are due to expire before the time they could be exercised upon delivery under the futures contract, then delivery of the rights will not be required.” In that scenario, the Clearing House will instead “ordinarily adjust the last settlement price established before the rights expire to reflect the value, if any, of the rights as determined by the Clearing House in its sole

discretion.” The interpretation provides that “[a]djustments will not ordinarily be made to reflect the issuance of so-called ‘poison pill’ rights that are not immediately exercisable, trade as a unit or automatically with the underlying security, and may be redeemed by the issuer.” The interpretation clarifies that “[i]n the event such rights become exercisable, being able to trade separately from the underlying security, or are redeemed, the Clearing House will determine whether an adjustment is appropriate.”

The Interpretation to Rule 70110 further provides that “[a]djustments will not be made to reflect a tender offer or exchange offer to the holders of the underlying security, whether such offer is made by the issuer of the underlying security or by a third person or whether the offer is for cash, securities or other property.” The interpretation clarifies that “[t]his policy will apply without regard to whether the price of the underlying security may be favorably or adversely affected by the offer or whether the offer may be deemed to be ‘coercive.’” The interpretation also provides that “[o]utstanding [SFPs] ordinarily will be adjusted to reflect a merger, consolidation or similar event that becomes effective following the completion of a tender offer or exchange offer.”

The Interpretation to Rule 70110 further provides that “[a]djustments will not be made to reflect changes in the capital structure of an issuer where all of the underlying securities outstanding in the hands of the public (other than dissenters’ shares) are not changed into another security, cash or other property.” The interpretation provides an example wherein “adjustments will not be made merely to reflect the issuance (except as a distribution on an underlying security) of new or additional debt, stock, or options, warrants or other securities convertible into or exercisable for the underlying security, the refinancing of the issuer’s outstanding debt, the repurchase by the issuer of less than all of the underlying securities outstanding, or the sale by the issuer of significant capital assets.”

The Interpretation to Rule 70110 further provides that “[w]hen an underlying security is converted into a right to receive a fixed amount of cash, such as in a merger, outstanding [SFPs] will be adjusted to replace such underlying security with such fixed amount of cash as the underlying interest, and the unit of trading shall remain unchanged.”

The Interpretation to Rule 70110 further provides that “[i]n the case of a corporate reorganization,

reincorporation or similar occurrence by the issuer of an underlying security which results in an automatic share-for-share exchange of shares in the issuer for shares in the resulting company, [SFPs] on the underlying security will ordinarily be adjusted by replacing such underlying security with a like number of units of the shares of the resulting company.” The interpretation clarifies that “[b]ecause the securities are generally exchanged only on the books of the issuer and the resulting company, and are not generally exchanged physically, deliverable shares will ordinarily include certificates that are denominated on their face as shares in the original issuer, but which, as a result of the corporate transaction, represent shares in the resulting company.”

The Interpretation to Rule 70110 further provides that “[w]hen an underlying security is converted in whole or in part into a debt security and/or a preferred stock, as in a merger, and interest or dividends on such debt security or preferred stock are payable in the form of additional units thereof, outstanding [SFPs] that have been adjusted by replacing the original underlying security with the security into which the original underlying security has been converted shall be further adjusted, effective as of the ex-date for each payment of interest or dividends thereon, by increasing the unit of trading by the number of units of the new underlying security distributed as interest or dividends thereon.”

The Interpretation to Rule 70110 further provides that, “[n]otwithstanding this Interpretation of Rule 70110, distributions of short-term and long-term capital gains in respect of stock fund shares by the issuer thereof shall not, as a general rule, be deemed to be ‘ordinary dividends or distributions’ within the meaning of [Rule 70110.3], and adjustments of the terms of [SFPs] on such stock fund shares for such distributions shall be made in accordance with applicable provisions of Rule 70110, unless the Clearing House determines, on a case-by-case basis, not to adjust for such a distribution.”

Finally, the Interpretation to Rule 70110 provides that “[i]n the event that a new series of Security Futures Products is introduced with a settlement price expressed in decimals and there is an outstanding series of [SFPs] on the same underlying security with a settlement price expressed as a fraction that could be expressed in whole cents, the Clearing House may restate the settlement price of the outstanding series as its equivalent decimal price.”

The interpretation specifies that “[i]f the settlement price for the outstanding series is a fraction that cannot be expressed in whole cents, the settlement price may not be restated as a decimal.”

Unavailability or Inaccuracy of Final Settlement Price—Rule 70120.1

provides that if the Clearing House determines “that the primary market(s) for the underlying security in respect of a maturing stock future did not open or remain open for trading at or before the time when the final settlement price for such futures would ordinarily be determined, or that the price or other value used to determine the final settlement price is unreported or otherwise unavailable, then, in addition to any other actions that the Clearing House may be entitled to take under the Rules, the Clearing House shall be empowered to do any or all of the following with respect to maturing futures affected by such event (‘affected futures’)[.]” First, “[t]he Clearing House may suspend the time for making the final variation payment with respect to affected futures and, in the case of physically-settled Security Futures Products, may postpone the delivery date.” “At such time as the Clearing House determines that the required price or other value is available or the Clearing House has fixed the final settlement price pursuant to [either of the two subparagraphs of Rule 70120.1], the Clearing House shall fix a new date for making the final variation payment and may fix a new delivery date for physically-settled [SFPs].” Second, “[t]he Clearing House may fix the final settlement price for affected futures, based on its judgment as to what is appropriate for the protection of investors and the public interest, taking into account such factors as fairness to buyers and sellers of affected futures, the maintenance of a fair and orderly market in such futures, and consistency of interpretation and practice.”

“Without limiting the generality of the foregoing, the Clearing House may, if it deems such action appropriate for the protection of investors and the public interest, fix the final settlement price on the basis of the reported price of the underlying security or reported level of the underlying index at the close of regular trading hours (as determined by the Clearing House) on the last preceding trading day for which a closing stock price or index level was reported by the reporting authority.”

Rule 70120.2 provides that “[t]he Clearing House may fix the final settlement price for affected futures using the opening prices of the relevant security or securities when the primary market(s) reopen.” In such a scenario,

“the date for making the final variation payment for the affected futures shall be postponed until the business day next following the day on which the final settlement price is fixed; and, in the case of physically-settled Security Futures Products, the delivery date shall also be postponed accordingly.”

Rule 70120.3 provides that “[e]very determination of the Clearing House pursuant to this Rule shall be within the discretion of the Clearing House and shall be conclusive and binding on all investors and not subject to review.” The rule further provides that, “[u]nless the Clearing House directs otherwise, the price of an underlying security and the current index value of an underlying index as initially reported by the relevant reporting authority shall be conclusively presumed to be accurate and shall be deemed final for the purpose of determining settlement prices and the final settlement price, even if such price or value is subsequently revised or determined to have been inaccurate.”

Rule 70120 provides an interpretation of the rule (“Interpretation to Rule 70120”). This interpretation provides that “[t]he Clearing House will not adjust officially reported stock prices for final settlement purposes, even if those prices or values are subsequently found to have been erroneous, except in extraordinary circumstances.” The interpretation provides an example of where such circumstances might be found to exist, that is where “the closing price or current index value as initially reported is clearly erroneous and inconsistent with prices or values reported earlier in the same trading day, and a corrected closing price or current index value is promptly announced by the reporting authority.” The interpretation clarifies that “[i]n no event will a completed settlement be adjusted due to errors in officially reported stock prices or current index values.”

CME also proposes adopting Rulebook Chapter 711 to set out Rules that more specifically apply to listing cash-settled futures on individual equity securities. The Rule Amendments are modeled after CME’s existing Rulebook Chapter 710, governing the trading of “Physically Delivered Single Security Futures.”

Rulebook Chapter 711 Cash-Settled Single Stock Security Futures

This section describes the generalized Rule framework proposed to govern the listing of such cash-settled futures contracts in Rulebook Chapter 711:

Scope of Chapter 711—Rule 71100 specifies that the rulebook chapter shall

be “limited in application to contract specifications applied to a security futures contract that provides for cash settlement at final settlement in reference to an individual equity security (each, a ‘Cash-Settled Single Stock Security Future’).” This rule further provides that “[a] contract is eligible to be listed as a Cash-Settled Single Stock Security Futures contract if it meets the initial listing standards set out in Exchange Rule 70001 and the maintenance listing standards set out in Exchange Rule 70002.” These listing standards are summarized below. Rule 71100.A provides that a “Primary Listing Exchange” shall be as defined in the “plan to Address Extraordinary Market Volatility Submitted to the Securities and Exchange Commission Pursuant to Rule 608 of Regulation NMS Under the Securities Exchange Act of 1934.” Rule 71100.B provides that a “Regulatory Halt” shall be as defined in the “Plan to Address Extraordinary Market Volatility Submitted to the Securities and Exchange Commission Pursuant to Rule 608 of Regulation NMS Under the Securities Exchange Act of 1934,” and as implemented under New York Stock Exchange Rule 7.12 for Trading Halts Due to Extraordinary Volatility or under Nasdaq Stock Market Rule 4121 for Trading Halts Due to Extraordinary Volatility.

Contract Specifications—Rule 71101 provides the contract specifications for Cash-Settled Single Stock Security Futures contracts.

Contract Size—Rule 71101.A., Trading Unit, specifies that “One Cash-Settled Single Stock Security Futures contract represents 100 shares or 10 shares of the underlying security, as specified by the Exchange for a specific contract, subject to potential adjustment as provided in the Chapter 700 Rules.”

Quotation Specification—Rule 71101.B., Price Increments, provides that the “minimum price fluctuation for each Cash-Settled Single Stock Security Futures shall be equivalent to 0.01 points, or \$1.00 per tick.” This provision is consistent with provisions associated with other SFPs that have been listed for trading. Further, a penny tick matches practices in the underlying security markets.

Trading Schedule—Rule 71101.C., Trading Schedule, provides that “Cash-Settled Single Stock Security Futures contracts may be traded during such hours and for such expiration months as determined by the Exchange.” CME proposes to allow trading of Cash-Settled Single Stock Security Futures during the same hours that trading is allowed on CME’s equity index futures. Specifically, Cash-Settled Single Stock

Security Futures will trade from 5:00 p.m. CT previous day to 4:00 p.m. CT, Monday through Friday. The products will not be traded during holidays and other periods when the underlying markets for the securities are not open. With respect to the trading schedule, the rule provides that CME will limit expiration months listed for trading to the nearest three quarters out at the time of listing.

Termination of Trading—Rule 71101.D.1, Cash-Settled Single Stock Security Futures, provides that “[a]ll trading in a particular Cash-Settled Single Stock Security Future contract shall terminate at 3:00 p.m. Central Prevailing Time (‘CPT’) on the third Friday of the contract month, unless otherwise noted.”

Further, Rule 71101.D.2., **Unscheduled Market Holiday**, provides that “[n]otwithstanding the aforementioned, if the primary listing exchange is closed in observance of an unscheduled market holiday on a day previously scheduled as a Business Day on which trading in the Cash-Settled Single Stock Security Future would terminate, then trading in Cash-Settled Single Stock Security Futures that had been scheduled to terminate on such day shall terminate on the Business Day immediately preceding such unscheduled market holiday.”

Position Limits—Rule 71101.E., **Position Limits**, provides that CME will set out the position limits and/or accountability levels in the Position Limit, Position Accountability and Reportable Level Table in the Interpretations & Special Notices Section of Chapter 5. It further provides that position limits are set at 200,000 contracts in the context of 100 share contracts, or the equivalent thereto for contracts listed in another size.

The Rule also sets out standards CME will apply for setting position limit levels, which the foregoing levels meet, should CME decide to set position limits at a different level for a particular contract. Specifically, it provides that that CME will apply position limits in accordance with CFTC Regulation § 41.25(b)(3), elaborating that “Cash-Settled Single Stock Security Futures limits will be set no greater than the equivalent of 12.5 percent of the estimated deliverable supply of the underlying security for securities exceeding 20 million shares in estimated deliverable supply and no greater than 25,000 contracts for securities at or below 20 million shares in estimated deliverable supply. Limits will be effective during the last three trading days of an expiring contract month.”

The Rule also provides that “[i]f a position exceeds position limits as a result of a security futures product adjustment, in accordance with Rule 701, such position shall not constitute a position limit violation.” The Rule further requires that “[a] person seeking an exemption from position limits for bona fide commercial purposes shall apply to the Market Regulation Department on forms provided by the Exchange, and the Market Regulation Department may grant qualified exemptions in its sole discretion.”

As noted, position limit levels are determined by reference to CFTC Regulation § 41.25(b)(3), which prescribes standards for imposing position limits based on the estimated deliverable supply of the underlying security or position accountability in lieu of position limits based on total trading volume in the security over the prior six (6) months and the deliverable supply of shares outstanding. As applicable, CME will also follow the guidance in Appendix A to Subpart C of Part 41—Guidance on and Acceptable Practices for Position Limits and Position Accountability for Security Futures Products.

CME’s Rulebook also contains Rule 559, **Position Limits and Exemptions**, and Rule 560, **Position Accountability**. Rule 559 generally governs how position limits adopted by the Exchange for any products listed by the Exchange apply to market participants with respect to aggregation of positions they hold or control and exemptions from position limits where they apply. Rule 560 generally governs position accountability requirements for market participants who own or control positions in excess of reportable levels or who hold substantial positions in contracts traded on the Exchange or cleared by the Clearing House. As noted, the Exchange may impose position accountability in accordance with the requirements of CFTC Regulation § 41.25(b)(3)(i)(B).¹⁰ The requisites for imposing position accountability under this Regulation include that the six-month total trading volume in the underlying security exceeds 2.5 billion shares and that the underlying security have more than 40 million shares of estimated deliverable supply.¹¹ Consequently, only the most liquid securities could potentially satisfy these requirements.

Price Limits and Trading Halts—Rule 71101.F., **Price Limits and Trading Halts**, provides that “[t]here is no daily price limit for Cash-Settled Single Stock

Security Futures contracts.” However, “[t]rading of Cash-Settled Single Stock Security Futures shall be halted at all times that a Regulatory Halt, as defined per SEC Rule 6h–1(a)(3) and CFTC Regulation § 41.1(I), has been instituted for the underlying security.” The rule also provides that “[d]uring times when the primary market is not open for trading, the contract shall also be subject to dynamic price fluctuation limits as set forth in Rule 589.D. and in the Special Price Fluctuation Limits and Daily Price Limits Table in the Interpretations & Special Notices Section of Chapter 5.” Rule 71101.F. is adopted consistent with the prescriptions of CFTC Regulation § 41.25(b)(2)(i) and SEC Rule 6h–1(a)(3).¹² Rule 71101.F. also provides that “[t]here shall be no trading of Cash-Settled Security Futures when the trading in the lead month of S&P 500 Stock Index Futures is locked in limits at 7%, restricted as set forth per Rule 35802.I.1 and Rule 35802.I.5.”

Settlement Price—Rule 71102 provides guidelines for determining Daily and Final Settlement Prices for Cash-Settled Single Stock Security Futures contracts.

Daily Settlement Price—Rule 71102.A., **Daily Settlement Price**, provides that, “[e]xcept for the last day of trading on an expiring contract, daily settlement prices shall be determined per Rule 813.” For the lead month contract, the daily settlement price shall be determined using the Volume-Weighted Average Price (VWAP) of the settlement period. If there is no trading in the contract during the settlement period, the Exchange shall use the Bid/Ask Midpoint at the settlement or during the settlement period. As a fallback provision, the Exchange may determine the settlement price based on other market prices, including closing prices for the relevant underlying security on its primary listing exchange. For all months other than the lead contract month, relevant spread relationships between the lead contract month will be used to derive the settlement.

Final Settlement Price—Rule 71102.B., **Final Settlement Price**, provides that, “[f]or the last day of trading of an expiring contract, the Final Settlement Price is the official closing price for the underlying security published by the primary listing exchange for the security for that day, unless the Final Settlement Price is fixed in accordance with Rule 70120.” The rule further provides that, “[i]n the case that the market for the underlying

¹⁰ 17 CFR 41.25(b)(3)(i)(B).

¹¹ Id.

¹² 17 CFR 240.6h–1(a)(3).

security closes without any trading activity that would permit the calculation of the Final Settlement Price, then such Final Settlement Price will be equal to the opening price for the underlying security on the primary listing exchange on the immediately following Business Day.” Finally, the rule provides that, “[i]n the event that the trading of a stock is halted and remains halted at the close of business at its primary listing exchange on the day of termination of trading of the corresponding Cash-Settled Single Stock Security Futures contract, or the official closing price of the stock is otherwise not publishable or published by its primary listing exchange on the day of termination of trading of the corresponding Cash-Settled Single Stock Security Futures contract, and therefore, CME cannot determine the contract’s Settlement Price, then CME may in its discretion defer or postpone determination of the Final Settlement Price to the next day on which the underlying stock is trading and set the Final Settlement Price taking into account the opening prices or prices upon the resumption of trading for the underlying stock on the primary listing exchange.”¹³

Final Settlement—Rule 71103 states “[c]learing members holding open positions in an expiring Cash-Settled Single Stock Security Futures contract at its termination of trading (Rule 71101.D.) shall make payment to or receive payment from the Clearing House in accordance with normal variation margin procedures based on such expiring contract’s Final Settlement Price (Rule 71102.B.).”

Approved Securities—Rule 71104 refers to a hyperlink provided at the end of the chapter to a table that list securities approved as the subject of Cash-Settled Single Stock Security Futures contracts.

Trading Prohibition—Rule 71105 states that “[a]ny person who is a director or officer, subject to Section 16 of the Securities Exchange Act of 1934 as amended from time to time, of a corporation that is the issuer of a security underlying a Cash-Settled Single Stock Security Futures contract”

and “[a]ny person who is in possession of material non-public information regarding a corporation that is the issuer of a security underlying a Cash-Settled Single Stock Security Futures contract” are prohibited from trading in Cash-Settled Single Stock Security Futures contracts.

Basis Trade at Index Close (“BTIC”) Transactions—Pursuant to Rule 524.B., CME may permit a transaction type referred to as a Basis Trade at Index Close (“BTIC”), for designated futures contracts it lists for trading. A BTIC transaction is a futures transaction that is priced with reference to the closing level of the futures contract’s underlying value.¹⁴ Rule 71106 provides for BTIC transactions. Rule 71106.A., regarding BTIC Block Trade Requirements, states that “BTIC block trades must be executed in accordance with the requirements of Rule 524.B.,” and that “[f]or a BTIC or BTIC block trade executed on a given Trading Day on or before the scheduled close of the Primary Listing Exchange, the corresponding futures price shall be made by reference to the stock closing value for the current Trading Day.” The Rule further provides that “[f]or a BTIC or BTIC block trade that is executed on a given Trading Day after the scheduled close of the Primary Listing Exchange, the corresponding futures price shall be made by reference to the stock closing value for the next Trading Day.” Rule 71106.B provides that “[t]he price assignment procedures for BTIC transactions shall follow Rule 524.B.3.” Rule 71106.C provides that “[t]he valid basis or price increment applied to the stock closing value to establish the BTIC futures price must be stated in full tick increments of \$0.01 per share.” Rule 71106.D provides that “[i]n the event of a market disruption in the Primary Listing Exchange, all pending and executed BTIC transactions in the corresponding futures contract shall be cancelled by the Exchange.” The Rule further provides that “[s]uch disruption shall be declared by the Exchange in its sole discretion, and may include, without limitation, an unscheduled early close of the Primary Listing Exchange, if the trading in the stock has been halted prior to the close of trading at the Primary Listing Exchanges and has not resumed trading prior to the close of trading and if the closing price cannot be otherwise established or a NYSE Rule 7.12 trading halt declared in

response to a Level 3 (20%) decline in the S&P 500 Index that necessitates an early close of the Primary Listing Exchange.” Pursuant to Rule 71106.E, BTIC transactions will not be permitted on the last day of trading on an expiring BTIC-eligible contract.

Compliance with Listing Standards—As noted, Rule 70001 provides that a contract must meet the initial listing standards set out in Exchange Rule 70001 to be listed as a Cash-Settled Single Stock Security Futures contract (and must thereafter meet the maintenance listing standards in Exchange Rule 70002 for continued listing). More specifically, to attain initial eligibility for listing, the security underlying a contract must meet certain requirements with respect to activity and issue size as discussed below:

- Per Rule 70001.4, “[t]here must be at least seven million shares or receipts evidencing the underlying security outstanding that are owned by persons other than those required to report their security holdings pursuant to Section 16(a) of the Exchange Act.”
- Per new Rule 70001.5, the underlying security’s “estimated deliverable supply, as reasonably determined by the Exchange consistent with Appendix A to Part 41 of the CFTC Regulations, must exceed 20 million shares.”
- Per new Rule 70001.6, the underlying security “must have a minimum market capitalization of at least \$100 billion.”
- Per new Rule 70001.7, the underlying security “must have had a minimum average daily value of transactions of at least \$450 million over the prior six months, except where the underlying security has been listed for trading for less than six months, in which case the underlying security must have had a minimum average daily value of transactions of at least \$1 billion over the prior month.”
- Per Rule 70001.10 (as revised in its numbering to accommodate new Rules 70001.5, 70001.6, and 70001.7), “the market price per share of the underlying security has been at least \$3.00 for the previous five consecutive business days preceding the date on which the Exchange commences to list and trade the Security Futures Product on said underlying security.”

As noted, Rule 70002 provides that, to maintain eligibility for listing a security must comply with certain requirements with respect to activity and issue size as discussed below:

- Per Rule 70002.1.b, “[t]here must be at least 6,300,000 shares or receipts evidencing the underlying security outstanding that are owned by persons

¹³ CME has separately submitted a request to the Commission for exemption from the requirement of SEC Rule 240.6h–1(b)(1) that the final settlement price for a cash-settled security futures contract should reflect the opening price for the underlying security on the last trading day, to enable CME to use the official closing price for the security instead, as that approach better insulates the contracts from being susceptible to manipulation and is preferable for other reasons. CME has also submitted a parallel request to the CFTC for exemption from its counterpart requirement in CFTC Regulation § 41.25(c)(1).

¹⁴ The Rule uses the term “underlying cash index” to refer to the underlying value. Another type of BTIC transaction permitted under Rule 524.B., not relevant here, is when the futures transaction is priced with reference to the closing level of a related index.

other than those who are required to report their security holdings pursuant to Section 16(a) of the Exchange Act.”

- Per Rule 70002.1.c, “[t]here must be at least 1,600 securityholders.”

- Per new Rule 70002.1.d, the underlying security “must have had a minimum average daily value of transactions of at least \$200 million for the prior calendar quarter, except where the underlying security has been listed for trading for less than a quarter, in which case the underlying security must have had a minimum average daily value of transactions of at least \$1 billion over the period traded during the calendar quarter.”

- Per new Rule 70002.1.e, the underlying security’s “estimated deliverable supply, as reasonably determined but the Exchange consistent with Appendix A to Part 41 of the CFTC Regulations, must exceed 20 million shares.”

- Per new Rule 70002.1.f, the underlying security “must have a minimum market capitalization of at least \$50 billion.”

The text of the proposed Rule Amendments is set forth in the attached Exhibit 4 and provided in blackline format—proposed new language is underlined; and proposed deletions are in [brackets].

2. Statutory Basis

Section 6(h)(3) of the Act¹⁵ contains listing standards and conditions for trading SFPs. The Exchange believes that the proposed amendments to Chapter 700 and adoption of Chapter 711 are consistent with Section 6(h)(3), and that they are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general to protect investors and the public interest, because:

- CME has established and shall monitor and enforce compliance with the rules of the contracts, including the listing standards for SFPs.

- The proposed listing standards require a liquid underlying market for any Cash-Settled Single Stock Security Futures contracts the Exchange will list for trading, and therefore the proposed contracts are not readily susceptible to manipulation. Specifically, CME’s proposed additions to Chapter 700 include requiring that the underlying security for each SFP must exceed 20 million shares in estimated deliverable supply (Rule 70001.5), have a minimum market capitalization of at least \$100 billion (Rule 70001.6), and have had a minimum ADVT of at least \$450 million

over the prior six months (with a higher ADVT requirement for securities with less than six months trading history) (Rule 70001.7). Indeed, CME initially intends to list Cash-Settled Single Stock Security Futures on the most highly liquid securities as measured by ADVT. Pursuant to Rule 70002.1, CME will not list for trading any single equity security futures with a new expiration or delivery month if the underlying security does not meet the maintenance listing standard requirements established under the rule. Under the maintenance standards, the minimum ADVT under Rule 70002.1.d is at least \$200 million for the prior calendar quarter (with a higher ADVT requirement for securities with less than one quarter trading history); Rule 70002.1.e is the same as Rule 70001.5; and the minimum market capitalization requirement of at least \$100 billion in Rule 70001.6 is reduced to \$50 billion in Rule 70002.1.f. In any case, the proposed listing standards assure a robust market for the underlying security to protect against manipulation. In this regard, CME has carefully structured the initial listing standards to assure that the contracts it will list at a minimum meet the more stringent requirements for CME to have the flexibility allowed under CFTC Regulation § 41.25(b)(3)(i)(A) to set positions limits as a percentage of the security’s estimated deliverable supply.

- Trading in the Cash-Settled Single Stock Security Futures contracts will be subject to the Rules of CME which include prohibitions on manipulation, price distortion, and disruption to the cash settlement process. As with any new product listed for trading on CME or on any other designated contract market owned by CME Group Inc. (“CME Group”), trading activity in the contracts proposed herein will be subject to monitoring and surveillance by CME Group’s Market Regulation Department.

- Pursuant to CME Rule 71101.E., CME will establish speculative position limits and/or accountability levels for any Cash-Settled Single Stock Security Futures contracts it lists pursuant to the Rule Amendments as required by and consistent with CFTC Regulation § 41.25(b)(3) and the CFTC’s guidance in Appendix A to Subpart C of Part 41—Guidance on and Acceptable Practices for Position Limits and Position Accountability for Security Futures Products.

- Transactions in the Cash-Settled Single Stock Security Futures contracts will be cleared by the Clearing House division of CME in CME’s capacity as a registered derivatives clearing

organization with the CFTC and are subject to all CFTC regulations related to clearing of futures.

- The Cash-Settled Single Stock Security Futures contracts will be listed for trading on the CME Globex electronic trading platform, which provides for competitive and open execution of transactions. Eligible participants may also execute and submit block trades in the contracts pursuant to and in accordance with CME Rule 526.

- The Globex platform and related CME systems will capture requisite trade information for the Cash-Settled Single Stock Security Futures contracts, which will ensure that the audit trail and the audit trail data for trading of the contracts will be sufficient for the Market Regulation Department to monitor for potential market abuse.

- CME Rulebook Chapters 4 and 5 contain multiple prohibitions precluding intermediaries from disadvantaging their customers. These rules apply to trading on all the Exchange’s competitive venues and will apply to transactions in the Cash-Settled Single Stock Security Futures contracts.

- Chapter 4 of the Rulebook also contains provisions that allow the Exchange to discipline, suspend or expel members or market participants that violate any applicable Rules of the Exchange. Trading in the Cash-Settled Single Stock Security Futures contracts will be subject to Chapter 4, and the Market Regulation Department has the authority to exercise its enforcement power in the event rule violations in these contracts are identified.

- Market participants may use the arbitration provisions set forth in Chapter 6 of the CME Rulebook to settle disputes with respect to trading of the Cash-Settled Single Stock Security Futures contracts.

- The Exchange will publish information regarding trading volume, open interest and price information daily on its website and through quote vendors for the Cash-Settled Single Stock Security Futures contracts.

- The Exchange will amend the CME Rulebook accordingly on the effective date, which will be publicly available on the CME Group website, to reflect the changes that will be made to the listing standards rules to cover Cash-Settled Single Stock Security Futures contracts. In addition, the Exchange will publish a Special Executive Report (“SER”) to inform the marketplace of the Rule Amendments. The SER will also be posted on the CME Group website.

Below is a summary of each requirement or condition under Section 6(h)(3) of the Act, followed by a brief

¹⁵ 15 U.S.C. 78f(h)(3).

explanation of how CME would comply with it, whether by particular provisions in CME's listing standards or otherwise.

Clause (A) of Section 6(h)(3) of the Act¹⁶ requires that any security underlying a SFP be registered pursuant to Section 12 of the Act.¹⁷ This requirement is addressed by CME Rules 70001.2, 70002.1.a., 70003.2.b, and 70004.2.a.

Clause (B) of Section 6(h)(3) of the Act¹⁸ is applicable only to physically delivered security futures products and is therefore not germane to the proposed products.

Clause (C) of Section 6(h)(3) of the Act¹⁹ provides that listing standards for SFPs must be no less restrictive than comparable listing standards for options traded on a national securities exchange or national securities association registered pursuant to Section 15A(a) of the Act.²⁰ CME believes that the listing standards proposed by CME for Cash-Settled Single Stock Security Futures are no less restrictive than comparable listing standards for exchange-traded options.

Clause (D) of Section 6(h)(3) of the Act²¹ requires that each SFP be based on common stock or such other equity securities as the Commission and CFTC jointly determine are appropriate. This requirement is addressed by CME Rules 70001.1 and 70002.1.

Clause (E) of Section 6(h)(3) of the Act²² imposes requirements with respect to linkages and coordinated clearing across clearing agencies that clear SFPs. This provision is inapplicable. The SEC and CFTC have not adopted rules implementing this part of the statute and no other clearing house currently clears the Cash-Settled Single Stock Security Futures contracts that CME proposes to list or any other SFPs.

Clause (F) of Section 6(h)(3) of the Act²³ requires that only a broker or dealer subject to suitability rules comparable to those of a national securities association registered pursuant to Section 15A(a) of the Act²⁴ effect transactions in a SFP. An intermediary acting on behalf of customers trading SFPs must be registered with the CFTC as a futures commission merchant ("FCM") and

registered or notice registered with the SEC as a broker-dealer. Any such intermediary that is fully registered as a broker-dealer will be a member of FINRA, which is a national securities exchange registered pursuant to Section 15A(a) of the Act, and will thus be subject to FINRA's suitability rules. In addition, the intermediary, as a registered FCM, must also be a member of the National Futures Association ("NFA"), which is a registered futures association under the CEA and thus will also be subject to the suitability and sales practice rules of NFA, which are comparable to those of FINRA.²⁵

Clause (G) of Section 6(h)(3) of the Act²⁶ requires that each SFP be subject to the prohibition against dual trading in Section 4j of CEA.²⁷ The Exchange does not contain a rule prohibiting dual trading as this provision is inapplicable to our circumstances. First, trading of Cash-Settled Single Stock Security Futures will occur on an electronic trading platform, Globex, and not on a trading floor and CME thus does not have floor brokers.

Second, with respect to electronic trading, the prohibition of dual trading in SFPs per Regulation § 41.27²⁸ adopted pursuant to Section 4j(a) of the CEA²⁹ applies to a contract market operating an electronic trading system only if such market provides participants with a time or place advantage or the ability to override a predetermined matching algorithm. The Exchange intends to offer SFPs on CME on its CME Globex electronic trading platform, where these features are not present.

Clause (H) of Section 6(h)(3) of the Act³⁰ provides that trading in a SFP must not be readily susceptible to manipulation of the price of such SFP, nor to causing or being used in the manipulation of the price of any underlying security, option on such security, or option on a group or index including such securities. CME believes that its listing standards are designed to ensure that CME SFPs and the underlying securities would not be readily susceptible to price manipulation. In particular, CME's revised listing standards for SFPs require that the estimated deliverable supply for each underlying security must exceed 20 million shares (Rule 70001.5), have a minimum market capitalization of at least \$100 billion

(Rule 70001.6), and have had a minimum ADVT of at least \$450 million over the prior six months (with a higher ADVT requirement for securities with less than six months trading history) (70001.7). Further, CME intends initially to list Cash-Settled Single Stock Security Futures on the most highly liquid securities as measured by ADVT. Pursuant to Rule 70002.1, CME will not list for trading any single equity security futures with a new expiration or delivery month if the underlying security does not meet the maintenance listing standard requirements established under the rule. Under the maintenance standards, the minimum ADVT under Rule 70002.1.g is at least \$200 million for the prior calendar quarter (with a higher ADVT requirement for securities with less than one quarter trading history); Rule 70002.1.e is the same as Rule 70001.5; and the minimum market capitalization requirement of at least \$100 billion in Rule 70001.6 is reduced to \$50 billion in Rule 70002.1.f. These listing standards are also the basis for establishing position limits based on a percentage of the estimated deliverable supply in accordance with CFTC Regulation § 41.25(b)(3)(i), which will assure the position limits are appropriately calibrated to protect against manipulation.³¹

In addition, as an overlay, CME Rule 432 provides that any activity "to engage in, or attempt to engage in, the manipulation of prices of Exchange futures or options contracts; to corner or squeeze, or attempt to corner or squeeze, the underlying cash market; to intentionally or recklessly use or employ, or attempt to use or employ, any manipulative device, scheme, or artifice to defraud; or to purchase or sell, or offer to purchase or sell Exchange futures or options contracts, or any underlying commodities or securities, for the purpose of upsetting the equilibrium of the market or creating a condition in which prices do not or will not reflect fair market values" is a "general offense." CME Rule 402.B. spells out the disciplinary capabilities of the Exchange which include, but are not limited to, expulsion, suspension, disgorgement, and/or a fine of not more than \$5 million per violation.

³¹ In the unique (and likely rare) circumstance where the estimated deliverable supply of an underlying security falls to or below 20 million shares, if CME continues listing the contract it will adjust the position limit in accordance with § 41.25, including § 41.25(b)(3)(i), which requires the limit to be set no higher than 25,000 contracts.

¹⁶ 15 U.S.C. 78f(h)(3)(A).

¹⁷ 15 U.S.C. 78l.

¹⁸ 15 U.S.C. 78f(h)(3)(B).

¹⁹ 15 U.S.C. 78f(h)(3)(C).

²⁰ 15 U.S.C. 78o-3(a). The listing standards are also consistent with the sample listing standards published in SLB 15, *supra* note 6.

²¹ 15 U.S.C. 78f(h)(3)(D).

²² 15 U.S.C. 78f(h)(3)(E).

²³ 15 U.S.C. 78f(h)(3)(F).

²⁴ 15 U.S.C. 78o-3(a).

²⁵ *Id.*

²⁶ 15 U.S.C. 78f(h)(3)(G).

²⁷ 7 U.S.C. 6j.

²⁸ 17 CFR 41.27.

²⁹ 7 U.S.C. 6j(a).

³⁰ 15 U.S.C. 78f(h)(3)(H).

Clause (I) of Section 6(h)(3) of the Act³² requires that procedures be in place for coordinated surveillance among the market on which a SFP is traded, any market on which any security underlying the SFP is traded, and other markets on which any related security is traded to detect manipulation and insider trading. The Exchange has procedures in place for coordinated surveillance consistent with these requirements. In particular, CME and the markets on which the underlying securities are traded are members of the Intermarket Surveillance Group (“ISG”). One purpose of the ISG is the coordination and development of programs and procedures that are designed to assist in identifying abusive practices across markets, where possible. An information sharing agreement between the ISG members allows for the routine exchange of information or documents for coordinated market surveillance purposes. Finally, CME Rule 414 permits CME to enter into agreements for the exchange of information and other forms of mutual assistance with domestic or foreign self-regulatory organizations, associations, boards of trade, and their respective regulators.

Clause (J) of Section 6(h)(3) of the Act³³ requires that the market on which the security futures product is traded has in place audit trails necessary or appropriate to facilitate the coordinated surveillance required in subparagraph (I), as discussed above. The Exchange relies on its Market Regulation Department to perform surveillance of listed contracts. The Market Regulation Department maintains an exceptionally detailed and robust suite of proprietary automated surveillance technologies that leverage a mix of both high-performance, on-premises databases and multi-region, cloud-hosted, elastic-capacity datastores to process, store, and analyze datasets that contain daily order and trade messages timestamped to the nanosecond, cleared trades and allocations, positions, as well as other referential data, which includes news feeds, street events, and corporate events (*i.e.*, the audit trail). The Exchange’s Globex system will capture audit trail data for trading of Cash-Settled Single Stock Security Futures contracts, as explained above. The Exchange’s audit trail is maintained in accordance with Core Principle 10 in CEA Section 5(d)(10)³⁴ and CFTC

Regulations § 38.550,³⁵ § 38.551³⁶ and § 38.552.³⁷ The Exchange retains this highly granular audit trail for a minimum of 5 years, as required by CFTC Regulation § 1.31(b).³⁸

The audit trail datasets are accessed by Market Regulation Department staff through a proprietary surveillance application called ARES (Advanced Regulatory Enterprise System), which provides a single, harmonized, web-based user interface that seamlessly integrates trade practice, messaging practice, market surveillance, and data science functions. The data analysis tools provided by ARES allow Market Regulation Department staff to examine order, trade, and position data, identify patterns indicative of potential abuses, and reconstruct and replay trading and order book activity to efficiently conduct surveillance and investigations. The four primary modules within ARES are as follows:

- *Globex Messaging* provides the Market Regulation Department with real-time and historical access to Globex order messaging and market data using high-performance, columnar-store, database technology. The Globex Messaging module in ARES provides performant big data capabilities for aggregation and message-by-message order book reconstruction.

- *Cleared Trades* serves as the primary trade practice application for the Market Regulation Department. The system consists of a collection of backend daily batch processes that profile and mine all cleared trade transactions from execution through final allocation across three venues to identify potential trade practice abuses.

- *Large Trader* is the primary tool used by the Market Regulation Department to conduct market surveillance. The system processes and loads firm-reported customer positions and integrates position data with contract-level open interest and market information to provide a macro-level view of participant concentration within each product. The system also integrates Ownership & Control Reporting (OCR) data and serves as the central regulatory repository for market participant identification records.

- *RAMP* is a self-service data science platform for accessing regulatory data via REST services and executing Python and R scripts in a secure sandbox via the ARES UI. RAMP provides a suite of capabilities for accessing cloud native datasets, integrating Tableau data

visualizations, scraping external data sources, and scheduling recurring processes.

To best ensure the Exchange’s audit trail is accurate, the Market Regulation Department performs examinations of certain data elements submitted to the Exchange by market participants during the course of their trading activity. As required by Core Principle 10 in CEA Section 5(d)(10)³⁹ and CFTC Regulation § 38.553,⁴⁰ these examinations include: reviews of randomly selected samples of front-end audit trail data from participants; a review of the process by which user identifications are assigned and user identification records are maintained; a review of usage patterns associated with user identifications to monitor for violations of user identification rules; and reviews of account numbers and customer type indicator codes in trade records to test for accuracy and improper use.

The Market Regulation Department also reviews for accuracy other data elements that participants are required to submit to the Exchange pursuant to Exchange Rule 536.B. (“Globex Order Entry”). This rule specifically requires each person who physically enters orders into CME Globex or any automated trading system which enters orders into Globex to accurately input for each message all fields required to be populated by the CME iLink® Message Specifications in effect at the time, including, but not limited to the: Globex operator ID; price; quantity; product; expiration month; CTI code; manual order indicator; and account number. The iLink specifications further require users to identify whether an order message was submitted manually or through automated means, and the location (geographically) of the participant at the time the order message was sent.

Audit trail and recordkeeping violations by participants are subject to the Exchange’s disciplinary rules, including Rule 512 (“Reporting Infractions”), which permits the Market Regulation Department to impose summary fines against firms and/or participants for minor recordkeeping or reporting violations. More significant violations are subject to the full sanctioning authority of the Exchange’s Business Conduct Committee, as set forth in Exchange Rule 402, which includes the authority to issue fines up to \$5 million per violation, suspensions of trading access, undertakings, or other actions deemed appropriate to

³² 15 U.S.C. 78f(h)(3)(I).

³³ 15 U.S.C. 78f(h)(3)(J).

³⁴ 7 U.S.C. 7(d)(10).

³⁵ 17 CFR 38.550.

³⁶ 17 CFR 38.551.

³⁷ 17 CFR 38.552.

³⁸ 17 CFR 1.31(b).

³⁹ 7 U.S.C. 7(d)(10).

⁴⁰ 17 CFR 38.553.

remediate reporting errors and deter further violations.

This highly granular and accurate audit trail, combined with the Market Regulation Department's surveillance tools, allows the Market Regulation Department to perform market and trade practice surveillance of the Exchange's products, and further enables the Market Regulation Department to facilitate coordinated surveillance with any market on which any security underlying the security futures product is traded.

Clause (K) of Section 6(h)(3) of the Act⁴¹ requires that a market on which a SFP is traded have in place procedures to coordinate trading halts between such market and any market on which any security underlying the SFP is traded and other markets on which any related security is traded. Proposed CME Rule 71101.F. provides, in accordance with CFTC Regulation § 41.25(b)(2)(i),⁴² that "[t]rading of Cash-Settled Single Stock Security Futures shall be halted at all times that a Regulatory Halt, as defined per SEC Rule 6h-1(a)(3) and CFTC Regulation § 41.1(I), has been instituted for the underlying security."

Clause (L) of Section 6(h)(3) of the Act⁴³ requires that the margin requirements for a SFP comply with the regulations prescribed pursuant to Section 7(c)(2)(B) of the Act.⁴⁴ CME has proposed amendments to its margin rules generally imposing a minimum margin requirement of 15% of the current market value of the security futures consistent with the requirements of CFTC Regulation § 41.45(b)(1)⁴⁵ and SEC Rule 242.403(b)(1).^{46 47} Thus, CME believes that its customer margin rules are consistent with the requirements of the Act.

For the reasons described above, CME believes that the listing standards submitted herewith satisfy the requirements set forth in Section 6(h)(3) of the Act.

CME also believes that its proposed rule changes are consistent with Section 6(b) of the Act,⁴⁸ in general, and further the objectives of Section 6(b)(5) of the Act,⁴⁹ in particular, in that they are designed to remove impediments to and perfect the mechanism for a free and open market and a national market

system, and, in general, to protect investors and the public interest.

B. CME's Statement on Burden on Competition

CME does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Currently, no other exchange lists any security futures contracts for trading. The proposed rule changes will simply allow CME to list certain security futures contracts. Nothing in the filing restricts or impedes another exchange for offering security futures products for trading subject to its compliance with applicable regulatory requirements under the Exchange Act, CEA, and respective rules of the Commission and CFTC governing security futures products.

C. CME's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change became effective on June 29, 2026, which is the date on which CME filed this rule change with the Commission and concurrently submitted the related rule filing with the CFTC. Notwithstanding the foregoing, CME intends to implement the rule change following the receipt of all required regulatory approvals from the Commission and the CFTC. For the avoidance of doubt, CME recognizes that the listing of P.M. Settled SFPs will require exemptive relief from Rule 6h-1(b) under the Act and from CFTC Regulation 41.25(c). Within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule change and require that the proposed rule change be refilled in accordance with the provisions of Section 19(b)(1) of the Act.⁵⁰

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CME-2026-002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-CME-2026-002. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://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-CME-2026-002 and should be submitted on or before July 28, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵¹

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-13712 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105838; File Nos. SR-NYSEAMER-2026-59, SR-NYSEARCA-2026-75]

Self-Regulatory Organizations; NYSE American LLC and NYSE Arca, Inc.; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Changes Concerning the Single Component Concentration Limit of the MSCI Emerging Markets Index

July 1, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

⁴¹ 15 U.S.C. 78f(h)(3)(K).

⁴² 17 CFR 41.25(b)(2).

⁴³ 15 U.S.C. 78f(h)(3)(L).

⁴⁴ 15 U.S.C. 78g(c)(2)(B).

⁴⁵ 17 CFR 41.45(b)(1).

⁴⁶ 17 CFR 242.403(b)(1).

⁴⁷ See Customer Margin Rules Relating to Security Futures, 85 FR 75112 (Nov. 24, 2020).

⁴⁸ 15 U.S.C. 78f(b).

⁴⁹ 15 U.S.C. 78f(b)(5).

⁵⁰ 15 U.S.C. 78s(b)(1).

⁵¹ 17 CFR 200.30-3(a)(73).

(“Act”)¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 1, 2026, NYSE American LLC (“NYSE American”) and NYSE Arca, Inc. (“NYSE Arca”) (collectively, the “Exchanges”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule changes as described in Items I, II, and III below, which Items have been prepared by the Exchanges. This notice and order requests comment on the proposal from interested persons and approves the amended proposal on an accelerated basis.

I. Self-Regulatory Organizations’ Statements of the Terms of Substance of the Proposed Rule Changes

The Exchanges propose to increase the single component concentration limit from 15% of the weight of the MSCI Emerging Markets Index (“MSCI EM Index”) to 20% to allow the continued listing and trading of options that overlie the MSCI EM Index (“EM Options”). The proposed rule changes are available on the Exchanges’ websites at www.nyse.com and at the principal offices of the Exchanges.

II. NYSE American’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In its filing with the Commission, NYSE American included statements concerning the purpose of, and basis for, its proposed rule change and discussed any comments they received on the proposed rule changes. The text of those statements may be examined at the places specified in Item V below. NYSE American has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.³

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Changes

1. Purpose

The Exchange proposes to amend the listing criteria for EM Options in Rule 901C. Specifically, the Exchange proposes to amend Commentary .05(a)(6) to Rule 901C to increase the single component concentration limit from 15% of the weight of the MSCI Emerging Markets Index (“MSCI EM Index”) to 20%.

Background

The MSCI EM Index, launched in 1988, is a free float-adjusted market capitalization index that is designed to measure equity market performance of emerging markets.⁴ The MSCI EM Index consists of large and midcap components, currently has 1,205 constituents and “covers approximately 85% of the free float-adjusted market capitalization in each country.”⁵

On March 10, 2026, the Exchange adopted rules to facilitate the listing of EM Options.⁶ The Exchange listed and made EM Options available for trading on March 16, 2026.⁷ As noted in the EM Options Notice, the MSCI EM Index is a broad-based index, as defined in Rule 900C(b)(1), for the purpose of determining which of the Exchange’s rules apply to options on such indices.⁸

The Exchange created specific initial and continued listing criteria for a number of options for which an MSCI Index was the underlying, including EM Options. Specifically, Commentary .05(a) to Rule 901C (Designation of Stock Index Options) provides that the Exchange may list EM Options if each of the conditions set forth therein are satisfied. Included in the listed conditions is that “[n]o single component security accounts for more than 15% of the weight of the index, and the five highest weighted component securities in the index do not, in the aggregate, account for more than 50% of the weight of the index.”⁹

As set forth in Commentary .05(b) to Rule 901C, this condition, relative to all MSCI Indexes, including the MSCI EM Index, must be satisfied only as of the first day of January and July in each year, respectively. In the event a class of index options listed on the Exchange fails to satisfy the continued listing standards, including the single

component weighting standard, the Exchange shall not open for trading any additional series of options of that class unless the continued listing of that class of index options has been approved by the Commission under Section 19(b)(2) of the Act.¹⁰

Proposal

As noted above, the Exchange proposes to amend Rule 901C, Commentary .05(a)(6) to increase the single component concentration limit from 15% of the weight of the MSCI EM Index to 20%.¹¹ The proposed increase is necessary to address the potential delisting of EM Options and restriction on currently open positions to closing only, which would deny market participants the opportunity to hedge their investments and manage risk through the use of this index option and, therefore, such results would be to the detriment of investors and the public interest.

Specifically, EM Options is a unique product that allows investors to gain exposure to the emerging markets on a cash settled basis. Often, cash settlement is the only avenue for investors to get exposure to emerging markets. Such exposure may be obtained through an Exchange Traded Fund (“ETF”) tracking similar underlying benchmarks, however access to such ETFs is often unavailable to investors who are unable to take delivery of shares into their accounts. Cash settlement offered by EM Options is needed to obtain such exposure.

The inability to open a new series of EM Options would result in current investors being unable to roll over their positions and, as a consequence, unable to maintain their exposure to emerging markets over time. In addition, all liquidity in EM Options would essentially dry up meaning holders of the position would only be able to sell out of their position at an inferior price. Such investors will be left in the unenviable position of having to either accept an inferior or poor sales price, or hold until expiration, at which point they will be unable to maintain their exposure to the benchmark and risk violating their investment mandate.

These potential concerns are currently most evident with MSCI EM Index component security Taiwan Semiconductor MFG (“TSM”), which, on March 16, 2026, the day that EM Options were first listed on the Exchange, had a closing price of \$340.23

⁴ The MSCI EM Index consists currently of the following 24 emerging market country indexes: Brazil, Chile, China, Colombia, Czech Republic, Egypt, Greece, Hungary, India, Indonesia, Korea, Malaysia, Mexico, Pakistan, Peru, Philippines, Poland, Qatar, Russia, South Africa, Taiwan, Thailand, Turkey and United Arab Emirates.

⁵ See MSCI EM Index fact sheet (dated May 29, 2026), available at <https://www.msci.com/documents/10199/10c3f32f-4565-4a92-aa1c-edf6f3a4e03f>.

⁶ See Securities Exchange Act Release No. 104957 (March 10, 2026), 91 FR 12473 (March 13, 2026) (SR–NYSEAMER–2026–15) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Facilitate the Transfer and Trading of Options That Overlie the MSCI EAFE Index and the MSCI Emerging Markets Index) (“EM Options Notice”).

⁷ See <https://www.nyse.com/trader-update/history#110000955053>.

⁸ Rule 900C(b)(1) defines a broad stock index group to mean a stock index group designed to be representative of stock market values or prices of a broad segment of the stock market.

⁹ See Rule 901C/Commentary .05(a)(6).

¹⁰ See Rule 901C/Commentary .05(b)(2).

¹¹ The Exchange notes that its proposal is consistent with the methodology applicable to the NASDAQ–100 Index Fund, which imposes a 24% single component percentage weight limit.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ For purposes of this Section II, the term “Exchange” refers to NYSE American.

and at such time, accounted for 12.55% of the weight of the index.¹² However, on May 29, 2026, TSM closed at \$418.45—an approximate 23% increase. This had a corresponding impact on TSM's overall market capitalization and its percentage component weighting within the MSCI EM Index. Specifically, at the end of Q1 2026, TSM had market capitalization of approximately \$1.42T, which, as of May 29, 2026, grew to \$1.85T (a 30% increase). There was a similar increase on TSM's percentage weighting within MSCI EM Index, increasing from 12.55% to 14.46%, resulting in it having the highest percentage weighting within the index.¹³

The level of TSM's weighting within the MSCI EM Index is the direct result of independent natural market forces, *i.e.*, its significant share price increase, and not a design flaw within the MSCI EM Index. The recent surge in prices of shares of stocks in the semi-conductor sector may cause TSM to exceed the Rule 901C single component percentage weighting limit, when measured at its next scheduled semi-annual review. The purpose of this filing is to forestall the Exchange having to prevent the opening of additional series of EM Options for trading and thereby deprive market participants of the opportunity to manage risk through the use of EM Options.

Because of the potential harm to investors in delisting EM Options and restricting currently open positions to closing only, along with the fact that the potential for exceeding the single component percentage weighting limit would be an independent market outcome and not a design flaw with the MSCI EM Index, the Exchange believes that the proposal would allow market participants to continue to manage their risk through the use of EM Options. In addition, given the size and liquidity of TSM, the weight percentage of other components within the same sector of TSM (*i.e.*, information technology) and the design of the MSCI EM Index to transparently measure equity performance of emerging markets any concerns related to fraud or manipulation are mitigated.

The delisting of EM Options and restricting currently open positions to closing only would put investors at risk and run contrary to the public interest. As highlighted in the EM Options

Notice, the Exchange believed that the listing and trading of EM Options would increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk. The Exchange further noted that the listing and trading of EM Options would remove impediments to and perfect the mechanism of a free and open market as they would continue to provide greater opportunities for market participants to manage risk through the use of an index options product, maintain their exposure to the benchmark to the benefit of investors and the public interest.

Adopting the Exchange's proposal would not create a potential for fraud or market manipulation. As noted in the EM Options Notice, the MSCI EM Index is not easily susceptible to manipulation. It is a broad-based index with high market capitalization. As noted, the MSCI EM Index is currently comprised of 1,205 component stocks and, with the exception of TSM, none exceeding 8% of the index, with only two other component stocks exceeding 5%.

Additionally, the iShares MSCI Emerging Markets ETF, which tracks the MSCI EM Index, is an actively traded product, as are options on that ETF. Because the MSCI EM Index has a large number of component securities, is representative of many countries and trades a large volume with respect to the ETF and options on that ETF, the Exchange believes that the continued listing of EM Options is appropriate.

Finally, as noted in the EM Options Notice, the same surveillance procedures applicable to all other options currently listed and traded on the apply to EM Options and it has the necessary systems capacity to support the option series.

As further noted, the Exchange's existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior and other improper trading. In addition, the Exchange has a Regulatory Services Agreement ("RSA") with the Financial Industry Regulatory Authority ("FINRA"). Pursuant to a multi-party 17d-2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillances.¹⁴ The

Exchange is also a member of the Intermarket Surveillance Group ("ISG") under the ISG Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets.

Given the enormous liquidity in the underlying components of the MSCI EM Index and large number of market participants trading those components, the Exchange believes that any attempt to manipulate the price of the underlying security or options overlying such security in order to affect the price of the indices would be cost prohibitive and unlikely to succeed. Moreover, the Exchange believes that its existing surveillances and procedures adequately address potential concerns regarding possible manipulation of the settlement value at or near the close of the market.

As it relates to TSM, the MSCI EM Index is a free float-adjusted market capitalization index that is designed to measure equity market performance of emerging markets. The weight of any single component within it, such as TSM, is the result of transparent public market activity and not discretionary choices of the index. TSM's concentration is the result of independent market activity and not a design flaw with the MSCI EM Index. The Exchange also notes that the MSCI EM Index is designed to include companies from foreign markets, which themselves are of varying size, often much smaller than the U.S. markets overall. As a result, the potential concentration risk of a single component associated with such an index can be, and in this case is, higher than for other indexes. The proposal to raise the percentage limit for a single component in this Index in particular is therefore to the benefit of investors and reasonable, as it will avoid unnecessary investor harm resulting from such market conditions, while continuing to protect against any long-term overweighting.

Moreover, given its average daily notional value and national average daily volume, TSM is resistant to manipulation. The Exchange believes that average daily notional value and national average daily volume are,

78q(d)(1) and 17 CFR 240.17d-2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO. Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

¹² The Exchange notes that the MSCI EM Index uses TSM's underlying common stock in its calculation methodology.

¹³ The increase in TSM's share price and market capitalization has continued. On June 24, 2026, TSM closed at \$440.83 and had a market capitalization of \$2.286T.

¹⁴ Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C.

collectively, an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation. Average daily notional value considers both the trading activity and the price of a security. As a general matter, the more expensive an underlying security's price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded.

As of December 31, 2025, TSM had an average daily notional value of \$3,246,781,038 and national average daily volume of 12,008,931 shares. It is, therefore, substantially liquid. In addition, there is significant depth and breadth of market participants providing liquidity. As such, any concern over the potential for manipulation of the MSCI EM Index domination by TSM is significantly mitigated. The sheer size and liquidity of TSM makes manipulative scenarios implausible and cost prohibitive. The concern over potential manipulation is further mitigated by the fact that the sector in which TSM belongs (Information Technology) makes up 43% of the total sector weights of the MSCI EM Index, which should generally move in the same direction. Thus, the organic growth of TSM, which is part of a larger sector within the MSCI EM Index should not materially increase the index's vulnerability to single stock manipulation.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the "Act"),¹⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁶ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that the proposed change is designed to remove impediments to and to perfect the mechanism for a free and open market and a national market system by facilitating the continued listing and trading of EM options. The continued listing of EM options would continue to

increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk, to the benefit of investors and the public interest. Moreover, the continued listing of EM options would continue to create greater trading and hedging opportunities and flexibility while providing investors with an additional tool to manage their risk, particularly where certain investors have no alternative. The proposed rule change would also continue to result in enhanced efficiency in initiating and closing out positions and heightened contra-party creditworthiness given OCC's role as issuer and guarantor of the proposed index option products.

Further, the Exchange believes that the MSCI EM Index is not easily susceptible to manipulation. The index is broad-based and its component securities have large market capitalizations. As noted, the MSCI EM Index is currently comprised of 1,205 component stocks and, with the exception of TSM, none exceeding 8% of the index, with only two other component stocks exceeding 5%. Additionally, the iShares MSCI Emerging Markets ETF, which tracks the MSCI EM Index, is an actively traded product, as are options on it. Because the index has a large number of component securities, is representative of many countries and trades a large volume with respect to the ETF and options on that ETF, the Exchange believes that the proposed continued listing and trading of EM Options is appropriate.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in EM Options. The Exchange also represents that it has the necessary systems capacity to support continued listing of the options series. Additionally, as stated in the filing, the Exchange has rules in place to protect public customer trading.

B. Self-Regulatory Organizations' 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 believes that the proposed rule change would continue to facilitate trading of EM Options while also competing with domestic products such as EM Futures and European-traded derivatives on the MSCI EM Index, which would enhance competition among market participants, to the

benefit of investors and the marketplace. The Exchange thus believes that the proposed change does not impose a burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition. The Exchange also believes that the proposed change would not place any undue burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as EM Options would continue to be equally available to all market participants who wish to trade such options and use such options to manage risk.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Changes Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. NYSE Arca's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In its filing with the Commission, NYSE Arca included statements concerning the purpose of, and basis for, its proposed rule change and discussed any comments it received on the proposed rule changes. The text of those statements may be examined at the places specified in Item V below. NYSE Arca has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.¹⁷

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Changes

1. Purpose

The Exchange proposes to amend the listing criteria for EM Options 5.12–O. Specifically, the Exchange proposes to amend Commentary .01(a)(6) of Rule 5.12–O to increase the single component concentration limit from 15% of the weight of the MSCI Emerging Markets Index ("MSCI EM Index") to 20%.

Background

The MSCI EM Index, launched in 1988, is a free float-adjusted market capitalization index that is designed to measure equity market performance of emerging markets.¹⁸ The MSCI EM

¹⁷ For purposes of this Section III, the term "Exchange" refers to NYSE Arca.

¹⁸ The MSCI EM Index consists currently of the following 24 emerging market country indexes: Brazil, Chile, China, Colombia, Czech Republic, Egypt, Greece, Hungary, India, Indonesia, Korea, Malaysia, Mexico, Pakistan, Peru, Philippines,

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(5).

Index consists of large and midcap components, currently has 1,205 constituents and “covers approximately 85% of the free float-adjusted market capitalization in each country.”¹⁹

On February 18, 2026, the Exchange adopted rules to facilitate the listing of EM Options.²⁰ The Exchange listed and made EM Options available for trading on February 25, 2026.²¹ As noted in the EM Options Notice, the MSCI EM Index is a broad-based index, as defined in Rule 5.10–O(b)(23), for the purpose of determining which of the Exchange’s rules apply to options on such indices.²²

The Exchange created specific initial and continued listing criteria for a number of options for which an MSCI Index was the underlying, including EM Options. Specifically, Commentary.01(a) to Rule 5.12–O (Designation of the Index Broad-Based Index Options) provides that the Exchange may list EM Options if each of the conditions set forth therein are satisfied. Included in the listed conditions is that “[n]o single component security accounts for more than 15% of the weight of the index, and the five highest weighted component securities in the index do not, in the aggregate, account for more than 50% of the weight of the index.”²³

As set forth in Commentary .01(b) to Rule 5.12–O, this condition, relative to all MSCI Indexes, including the MSCI EM Index, must be satisfied only as of the first day of January and July in each year, respectively. In the event a class of index options listed on the Exchange fails to satisfy the continued listing standards, including the single component weighting standard, the Exchange shall not open for trading any additional series of options of that class unless the continued listing of that class of index options has been approved by the Commission under Section 19(b)(2) of the Act.²⁴

Poland, Qatar, Russia, South Africa, Taiwan, Thailand, Turkey and United Arab Emirates.

¹⁹ See MSCI EM Index fact sheet (dated May 29, 2026), available at <https://www.msci.com/documents/10199/10c3f32f-4565-4a92-aa1c-edf6f3a4e03f>.

²⁰ See Securities Exchange Act Release No. 104862 (February 18, 2026), 91 FR 8538 (February 23, 2026) (SR–NYSEARCA–2026–13) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change of Amendments To Facilitate the Transfer and Trading of Options That Overlie the MSCI EAFE Index and the MSCI Emerging Markets Index) (“EM Options Notice”).

²¹ See <https://www.nyse.com/trader-update/history#110000954571>.

²² Rule 5.10–O(b)(23) defines broad-based index to mean an index designed to be representative of a stock market as a whole or of a range of companies in unrelated industries.

²³ See Rule 5.12–O/Commentary .01(a)(6).

²⁴ See Rule 5.12–O/Commentary .01(b).

Proposal

As noted above, the Exchange proposes to amend Rule 5.12–O Commentary .01(a)(6) to increase the single component concentration limit from 15% of the weight of the MSCI EM Index to 20%.²⁵ The proposed increase is necessary to address the potential delisting of EM Options and restriction on currently open positions to closing only, which would deny market participants the opportunity to hedge their investments and manage risk through the use of this index option and, therefore, such results would be to the detriment of investors and the public interest.

Specifically, EM Options is a unique product that allows investors to gain exposure to the emerging markets on a cash settled basis. Often, cash settlement is the only avenue for investors to get exposure to emerging markets. Such exposure may be obtained through an Exchange Traded Fund (“ETF”) tracking similar underlying benchmarks, however access to such ETFs is often unavailable to investors who are unable to take delivery of shares into their accounts. Cash settlement offered by EM Options is needed to obtain such exposure.

The inability to open a new series of EM Options would result in current investors being unable to roll over their positions and, as a consequence, unable to maintain their exposure to emerging markets over time. In addition, all liquidity in EM Options would essentially dry up meaning holders of the position would only be able to sell out of their position at an inferior price. Such investors will be left in the unenviable position of having to either accept an inferior or poor sales price, or hold until expiration, at which point they will be unable to maintain their exposure to the benchmark and risk violating their investment mandate.

This potential concerns are currently most evident with MSCI EM Index component security Taiwan Semiconductor MFG (“TSM”), which, on February 25, 2026, the day that EM Options were first listed on the Exchange, had a closing price of \$387.73 and at such time, accounted for 12.55% of the weight of the index.²⁶ However, on May 29, 2026, TSM closed at \$418.45—an approximate 8% increase. This had a corresponding impact on

²⁵ The Exchange notes that its proposal is consistent with the methodology applicable to the NASDAQ–100 Index Fund, which imposes a 24% single component percentage weight limit.

²⁶ The Exchange notes that the MSCI EM Index uses TSM’s underlying common stock in its calculation methodology.

TSM’s overall market capitalization and its percentage component weighting within the MSCI EM Index. Specifically, at the end of Q1 2026, TSM had market capitalization of approximately \$1.42T, which, as of May 29, 2026 grew to \$1.85T (a 30% increase). There was a similar increase on TSM’s percentage weighting within MSCI EM Index, increasing from 12.55% to 14.46% resulting in it having the highest percentage weighting within the Index.²⁷

The level of TSM’s weighting within the MSCI EM Index is the direct result of independent natural market forces, *i.e.*, its significant share price increase, and not a design flaw within the MSCI EM Index. The recent surge in prices of shares of stocks in the semi-conductor sector may cause TSM to exceed the Rule 5.12–O single component percentage weighting limit, when measured at its next scheduled semi-annual review. The purpose of this filing to forestall the Exchange having to prevent the opening of additional series of EM Options for trading and thereby deprive market participants of the opportunity to manage risk through the use of EM Options.

Because of the potential harm to investors in delisting EM Options and restricting currently open positions to closing only, along with the fact that the potential for exceeding the single component percentage weighting limit would be an independent market outcome and not a design flaw with the MSCI EM Index, the Exchange believes that the proposal would allow market participants to continue to manage their risk through the use of EM Options. In addition, given the size and liquidity of TSM, the weight percentage of other components within the same sector of TSM (*i.e.*, information technology) and the design of the MSCI EM Index to transparently measure equity performance of emerging markets any concerns related to fraud or manipulation are mitigated.

The delisting of EM Options and restricting currently open positions to closing only would put investors at risk and run contrary to the public interest. As highlighted in the EM Options Notice, the Exchange believed that the listing and trading of EM Options would increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk. The Exchange further noted that

²⁷ The increase in TSM’s share price and market capitalization has continued. On June 24, 2026, TSM closed at \$440.83 and had a market capitalization of 2.286T.

the listing and trading of EM Options would remove impediments to and perfect the mechanism of a free and open market as they would continue to provide greater opportunities for market participants to manage risk through the use of an index options product, maintain their exposure to the benchmark to the benefit of investors and the public interest.

Adopting the Exchange's proposal would not create a potential for fraud or market manipulation. As noted in the EM Options Notice, the MSCI EM Index is not easily susceptible to manipulation. It is a broad-based index with high market capitalization. As noted, the MSCI EM Index is currently comprised of 1,205 component stocks and, with the exception of TSM, none exceeding 8% of the index, with only two other component stocks exceeding 5%.

Additionally, the iShares MSCI Emerging Markets ETF, which tracks the MSCI EM Index, is an actively traded product, as are options on that ETF. Because the MSCI EM Index has a large number of component securities, is representative of many countries and trades a large volume with respect to the ETF and options on that ETF, the Exchange believes that the continued listing of EM Options is appropriate.

Finally, as noted in the EM Options Notice, the same surveillance procedures applicable to all other options currently listed and traded on the apply to EM Options and it has the necessary systems capacity to support the option series.

As further noted, the Exchange's existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior and other improper trading. In addition, the Exchange has a Regulatory Services Agreement ("RSA") with the Financial Industry Regulatory Authority ("FINRA"). Pursuant to a multi-party 17d-2 joint plan, all options exchanges allocate regulatory responsibilities to FINRA to conduct certain options-related market surveillances.²⁸ The

Exchange is also a member of the Intermarket Surveillance Group ("ISG") under the ISG Agreement. ISG members work together to coordinate surveillance and investigative information sharing in the stock, options, and futures markets.

Given the enormous liquidity in the underlying components of the MSCI EM Index and large number of market participants trading those components, the Exchange believes that any attempt to manipulate the price of the underlying security or options overlying such security in order to affect the price of the indices would be cost prohibitive and unlikely to succeed. Moreover, the Exchange believes that its existing surveillances and procedures adequately address potential concerns regarding possible manipulation of the settlement value at or near the close of the market.

As it relates to TSM, the MSCI EM Index is a free float-adjusted market capitalization index that is designed to measure equity market performance of emerging markets. The weight of any single component within it, such as TSM, is the result of transparent public market activity and not discretionary choices of the index. TSM's concentration is the result of independent market activity and not a design flaw with the MSCI EM Index. The Exchange also notes that the MSCI EM Index is designed to include companies from foreign markets, which themselves are of varying size, often much smaller than the U.S. markets overall. As a result, the potential concentration risk of a single component associated with such an index can be, and in this case is, higher than for other indexes. The proposal to raise the percentage limit for a single component in this Index in particular is therefore to the benefit of investors and reasonable, as it will avoid unnecessary investor harm resulting from such market conditions, while continuing to protect against any long-term overweighting.

Moreover, given its average daily notional value and national average daily volume, TSM is resistant to manipulation. The Exchange believes that average daily notional value and national average daily volume are, collectively, an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation. Average daily notional value considers both the trading activity and the price of a security. As a general matter, the more expensive an underlying security's

price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded.

As of December 31, 2025, TSM had an average daily notional value of \$3,246,781,038 and national average daily volume of 12,008,931 shares. It is, therefore, substantially liquid. In addition, there is significant depth and breadth of market participants providing liquidity. As such, any concern over the potential for manipulation of the MSCI EM Index domination by TSM is significantly mitigated. The sheer size and liquidity of TSM makes manipulative scenarios implausible and cost prohibitive. The concern over potential manipulation is further mitigated by the fact that the sector in which TSM belongs (Information Technology) makes up 43% of the total sector weights of the MSCI EM Index, which should generally move in the same direction. Thus, the organic growth of TSM, which is part of a larger sector within the MSCI EM Index should not materially increase the index's vulnerability to single stock manipulation.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the "Act"),²⁹ in general, and furthers the objectives of Section 6(b)(5) of the Act,³⁰ in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that the proposed change is designed to remove impediments to and to perfect the mechanism for a free and open market and a national market system by facilitating the continued listing and trading of EM options. The continued listing of EM options would continue to increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk, to the benefit of investors and the public interest. Moreover, the continued listing of EM options would continue to

²⁸ Section 19(g)(1) of the Act, among other things, requires every SRO registered as a national securities exchange or national securities association to comply with the Act, the rules and regulations thereunder, and the SRO's own rules, and, absent reasonable justification or excuse, enforce compliance by its members and persons associated with its members. See 15 U.S.C. 78q(d)(1) and 17 CFR 240.17d-2. Section 17(d)(1) of the Act allows the Commission to relieve an SRO of certain responsibilities with respect to members of the SRO who are also members of another SRO. Specifically, Section 17(d)(1) allows the Commission to relieve an SRO of its responsibilities to: (i) receive regulatory reports from such members; (ii) examine such members for compliance with the Act and the rules and

regulations thereunder, and the rules of the SRO; or (iii) carry out other specified regulatory responsibilities with respect to such members.

²⁹ 15 U.S.C. 78f(b).

³⁰ 15 U.S.C. 78f(b)(5).

create greater trading and hedging opportunities and flexibility while providing investors with an additional tool to manage their risk, particularly where certain investors have no alternative. The proposed rule change would also continue to result in enhanced efficiency in initiating and closing out positions and heightened contra-party creditworthiness given OCC's role as issuer and guarantor of the proposed index option products.

Further, the Exchange believes that the MSCI EM Index is not easily susceptible to manipulation. The index is broad-based and its component securities have large market capitalizations. As noted, the MSCI EM Index is currently comprised of 1,205 component stocks and, with the exception of TSM, none exceeding 8% of the index, with only two other component stocks exceeding 5%. Additionally, the iShares MSCI Emerging Markets ETF, which tracks the MSCI EM Index, is an actively traded product, as are options on it. Because the index has a large number of component securities, is representative of many countries and trades a large volume with respect to the ETF and options on that ETF, the Exchange believes that the proposed continued listing and trading of EM Options is appropriate.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in EM Options. The Exchange also represents that it has the necessary systems capacity to support continued listing of the options series. Additionally, as stated in the filing, the Exchange has rules in place to protect public customer trading.

B. Self-Regulatory Organizations' 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 believes that the proposed rule change would continue to facilitate trading of EM Options while also competing with domestic products such as EM Futures and European-traded derivatives on the MSCI EM Index, which would enhance competition among market participants, to the benefit of investors and the marketplace. The Exchange thus believes that the proposed change does not impose a burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition. The Exchange also believes that the proposed change would not place any undue burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as EM Options would continue to be equally available to all market participants who wish to trade such options and use such options to manage risk.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Changes Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

IV. Discussion

After careful review, the Commission finds that the proposal, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.³¹ In particular, the Commission believes that the proposal is consistent with the requirements of Section 6(b)(5) of the Act,³² which requires, among other things, that the rules of a national securities exchange be designed 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 MSCI EM Index currently is, and after this proposed rule change will remain, a broad based index. Other broad based indices on which index options are listed on other exchanges have concentration limits that meet or exceed the Exchanges' proposed 20% limit.³³

The proposed rule changes are necessary because one component security, TSM as discussed above, has seen its share price increase along with a number of other companies in the semiconductor sector. As a consequence, TSM may possibly exceed the current 15% limit due to its rising share price when measured at the index's next scheduled semi-annual review on July 1, 2026. By amending its rules to increase the concentration limit to a level that is not novel, the Exchanges are ensuring that investors will continue to have uninterrupted access to these index options. Further,

³¹ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³² 15 U.S.C. 78f(b)(5).

³³ See *supra* notes 11 and 25 (citing to the NASDAQ-100 Index Fund, which imposes a 24% limit).

as the Exchanges discuss in their proposal, the broad-based nature of the MSCI EM Index together with the Exchanges' regulatory oversight, should continue to help protect investors against manipulation at the higher concentration limit.

The Commission finds good cause pursuant to Section 19(b)(2) of the Act³⁴ for approving the amended proposal prior to the thirtieth day after its publication in the **Federal Register**. Specifically, accelerated approval will allow the Exchanges to implement this discrete change to their listing rules, which change does not raise any novel concerns or establish a novel concentration limit, without delay in order to provide investors with continued access to EM Options.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule changes are 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 numbers SR-NYSEAMER-2026-59, SR-NYSEARCA-2026-75 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 numbers SR-NYSEAMER-2026-59, SR-NYSEARCA-2026-75. These file numbers 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 filings also will be available for inspection and copying at the principal office of the Exchanges. 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

³⁴ 15 U.S.C. 78s(b)(2).

numbers SR–NYSEAMER–2026–59, SR–NYSEARCA–2026–75 and should be submitted on or before July 28, 2026.

V. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule changes, as amended, are consistent with the requirements of the Act and the rules and regulations thereunder.

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,³⁵ that the proposed rule changes (SR–NYSEAMER–2026–59, SR–NYSEARCA–2026–75) are hereby approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–13654 Filed 7–6–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105831; File No. SR–NYSEAMER–2026–54]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing of a Proposed Rule Change To Amend Rule 903G and 906G

July 1, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b–4 thereunder, ³ notice is hereby given that, on June 29, 2026, NYSE American LLC (“NYSE American” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 903G and 906G related to Flexible Exchange (“FLEX”) Options. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rules 903G and 906G related to FLEX Options.

FLEX Options are customized equity or index contracts that allow investors to tailor contract terms for exchange-listed equity and index options. A “FLEX Equity Option” is an option on a specified underlying equity security that is subject to the rules of Section 15.⁴

Generally, FLEX Equity Options are settled by physical delivery of the underlying security,⁵ while all FLEX Index Options are settled in cash.⁶ In February 2020, however, the Exchange amended Rule 903G to permit cash settlement for up to 50 FLEX Equity Options with an underlying security that is an ETF meeting certain criteria: an average daily notional value of \$500 Million or more and a national average daily volume of 4,680,000 shares, measured over the prior six-month period. Where more than 50 ETFs qualify, the Exchange selects the 50 with the highest average daily volume.⁷

The Exchange proposes to: (i) amend paragraph (c)(3)(ii) of Rule 903G to permit cash settlement for up to 50 non-ETF FLEX Equity Options whose underlying security meets the same

criteria currently applicable to ETF FLEX Equity Options noted above; and (ii) amend paragraph (c)(3)(ii)(A) of Rule 903G to provide that, where more than 50 underlying ETFs or 50 underlying non-ETFs qualify, the Exchange will select the 50 qualifying securities with the highest average daily notional value, replacing the current usage of highest average daily volume.⁸

The Exchange proposes to amend Rule 903G, paragraph (c)(3)(ii), to permit cash settlement for up to 50 non-ETF FLEX Equity Options whose underlying security meets the same criteria currently applicable to ETF FLEX Equity Options: an average daily notional value of \$500 Million or more and a national average daily volume of at least 4,680,000 shares, measured over the prior six-month period.⁹ The Exchange believes that average daily notional value and national average daily volume are, collectively, an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation for purposes of establishing a settlement price. Average daily notional value considers both the trading activity and the price of an underlying security. As a general matter, the more expensive an underlying security’s price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded.

To calculate average daily notional value (provided in the table below), the Exchange summed the notional value of each trade for each symbol (*i.e.*, the number of shares multiplied by the execution price) and divided that total by the number of trading days in the six-month period reviewed (July 1, 2025 through December 31, 2025). To calculate national average daily volume (provided in the table below), the Exchange summed the share volume of each trade for each symbol and divided that total by the number of trading days in the same six-month period. Based on these calculations, the Exchange identified 143 non-ETF securities eligible for cash settlement of FLEX options overlying them. As noted in the proposed amendment to Rule

⁴ See Rule 900G(b)(10).

⁵ See Rule 903G(c)(3)(i).

⁶ See Rule 903G(b)(2) and (3). Similarly, pursuant to Exchange rules, Binary Return Derivatives (“ByRDS”) are also settled in cash (See Rule 900ByRDS(b)) and, as discussed below, cash settlement is also permitted in the over-the-counter (“OTC”) market.

⁷ See Rule 903G(c)(3)(ii). See also Securities Exchange Release No. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (SR–NYSEAMER–2019–38) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Allow Certain Flexible Equity Options To Be Cash Settled).

⁸ The Exchange acknowledges that this change will become moot as it relates to FLEX ETF Equity options if CBOE’s current rule filing proposing to amend its Rule 4.21 to, among other things, eliminate the provision limiting cash settlement as a contract term to no more than 50 ETFs. See Securities Exchange Act Release No. 105277 (April 20, 2026) (SR–CBOE–2026–35) (Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change to Amend Rule 4.21 (Series of FLEX Options)).

⁹ See proposed Rule 903G(3)(ii).

³⁵ 15 U.S.C. 78s(b)(2).

³⁶ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

903G(c)(3)(ii)(A), however, only the FLEX Equity Options overlying the non-ETF securities with the highest average daily notional value would be eligible for cash settlement. The table below identifies the 50 non-ETF FLEX Equity

Options that would qualify for cash settlement under the Exchange's most recent review, effective February 2, 2026.¹⁰ The table also includes, for each symbol, closing auction average daily volume and closing auction average

daily notional value over the same six-month period, which reflect the depth of trading activity specifically at the close and thereby illustrate each symbol's resilience to potential price manipulation at the time of settlement.

Symbol	Name	National average daily volume	Average daily notional value	Closing auction average daily volume	Closing auction average daily notional value
TSLA	Tesla, Inc	86,178,496	33,900,266,523	3,190,644	1,269,430,007
NVDA	Nvidia Corp	179,041,356	32,307,823,899	12,868,161	2,321,433,344
AAPL	Apple Inc	50,490,993	12,378,849,915	7,226,393	1,806,481,590
MSFT	Microsoft Corp	21,252,429	10,744,061,849	3,544,334	1,784,873,081
AMD	Advanced Micro Devices	53,267,301	10,373,623,850	2,493,925	488,464,603
META	Meta Platforms, Inc	14,808,166	10,257,169,282	1,446,720	1,002,367,069
AMZN	Amazon.Com Inc	43,640,268	9,944,290,596	4,938,798	1,124,263,780
PLTR	Palantir Technologies Inc	56,659,273	9,609,181,571	2,638,743	456,276,952
GOOGL	Alphabet Inc. Class A	35,705,006	8,886,422,708	3,721,259	943,979,178
AVGO	Broadcom Inc	24,847,975	8,399,788,094	3,670,925	1,240,180,161
GOOG	Alphabet Inc. Class C	22,971,782	5,726,646,457	2,445,189	626,368,731
ORCL	Oracle Corp	22,510,933	5,639,724,093	1,572,261	381,075,627
MU	Micron Technology, Inc	24,285,194	4,467,837,733	1,970,831	361,184,152
HOOD	Robinhood Markets, Inc	36,997,040	4,306,868,213	1,954,129	238,103,937
NFLX	Netflix Inc	13,214,039	4,287,659,509	1,465,607	405,513,118
MSTR	Strategy Inc	14,042,388	3,950,992,841	1,040,765	297,429,799
UNH	UnitedHealth Group Incorporated	11,961,746	3,729,620,578	826,104	262,526,732
COIN	Coinbase Global, Inc	10,231,567	3,331,720,883	614,219	197,541,974
TSM	Taiwan Semiconductor Manufacturing Company Ltd	12,008,931	3,246,781,038	752,418	203,136,969
INTC	Intel Corp	103,754,853	3,219,916,507	6,929,263	218,261,697
APP	Applovin Corporation	5,782,947	3,195,229,826	566,833	341,886,958
CRWV	CoreWeave, Inc	26,134,544	2,786,774,579	945,274	92,136,014
JPM	JPMorgan Chase & Co	8,447,294	2,563,687,629	1,612,884	491,974,304
BABA	Alibaba Group Holding Limited	15,702,967	2,330,733,305	417,707	61,037,911
BMNR	BitMine Immersion Technologies, Inc	45,742,244	2,114,623,207	1,538,644	62,322,489
V	VISA Inc	6,064,874	2,079,103,486	1,346,605	461,301,568
CRM	Salesforce, Inc	8,170,611	2,033,145,491	895,261	223,551,717
CRCL	Circle Internet Group, Inc	13,890,967	1,876,964,806	438,058	50,218,550
BAC	Bank of America Corporation	36,433,684	1,848,841,746	5,536,718	282,799,082
RGTI	Rigetti Computing, Inc	61,001,534	1,818,953,391	2,249,745	64,386,440
WMT	Walmart Inc	17,171,708	1,785,470,800	3,965,604	452,283,958
SOFI	SoFi Technologies, Inc	68,778,271	1,774,108,244	2,462,163	63,663,350
OKLO	Oklo Inc	17,056,654	1,722,406,038	636,877	63,026,808
XOM	Exxon Mobil Corporation	14,923,963	1,694,641,338	2,369,124	269,222,575
BA	Boeing Company	7,771,390	1,664,026,520	647,649	138,422,692
UBER	Uber Technologies, Inc	17,771,441	1,623,852,154	1,748,330	159,554,138
AMAT	Applied Materials Inc	7,630,690	1,590,411,121	1,239,413	264,834,901
JNJ	Johnson & Johnson	8,508,238	1,570,954,763	1,590,260	295,976,568
MRVL	Marvell Technology, Inc	19,141,701	1,534,320,570	2,125,390	172,519,290
NBIS	Nebius Group N.V	16,580,887	1,509,559,015	530,793	49,592,906
IREN	IREN Limited	35,551,466	1,465,271,072	817,801	33,589,290
QCOM	Qualcomm Inc	8,743,386	1,462,236,794	1,589,760	263,590,678
LRCX	Lam Research Corp	11,098,219	1,443,543,642	1,936,139	259,497,229
CSCO	Cisco Systems, Inc	19,993,372	1,430,793,231	3,451,961	248,085,586
PFE	Pfizer Inc	55,503,187	1,385,704,301	4,483,737	112,014,095
SMCI	Super Micro Computer, Inc	30,070,928	1,385,222,973	1,592,481	70,488,062
IBM	International Business Machines Corporation	4,915,186	1,372,464,742	715,181	200,577,771
C	Citigroup Inc	13,787,319	1,366,461,810	1,972,207	197,886,096
IONQ	IonQ, Inc	24,413,055	1,339,549,825	1,588,871	86,626,817
TXN	Texas Instruments Incorporated	7,247,390	1,314,583,022	1,350,604	244,860,485

The Exchange believes that expanding cash settlement to a select group of non-ETF options reflects changes in the

marketplace since cash settlement was first expanded to options overlying ETFs.¹¹ Specifically, in 2020, only 52

single stocks within the S&P 500 and 32 ETFs met the above-captioned criteria (*i.e.*, average daily notional value of

¹⁰ The Exchange notes that, if approved after August 3, 2026, the Exchange's list of eligible symbols may differ slightly from the table below, as a new semiannual review would be effective on that date.

¹¹ See Securities Exchange Act Release No. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (NYSEAMER-2019-38) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified

by Amendment No. 1, To Allow Certain Flexible Equity Options To Be Cash Settled).

\$500 Million and average daily volume of 4,680,000 shares). As of December 31, 2025, however, 143 S&P 500 single stocks meet these same criteria, evidencing that the eligible single stocks are far deeper and more liquid than the ETF universe was at the time cash settlement for them was approved.

The Exchange believes it is appropriate to introduce cash settlement as an alternative contract term to this select group of non-ETF securities because they are among the most highly liquid and actively traded securities. As described more fully below, the Exchange believes that the deep liquidity and robust trading activity (in general and at the close) in the securities identified by the Exchange as meeting the criteria mitigate historic concerns regarding susceptibility to manipulation.

Moreover, the Exchange believes that permitting cash settlement as a contract term for the FLEX non-ETF Equity Options for the securities in the above table or later found to be in the top 50 would broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply.

Equity options are generally settled physically at The Options Clearing Corporation ("OCC"), (*i.e.*, upon exercise, shares of the underlying security must be assumed or delivered). Physical settlement entails certain risks with respect to volatility and movement of the underlying security at expiration that market participants may need to hedge against. Cash settlement may be preferable to physical delivery in some circumstances as it does not present the same risk. If an issue with the delivery of the underlying security arises, it may become more expensive and time-consuming to reverse the delivery because the price of the underlying security would almost certainly have changed. Reversing a cash payment, on the other hand, would not involve any such issue because reversing a cash delivery would simply involve the exchange of cash. Additionally, with physical settlement, market participants that have a need to generate cash would have to sell the underlying security while incurring the costs associated with liquidating their position in the underlying security as well as the risk of an adverse movement in the price of the underlying security.¹²

¹² Market participants have voiced additional concerns with physical delivery to explain why they participate in the OTC markets that allow cash settlement for equity options including, among

The Exchange notes that cash settlement for options is not a unique feature and other options exchanges have previously received approval that allow for the trading of cash-settled options¹³ and cash settled FLEX ETF Options.¹⁴

With respect to position limits, like ETF FLEX options, cash-settled FLEX non-ETF Equity Options would be subject to the position limits set forth in Rule 906G. Accordingly, the Exchange proposes to amend Rule 906G(b)(ii) to remove reference to Exchange-Traded Funds and would provide that positions for all FLEX Equity Options settled in cash pursuant to Rule 903G(c)(3)(ii) would be subject to the limits set forth in Rule 904, and the exercise limits set forth in Rule 905.¹⁵ Given that each of the underlying securities that would currently be eligible to have cash-settlement as a contract term have established position and exercise limits

other things, that certain custodians will not permit short options positions requiring physical delivery and physical settlement certain tax triggering events.

¹³ See *e.g.* PHLX FX Options traded on Nasdaq PHLX and S&P 500® Index Options traded on Cboe Options Exchange. More recently, the Commission approved, on a pilot basis, the listing and trading of RealDay™ Options on the SPDR S&P 500 Trust on the BOX Options Exchange LLC ("BOX"). See Securities Exchange Act Release No. 79936 (February 2, 2017), 82 FR 9886 (February 8, 2017) ("RealDay Pilot Program"). The RealDay Pilot Program was extended until February 2, 2019. See Securities Exchange Act Release No. 82414 (December 28, 2017), 83 FR 577 (January 4, 2018) (SR-BOX-2017-38). The RealDay Pilot Program was never implemented by BOX. See also Securities Exchange Act Release Nos. 56251 (August 14, 2007), 72 FR 46523 (August 20, 2007) (SR-Amex-2004-27) (Order approving listing of cash-settled Fixed Return Options ("FROs")); and 71957 (April 16, 2014), 79 FR 22563 (April 22, 2014) (SR-NYSEMKT-2014-06) (Order approving name change from FROs to ByRDs and re-launch of these products, with certain modifications).

¹⁴ See Securities Exchange Act Release Nos. 102839 (April 11, 2025), 90 FR 16410 (April 17, 2025) (SR-BOX-2025-07) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 5055 To Allow for Cash Settlement of Certain FLEX Equity Options); 98044 (August 2, 2023), 88 FR 53548 (August 8, 2023) (SR-CBOE-2023-036) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Allow Certain Flexible Exchange Equity Options To Be Cash Settled); and 101720 (November 22, 2024), 89 FR 94986 (November 29, 2024) (SR-ISE-2024-12) (Notice of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt Rules To List and Trade FLEX Options). See also Securities Exchange Act Release Nos. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (SR-NYSEAMER-2019-38) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Allow Certain Flexible Equity Options To Be Cash Settled); and 97231 (March 31, 2023), 88 FR 20587 (April 6, 2023) (SR-NYSEAMER-2023-22) (Notice of Filing and Immediate Effectiveness of Proposed Change to Make a Clarifying Change to the Term Settlement Style Applicable to Flexible Exchange Options).

¹⁵ See proposed Rule 906G(b)(ii).

applicable to physically-settled options, the Exchange believes it is appropriate for the same position and exercise limits to also apply to cash-settled options. Accordingly, as of December 31, 2025, of the 143 non-ETF underlying securities that would currently be eligible to have cash settlement as a contract term, all 143 (and all 50 on the above chart) would have a position limit of 250,000 contracts pursuant to Rule 904, Commentary .07(a).¹⁶

The Exchange understands that cash-settled FLEX non-ETF Equity Options are currently traded in the OTC market by a variety of market participants (*e.g.*, hedge funds, proprietary trading firms, and pension funds). The Exchange believes some of these market participants would prefer to trade these instruments on an exchange, where they would be cleared and settled through a regulated clearing agency. The Exchange expects that users of these OTC products would be among the primary users of exchange-traded cash-settled FLEX non-ETF Equity Options. The Exchange also believes that the trading of cash-settled FLEX non-ETF Equity Options would allow these same market participants to better manage the risk associated with the volatility of underlying equity positions given the enhanced liquidity that an exchange-traded product would bring.

Cash-settled FLEX non-ETF Equity Options traded on the Exchange would have three important advantages over the contracts that are traded in the OTC market. First, as a result of greater standardization of contract terms, exchange-traded contracts should develop more liquidity. Second, counter-party credit risk would be mitigated by the fact that the contracts are issued and guaranteed by the OCC. Finally, the price discovery and dissemination provided by the Exchange and its members would lead to more transparent markets. The Exchange believes that its ability to offer cash-settled FLEX non-ETF Equity Options would aid it in competing with the OTC market and, at the same time, expand the universe of products available to interested market participants. The Exchange believes that an exchange-traded alternative may provide a useful risk management and

¹⁶ Rule 904, Commentary .07(a) provides that the position limit shall be 250,000 contracts for options: (i) on an underlying security that had trading volume of at least 100,000,000 shares during the most recent six-month trading period; or (ii) on an underlying security that had trading volume of at least 75,000,000 shares during the most recent six-month trading period and has at least 300,000,000 shares currently outstanding.

trading vehicle for market participants and their customers.

The Exchange notes that cash-settled FLEX non-ETF Equity Options would not be available for trading until OCC represents to the Exchange that it is fully able to clear and settle such options.¹⁷ The Exchange has also analyzed its capacity and represents that it and The Options Price Reporting Authority (OPRA) have the necessary systems capacity to handle the additional traffic associated with the listing of cash-settled FLEX Equity Options. The Exchange believes any additional traffic that would be generated from the introduction of cash-settled FLEX non-ETF Equity Options would be manageable. The Exchange represents that ATP Holders will not have a capacity issue as a result of this proposed rule change.

The Exchange also represents that it does not believe this proposed rule change will cause fragmentation of liquidity. The Exchange will monitor the trading volume associated with the additional options series listed as a result of this proposed rule change and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

The Exchange believes it has an adequate surveillance program in place for cash-settled FLEX non-ETF equity Options and intends to apply the same program procedures that it applies to the Exchange's other options products.

FLEX option products, including non-ETF equity options, and their respective symbols are integrated into the Exchange's existing surveillance system architecture and are thus subject to the relevant surveillance processes. The Exchange believes that the existing surveillance procedures at the Exchange are capable of properly identifying unusual and/or illegal trading activity, which procedures the Exchange would utilize to surveil for aberrant trading in cash-settled FLEX non-ETF Options. As a result, the Exchange believes it would be able to effectively regulate the trading of cash-settled FLEX non-ETF Equity Options using means that include its surveillance for manipulation. The Exchange believes that manipulating the settlement price of cash-settled FLEX non-ETF Equity Options would be difficult based on the size of the market for the securities that are the subject of this proposed rule change.

With respect to regulatory scrutiny, the Exchange believes its existing

surveillance technologies and procedures adequately address potential concerns regarding possible manipulation of the settlement value at or near the close of the market. The Exchange notes that the regulatory program operated by, and overseen by NYSE Regulation,¹⁸ includes cross-market surveillance designed to identify manipulative and other improper trading, including spoofing, algorithm gaming, marking the close and open, as well as more general, abusive behavior related to front running, wash sales, quoting/routing, and Reg SHO violations, that may occur on the Exchange and other markets. These cross-market patterns incorporate relevant data from various markets beyond the Exchange and its affiliates and from markets not affiliated with the Exchange. The Exchange represents that its existing trading surveillances are adequate to monitor the trading in the underlying equity securities and subsequent trading of options on those securities on the Exchange, including cash-settled FLEX non-ETF Options.¹⁹

Additionally, for options, the Exchange utilizes an array of patterns that monitor manipulation of options, or manipulation of equity securities (regardless of venue) for the purpose of impacting options prices on the Exchange (*i.e.*, mini-manipulation strategies). That surveillance coverage is initiated once options begin trading on the Exchange. Accordingly, the Exchange believes that the cross-market surveillance performed by the Exchange or FINRA, on behalf of the Exchange, coupled with NYSE Regulation's own monitoring for violative activity on the Exchange comprise a comprehensive surveillance program that is adequate to monitor for manipulation of the underlying security and overlying option. Furthermore, the Exchange believes that the existing surveillance procedures at the Exchange are capable of properly identifying unusual and/or illegal trading activity, which the Exchange would utilize to surveil for aberrant trading in cash-settled FLEX non-ETF Options.

¹⁸ The Exchange maintains regulatory services agreements with Financial Industry Regulatory Authority, Inc. ("FINRA") whereby FINRA provides certain regulatory services to the exchanges, including cross-market surveillance, investigation, and enforcement services.

¹⁹ Such surveillance procedures generally focus on detecting securities trading subject to opening price manipulation, closing price manipulation, layering, spoofing or other unlawful activity impacting an underlying security, the option, or both. The Exchange has price movement alerts, unusual market activity and order book alerts active for all trading symbols.

In addition to the surveillance procedures and processes described above, improvements in audit trails (*i.e.*, the Consolidated Audit Trail), recordkeeping practices, and inter-exchange cooperation over the last two decades have greatly increased the Exchange's ability to detect and punish attempted manipulative activities. In addition, the Exchange is a member of the Intermarket Surveillance Group ("ISG").²⁰ The ISG members work together to coordinate surveillance and investigative information sharing in the stock and options markets. For surveillance purposes, the Exchange would therefore have access to information regarding trading activity in the pertinent underlying securities. The Exchange is confident that its existing surveillance procedures, which have proven effective with respect to FLEX ETF Options, are sufficient for the cash settlement of FLEX non-ETF Options and will monitor and adjust such procedures as needed.

Additionally, the Exchange notes that each cash-settled FLEX non-ETF Equity Option that is subject to this proposed rule change is sufficiently active so as to alleviate concerns about potential manipulative activity. Further, in the Exchange's view, the vast liquidity of the 143 underlying securities ensures a multitude of market participants at any given time. Given the high level of participation among market participants that enter quotes and/or orders in the options on these securities, the Exchange believes it would be very difficult for a single participant to alter the price of each of the underlying securities in any significant way without exposing the would-be manipulator to regulatory scrutiny. The Exchange further believes any attempt to manipulate the price of the underlying securities would also be cost prohibitive.

The Exchange does not believe that allowing cash settlement as a contract term would render the marketplace for equity options more susceptible to manipulative practices. In addition to the surveillance procedures and processes described above, improvements in audit trails, recordkeeping practices, and inter-exchange cooperation over the last two decades have greatly increased the Exchange's ability to detect and punish

²⁰ ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by cooperatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

¹⁷ It is the Exchange's understanding that the OCC intends to make rule filing to allow it to clear cash settled non-ETF equity options.

attempted manipulative activities. The Exchange therefore believes that the decision of whether or not to allow cash settlement as a contract term should rest on the ability of the Exchange to monitor and detect manipulative activity, not on any perceived threat of increased attempted manipulative activity.

The proposed rule change is designed to allow investors seeking to effect cash-settled FLEX non-ETF Equity Options with the opportunity for a different method of settling option contracts at expiration if they choose to do so. As noted above, market participants may choose cash settlement because physical settlement possesses certain risks with respect to volatility and movement of the underlying security at expiration that market participants may need to hedge against. The Exchange believes that offering innovative products flows to the benefit of the investing public. A robust and competitive market requires that exchanges respond to members' evolving needs by constantly improving their offerings. Such efforts would be stymied if exchanges were prohibited from offering innovative products for reasons that are generally debated in academic literature.

The Exchange believes that introducing cash-settled FLEX non-ETF Equity Options would further broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC markets for customized options, where settlement restrictions do not apply. The proposed rule change is also designed to encourage market makers to shift liquidity from the OTC market onto the Exchange, which, the Exchange believes, will enhance the process of price discovery conducted on the Exchange through increased order flow. The Exchange also believes that this may open up cash settled FLEX non-ETF Equity Options to more retail investors.

The Exchange also proposes to amend paragraph (c)(3)(ii)(A) of Rule 903G to provide that, where more than 50 underlying ETFs or 50 underlying non-ETFs qualify for cash settlement, the Exchange will select the 50 qualifying securities with the highest average daily notional value, replacing the current usage of highest average daily volume. The Exchange believes that, in making this determination, average daily notional value is a more appropriate metric. Specifically, it accounts for both trading activity and the price of the underlying security, which average daily volume alone does not capture.

As a general matter, higher-priced securities are less susceptible to cost-effective manipulation. Manipulative price impact is better measured by value, not share count. Thus, notional value more accurately identifies securities where potential manipulation is economically feasible and meaningful. Moreover, average daily notional value reduces the potential of a low-priced underlying equity that is potentially more susceptible to manipulation from being eligible for participating in the program.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²¹ in general, and furthers the objectives of Section 6(b)(5) of the Act,²² in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. In addition, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5)²³ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that introducing cash-settled FLEX non-ETF Equity Options will increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk. The Exchange further believes that using average daily notional value, rather than average daily volume, in determining eligibility where more than 50 underlying equity securities qualify ensures that cash settlement eligibility is tied to a more robust and meaningful measure of market activity, thereby better protecting investors and the public interest.

The Exchange believes that the proposal to permit cash settlement as a contract term for options on the specified group of non-ETF equity securities would remove impediments to and perfect the mechanism of a free and open market as cash-settled FLEX non-ETF Equity Options would enable market participants to receive cash in lieu of shares of the underlying security,

which would, in turn, provide greater opportunities for market participants to manage risk through the use of a cash-settled product to the benefit of investors and the public interest.

The Exchange does not believe that allowing cash settlement as a contract term for options on the specified group of non-ETF equity securities would render the marketplace for equity options more susceptible to manipulative practices. As illustrated in the table above, each of the qualifying underlying securities is actively traded and highly liquid (in general and at the close) and, thus, would not be susceptible to manipulation because, over a six-month period, each security had an average daily notional value of at least \$500 Million and an ADV of at least 4,680,000 shares, which indicates that there is substantial liquidity present in the trading of these securities, and that there is significant depth and breadth of market participants providing liquidity and of investor interest.

The Exchange believes that the data provided by the Exchange supports the supposition that permitting cash settlement as a FLEX term for the 143 underlying securities that would currently qualify to have cash settlement as a contract term would broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply.

The Exchange believes that the proposal to permit cash settlement would remove impediments to and perfect the mechanism of a free and open market because the proposed rule change would provide ATP Holders with enhanced methods to manage risk by receiving cash if they choose to do so instead of the underlying security. In addition, this proposal would promote just and equitable principles of trade and protect investors and the general public because cash settlement would provide investors with an additional tool to manage their risk. Further, the Exchange notes that its proposal to introduce cash-settled FLEX non-ETF Equity Options is not novel in that other exchanges have previously received approval that allow for the trading of cash-settled options. The proposed rule change therefore should not raise issues for the Commission that have not been previously addressed.²⁴

The proposed rule change to permit cash settlement as a contract term for options on the 143 underlying securities is designed to promote just and

²¹ 15 U.S.C. 78f(b).

²² 15 U.S.C. 78f(b)(5).

²³ 15 U.S.C. 78f(b)(5).

²⁴ See *supra*, Notes 13 and 14.

equitable principles of trade in that the availability of cash settlement as a contract term would give market participants an alternative to trading similar products in the OTC market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market), the Exchange would be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that it would lead to the migration of options currently trading in the OTC market to trading on the Exchange. Also, any migration to the Exchange from the OTC market would result in increased market transparency. Additionally, the Exchange believes the proposed rule change is designed to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest in that it should create greater trading and hedging opportunities and flexibility. The proposed rule change should also result in enhanced efficiency in initiating and closing out positions and heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of the proposed cash-settled options. Further, the proposed rule change would result in increased competition by permitting the Exchange to offer products that are currently available for trading only in the OTC market.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in cash-settled FLEX non-ETF Equity Options. Regarding the proposed cash settlement, the Exchange would use the same surveillance procedures currently utilized for the Exchange's other FLEX Options. For surveillance purposes, the Exchange would have access to information regarding trading activity in the pertinent underlying securities. The Exchange believes that limiting cash settlement to options on 50 non-ETF underlying securities that would currently be eligible to have cash-settlement as a contract term would minimize the possibility of manipulation due to the robust liquidity in both the equities and options markets. Further, the Exchange believes that assessing eligibility of qualifying securities using the highest average daily notional value, rather than with the highest average daily volume, ensures that cash settlement eligibility is tied to a more robust and meaningful measure of market activity that is less susceptible to manipulation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as all Floor Brokers and FLEX Market Makers that are authorized to trade FLEX Equity Options, including non-ETF options, in accordance with the Exchange's Rules will be able to trade cash-settled FLEX non-ETF Equity Options in the same manner. This includes that, for all FLEX Equity Options at least one of exercise style, expiration date, and exercise price must differ from options in the non-FLEX market. Additionally, positions in cash-settled FLEX non-ETF Equity Options of all ATP Holders will be subject to the same position limits, and such positions will be aggregated with positions in physically settled options on the same underlying in the same manner.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as the proposal is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors because it is designed to provide investors seeking to transact in FLEX non-ETF Equity Options with the opportunity for an alternative method of settling their option contracts at expiration. The Exchange believes the proposed rule change will encourage competition, as it may broaden the base of investors that use FLEX Equity Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply. The proposed rule change would give market participants an alternative to trading similar products in the OTC market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market), the Exchange would be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change may increase competition as it may lead to the migration of options currently trading in the OTC market to trading on the Exchange. Also, any migration to the Exchange from the OTC market would result in increased market transparency and thus increased price competition.

The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. The Exchange believes the proposed rule change encourages competition amongst market participants to provide tailored cash-settled FLEX non-ETF Equity Option contracts.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 the 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-NYSEAMER-2026-54 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEAMER-2026-54. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/>

rules/sro.shtml). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEAMER-2026-54 and should be submitted on or before July 28, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-13650 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105830; File No. SR-NYSE-2026-32]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Connectivity Fee Schedule

July 1, 2026.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (“Act”) ² and Rule 19b-4 thereunder, ³ notice is hereby given that on June 18, 2026, New York Stock Exchange LLC (“NYSE” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared

by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Connectivity Fee Schedule to amend the list of third party data feeds to which Users can connect. The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Connectivity Fee Schedule to amend the list of third party data feeds to which Users ⁴ can connect. Currently, Users are offered connectivity to data feeds from third party markets and other content service providers (“Third Party Data

Feeds”) at the Mahwah, New Jersey data center (“MDC”).⁵ The Exchange now proposes to amend the names of the Cboe Global Markets, Inc. Third Party Data Feeds (excluding Cboe Canada) (“Cboe Data Feeds”) and incorporate a new feed from Investors Exchange LLC (“IEX”).

The Exchange expects that the proposed rule change would become operative by August 31, 2026. The Exchange will announce the date through a customer notice.

Proposed Change to the Cboe Data Feeds

Currently, the Cboe Data Feeds are set forth in the list of Third Party Data Feeds by market. However, Users have requested that certain of the Cboe Data Feeds be broken out by asset class instead, so that if a User wanted all of the Cboe equities ⁶ data, Cboe options ⁷ data, or Cboe indices data ⁸ it would not have to sign up for connectivity to more than one Third Party Data Feed.⁹ The Exchange proposes to make the requested change and to indicate the exchanges from which data is included in the Cboe equities (“Cboe U.S. Equities”) and Cboe options (“Cboe Options”) data feeds.

The Exchange also proposes to change the name of “Cboe CFE Futures” to “Cboe Futures Exchange (CFE)” to mirror the name of Cboe Futures Exchange ¹⁰ and to reorder the Cboe Data Feeds to maintain alphabetical order.

Accordingly, the Exchange proposes to make the following changes to the Cboe Data Feeds listed under “Connectivity to Third Party Data Feeds” (proposed additions italicized, proposed deletions in brackets):

Third Party data feed	Monthly recurring connectivity fee per third party data feed
[Cboe BZX Exchange (CboeBZX) and Cboe BYX Exchange (CboeBYX)]	[\$1,500]
Cboe Canada	2,000

²⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ For purposes of the Exchange’s colocation services, a “User” means any market participant that requests to receive colocation services directly from the Exchange. See Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR-NYSE-2015-40). As specified in the Fee Schedule, a User that incurs colocation fees for a particular colocation service pursuant thereto would not be subject to colocation fees for the same colocation service charged by NYSE American LLC, NYSE Arca, Inc., NYSE National, Inc. and NYSE Texas, Inc. (together, the “Affiliate SROs”). Each Affiliate SRO has submitted

substantially the same proposed rule change to propose the change described herein.

⁵ Through its Fixed Income and Data Services (“FIDS”) business, Intercontinental Exchange, Inc. (“ICE”) operates the MDC. The Exchange and the Affiliate SROs are indirect subsidiaries of ICE.

⁶ See Cboe U.S. Equities | Cboe (representing the four U.S. equities exchanges that Cboe operates as BZX Equities, BYX Equities, EDGA Equities, and EDGX Equities).

⁷ See Cboe U.S. Options | Trade Equity, Index & ETF Options | Cboe (stating that the four U.S.-listed cash equity options markets that Cboe operates are the Cboe Options Exchange, the Cboe C2 Options Exchange, Cboe BZX Options Exchange, and Cboe EDGX Options Exchange).

⁸ The Cboe indices data is set out in the Cboe Global Indices Feed. See Cboe Global Indices Feed (stating that the Cboe Global Indices Feed has more than 1,900 Index Values available).

⁹ Currently, in order to connect to all of the Cboe U.S. Equity data feeds a User would have to connect to two Third Party Data Feeds, and to connect to all of the Cboe Options data feeds a User would have to connect to three Third Party Data Feeds. In order to connect to the Cboe indices data a User currently would have to connect to one Third Party Data Feed and the proposed change would ensure that remains true.

¹⁰ See, e.g., Exchange Act Release No. 104973 (March 11, 2026), 91 FR 12631 (March 16, 2026) (SR-CFE-2026-002) (presenting the name as “Cboe Futures Exchange, LLC,” abbreviated to “CFE”).

Third Party data feed	Monthly recurring connectivity fee per third party data feed
Cboe [CFE] Futures Exchange (CFE)	1,500
Cboe Global Indices Feed	1,500
Cboe Options [EDGX] Exchanges (Cboe Options Exchange, Cboe C2 Options Exchange, Cboe BZX Options Exchange, and Cboe EDGX Options Exchange) [and Cboe EDGA Exchange (CboeEDGA)]	1,500
Cboe U.S Equities Exchanges (Cboe EDGA Equities, Cboe EDGX Equities, Cboe BYX Equities and Cboe BZX Equities) [and C2 Exchange (C2)]	1,500

Proposed Change to the IEX Third Party Data Feed

IEX has announced that it will launch a new options exchange (“IEX Options”)¹¹ and that it intends to

launch IEX Options on October 2, 2026.¹²

So that the Exchange may both offer connectivity to IEX Options and distinguish between IEX Options and

the existing IEX equities exchange (“IEX Equities”), it proposes to make the following changes to the list of available Third Party Data Feeds (proposed additions italicized):

Third party data feed	Monthly recurring connectivity fee per third party data feed
Investors Exchange (IEX) <i>Equities</i>	\$1,300
<i>Investors Exchange (IEX) Options</i>	1,300

The Exchange would provide connectivity to IEX Options as a convenience to Users.

As with the existing connections to Third Party Data Feeds, including the existing connections to Cboe Data Feeds and to the IEX Equities data feed, the Exchange would receive a connection to the IEX Options data feed (the “Proposed Third Party Data Feed”) from the content service provider at the relevant source. The Exchange would then provide connectivity to that data to Users for a fee. Users would connect to IEX Options over the internet protocol (“IP”) network, a local area network available in the MDC. The Proposed Third Party Data Feed would include trading and other information concerning the securities that are traded on IEX Options.

As with the existing connections to Third Party Data Feeds, including the existing connection to Cboe Data Feeds and the IEX Equities data feed, in order to connect to a Proposed Third Party Data Feed, a User would enter into a contract with the third party content service provider, pursuant to which it may charge the User for the data feed. The Exchange would receive the Proposed Third Party Data Feed in

remote locations and transport it over its fiber optic network to the MDC. After the content service provider and User entered into an agreement and the Exchange received authorization from the content service provider, the Exchange would retransmit the data to the User over the User’s port. The Exchange would charge the User for connectivity to the Proposed Third Party Data Feed. A User would only receive, and would only be charged the fee for, connectivity to a Proposed Third Party Data Feed for which it entered into a contract.

The Exchange has no affiliation with the seller of the Proposed Third Party Data Feed and would have no right to use the feed other than as a redistributor of the data. The Proposed Third Party Data Feed would not provide access or order entry to the Exchange’s execution system. The Proposed Third Party Data Feed would not provide access or order entry service to the execution systems of any third party generating the feed. The Exchange would receive the Proposed Third Party Data Feed via arms-length agreements and would have no inherent advantage over any other distributor of such data.

Application and Impact of the Proposed Changes

The proposed rule change would not apply differently to distinct types or sizes of market participants. Rather, it would apply to all Users equally. As is currently the case, the purchase of any colocation service is completely voluntary and the Connectivity Fee Schedule is applied uniformly to all Users.

Users have requested that certain of the Cboe Data Feeds be broken out by asset class, instead of by market. The Exchange believes that one current User would benefit from the change. It does not expect to gain customers as a result of breaking out certain of the Cboe Data Feeds by asset class or the other proposed changes to the Cboe Data Feeds.

Connectivity to the Proposed Third Party Data Feed was requested by Users, but the Exchange believes that it would gain at most a handful of new customers due to the proposed change to the IEX data feeds.

Competitive Environment

The Exchange operates in a highly competitive market in which other vendors offer colocation services as a

connect, and test their connection, to IEX Options. The Exchange does not plan to charge for the connection until the IEX Options Third Party Data Feed is available.

¹¹ See “IEX Announces Planned Launch of Options Exchange End of Q1 2026,” available at <https://www.iex.io/article/iex-announces-planned-launch-of-options-exchange-end-of-q1-2026>.

¹² See “IEX Options Frequently Asked Questions,” question 1, available at <https://>

cdn.prod.website-files.com/696f8ac812dcabe749e3aa49/69d7ddd79256713d06405c46/IEX%20Options%20FAQs.pdf. The proposed rule change is proposed to become operative before IEX offers IEX Options in order to allow Users time to

means to facilitate the trading and other market activities of those market participants who believe that colocation enhances the efficiency of their operations. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”¹³

As explained below, the Exchange’s provision of connectivity to the Proposed Third Party Data Feed (“Connectivity”) may compete with connectivity provided by other third parties. Third-party vendors are not at any competitive disadvantage created by the Exchange.

The proposed change is not otherwise intended to address any other issues relating to colocation services or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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 and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange further believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁶ because it provides for the equitable allocation of reasonable dues, fees, and other charges

among its members and issuers and other persons using its facilities.

The Proposed Rule Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable.

In considering the reasonableness of proposed services and fees, the Commission’s market-based test considers “whether the exchange was subject to significant competitive forces in setting the terms of its proposal . . . , including the level of any fees.”¹⁷ If the Exchange meets that burden, “the Commission will find that its proposal is consistent with the Act unless ‘there is a substantial countervailing basis to find that the terms’ of the proposal violate the Act or the rules thereunder.”¹⁸ Here, the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because substantially similar substitutes are available and the Exchange has not placed present or future third party vendors at a competitive disadvantage created by the Exchange.

Substantially Similar Substitutes Are Available

As described above,¹⁹ Users may connect to the Proposed Third Party Data Feed independent of the options provided by the Exchange, creating competition for the Exchange’s proposed Connectivity. A User may connect to a Proposed Third Party Data Feed by, first, entering into an agreement with the relevant third party for connectivity, and second, connecting to the Proposed Third Party Data Feed through one of the Telecoms. Users that establish access or connectivity independent of the Connectivity offered by the Exchange are not at any competitive disadvantage created by the Exchange. As of April 30, 2026, more than 98% of the circuits for which Users contracted were supplied by the

Telecoms. Although IEX Options does not currently offer the Proposed Third Party Data Feed, the Exchange believes that once it is available, Users may independently establish connectivity to the Proposed Third Party Data Feed through one of the Telecoms.

Because Users are third parties and are not required to make such information public, the Exchange does not have visibility into how many Users will connect to the Proposed Third Party Data Feed (once it becomes available) independently, as described above.²⁰ However, the market for connectivity to the Proposed Third Party Data Feed is competitive, and there is no reason to believe that other actual or potential Users would not obtain connectivity independently if they considered it to be in their commercial interest.

Such Users compete, or would compete, with the Exchange’s Connectivity and exert, or would exert, significant competitive forces on the Exchange in setting the terms of its proposal, including the level of the Exchange’s proposed fees.²¹ If the Exchange were to set its proposed fees too high, Users could respond by instead selecting other substantially similar access and connectivity by independently establishing access and connectivity as described above.

Users Are Not at a Competitive Disadvantage Created by the Exchange

The Exchange does not believe that FIDS would have any competitive advantage over Users that establish independent connectivity to the Proposed Third Party Data Feed. The Exchange’s proposed service for Connectivity does not have (a) any special access to the Proposed Third Party Data Feeds or (b) advantage within the MDC, as all distances in the MDC are normalized.

Moreover, the Exchange does not believe that FIDS would have any competitive advantage because it would charge for connectivity only, not the Proposed Third Party Data Feed itself. All Users that connect to the Proposed Third Party Data Feed, whether they elect to connect using the Exchange’s proposed service or not, would have to pay a third party for the Proposed Third Party Data Feed.

²⁰ As they are third parties, the Exchange does not have visibility into whether Users intend to connect to the Proposed Third Party Data Feed (once it is available) for their own use, or if they intend to offer other Users such connectivity.

²¹ See 2008 ArcaBook Approval Order, *supra* note 17, at 74789 and n.295 (recognizing that products need not be identical to be substitutable).

¹³ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

¹⁴ 15 U.S.C. 78f(b)(0) [sic]

¹⁵ 15 U.S.C. 78f(b)(5).

¹⁶ 15 U.S.C. 78f(b)(4).

¹⁷ See Securities Exchange Act Release No. 90209 (October 15, 2020), 85 FR 67044, 67049 (October 21, 2020) (Order Granting Accelerated Approval to Establish a Wireless Fee Schedule Setting Forth Available Wireless Bandwidth Connections and Wireless Market Data Connections) (SR–NYSE–2020–05, SR–NYSEAMER–2020–05, SR–NYSEARCA–2020–08, SR–NYSECHX–2020–02, SR–NYSENAT–2020–03, SR–NYSE–2020–11, SR–NYSEAMER–2020–10, SR–NYSEARCA–2020–15, SR–NYSECHX–2020–05, SR–NYSENAT–2020–08) (“Wireless Approval Order”), citing Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (“2008 ArcaBook Approval Order”). See *NetCoalition v. SEC*, 615 F.3d 525 (D.C. Cir. 2010).

¹⁸ See Wireless Approval Order, *supra* note 17, at 67049, citing 2008 ArcaBook Approval Order, *supra* note 17, at 74781.

¹⁹ See “Competitive Environment,” above.

Nor does the Exchange believe that FIDS has a competitive advantage by virtue of the fact that ICE owns and operates the MDC's meet-me-rooms. Users purchasing Connectivity—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by Telecoms.²² Currently, 17 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level²³ so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.²⁴ Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange would be subject to a competitive disadvantage vis-à-vis Users regarding connectivity to the Proposed Third Party Data Feed. Users that choose to independently

establish connectivity may negotiate terms with the Telecoms through whom such connectivity is delivered, in response to competitive forces. Such prices are not required to be filed by any party with the Commission. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

In sum, because the Exchange is subject to significant competitive forces in setting the terms on which it offers its proposal, in particular because the Exchange believes that a substantially similar substitute is available, and the Exchange has not placed actual or proposed Users that already have or establish connectivity at a competitive disadvantage created by the Exchange, the proposed fee for the Exchange's access to the Proposed Third Party Data Feed is reasonable.²⁵ If the Exchange were to set its prices for connectivity to the Proposed Third Party Data Feeds at a level that Users found to be too high, Users could easily choose to connect to the Proposed Third Party Data Feed through Telecoms, as detailed above.

Additional Considerations

The Exchange believes that the proposed changes to the Cboe Data Feeds are reasonable. Specifically, the Exchange believes that the proposed changes are a reasonable response to the request from Users that certain Cboe Data Feeds be broken out by asset class, instead of by market. Under the proposed change, if a User wanted all Cboe U.S. Equities data, Cboe Options data or Cboe indices data it would not have to sign up for connectivity to more than one Third Party Data Feed. The Exchange believes that changing the placement of the "CFE" in, and adding the word "Exchange" to, Cboe Futures Exchange would be reasonable, given that the resulting change would mirror the name of the Cboe Futures Exchange.²⁶ The monthly recurring connectivity fees for each Cboe Data Feed would remain the same as they are now.

Additionally, as with the Proposed Third Party Data Feed, Users may connect to the Cboe Data Feeds independent of the options provided by the Exchange, creating competition for the Exchange's proposed Connectivity. A User may connect to a Cboe Data Feed by, first, entering into an agreement with the relevant third party for

connectivity, and second, connecting to the Cboe Data Feed through one of the Telecoms. The Exchange believes that the proposed fee for the Proposed Third Party Data Feed is reasonable, as it is the same as the existing fee for connectivity to IEX, which encompasses IEX Equities only. The Exchange believes that adding "Equities" after the existing text for connectivity to the IEX feed is reasonable, as it would clarify which IEX data feed was referenced.

The Proposed Rule Change Is Equitable

The Exchange believes that the proposed rule change is equitable.

The Exchange believes that the proposed changes to the Cboe Data Feeds is equitable because the monthly recurring connectivity fee for each Cboe Data Feed would remain the same as it is now. However, under the proposed change, if a User wanted all Cboe U.S. Equities data, Cboe Options data or Cboe indices data it would not have to sign up for connectivity to more than one Third Party Data Feed.

The Exchange believes that changing the placement of the "CFE" in, and adding "Exchange" to, Cboe Futures Exchange would be equitable, given that the resulting change would mirror the name of the Cboe Futures Exchange.²⁷ The proposed changes would make the Fee Schedule easier to read and understand and alleviate any possible market participant confusion caused by the current text.

For the same reason, the Exchange believes that adding "Equities" after the existing text for connectivity to the IEX feed is equitable, as it would clarify which IEX data feed was referenced, therefore making the Fee Schedule easier to read and understand and alleviating any possible market participant confusion caused by the current text.

The Exchange believes that the proposed fee for connectivity to the Proposed Third Party Data Feed is an equitable allocation of fees. The proposed fee is the same as the existing fee for connectivity to IEX Equities.

Without this proposed rule change, Users would have fewer options for connectivity to the Proposed Third Party Data Feed, once that feed becomes available. By offering Connectivity, the Exchange gives each User additional options for addressing its needs, responding to User demand for options. Offering these additional services would help each User tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of

²² Note that in the case of wireless connectivity, a User in colocation still requires a fiber circuit to transport data. If a Telecom is used, the data is transmitted wirelessly to the relevant pole, and then from the pole to the meet-me-room using a fiber circuit.

²³ See Securities Exchange Act Release No. 97998 (July 26, 2023), 88 FR 50238 (August 1, 2023) (SR-NYSE-2023-27) ("MMR Notice").

²⁴ See *id.* at 50241. Importantly, the Exchange is prevented from making any alteration to its meet-me-room services or fees without filing a proposal for such changes with the Commission.

²⁵ See Wireless Approval Order, *supra* note 17.

²⁶ See *supra* note 10.

²⁷ See *id.*

connectivity that best suits its needs. Users that do not opt to utilize the Exchange's proposed Connectivity would still be able to connect to the Proposed Third Party Data Feed using Telecoms.

The Exchange believes that the proposed change is equitable because it will result in fees being charged only to Users that voluntarily select to receive the corresponding services and because those services will be available to all Users.

Furthermore, the Exchange believes that the services and fees proposed herein are equitably allocated because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.*, the same products and services are available to all Users). All Users that voluntarily select the Exchange's Connectivity would be charged the same amount for the same services. Users who opt not to use Connectivity would not be charged. In this way, the proposed rule change equitably allocates the proposed fees only to Users who choose to use the Exchange's Connectivity.

The Proposed Change Is Not Unfairly Discriminatory

The Exchange believes that the proposed rule change is not unfairly discriminatory, for the following reasons.

The Exchange believes that the proposed changes to the Cboe Data Feeds are not unfairly discriminatory because the monthly recurring connectivity fee for each Cboe Data Feed would remain the same as they are now. However, under the proposed change, if a User wanted all Cboe U.S. Equities data, Cboe Options data or Cboe indices data it would not have to sign up for connectivity to more than one Third Party Data Feed.

Without this proposed rule change, Users would have fewer options for connectivity to the Proposed Third Party Data Feed. The proposed change would provide Users with an additional choice with respect to the form and optimal latency of their connectivity to the Proposed Third Party Data Feed, allowing a User to select the connectivity that better suits its needs, helping it tailor its colocation operations to the requirements of its business operations. Users that do not opt to utilize the Exchange's proposed Connectivity would still be able to connect to the Proposed Third Party Data Feed using Telecoms.

The Exchange believes that the proposed change is not unfairly discriminatory because it will result in fees being charged only to Users that

voluntarily select to receive the corresponding services and because those services will be available to all Users. Furthermore, the Exchange believes that the services and fees proposed herein are not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.*, the same products and services are available to all Users). All Users that voluntarily select the Exchange's Connectivity would be charged the same amount for the same services.

For all these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,²⁸ the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change would not affect competition among national securities exchanges or among members of the Exchange, but rather between FIDS and its commercial competitors.

The Exchange does not believe that the proposed rule change regarding Cboe Data Feeds will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The monthly recurring connectivity fee for each Cboe Data Feed would remain the same as it is now. However, under the proposed change, if a User wanted all Cboe U.S. Equities data, Cboe Options data or Cboe indices data it would not have to sign up for connectivity to more than one Third Party Data Feed. The other changes to the Cboe Data Feeds would not affect competition.

By offering Connectivity, the Exchange would give each User additional options for addressing its needs, responding to User demand for options. Providing additional services would help each User tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of connectivity that best suits its needs. Users that do not opt to utilize the Exchange's proposed Connectivity would still be able to connect to the Proposed Third Party Data Feed using Telecoms.

The Exchange does not believe that FIDS would have any competitive advantage over Users that establish independent connectivity to the

Proposed Third Party Data Feed. The Exchange's proposed service for Connectivity does not have (a) any special access to the Proposed Third Party Data Feed or (b) advantage within the MDC, as all distances in the MDC are normalized.

Moreover, the Exchange does not believe that FIDS would have any competitive advantage because it would charge for connectivity only, not the Proposed Third Party Data Feed itself. All Users that connect to the Proposed Third Party Data Feed, whether they elect to connect using the Exchange's proposed service or not, would have to pay a third party for the Proposed Third Party Data Feed.

Nor does the Exchange believe that FIDS has a competitive advantage over any third-party competitors offering connectivity by virtue of the fact that ICE owns and operates the MDC's meet-me-rooms. Users purchasing Connectivity—like Users of any other colocation service—would require a circuit connecting out of the MDC, and in most cases, such circuits are provided by third-party Telecoms. Currently, 17 Telecoms operate in the meet-me-rooms and provide a variety of circuit choices. It is in the Exchange's best interest to set the fees that Telecoms pay to operate in the meet-me-rooms at a reasonable level²⁹ so that market participants, including Telecoms, will maximize their use of the MDC. By setting the meet-me-room fees at a reasonable level, the Exchange encourages Telecoms to participate in the meet-me-rooms and to sell circuits to Users for connecting into and out of the MDC. These Telecoms then compete with each other by pricing such circuits at competitive rates. These competitive rates for circuits help draw in more Users and Hosted Customers to the MDC, which directly benefits the Exchange by increasing the customer base to whom the Exchange can sell its colocation services, which include cabinets, power, ports, and connectivity to many third-party data feeds, and because having more Users and Hosted Customers leads, in many cases, to greater participation on the Exchange. In this way, by setting the meet-me-room fees at a level attractive to telecommunications firms, the Exchange spurs demand for all of the services it sells at the MDC, while setting the meet-me-room fees too high would negatively affect the Exchange's ability to sell its services at the MDC.³⁰ Accordingly, there are real constraints on the meet-me-room fees the Exchange charges, such that the Exchange does not have an

²⁹ See MMR Notice, *supra* note 23.

³⁰ See *supra* note 24.

²⁸ 15 U.S.C. 78f(b)(8).

advantage in terms of costs when compared to third parties that enter the MDC through the meet-me-rooms to provide services to compete with the Exchange's services.

If anything, the Exchange would be subject to a competitive disadvantage vis-à-vis Users regarding connectivity to the Proposed Third Party Data Feed. Users that choose to independently establish connectivity may negotiate terms with the Telecoms or other Users through whom such connectivity is delivered, in response to competitive forces. Such prices are not required to be filed by any party with the Commission. In contrast, the Exchange's service and pricing would be standardized as set out in this filing, and the Exchange would be unable to respond to pricing pressure from its competitors without seeking a formal fee change in a filing before the Commission.

The changes would not put any market participants at a relative disadvantage compared to other market participants or penalize one or more categories of market participants in a manner that would impose an undue burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³¹ and Rule 19b-4(f)(6) thereunder.³² Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act³³ and Rule 19b-4(f)(6)³⁴ thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)³⁵ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSE-2026-32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSE-2026-32. 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-NYSE-2026-32 and should be submitted on or before July 28, 2026.

at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³⁵ 15 U.S.C. 78s(b)(2)(B).

³⁶ 17 CFR 200.30-3(a)(12).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-13649 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105837; File No. SR-TXSE-2026-006]

Self-Regulatory Organizations; Texas Stock Exchange LLC; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Amend Certain Parts of Its Opening and Closing Auctions

July 1, 2026.

On April 17, 2026, Texas Stock Exchange LLC (the "Exchange" or "TXSE") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² a proposed rule change to amend certain parts of its opening and closing auctions. The proposed rule change was published for comment in the **Federal Register** on April 29, 2026.³ On June 10, 2026, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On June 30, 2026, the Exchange filed Amendment No. 1 to the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. Amendment No. 1 superseded the proposed rule change as originally filed and replaced it in its entirety. The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend certain parts of its Opening and

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 105309 (Apr. 24, 2026), 91 FR 23128.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 105654, 91 FR 36019 (Jun. 15, 2026). The Commission designated July 28, 2026, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

³¹ 15 U.S.C. 78s(b)(3)(A)(iii).

³² 17 CFR 240.19b-4(f)(6).

³³ 15 U.S.C. 78s(b)(3)(A).

³⁴ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change,

Closing Auctions, as further described below.

The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is available on the Commission's website (<https://www.sec.gov/rules/sro.shtml>) at the Exchange's website (<https://txse.com/rule-filings>), 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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

This Amendment No. 1 to SR-TXSE-2026-006 amends and replaces in its entirety the proposal as originally submitted on April 17, 2026. The Exchange submits this Amendment No. 1 in order to clarify certain points and add additional details to the proposal regarding the Participation Bands.

The Exchange proposes to amend Rule 11.022 to make certain changes to its Opening⁶ and Closing Auctions⁷ to enhance the price discovery process and make the Exchange's auction process more robust. Specifically, the Exchange is proposing to make changes to its late limit order types, Late-Limit-On-Close ("LLOC")⁸ and Late-Limit-On-Open

("LLOO" and, collectively with LLOC, "Late Auction Orders")⁹ as currently described under Rule 11.022(a)(11) and (12), respectively, such that they will be constrained by recent transaction- and/or quotation-based calculations (described more fully below as "Participation Bands") rather than by the NBBO. The Exchange is also proposing to: (i) change the time that LOC,¹⁰ MOC,¹¹ and LLOC orders can be submitted to the Exchange and prevent LOC, MOC, and LLOC orders from being amended or cancelled after 3:58 p.m. and to prevent Regular Hours Only ("RHO")¹² orders from being modified between 9:28 a.m. and 9:30 a.m.; (ii) change the information related to Opening and Closing Auctions that is disseminated prior to the auction; (iii) add an additional tiebreaker step to the waterfall it uses to break ties in determining the TXSE Official Opening

⁹ As provided in Rule 11.022(a)(12), the term "Late-Limit-On-Open" or "LLOO" means a TXSE limit order that is designated for execution only in the Opening Auction. To the extent a LLOO bid or offer received by the Exchange has a limit price that is more aggressive than the NBB or NBO, the price of such bid or offer is adjusted to be equal to the NBB or NBO, respectively, at the time of receipt by the Exchange. Where the NBB or NBO becomes more aggressive, the limit price of the LLOO bid or offer will be adjusted to the more aggressive price, only to the extent that the more aggressive price is not more aggressive than the original User entered limit price. The limit price will not be adjusted to a less aggressive price, unless otherwise provided by Exchange Rules. If there is no NBB or NBO, the LLOO bid or offer, respectively, will assume its entered limit price. Notwithstanding the foregoing, a LLOO order entered during the Quote-Only Period of an IPO will be converted to a limit order with a limit price equal to the original User entered limit price and any LLOO orders not executed in their entirety during the IPO Auction will be cancelled upon completion of the IPO Auction.

¹⁰ As provided in Rule 11.022(a)(13), the term "Limit-On-Close" or "LOC" means a TXSE limit order that is designated for execution only in the Closing Auction.

¹¹ As provided in Rule 11.022(a)(15), the term "Market-On-Close" or "MOC" means a TXSE market order that is designated for execution only in the Closing Auction.

¹² As defined in Rule 11.006(o)(5), RHO means an instruction a User may attach to an order stating that an order to buy or sell is designated for execution only during Regular Trading Hours which includes the Opening Auction, the Closing Auction and IPO/Halt Auctions for TXSE-Listed securities and the Opening Process for non-TXSE-Listed securities (as such terms are defined in TXSE Rules 11.022 and 11.023) and, if not executed, expires at the end of Regular Trading Hours. Any order with a TIF instruction of RHO entered into the System after the closing of Regular Trading Hours will be rejected. Any portion of a market RHO order will be cancelled immediately following any auction in which it is not executed.

Price,¹³ TXSE Official Closing Price,¹⁴ and to the Auction Only Price;¹⁵ and (iv) change the name of LLOC and

¹³ As provided in Rule 11.022(b)(2)(B), the Opening Auction price will be established by determining the price level within the Collar Price Range that maximizes the number of shares executed between the Continuous Book and Auction Book in the Opening Auction. In the event of a volume based tie at multiple price levels, the Opening Auction price will be the price which results in the minimum total imbalance. In the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Opening Auction price will be the price closest to the Volume Based Tie Breaker. The Opening Auction price will be the TXSE Official Opening Price. In the event that there is no Opening Auction for an issue, the TXSE Official Opening Price will be the price of the Final Last Sale Eligible Trade, which will be the previous TXSE Official Closing Price. As provided in Rule 11.022(a)(6), the term "Collar Price Range" shall mean the range from a set percentage below the Collar Midpoint (as defined below) to above the Collar Midpoint, such set percentage being dependent on the value of the Collar Midpoint at the time of the auction, as described below. The Collar Midpoint will be the Volume Based Tie Breaker for all applicable auctions, except for IPO Auctions (as defined below) in exchange traded products ("ETPs"), for which the Collar Midpoint will be the issue price. Specifically, the Collar Price Range will be determined as follows: where the Collar Midpoint is \$25.00 or less, the Collar Price Range shall be the range from 10% below the Collar Midpoint to 10% above the Collar Midpoint; where the Collar Midpoint is greater than \$25.00 but less than or equal to \$50.00, the Collar Price Range shall be the range from 5% below the Collar Midpoint to 5% above the Collar Midpoint; and where the Collar Midpoint is greater than \$50.00, the Collar Price Range shall be the range from 3% below the Collar Midpoint to 3% above the Collar Midpoint. As provided in current Rule 11.022(a)(22), the term "Volume Based Tie Breaker" shall mean the midpoint of the NBBO for a particular security where the NBBO is a Valid NBBO. A NBBO is a Valid NBBO where: (i) there is both a NBB and NBO for the security; (ii) the NBBO is not crossed; and (iii) the midpoint of the NBBO is less than the "Maximum Percentage" away from both the NBB and the NBO. The "Maximum Percentage" will be determined by the Exchange and will be published in a circular distributed to Members with reasonable advance notice prior to initial implementation and any change thereto. Where the NBBO is not a Valid NBBO, the price of the Final Last Sale Eligible Trade will be used.

¹⁴ As provided in Rule 11.022(c)(2)(B), the Closing Auction price will be established by determining the price level within the Collar Price Range that maximizes the number of shares executed between the Continuous Book and Auction Book in the Closing Auction. In the event of a volume based tie at multiple price levels, the Closing Auction price will be the price which results in the minimum total imbalance. In the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Closing Auction price will be the price closest to the Volume Based Tie Breaker.

¹⁵ As provided in current Rule 11.022(a)(2), the term "Auction Only Price" means the price at which the most shares from the Auction Book would match. In the event of a volume based tie at multiple price levels, the Auction Only Price will be the price which results in the minimum total imbalance. In the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Auction Only Price will be the price closest to the Volume Based Tie Breaker (as defined below).

⁶ The Exchange's Opening Auction is described in Rule 11.022(b).

⁷ The Exchange's Closing Auction is described in Rule 11.022(c).

⁸ As provided in Rule 11.022(a)(11), the term "Late-Limit-On-Close" or "LLOC" means a TXSE limit order that is designated for execution only in the Closing Auction. To the extent a LLOC bid or offer received by the Exchange has a limit price that is more aggressive than the NBB or NBO, the price of such bid or offer is adjusted to be equal to the NBB or NBO, respectively, at the time of receipt by the Exchange. Where the NBB or NBO becomes more aggressive, the limit price of the LLOC bid or offer will be adjusted to the more aggressive price, only to the extent that the more aggressive price is not more aggressive than the original User entered limit price. The limit price will not be adjusted to a less aggressive price, unless otherwise provided by Exchange Rules. If there is no NBB or NBO, the LLOC bid or offer, respectively, will assume its entered limit price.

LLOO orders to “Limit-On-Close-Late” or “LOC.L” orders and “Limit-On-Open-Late” or “LOO.L.” The Exchange is also proposing to make one clarifying change to Rule 11.022(c)(2)(B) and to make corresponding renumbering changes to Rule 11.022(a). While the analysis below largely focuses on closing auctions, the Exchange believes that the points raised apply equally to opening auctions.

Overview

Currently, between 9:28 a.m. and 9:30 a.m. and 3:59 p.m. and 4:00 p.m. Users¹⁶ can submit Late Auction Orders for participation in the Opening Auction and Closing Auction, respectively. To the extent that such a Late Auction Order is priced more aggressively than the NBB¹⁷ (for bids) or NBO (for offers), the price of such Late Auction Order bids and offers will be the NBB and NBO. Where the NBB or NBO becomes more aggressive, the limit price of the Late Auction Order bid or offer will be adjusted to the more aggressive price, only to the extent that the more aggressive price is not more aggressive than the original User entered limit price. The limit price will not be adjusted to a less aggressive price, unless otherwise provided by Exchange Rules. If there is no NBB or NBO, the Late Auction Order bid or offer, respectively, will assume its entered limit price.

Because Late Auction Orders are the only Eligible Auction Order¹⁸ that can be submitted after 9:28 a.m. and 3:59 p.m. and are constrained to the less aggressive side of the NBBO, the current Late Auction Order functionality limits Users’ ability to enter marketable orders at a time critical to price formation and price discovery. Late Auction Order functionality also prevents liquidity

providers from being able to support auction liquidity within the NBBO, which can lead to auction volatility, especially in securities with wider spreads. Finally, Late Auction Order functionality also creates uncertainty around executions in the Opening and Closing Auctions which hinders hedging activity for liquidity providers. As noted above, this inability to provide liquidity in Opening and Closing Auctions can result in significant price swings around the open and close and into the Opening and Closing Auctions.

Proposed Changes

As such, the Exchange is proposing to make several changes to its Opening and Closing Auctions. Specifically, the Exchange is proposing to change the functionality of Late Auction Orders such that they are constrained by the Participation Bands,¹⁹ a dynamic price

band applied on a security-by-security basis that is based on quotes and/or trades in the applicable TXSE-listed security, instead of the NBBO.²⁰ At a high level, the midpoint of the Participation Bands will be the median of all of the prices in the Observation Window (the “Participation Bands Midpoint”) and the width of the Participation Bands will be the median of all of the absolute differences between the prices in the Observation Window and the Participation Bands Midpoint multiplied by k . The Participation Bands are thus self-calibrating—both the midpoint and width are derived from the security’s own recent market activity, producing a narrow Participation Band for less volatile securities and a wider Participation Band for more volatile ones. The Exchange will apply objective Quality Gates²¹ to trade and quote data

¹⁹ The term “Participation Bands” shall mean a dynamic upper and lower price band within the Collar Price Range that are calculated on a security-by-security basis that is based on quotes and/or trades in the applicable TXSE-listed security. The Exchange will establish Participation Bands using the following formula: $\text{median}(P) \pm k \times \text{MAD}(P)$, where P represents eligible event prices within the Observation Window, $\text{median}(P)$ is their median (the “Participation Bands Midpoint”), $\text{MAD}(P)$ is the median absolute deviation of the series of eligible event prices within the Observation Window defined as $\text{median}(|P_i - \text{median}(P)|)$, and k is a multiplier determining the half-width of the Participation Bands. The “Observation Window” means the trailing period over which eligible events (*i.e.*, trades and/or NBBO midpoint changes) are collected. The Observation Window may be set by a number of events and/or a period of time (*e.g.*, the Observation Window could include up to the most recent 500 events, all events over the preceding five minutes, or up to the most recent 500 events that occurred within the preceding 5 minutes). The Observation Window will use the following events: (1) eligible trade prices within the Observation Window (the “Trade Method”); (2) if trade data are insufficient or do not satisfy the applicable quality gates (“Quality Gates”), NBBO midpoint observations within the Observation Window, where each midpoint is defined as $(\text{NBB} + \text{NBO})/2$ each time the NBBO changes (the “Quote Method”); or (3) if NBBO midpoint observations are also insufficient or do not satisfy the applicable Quality Gates, a Reference Price will be used as the Participation Bands Midpoint and the Participation Bands will be set using the Reference Price Width Percentage (the “Reference Price Method”). When the Reference Price Method is used, the Reference Price will be determined according to an objective process which includes only: the median eligible trade price, median eligible NBBO midpoint, volume-weighted average price, last eligible sale, prior official closing price, or an approximated net asset value calculation for ETPs. The Reference Price process will be set forth in the circular distributed to Members described below and may be changed via notice on the Exchange website and in a circular provided to Members at least 5 business days prior to the effective date. The Participation Bands will never be narrower than the Minimum Half-Width, defined as the greater of a multiple of the symbol’s minimum price variation (“MPV Floor”) and a basis-point percentage of the Participation Bands Midpoint (“Basis Point Floor”). The Maximum Half-Width will act as a percentage limit on how far the Participation Bands can be

from the Participation Bands Midpoint. The Participation Bands are recalculated and disseminated at regular intervals during the auction period (the “Recalculation Interval”). The Exchange will determine the specific parameters, formulas, and values applicable to the calculation of the Participation Bands and all other details necessary for calculation and reproduction of the Participation Bands and any subsequent changes thereto in a circular distributed to Members. Permissible ranges for such values are as follows: Observation Window, 2 to 30 minutes; Recalculation Interval, 1 to 5 seconds; minimum trade count for Trade Method, 20 to 200; minimum midpoint count for Quote Method, 20 to 500; Trade Method k , 1.0 to 10.0; minimum notional value of trades, \$0 to \$1,000,000; Quote Method k , 1.0 to 10.0; Reference Price Width Percentage, 0.50% to 2.50% per side; Minimum Half-Width: MPV Floor, 3 to 10 times minimum price variation; Basis Point Floor, 1 to 25 basis points of Participation Bands Midpoint; Maximum Half-Width, 1.0% to 5.0% per side. The lower priced side of the Participation Bands is the “Lower Band” and the higher priced side of the Participation Bands is the “Upper Band.” The Exchange will provide notice to its Members of any changes to the Quality Gate thresholds, the Reference Price process and calculation, or any of the values above on its website and in a circular to Members at least 5 business days prior to the effective date; provided, however, that reductions to Trade Method k , Quote Method k , Reference Price Width Percentage, or Maximum Half-Width, which would generally result in narrower Participation Bands, require notice only 1 business day prior to the effective date. The Exchange will establish the formulas and values, along with all other details described above, in a circular distributed to Members no fewer than 30 calendar days prior to initial implementation.

²⁰ The Participation Bands remain subject to any applicable auction collar or other auction restrictions or risk controls established by Exchange rules.

²¹ Quality Gates for the Trade Method include only: minimum trade count, minimum notional value of trades, and the exclusion of all erroneous, cancelled, corrected, late-reported, or non-regular-way trades. Quality Gates for the Quote Method will include only: exclusion of crossed, locked, one-sided, stale, or extremely wide NBBO observations and minimum midpoint value count. Specific Quality Gate thresholds will be set forth in the circular distributed to Members described above

Continued

¹⁶ As provided in Rule 1.005(jj), the term “User” means any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to TXSE Rule 11.003.

¹⁷ As provided in Rule 1.005(jj), the terms “National Best Bid” and “NBB” mean the national best bid; the terms “National Best Offer” and “NBO” shall mean the national best offer; and the term “NBBO” shall mean the national best bid or offer.

¹⁸ As provided in current Rule 11.022(a)(8), the term “Eligible Auction Order” means any MOO, LOO, LLOO, MOC, LOC or LLOC order (each as defined below) that is entered in compliance with its respective cutoff for an Opening Auction (as defined below) or Closing Auction (as defined below), any RHO order prior to the Opening Auction, any limit or market order not designated to exclusively participate in the Closing Auction entered during the Quote-Only Period (as defined below) of an IPO Auction subject to the below restrictions, and any limit or market order not designated to exclusively participate in the Opening Auction or Closing Auction entered during the Quote-Only Period of a Halt Auction (as defined below).

before inclusion in the Observation Window.²²

This proposed functionality will allow Late Auction Orders to be entered at prices that are more likely to be able to participate in the Opening and Closing Auction than current functionality while at the same time still constraining a Late Auction Order's limit price to mitigate volatility around the Opening and Closing Auction.²³ The Exchange is also proposing to make several changes related to cut-off times, the ability to modify Auction Eligible Orders, the way that tiebreakers are applied, the data disseminated prior to the Opening and Closing Auction, and to refer to LLOO orders as "Limit-On-Open-Late" or "LOO.L" orders and LLOC orders as "Limit-On-Close-Late" or "LOC.L" orders.

In order to accomplish these changes, the Exchange proposes to amend the definition of LLOO and LLOC under Rule 11.022(a)(12) and (11), respectively, to reflect that the names are changing to LOO.L and LOC.L, respectively. Late Auction Orders continue to represent TXSE limit orders that are designated for execution only in the Opening or Closing Auction, as applicable. Late Auction Orders cannot be amended or cancelled after entry. To the extent that Late Auction Order bids and offers received by the Exchange have a limit price that is more aggressive than the Upper Band or Lower Band, respectively, immediately prior to the Opening or Closing Auction, as applicable, the price of such bid or offer is adjusted to be equal to the Upper Band or Lower Band, respectively.

The Exchange is also proposing to change the information that it disseminates before the Opening and Closing Auction. Rule 11.022(b)(2)(A) currently provides that beginning at 8:00 a.m. and disseminated every five seconds thereafter, the Reference Price, Indicative Price, Auction Only Price, Reference Buy Shares, and Reference Sell Shares associated with the Opening Auction will be disseminated via electronic means until the Opening Auction occurs. Similarly, Rule 11.022(c)(2) currently provides that

and may be changed via notice on the Exchange website and in a circular provided to Members at least 5 business days prior to the effective date.

²² The Exchange will not make changes that are not explicitly contemplated herein until and unless it submits a rule filing pursuant to Section 19(b) of the Securities Exchange Act of 1934 that becomes effective and operative.

²³ As further discussed below, the Exchange believes that this functionality, combined with several of the Exchange's other rule changes proposed herein, will help enhance liquidity in the Opening and Closing Auctions while also mitigating volatility.

beginning at 3:00 p.m. and updated every five seconds thereafter, the Reference Price, Indicative Price, Auction Only Price, Reference Buy Shares, and Reference Sell Shares associated with the Closing Auction will be disseminated via electronic means until the Closing Auction occurs. The Exchange is instead proposing to disseminate information related to the Opening and Closing Auction in two separate periods: first, the Exchange will disseminate Matched Shares²⁴ and the Offset Side²⁵ associated with the applicable auction every five seconds between 8:00 a.m. and 9:28 a.m. for Opening Auctions and between 3:00 p.m. and 3:58 p.m. for Closing Auctions; beginning at 9:28 a.m. for Opening Auctions and 3:58 p.m. for Closing Auctions, the Exchange will disseminate the Participation Bands, the Lower Band Auction Interest,²⁶ and the Upper Band Auction Interest.²⁷ Such data will be updated no less frequently than every five seconds. The Lower Band Auction Interest and Upper Band Auction Interest provide participants with visibility into buy and sell interest at the boundaries of the Participation Bands. By comparing quantities at each boundary and observing how those quantities change, participants can assess the relative balance of supply and demand within the band. This informs decisions about the size, direction, and pricing of any Late Auction Orders or Continuous Book²⁸ interest they may wish to enter during the final two minutes of trading.²⁹

²⁴ As proposed in Rule 11.022(a)(18), the term "Matched Shares" means the number of shares that would match at the Auction Only Price.

²⁵ As proposed in Rule 11.022(a)(19), the term "Offset Side" means the side (either Buy, Sell, or Equal) for which there are more shares available if a Closing Auction took place at the Auction Only Price. Where there are the same number of shares on the buy side and the sell side, the Offset Side will be "Equal".

²⁶ As proposed in Rule 11.022(a)(15), the term "Lower Band Auction Interest" means the number of Eligible Auction Order shares to buy that are priced equal to or more aggressively than the Lower Band and the number of Eligible Auction Order shares to sell that are priced equal to or more aggressively than the Lower Band.

²⁷ As proposed in Rule 11.022(a)(26), the term "Upper Band Auction Interest" means the number of Eligible Auction Order shares to buy that are priced equal to or more aggressively than the Upper Band and the number of Eligible Auction Order shares to sell that are priced equal to or more aggressively than the Upper Band.

²⁸ As defined in Rule 11.022(a)(7), the term "Continuous Book" means all orders on the TXSE Book that are not Eligible Auction Orders.

²⁹ These data points are designed to provide market makers and LMMs with the information necessary to make informed decisions about providing liquidity in the Opening and Closing Auctions. Specifically, the dissemination of Matched Shares and the Offset Side beginning at 8:00 a.m. and 3:00 p.m. enables liquidity providers

The Exchange is also proposing to amend Rule 11.022(c)(1)(A) and (B) in order to provide that LOC and MOC orders may be submitted until 3:58 p.m. instead of 3:59 p.m., that LOC.L orders (formerly LLOC orders) can be submitted starting at 3:58 p.m. instead of 3:59 p.m., and that Eligible Auction Orders may not be modified or cancelled after 3:58 p.m. whereas they were previously non-cancellable after 3:59 p.m. and could be modified any time prior to the Closing Auction. Similarly, the Exchange is proposing to delete text in Rule 11.022(b)(1)(B) to provide that RHO orders cannot be modified or cancelled between 9:28 a.m. and 9:30 a.m. in order to ensure consistent treatment across Eligible Auction Orders in the Opening Auction. The Exchange is proposing these changes in order to both align the functionality across its Opening and Closing Auctions and to create a longer period before an auction in which Eligible Auction Orders cannot be cancelled or modified, providing greater certainty around the liquidity available in Exchange auctions in support of price formation. The Exchange is not proposing to make any equivalent changes for MOO, LOO, or LOO.L orders in Opening Auctions because the Opening Auction rules already reflect this same functionality beginning at 9:28 a.m. (two minutes before the Opening Auction occurs).

The Exchange is also proposing to add one additional step to the waterfall that it uses to break ties in determining the TXSE Official Opening Price, TXSE Official Closing Price, and Auction Only Price. Currently, Rule 11.022(c)(2)(B) provides that the Closing Auction price will be established by: (i) determining the price level within the Collar Price Range that maximizes the number of shares executed between the Continuous Book and Auction Book³⁰ in the Closing Auction; (ii) in the event of a volume based tie at multiple price levels, the Closing Auction price will be the price which results in the minimum total imbalance; and (iii) in the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Closing Auction price

to assess the direction and magnitude of order flow, while the dissemination of the Participation Bands, Lower Band Auction Interest, and Upper Band Auction Interest beginning at 9:28 a.m. and 3:58 p.m. enables them to calibrate the pricing and size of Late Auction Orders within the constraints of the band. Together, these data points reduce the informational uncertainty that might otherwise discourage liquidity provision in the Exchange's Opening and Closing Auction processes.

³⁰ As defined in Rule 11.022(a)(1), the term "Auction Book" means all Eligible Auction Orders (as defined below) on the TXSE Book.

will be the price closest to the Volume Based Tie Breaker. The Opening Auction has an identical tie-breaking waterfall.³¹ The Exchange is proposing to add a new step to this process before step (iii) which states that “in the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Closing Auction price will be the entered price at which shares will remain unexecuted in the Closing Auction.” If more than one price exists under this new step (iii), the Closing

Auction price would then be the price closest to the Volume Based Tie Breaker. The Exchange notes that this proposed change is substantively identical to Nasdaq Rule 4754(b)(2)(C) with respect to its closing auction. The Exchange is proposing to make equivalent changes to the Opening Auction under Rule 11.022(b)(2)(B) and the definition of Auction Only Price in Rule 11.022(a)(2).

Examples

The following examples are based on the Closing Auction and Closing Auction orders, including MOC, LOC, and LOC.L, but the same scenarios in the Opening Auction with MOO, LOO, and LOO.L orders would yield identical results.

Example 1 (Data Calculation and LOC.L Basics): Below is a snapshot of the Auction Book and Continuous Book immediately prior to 3:58:00 p.m. where the Volume Based Tie Breaker is \$50.10.

AUCTION BOOK PRIOR TO 3:58:00 P.M

Time	Order	Side	Type	Limit	Shares
3:05:00	Order A	Sell	MOC	N/A	4,000
3:30:00	Order B	Buy	LOC	\$50.10	2,000

CONTINUOUS BOOK

Time	Order	Side	Type	Limit	Shares
3:55:15	Order C	Buy	Displayed Limit	\$50.00	2,000
3:57:00	Order D	Sell	Displayed Limit	50.10	4,000

Before 3:58 p.m. the Exchange is proposing to disseminate Matched Shares and Offset Side every five seconds, both of which are calculated based on the Auction Only Price³² at that time. Based on the above Auction Book, the Auction Only Price would be \$50.10 and 2,000 shares would execute.³³ This means that the Exchange would disseminate a Matched Shares of 2,000 and an Offset Side of Sell.

LOC.L Orders Entered After 3:58:00 p.m.

At 3:58:00 p.m. all Eligible Auction Orders (MOCs and LOCs) may no longer be modified or cancelled and LOC.L Orders are the only Eligible Auction Orders that can be entered. As described above, the Exchange is proposing that such LOC.L orders can be entered at their limit price without restriction but

cannot be modified or cancelled. Immediately prior to the Closing Auction, LOC.L bids and offers that have a limit price that is more aggressive than the Upper Band or Lower Band, respectively, will be adjusted to be equal to the Upper Band or Lower Band, respectively.

For purposes of this example, the Participation Bands are \$49.80 × \$50.20.

Time	Order	Side	Type	Limit	Shares
3:59:00	Order E	Buy	LOC.L	\$50.10	5,000
3:59:30	Order F	Sell	LOC.L	49.00	2,000

At 3:58:00 p.m., the Exchange will also start calculating and disseminating the following values no less frequently than every five seconds: (i) the Participation Bands (which includes both the Lower Band and the Upper Band); (ii) the Lower Band Auction Interest (which includes both the buy shares and the sell shares); (iii) and the Upper Band Auction Interest (which

also includes both the buy shares and the sell shares.

The Lower Band Auction Interest buy shares includes all bids that are Eligible Auction Orders priced more aggressively than the Lower Band (\$49.80). At 3:58, the Lower Band Auction Interest buy shares is calculated as follows: Order B (2,000 shares at \$50.10) = 2,000 shares. When Order E

(5,000 shares at \$50.10) comes in at 3:59:00, Lower Band Auction Interest buy shares would increase to 7,000 shares.

The Lower Band Auction Interest sell shares includes all offers that are Eligible Auction Orders priced more aggressively than the Lower Band (\$49.80). At 3:58, the Lower Band Auction Interest sell shares is calculated

³¹ See Exchange Rule 11.022(b)(2)(B).

³² As defined in proposed amended Rule 11.022(a)(2), the term “Auction Only Price” means the price at which the most shares from the Auction Book would match. In the event of a volume based tie at multiple price levels, the Auction Only Price will be the price which results in the minimum total imbalance. In the event of a volume based tie and a tie in minimum total imbalance at multiple price levels, the Closing Auction price will be the entered price at which shares will remain unexecuted in the Closing Auction. In the event of

a volume based tie, a tie in minimum total imbalance, and a tie in shares unexecuted at multiple price levels, the Auction Only Price will be the price closest to the Volume Based Tie Breaker (as defined below).

³³ This calculation provides an example of the proposed new tie breaker language in Rule 11.022(a)(2). In determining the Auction Only Price as proposed, 2,000 shares would execute at each price level below \$50.10 with an imbalance of 2,000 shares. In the event of a volume-based tie at multiple price levels and a tie in minimum total

imbalance at multiple price levels, the Auction Only Price will be the entered price at which shares will remain unexecuted. Here, there are no price levels at which an entered price will have unexecuted shares (Order B executes fully and Order A has no entered price), so the Auction Only Price will be the price closest to the Volume Based Tie Breaker. Because the Volume Based Tie Breaker is \$50.10, the Auction Only Price would be \$50.10 and because there are 2,000 buy shares and 4,000 sell shares at \$50.10, the Offset Side would be “Sell.”

as follows: Order A (4,000 shares at market) = 4,000 shares. When Order F (2,000 shares at \$49.00) comes in at 3:59:30, Lower Band Auction interest sell shares would increase to 6,000 shares.

The Upper Band Auction Interest buy shares includes all bids that are Eligible Auction Orders priced more aggressively than the Upper Band (\$50.20). At 3:58, the Upper Band

Auction Interest buy shares is calculated as follows: no Eligible Auction Orders to buy priced more aggressively than \$50.20 = 0 shares. There are no subsequent LOC.L buy orders priced more aggressively than \$50.20, so there are no changes to the Upper Band Auction Interest buy shares.

The Upper Band Auction Interest sell shares includes all offers that are Eligible Auction Orders priced more

aggressively than the Upper Band (\$50.20). At 3:58, the Upper Band Auction Interest sell shares is calculated as follows: Order A (4,000 shares at market) = 4,000 shares. When Order F (2,000 shares at \$49.00) comes in at 3:59:30, Upper Band Auction interest sell shares would increase to 6,000 shares.

Complete Order Book Immediately Prior to Closing Auction Sorted by Priority

Time	Order	Side	Type	Limit	Shares
3:05:00	Order A	Sell	MOC	N/A	4,000
3:59:30	Order F	Sell	LOC.L	\$49.00	2,000
3:57:00	Order D	Sell	Displayed Limit	50.10	4,000

Time	Order	Side	Type	Limit	Shares
3:59:00	Order E	Buy	LOC.L	\$50.10	5,000
3:30:00	Order B	Buy	LOC	50.10	2,000
3:55:15	Order C	Buy	Displayed Limit	50.00	2,000

Immediately prior to the beginning of the Closing Auction process, LOC.L bids and offers that have a limit price more aggressive than the Upper Band or Lower Band, respectively, will be adjusted to be equal to the Upper Band or Lower Band, respectively. Here, there

are two LOC.L orders: Order E and Order F. Order F is a sell order with a limit price of \$49.00, which is more aggressive than the Lower Band of \$49.80, so it will be adjusted to a limit price of \$49.80 for participation in the Closing Auction. Order E is a buy order

with a limit price of \$50.10, which is less aggressive than the Upper Band of \$50.20, so it will not be adjusted and will participate in the Closing Auction with a limit price of \$50.10.

Complete Order Book for Closing Auction Sorted by Priority

Time	Order	Side	Type	Limit	Shares
3:05:00	Order A	Sell	MOC	N/A	4,000
3:59:30	Order F	Sell	LOC.L	\$49.80	2,000
3:57:00	Order D	Sell	Displayed Limit	\$50.10	4,000

Time	Order	Side	Type	Limit	Shares
3:59:00	Order E	Buy	LOC.L	\$50.10	5,000
3:30:00	Order B	Buy	LOC	50.10	2,000
3:55:15	Order C	Buy	Displayed Limit	50.00	2,000

Based on the above combined Auction Order Book and Continuous Order Book, 4,000 shares would execute at every price up to \$49.79, 6,000 shares would execute between \$49.80 and \$50.09, 7,000 shares would execute at \$50.10, and 0 shares would execute above \$50.10. Based on the logic in Rule 11.022(c)(2)(B), which provides that the Closing Auction will occur at the price

level within the Collar Price Range³⁴ that maximizes the number of shares executed between the Continuous Book and Auction Book, the Closing Auction would occur at \$50.10.

In this instance, the adjustment of Order F did not impact the price of the Closing Auction because the most shares that could execute would have been at \$50.10 (still 7,000 shares) even

if the LOC.L was priced at \$49.00 (would have been 6,000 shares at each price level between \$49.00 and \$50.09 instead of \$49.80 and \$50.09).

Example 2 (Participation Bands Impact Closing Auction Price): Taking the same example as above, but in this example Order F is for 10,000 shares instead of 2,000, and one additional order is entered as follows:

Time	Order	Side	Type	Limit	Shares
3:59:30	Order F	Sell	LOC.L	\$49.00	10,000
3:59:50	Order G	Buy	LOC.L	49.00	1,000

³⁴ The Exchange notes that because it is not proposing to make any changes to the Collar Price Range in this proposal, it is not discussing the

Collar Price Range in the examples in this filing in order to keep the examples as straight-forward as

possible as it relates to the rules that it is proposing to change.

In this instance, Order F would again be adjusted to a limit price of \$49.80 because it is an LOC.L sell order that is priced more aggressively than the Lower Band. Order G would not be adjusted because it is an LOC.L buy order that is not priced more aggressively than the Upper Band. Based on updated orders and the new combined Auction Order Book and Continuous Book, 4,000 shares would execute at every price up to \$49.79, 9,000 shares would execute between \$49.80 and \$50.00, 7,000 shares would execute between \$50.01 and \$50.10, and 0 shares would execute above \$50.10. Based on the logic in Rule 11.022(c)(2)(B), which provides that the Closing Auction will occur at the price level within that maximizes the number of shares executed between the Continuous Book and Auction Book, there would be a volume based tie between \$49.80 and \$50.00.³⁵ The next step is to find the price level within that range that minimizes the imbalance, but every price in that range has an imbalance of 5,000 sell shares. The next step (which is the proposed new tie breaker functionality) is to find the entered price at which shares will remain unexecuted in the Closing Auction, and here the only entered price within the range at which shares will remain unexecuted is \$49.80 (Order F's adjusted price). Therefore, 9,000 shares would execute in the Closing Auction at \$49.80.

In this instance, the adjustment of Order F did impact the price of the Closing Auction because the most shares that could execute would have been at \$49.00 if the LOC.L was priced at \$49.00 (would have been 10,000 shares that could have executed at \$49.00, greater than any other price level). Consistent with the logic above, the Participation Bands, which are based on actual executions and quotes in the market, allowed price formation to occur in the Closing Auction within reasonable market-based bounds.

Policy Argument

The Exchange believes that these proposed changes collectively provide a deterministic, market-based solution to creating orderly closing auctions that is conceptually similar to both the Exchange's current functionality (gating Late Auction Orders based on market conditions, which under current

Exchange Rules are the NBB and NBO), other similar late auction order functionality on other exchanges (which provide similar market-based restrictions on the price of late auction orders),³⁶ and the Designated Market Maker ("DMM") closing auction process on New York Stock Exchange LLC ("NYSE"). Under NYSE Rule 7.35B(g), DMMs are responsible for deciding the Auction Price for a Closing Auction on NYSE and have significant discretion in determining what that Auction Price should be. NYSE describes the criteria for the DMM to decide on the Closing Price as follows: "the Auction Price must be at or between the last-published Imbalance Reference Price, which is the Exchange Last Sale Price bound by the Exchange BBO,³⁷ and the last-published non-zero Continuous Book Clearing Price, which is the price at which all better-priced orders eligible to trade in the Closing Auction on the Side of the Imbalance can be traded."³⁸ Rule 7.35B promotes determinism with respect to the Closing Auction because the Closing Auction Price must be within the predetermined range of prices that have been disseminated via the Closing Auction Imbalance Information and that

³⁶ Cboe BZX Exchange, Inc. ("BZX") has identical late auction order functionality as the Exchange's current functionality—late auction orders in both the opening and closing auctions are collared by the NBBO. See BZX Rules 11.23(a)(12) and (13). NYSE Arca, Inc.'s ("Arca") opening auction does not allow cancel and cancel and replace requests for one minute prior to the Opening Auction and a Core Open Auction Imbalance Freeze occurs five seconds before the scheduled Core Open Auction. During this period the only orders accepted for auction participation are Limit Orders designated for the Core Trading Session and such orders are only allowed to participate in the Core Open Auction to offset an imbalance remaining after all orders entered before the Core Open Auction Imbalance Freeze. For the Arca closing auction, the Closing Auction Imbalance Freeze begins one minute prior to the closing auction. During this period, all LOC and MOC orders that are on the same side of the Total Imbalance, would flip the Total Imbalance, or would create a new Total Imbalance are rejected and no LOC Orders or MOC Orders can be cancelled or cancelled and replaced. See Arca Rule 7.35—E. Nasdaq Stock Market LLC's ("Nasdaq") allows LOO orders to be entered until 9:29:30 a.m. but restricts LOO orders received after 9:28 a.m. to only be priced to the more aggressive of the 9:28 a.m. price or the previous day's official closing price. Similarly, LOC orders received after 3:55 p.m. are accepted at their limit price unless it is more aggressive than the 3:50 p.m. or the 3:55 p.m. Reference Prices, in which case it will be re-priced to the more aggressive of the two prices. Nasdaq accepts Imbalance Only orders for both the opening and closing auction and if those orders are re-priced to the best bid/ask price prior to the execution of the auction, up to their limit price. See Nasdaq Rules 4752 and 4754.

³⁷ See NYSE Rule 7.35(a)(4)(C). In the case of a buy Imbalance, the Continuous Book Clearing Price would be the highest potential Closing Auction Price and in the case of a sell Imbalance, the Continuous Book Clearing Price would be the lowest potential Closing Auction Price.

³⁸ See NYSE Rule 7.35B(e)(3).

cannot be changed after the end of Core Trading Hours."³⁹ Providing a market conditions-based price range at which the DMM can choose the auction price serves a similar function to the restrictions on late auction orders on other exchanges and the Participation Band restrictions on LOO.L and LOC.L orders entered after 9:28 a.m. and 3:58 p.m., respectively. They all serve to allow for liquidity providers to participate in the auction process but in a way that does not impact the price of the auction in a way that diverges from the exchanges' respective chosen measure of "current market conditions."

To this point, the Exchange believes that restricting the price of Late Auction Order bids and offers to the Upper Band and Lower Band, respectively, immediately prior to the Opening and Closing Auction is a reasonable way to ensure that participants are able to add liquidity in Opening and Closing Auctions on the Exchange while mitigating volatility and ensuring that Opening and Closing Auctions remain tethered to market conditions in a security.⁴⁰ The data points that the Exchange is proposing to disseminate prior to its Opening and Closing Auctions further bolster this ability. The Exchange believes that the examples above support this belief.

Clarifying Changes

Finally, the Exchange is proposing to add a clarifying clean-up change in Rule 11.022(c)(2)(B) to add the phrase "that is a corporate security" in two places in order to make the following language clear "For a TXSE-Listed Security *that is a corporate security*, the Closing Auction price will be the TXSE Official Closing Price. In the event that there is no Closing Auction for a TXSE-Listed Security *that is a corporate security*, the TXSE Official Closing Price will be the price of the Final Last Sale Eligible Trade." Without this clarifying language, the following sentence related to "The TXSE Official Closing Price for all other TXSE-Listed Securities will be determined as follows:" would never apply. The language under this provision is intended to apply to ETPs in order to find a TXSE Official Closing

³⁹ See Securities Exchange Act Release No. 104887 (February 25, 2026), 91 FR 10175 (March 2, 2026) (File No. SR-NYSE-2026-11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 7.35B(g)(2)).

⁴⁰ As noted above, the Participation Bands are calculated utilizing real-time transaction and/or quotation data from the consolidated tape for the applicable security and a mathematical calculation to determine a dynamic, symbol-specific price range within the Collar Price Range and will be disseminated every five seconds between 3:58 p.m. and 4:00 p.m.

³⁵ The Exchange notes that Rule 11.022(c)(2)(B) specifically refers to the price level within the Collar Price Range that maximizes the number of shares executed, but is intentionally not including the Collar Price Range in the examples in this proposal in order to prevent the overcomplication of these examples in areas of its rules that it is not proposing to change.

Price for ETPs where there is less than one round lot executed in the Closing Auction. Without the qualifier “that is a corporate security” all securities would have their TXSE Official Closing Price determined by the preceding language. The Exchange is also proposing to renumber certain defined terms under Rule 11.022(a) in order to accommodate the new definitions proposed herein.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁴¹ in general, and furthers the objectives of Section 6(b)(5) of the Act,⁴² in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the 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 that the proposed rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that the proposed changes to LOO.L and LOC.L functionality, the new data points that will be provided in advance of the Opening and Closing Auctions, and the changes to the timing and cancellability of RHO, MOC, LOC, and LOC.L orders collectively provide a deterministic, market-based solution to creating orderly auctions. To this point, the Exchange believes that restricting the price of Late Auction Order bids and offers to the Upper Band and Lower Band, respectively, immediately prior to the Opening and Closing Auction is a reasonable way to ensure that participants are able to add liquidity in Opening and Closing Auctions on the Exchange while mitigating volatility and ensuring that Opening and Closing Auctions remain tethered to market conditions in a security.⁴³ The data

points that the Exchange is proposing to disseminate prior to its Opening and Closing Auctions further bolster this ability.

The Exchange also notes that the proposed Late Auction Order functionality is conceptually similar to both the Exchange’s current functionality (gating Late Auction Orders based on market conditions, which under current Exchange Rules are the NBB and NBO), other similar late auction order functionality on other exchanges (which provide similar market-based restrictions on the price of late auction orders),⁴⁴ and the DMM closing auction process on NYSE. Under NYSE Rule 7.35B(g), DMMs are responsible for deciding the Auction Price for a Closing Auction on NYSE and have significant discretion in determining what that Auction Price should be. NYSE describes the criteria for the DMM to decide on the Closing Price as follows: “the Auction Price must be at or between the last-published Imbalance Reference Price, which is the Exchange Last Sale Price bound by the Exchange BBO,⁴⁵ and the last-published non-zero Continuous Book Clearing Price, which is the price at which all better-priced orders eligible to trade in

⁴⁴ BZX has identical late auction order functionality as the Exchange’s current functionality—late auction orders in both the opening and closing auctions are collared by the NBBO. See BZX Rules 11.23(a)(12) and (13). Arca’s opening auction does not allow cancel and cancel and replace requests for one minute prior to the Opening Auction and a Core Open Auction Imbalance Freeze occurs five seconds before the scheduled Core Open Auction. During this period the only orders accepted for auction participation are Limit Orders designated for the Core Trading Session and such orders are only allowed to participate in the Core Open Auction to offset an imbalance remaining after all orders entered before the Core Open Auction Imbalance Freeze. For the Arca closing auction, the Closing Auction Imbalance Freeze begins one minute prior to the closing auction. During this period, all LOC and MOC orders that are on the same side of the Total Imbalance, would flip the Total Imbalance, or would create a new Total Imbalance are rejected and no LOC Orders or MOC Orders can be cancelled or cancelled and replaced. See Arca Rule 7.35–E. Nasdaq’s allows LOO orders to be entered until 9:29:30 a.m. but restricts LOO orders received after 9:28 a.m. to only be priced to the more aggressive of the 9:28 a.m. price or the previous day’s official closing price. Similarly, LOC orders received after 3:55 p.m. are accepted at their limit price unless it is more aggressive than the 3:50 p.m. or the 3:55 p.m. Reference Prices, in which case it will be re-priced to the more aggressive of the two prices. Nasdaq accepts Imbalance Only orders for both the opening and closing auction and if those orders are re-priced to the best bid/ask price prior to the execution of the auction, up to their limit price. See Nasdaq Rules 4752 and 4754.

⁴⁵ See NYSE Rule 7.35(a)(4)(C). In the case of a buy Imbalance, the Continuous Book Clearing Price would be the highest potential Closing Auction Price and in the case of a sell Imbalance, the Continuous Book Clearing Price would be the lowest potential Closing Auction Price.

the Closing Auction on the Side of the Imbalance can be traded.⁴⁶ Rule 7.35B promotes determinism with respect to the Closing Auction because the Closing Auction Price must be within the predetermined range of prices that have been disseminated via the Closing Auction Imbalance Information and that cannot be changed after the end of Core Trading Hours.”⁴⁷ Providing a market conditions-based price range at which the DMM can choose the auction price serves a similar function to the restrictions on late auction orders on other exchanges and the Participation Band restrictions on LOO.L and LOC.L orders entered after 9:28 a.m. and 3:58 p.m., respectively, being proposed herein. They all serve to allow for liquidity providers to participate in the auction process but in a way that does not impact the price of the auction in a way that diverges from the exchanges’ respective chosen measure of “current market conditions.” While the analysis above focuses on closing auctions, the Exchange believes that the points raised apply equally to opening auctions as well.

The Exchange further believes that its proposal to add a new third tie-breaker to the calculation of the TXSE Official Opening Price, TXSE Official Closing Price, and the Auction Only Price is consistent with the Act because the proposed change adds another tie breaker that is based on actual auction orders in the Auction Book before using the Volume Based Tie Breaker, which the Exchange believes better reflects actual market interest. Further, the proposed change is substantively identical to Nasdaq Rule 4754(b)(2)(C).

Finally, the Exchange believes that the proposed clarifying clean-up and corresponding numbering changes are consistent with the Act because they make the Exchange’s Rules more clear and understandable. As it specifically relates to adding the phrase “that is a corporate security” in two places, the proposed rule change will correct a drafting error to make clear how the TXSE Official Closing Price is determined for non-corporate securities.

For these reasons, the Exchange believes that the proposed changes are consistent with the Act.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposal will impose any burden on

⁴⁶ See NYSE Rule 7.35B(e)(3).

⁴⁷ See Securities Exchange Act Release No. 104887 (February 25, 2026), 91 FR 10175 (March 2, 2026) (File No. SR–NYSE–2026–11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Rule 7.35B(g)(2)).

⁴¹ 15 U.S.C. 78f(b).

⁴² 15 U.S.C. 78f(b)(5).

⁴³ As noted above, the Participation Bands are calculated utilizing real-time transaction and/or quotation data from the consolidated tape for the applicable security and a mathematical calculation to determine a dynamic, symbol-specific price range within the Collar Price Range and will be disseminated every five seconds between 3:58 p.m. and 4:00 p.m.

competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is designed to revise auctions on the Exchange to make it more transparent, robust, and deterministic. The Exchange believes that the proposed rule change would promote intermarket competition, particularly for issuers in connection with their determination of which exchange to select as a primary listing venue and among market participants that may decide to participate in auctions on the Exchange. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Competing exchanges have their own auction functionality and are free to adopt similar rules if they so choose.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Members would be eligible to participate in the Exchange's auctions and all issuers would have their securities participate in the auctions on the same terms.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File No. SR-TXSE-2026-006 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 No. SR-TXSE-2026-006. 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-TXSE-2026-006 and should be submitted on or before July 22, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2026-13653 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36236; 812-16022]

Goehring & Rozencwajg Investment Funds and Goehring & Rozencwajg Associates, LLC

July 1, 2026.

AGENCY: Securities and Exchange Commission ("Commission" or "SEC").
ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from sections 2(a)(32), 5(a)(1), 18(f)(1), 18(i), 22(d) and 22(e) of the Act and rule 22c-1 under the Act and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

SUMMARY OF APPLICATION: Applicants request an order ("Order") that would permit a registered open-end management investment company to offer one class of exchange-traded shares that operates as an exchange-traded fund (an "ETF Class," and such shares, "ETF Shares") and one or more classes of shares that are not exchange-traded (each such class, a "Mutual Fund Class," and such shares, "Mutual Fund Shares," and each such fund, a "Multi-Class ETF Fund"). The Order would provide Multi-Class ETF Funds with two broad categories of relief: (i) the

relief necessary to permit standard exchange-traded fund ("ETF") operations consistent with Rule 6c-11 under the Act ("ETF Operational Relief") and (ii) the relief necessary for a fund to offer an ETF Class and one or more Mutual Fund Classes ("ETF Class Relief").

APPLICANTS: Goehring & Rozencwajg Investment Funds and Goehring & Rozencwajg Associates, LLC.

FILING DATES: The application was filed on April 29, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at Secretarys-Office@sec.gov and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time, on July 27, 2026, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at Secretarys-Office@sec.gov.

ADDRESSES: The Commission: Secretarys-Office@sec.gov. Applicants: Kevin O'Friel, kofriel@gorozen.com; and Michael G. Doherty, Esq., Ropes & Gray LLP, Michael.Doherty@ropesgray.com.

FOR FURTHER INFORMATION CONTACT: Jill Ehrlich, Senior Counsel, or Thomas Ahmadifar, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' application, filed April 29, 2026, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at <https://www.sec.gov/search-filings>. You may also call the SEC's Office of Investor Education and Assistance at (202) 551-8090.

⁴⁸ 17 CFR 200.30-3(a)(12).

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-13638 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105833; File No. SR-NYSEARCA-2026-68]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of a Proposed Rule Change To Amend Rules 5.32-O and 5.35-O

July 1, 2026.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b-4 thereunder,³ notice is hereby given that, on June 18, 2026, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rules 5.32-O and 5.35-O related to Flexible Exchange (“FLEX”) Options.⁴ The proposed rule change is available on the Exchange’s website at www.nyse.com and at the principal office of the Exchange.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rules 5.32-O and 5.35-O related to FLEX Options.

FLEX Options are customized equity or index contracts that allow investors to tailor contract terms for exchange-listed equity and index options. A “FLEX Equity Option” is an option on a specified underlying equity security or Exchange-Traded Fund Share that is subject to the rules of Section 4.⁵

Generally, FLEX Equity Options are settled by physical delivery of the underlying security,⁶ while all FLEX Index Options are settled in cash.⁷ In February 2020, however, the Exchange amended Rule 5.32-O to permit cash settlement for up to 50 FLEX Equity Options with an underlying security that is an ETF meeting certain criteria: an average daily notional value of \$500 Million or more and a national average daily volume of 4,680,000 shares, measured over the prior six-month period. Where more than 50 ETFs qualify, the Exchange selects the 50 with the highest average daily volume.⁸

The Exchange proposes to: (i) amend paragraph (f)(3)(ii) of Rule 5.32-O to permit cash settlement for up to 50 non-ETF FLEX Equity Options whose underlying security meets the same criteria currently applicable to ETF FLEX Equity Options noted above; and (ii) amend paragraph (f)(3)(ii)(A) of Rule 5.32-O to provide that, where more than 50 underlying ETFs or 50 underlying non-ETFs qualify, the Exchange will select the 50 qualifying securities with the highest average daily notional value, replacing the current usage of highest average daily volume.⁹

⁵ See 5.30-O(b)(5).

⁶ See Rule 5.32-O(f)(3)(i).

⁷ See Rule 5.32-O(e)(2) and (3). Similarly, pursuant to Exchange rules, Binary Return Derivatives (“ByRDs”) are also settled in cash (See Rule 5.82-O(b)) and, as discussed below, cash settlement is also permitted in the over-the-counter (“OTC”) market.

⁸ See Rule 5.32-O(e)(3)(ii). See also Securities Exchange Release No. 104692 (January 27, 2026), 91 FR 4145 (January 27, 2026) (SR-NYSEARCA-2026-4) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend Rules 5.32-O and 5.35-O Related to Flexible Exchange Options).

⁹ The Exchange acknowledges that this change will become moot as it relates to FLEX ETF Equity options if CBOE’s current rule filing proposing to amend its Rule 4.21 to, among other things, eliminate the provision limiting cash settlement as a contract term to no more than 50 ETFs. See Securities Exchange Act Release No. 105277 (April 20, 2026) (SR-CBOE-2026-35) (Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change to Amend Rule 4.21 (Series of FLEX Options)).

The Exchange proposes to amend Rule 5.32-O paragraph (f)(3)(ii), to permit cash settlement for up to 50 non-ETF FLEX Equity Options whose underlying security meets the same criteria currently applicable to ETF FLEX Equity Options: an average daily notional value of \$500 Million or more and a national average daily volume of at least 4,680,000 shares, measured over the prior six-month period.¹⁰ The Exchange believes that average daily notional value and national average daily volume are, collectively, an appropriate proxy for selecting underlying securities that are not readily susceptible to manipulation for purposes of establishing a settlement price. Average daily notional value considers both the trading activity and the price of an underlying security. As a general matter, the more expensive an underlying security’s price, the less cost-effective manipulation could become. Further, manipulation of the price of a security encounters greater difficulty the more volume that is traded.

To calculate average daily notional value (provided in the table below), the Exchange summed the notional value of each trade for each symbol (*i.e.*, the number of shares multiplied by the execution price) and divided that total by the number of trading days in the six-month period reviewed (July 1, 2025 through December 31, 2025). To calculate national average daily volume (provided in the table below), the Exchange summed the share volume of each trade for each symbol and divided that total by the number of trading days in the same six-month period. Based on these calculations, the Exchange identified 143 non-ETF securities eligible for cash settlement of FLEX options overlying them. As noted in the proposed amendment to Rule 5.32-O(f)(ii)(A), however, only the FLEX Equity Options overlying the non-ETF securities with the highest average daily notional value would be eligible for cash settlement. The table below identifies the 50 non-ETF FLEX Equity Options that would qualify for cash settlement under the Exchange’s most recent review, effective February 2, 2026.¹¹ The table also includes, for each symbol, closing auction average daily volume and closing auction average daily notional value over the same six-month period, which reflect the depth of trading activity specifically at the

¹⁰ See proposed Rule 5.32-O(f)(3)(ii).

¹¹ The Exchange notes that, if approved after August 3, 2026, the Exchange’s list of eligible symbols may differ slightly from the table below, as a new semiannual review would be effective on that date.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ In addition, the Exchange proposes a non-substantive amendment to Rule 5.36-O to correctly align its reference to Rule 5.35-O contained therein.

close and thereby illustrate each symbol's resilience to potential price manipulation at the time of settlement.

symbol's resilience to potential price manipulation at the time of settlement.

Symbol	Name	National average daily volume	Average daily notional value	Closing auction average daily volume	Closing auction average daily notional value
TSLA	Tesla, Inc	86,178,496	33,900,266,523	3,190,644	1,269,430,007
NVDA	Nvidia Corp	179,041,356	32,307,823,899	12,868,161	2,321,433,344
AAPL	Apple Inc	50,490,993	12,378,849,915	7,226,393	1,806,481,590
MSFT	Microsoft Corp	21,252,429	10,744,061,849	3,544,334	1,784,873,081
AMD	Advanced Micro Devices	53,267,301	10,373,623,850	2,493,925	488,464,603
META	Meta Platforms, Inc	14,808,166	10,257,169,282	1,446,720	1,002,367,069
AMZN	Amazon.Com Inc	43,640,268	9,944,290,596	4,938,798	1,124,263,780
PLTR	Palantir Technologies Inc	56,659,273	9,609,181,571	2,638,743	456,276,952
GOOGL	Alphabet Inc. Class A	35,705,006	8,886,422,708	3,721,259	943,979,178
AVGO	Broadcom Inc	24,847,975	8,399,788,094	3,670,925	1,240,180,161
GOOG	Alphabet Inc. Class C	22,971,782	5,726,646,457	2,445,189	626,368,731
ORCL	Oracle Corp	22,510,933	5,639,724,093	1,572,261	381,075,627
MU	Micron Technology, Inc	24,285,194	4,467,837,733	1,970,831	361,184,152
HOOD	Robinhood Markets, Inc	36,997,040	4,306,868,213	1,954,129	238,103,937
NFLX	Netflix Inc	13,214,039	4,287,659,509	1,465,607	405,513,118
MSTR	Strategy Inc	14,042,388	3,950,992,841	1,040,765	297,429,799
UNH	UnitedHealth Group Incorporated	11,961,746	3,729,620,578	826,104	262,526,732
COIN	Coinbase Global, Inc	10,231,567	3,331,720,883	614,219	197,541,974
TSM	Taiwan Semiconductor Manufacturing Company Ltd.	12,008,931	3,246,781,038	752,418	203,136,969
INTC	Intel Corp	103,754,853	3,219,916,507	6,929,263	218,261,697
APP	Applovin Corporation	5,782,947	3,195,229,826	566,833	341,886,958
CRWV	CoreWeave, Inc	26,134,544	2,786,774,579	945,274	92,136,014
JPM	JPMorgan Chase & Co	8,447,294	2,563,687,629	1,612,884	491,974,304
BABA	Alibaba Group Holding Limited	15,702,967	2,330,733,305	417,707	61,037,911
BMNR	BitMine Immersion Technologies, Inc	45,742,244	2,114,623,207	1,538,644	62,322,489
V	VISA Inc	6,064,874	2,079,103,486	1,346,605	461,301,568
CRM	Salesforce, Inc	8,170,611	2,033,145,491	895,261	223,551,717
CRCL	Circle Internet Group, Inc	13,890,967	1,876,964,806	438,058	50,218,550
BAC	Bank of America Corporation	36,433,684	1,848,841,746	5,536,718	282,799,082
RGTI	Rigetti Computing, Inc	61,001,534	1,818,953,391	2,249,745	64,386,440
WMT	Walmart Inc	17,171,708	1,785,470,800	3,965,604	452,283,958
SOFI	SoFi Technologies, Inc	68,778,271	1,774,108,244	2,462,163	63,663,350
OKLO	Oklo Inc	17,056,654	1,722,406,038	636,877	63,026,808
XOM	Exxon Mobil Corporation	14,923,963	1,694,641,338	2,369,124	269,222,575
BA	Boeing Company	7,771,390	1,664,026,520	647,649	138,422,692
UBER	Uber Technologies, Inc	17,771,441	1,623,852,154	1,748,330	159,554,138
AMAT	Applied Materials Inc	7,630,690	1,590,411,121	1,239,413	264,834,901
JNJ	Johnson & Johnson	8,508,238	1,570,954,763	1,590,260	295,976,568
MRVL	Marvell Technology, Inc	19,141,701	1,534,320,570	2,125,390	172,519,290
NBIS	Nebius Group N.V	16,580,887	1,509,559,015	530,793	49,592,906
IREN	IREN Limited	35,551,466	1,465,271,072	817,801	33,589,290
QCOM	Qualcomm Inc	8,743,386	1,462,236,794	1,589,760	263,590,678
LRCX	Lam Research Corp	11,098,219	1,443,543,642	1,936,139	259,497,229
CSCO	Cisco Systems, Inc	19,993,372	1,430,793,231	3,451,961	248,085,586
PFE	Pfizer Inc	55,503,187	1,385,704,301	4,483,737	112,014,095
SMCI	Super Micro Computer, Inc	30,070,928	1,385,222,973	1,592,481	70,488,062
IBM	International Business Machines Corporation ..	4,915,186	1,372,464,742	715,181	200,577,771
C	Citigroup Inc	13,787,319	1,366,461,810	1,972,207	197,886,096
IONQ	IonQ, Inc	24,413,055	1,339,549,825	1,588,871	86,626,817
TXN	Texas Instruments Incorporated	7,247,390	1,314,583,022	1,350,604	244,860,485

The Exchange believes that expanding cash settlement to a select group of non-ETF options reflects changes in the marketplace since cash settlement was first expanded to options overlying ETFs.¹² Specifically, in 2020, only 52

single stocks within the S&P 500 and 32 ETFs met the above-captioned criteria (i.e., average daily notional value of \$500 Million and average daily volume of 4,680,000 shares). As of December 31, 2025, however, 143 S&P 500 single stocks meet these same criteria, evidencing that the eligible single stocks

are far deeper and more liquid than the ETF universe was at the time cash settlement for them was approved.

The Exchange believes it is appropriate to introduce cash settlement as an alternative contract term to this select group of non-ETF securities because they are among the most highly liquid and actively traded securities. As described more fully below, the Exchange believes that the deep

¹² See Securities Exchange Act Release No. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (NYSEAMER-2019-38) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified

by Amendment No. 1, To Allow Certain Flexible Equity Options To Be Cash Settled).

liquidity and robust trading activity (in general and at the close) in the securities identified by the Exchange as meeting the criteria mitigate historic concerns regarding susceptibility to manipulation.

Moreover, the Exchange believes that permitting cash settlement as a contract term for the FLEX non-ETF Equity Options for the securities in the above table or later found to be in the top 50 would broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply.

Equity options are generally settled physically at The Options Clearing Corporation ("OCC"), (*i.e.*, upon exercise, shares of the underlying security must be assumed or delivered). Physical settlement entails certain risks with respect to volatility and movement of the underlying security at expiration that market participants may need to hedge against. Cash settlement may be preferable to physical delivery in some circumstances as it does not present the same risk. If an issue with the delivery of the underlying security arises, it may become more expensive and time-consuming to reverse the delivery because the price of the underlying security would almost certainly have changed. Reversing a cash payment, on the other hand, would not involve any such issue because reversing a cash delivery would simply involve the exchange of cash. Additionally, with physical settlement, market participants that have a need to generate cash would have to sell the underlying security while incurring the costs associated with liquidating their position in the underlying security as well as the risk of an adverse movement in the price of the underlying security.¹³

The Exchange notes that cash settlement for options is not a unique feature and other options exchanges have previously received approval that allow for the trading of cash-settled

options¹⁴ and cash settled FLEX ETF Options.¹⁵

With respect to position limits, like ETF FLEX options, cash-settled FLEX non-ETF Equity Options would be subject to the position limits set forth in Rule 5.35–O. Accordingly, the Exchange proposes to amend Rule 5.35–O(b)(ii) to remove reference to Exchange-Traded Funds and would provide that positions for all FLEX Equity Options settled in cash pursuant to Rule 5.32–O(f)(3)(ii) would be subject to the limits set forth in Rule 5.35–O, and the exercise limits set forth in Rule 5.36–O.¹⁶ Given that each of the underlying securities that would currently be eligible to have cash-settlement as a contract term have established position and exercise limits applicable to physically-settled options, the Exchange believes it is appropriate for the same position and exercise limits to also apply to cash-settled options. Accordingly, as of December 31, 2025, of the 143 non-ETF underlying securities that would currently be eligible to have cash settlement as a

¹⁴ See *e.g.* PHLX FX Options traded on Nasdaq PHLX and S&P 500® Index Options traded on Cboe Options Exchange. More recently, the Commission approved, on a pilot basis, the listing and trading of RealDay™ Options on the SPDR S&P 500 Trust on the BOX Options Exchange LLC ("BOX"). See Securities Exchange Act Release No. 79936 (February 2, 2017), 82 FR 9886 (February 8, 2017) ("RealDay Pilot Program"). The RealDay Pilot Program was extended until February 2, 2019. See Securities Exchange Act Release No. 82414 (December 28, 2017), 83 FR 577 (January 4, 2018) (SR–BOX–2017–38). The RealDay Pilot Program was never implemented by BOX. See also Securities Exchange Act Release Nos. 56251 (August 14, 2007), 72 FR 46523 (August 20, 2007) (SR–Amex–2004–27) (Order approving listing of cash-settled Fixed Return Options ("FROs")); and 71957 (April 16, 2014), 79 FR 22563 (April 22, 2014) (SR–NYSEMKT–2014–06) (Order approving name change from FROs to ByRDs and re-launch of these products, with certain modifications).

¹⁵ See Securities Exchange Act Release Nos. 102839 (April 11, 2025), 90 FR 16410 (April 17, 2025) (SR–BOX–2025–07) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 5055 To Allow for Cash Settlement of Certain FLEX Equity Options); 98044 (August 2, 2023), 88 FR 53548 (August 8, 2023) (SR–CBOE–2023–036) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Allow Certain Flexible Exchange Equity Options To Be Cash Settled); and 101720 (November 22, 2024), 89 FR 94986 (November 29, 2024) (SR–ISE–2024–12) (Notice of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Adopt Rules To List and Trade FLEX Options). See also Securities Exchange Act Release Nos. 88131 (February 5, 2020), 85 FR 7806 (February 11, 2020) (SR–NYSEAMER–2019–38) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, to Allow Certain Flexible Equity Options To Be Cash Settled); and 97231 (March 31, 2023), 88 FR 20587 (April 6, 2023) (SR–NYSEAMER–2023–22) (Notice of Filing and Immediate Effectiveness of Proposed Change to Make a Clarifying Change to the Term Settlement Style Applicable to Flexible Exchange Options).

¹⁶ See proposed Rule 5.35–O(b)(ii).

contract term, all 143 (and all 50 on the above chart) would have a position limit of 250,000 contracts pursuant to Rule 6.8, Commentary .06(e).¹⁷

The Exchange understands that cash-settled FLEX non-ETF Equity Options are currently traded in the OTC market by a variety of market participants (*e.g.*, hedge funds, proprietary trading firms, and pension funds). The Exchange believes some of these market participants would prefer to trade these instruments on an exchange, where they would be cleared and settled through a regulated clearing agency. The Exchange expects that users of these OTC products would be among the primary users of exchange-traded cash-settled FLEX non-ETF Equity Options. The Exchange also believes that the trading of cash-settled FLEX non-ETF Equity Options would allow these same market participants to better manage the risk associated with the volatility of underlying equity positions given the enhanced liquidity that an exchange-traded product would bring.

Cash-settled FLEX non-ETF Equity Options traded on the Exchange would have three important advantages over the contracts that are traded in the OTC market. First, as a result of greater standardization of contract terms, exchange-traded contracts should develop more liquidity. Second, counter-party credit risk would be mitigated by the fact that the contracts are issued and guaranteed by the OCC. Finally, the price discovery and dissemination provided by the Exchange and its members would lead to more transparent markets. The Exchange believes that its ability to offer cash-settled FLEX non-ETF Equity Options would aid it in competing with the OTC market and, at the same time, expand the universe of products available to interested market participants. The Exchange believes that an exchange-traded alternative may provide a useful risk management and trading vehicle for market participants and their customers.

The Exchange notes that cash-settled FLEX non-ETF Equity Options would not be available for trading until OCC represents to the Exchange that it is fully able to clear and settle such

¹⁷ Rule 6.8, Commentary .06(e) provides that the position limit shall be 250,000 contracts for options: (i) on an underlying security that had trading volume of at least 100,000,000 shares during the most recent six-month trading period; or (ii) on an underlying security that had trading volume of at least 75,000,000 shares during the most recent six-month trading period and has at least 300,000,000 shares currently outstanding.

¹³ Market participants have voiced additional concerns with physical delivery to explain why they participate in the OTC markets that allow cash settlement for equity options including, among other things, that certain custodians will not permit short options positions requiring physical delivery and physical settlement certain tax triggering events.

options.¹⁸ The Exchange has also analyzed its capacity and represents that it and The Options Price Reporting Authority (OPRA) have the necessary systems capacity to handle the additional traffic associated with the listing of cash-settled FLEX Equity Options. The Exchange believes any additional traffic that would be generated from the introduction of cash-settled FLEX non-ETF Equity Options would be manageable. The Exchange represents that OTP Holders will not have a capacity issue as a result of this proposed rule change.

The Exchange also represents that it does not believe this proposed rule change will cause fragmentation of liquidity. The Exchange will monitor the trading volume associated with the additional options series listed as a result of this proposed rule change and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

The Exchange believes it has an adequate surveillance program in place for cash-settled FLEX non-ETF equity Options and intends to apply the same program procedures that it applies to the Exchange's other options products.

FLEX option products, including non-ETF equity options, and their respective symbols are integrated into the Exchange's existing surveillance system architecture and are thus subject to the relevant surveillance processes. The Exchange believes that the existing surveillance procedures at the Exchange are capable of properly identifying unusual and/or illegal trading activity, which procedures the Exchange would utilize to surveil for aberrant trading in cash-settled FLEX non-ETF Options. As a result, the Exchange believes it would be able to effectively regulate the trading of cash-settled FLEX non-ETF Equity Options using means that include its surveillance for manipulation. The Exchange believes that manipulating the settlement price of cash-settled FLEX non-ETF Equity Options would be difficult based on the size of the market for the securities that are the subject of this proposed rule change.

With respect to regulatory scrutiny, the Exchange believes its existing surveillance technologies and procedures adequately address potential concerns regarding possible manipulation of the settlement value at or near the close of the market. The Exchange notes that the regulatory program operated by, and overseen by

NYSE Regulation,¹⁹ includes cross-market surveillance designed to identify manipulative and other improper trading, including spoofing, algorithm gaming, marking the close and open, as well as more general, abusive behavior related to front running, wash sales, quoting/routing, and Reg SHO violations, that may occur on the Exchange and other markets. These cross-market patterns incorporate relevant data from various markets beyond the Exchange and its affiliates and from markets not affiliated with the Exchange. The Exchange represents that its existing trading surveillances are adequate to monitor the trading in the underlying equity securities and subsequent trading of options on those securities on the Exchange, including cash-settled FLEX non-ETF Options.²⁰

Additionally, for options, the Exchange utilizes an array of patterns that monitor manipulation of options, or manipulation of equity securities (regardless of venue) for the purpose of impacting options prices on the Exchange (*i.e.*, mini-manipulation strategies). That surveillance coverage is initiated once options begin trading on the Exchange. Accordingly, the Exchange believes that the cross-market surveillance performed by the Exchange or FINRA, on behalf of the Exchange, coupled with NYSE Regulation's own monitoring for violative activity on the Exchange comprise a comprehensive surveillance program that is adequate to monitor for manipulation of the underlying security and overlying option. Furthermore, the Exchange believes that the existing surveillance procedures at the Exchange are capable of properly identifying unusual and/or illegal trading activity, which the Exchange would utilize to surveil for aberrant trading in cash-settled FLEX non-ETF Options.

In addition to the surveillance procedures and processes described above, improvements in audit trails (*i.e.*, the Consolidated Audit Trail), recordkeeping practices, and inter-exchange cooperation over the last two decades have greatly increased the Exchange's ability to detect and punish

attempted manipulative activities. In addition, the Exchange is a member of the Intermarket Surveillance Group ("ISG").²¹ The ISG members work together to coordinate surveillance and investigative information sharing in the stock and options markets. For surveillance purposes, the Exchange would therefore have access to information regarding trading activity in the pertinent underlying securities. The Exchange is confident that its existing surveillance procedures, which have proven effective with respect to FLEX ETF Options, are sufficient for the cash settlement of FLEX non-ETF Options and will monitor and adjust such procedures as needed.

Additionally, the Exchange notes that each cash-settled FLEX non-ETF Equity Option that is subject to this proposed rule change is sufficiently active so as to alleviate concerns about potential manipulative activity. Further, in the Exchange's view, the vast liquidity of the 143 underlying securities ensures a multitude of market participants at any given time. Given the high level of participation among market participants that enter quotes and/or orders in the options on these securities, the Exchange believes it would be very difficult for a single participant to alter the price of each of the underlying securities in any significant way without exposing the would-be manipulator to regulatory scrutiny. The Exchange further believes any attempt to manipulate the price of the underlying securities would also be cost prohibitive.

The Exchange does not believe that allowing cash settlement as a contract term would render the marketplace for equity options more susceptible to manipulative practices. In addition to the surveillance procedures and processes described above, improvements in audit trails, recordkeeping practices, and inter-exchange cooperation over the last two decades have greatly increased the Exchange's ability to detect and punish attempted manipulative activities. The Exchange therefore believes that the decision of whether or not to allow cash settlement as a contract term should rest on the ability of the Exchange to monitor and detect manipulative activity, not on any perceived threat of

¹⁹ The Exchange maintains regulatory services agreements with Financial Industry Regulatory Authority, Inc. ("FINRA") whereby FINRA provides certain regulatory services to the exchanges, including cross-market surveillance, investigation, and enforcement services.

²⁰ Such surveillance procedures generally focus on detecting securities trading subject to opening price manipulation, closing price manipulation, layering, spoofing or other unlawful activity impacting an underlying security, the option, or both. The Exchange has price movement alerts, unusual market activity and order book alerts active for all trading symbols.

²¹ ISG is an industry organization formed in 1983 to coordinate intermarket surveillance among the SROs by cooperatively sharing regulatory information pursuant to a written agreement between the parties. The goal of the ISG's information sharing is to coordinate regulatory efforts to address potential intermarket trading abuses and manipulations.

¹⁸ It is the Exchange's understanding that the OCC intends to make rule filing to allow it to clear cash settled non-ETF equity options.

increased attempted manipulative activity.

The proposed rule change is designed to allow investors seeking to effect cash-settled FLEX non-ETF Equity Options with the opportunity for a different method of settling option contracts at expiration if they choose to do so. As noted above, market participants may choose cash settlement because physical settlement possesses certain risks with respect to volatility and movement of the underlying security at expiration that market participants may need to hedge against. The Exchange believes that offering innovative products flows to the benefit of the investing public. A robust and competitive market requires that exchanges respond to members' evolving needs by constantly improving their offerings. Such efforts would be stymied if exchanges were prohibited from offering innovative products for reasons that are generally debated in academic literature.

The Exchange believes that introducing cash-settled FLEX non-ETF Equity Options would further broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC markets for customized options, where settlement restrictions do not apply. The proposed rule change is also designed to encourage market makers to shift liquidity from the OTC market onto the Exchange, which, the Exchange believes, will enhance the process of price discovery conducted on the Exchange through increased order flow. The Exchange also believes that this may open up cash settled FLEX non-ETF Equity Options to more retail investors.

The Exchange also proposes to amend paragraph (f)(3)(ii)(A) of Rule 5.32–O to provide that, where more than 50 underlying ETFs or 50 underlying non-ETFs qualify for cash settlement, the Exchange will select the 50 qualifying securities with the highest average daily notional value, replacing the current usage of highest average daily volume. The Exchange believes that, in making this determination, average daily notional value is a more appropriate metric. Specifically, it accounts for both trading activity and the price of the underlying security, which average daily volume alone does not capture.

As a general matter, higher-priced securities are less susceptible to cost-effective manipulation. Manipulative price impact is better measured by value, not share count. Thus, notional value more accurately identifies securities where potential manipulation is economically feasible and

meaningful. Moreover, average daily notional value reduces the potential of a low-priced underlying equity that is potentially more susceptible to manipulation from being eligible for participating in the program.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,²² in general, and furthers the objectives of Section 6(b)(5) of the Act,²³ in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. In addition, the Exchange believes that the proposed rule change is consistent with the Section 6(b)(5)²⁴ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that introducing cash-settled FLEX non-ETF Equity Options will increase order flow to the Exchange, increase the variety of options products available for trading, and provide a valuable tool for investors to manage risk. The Exchange further believes that using average daily notional value, rather than average daily volume, in determining eligibility where more than 50 underlying equity securities qualify ensures that cash settlement eligibility is tied to a more robust and meaningful measure of market activity, thereby better protecting investors and the public interest.

The Exchange believes that the proposal to permit cash settlement as a contract term for options on the specified group of non-ETF equity securities would remove impediments to and perfect the mechanism of a free and open market as cash-settled FLEX non-ETF Equity Options would enable market participants to receive cash in lieu of shares of the underlying security, which would, in turn, provide greater opportunities for market participants to manage risk through the use of a cash-settled product to the benefit of investors and the public interest.

The Exchange does not believe that allowing cash settlement as a contract term for options on the specified group

of non-ETF equity securities would render the marketplace for equity options more susceptible to manipulative practices. As illustrated in the table above, each of the qualifying underlying securities is actively traded and highly liquid (in general and at the close) and, thus, would not be susceptible to manipulation because, over a six-month period, each security had an average daily notional value of at least \$500 Million and an ADV of at least 4,680,000 shares, which indicates that there is substantial liquidity present in the trading of these securities, and that there is significant depth and breadth of market participants providing liquidity and of investor interest.

The Exchange believes that the data provided by the Exchange supports the supposition that permitting cash settlement as a FLEX term for the 143 underlying securities that would currently qualify to have cash settlement as a contract term would broaden the base of investors that use FLEX Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply.

The Exchange believes that the proposal to permit cash settlement would remove impediments to and perfect the mechanism of a free and open market because the proposed rule change would provide OTP Holders with enhanced methods to manage risk by receiving cash if they choose to do so instead of the underlying security. In addition, this proposal would promote just and equitable principles of trade and protect investors and the general public because cash settlement would provide investors with an additional tool to manage their risk. Further, the Exchange notes that its proposal to introduce cash-settled FLEX non-ETF Equity Options is not novel in that other exchanges have previously received approval that allow for the trading of cash-settled options. The proposed rule change therefore should not raise issues for the Commission that have not been previously addressed.²⁵

The proposed rule change to permit cash settlement as a contract term for options on the 143 underlying securities is designed to promote just and equitable principles of trade in that the availability of cash settlement as a contract term would give market participants an alternative to trading similar products in the OTC market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market), the Exchange would

²² 15 U.S.C. 78f(b).

²³ 15 U.S.C. 78f(b)(5).

²⁴ 15 U.S.C. 78f(b)(5).

²⁵ See *supra*, Notes 14 and 15.

be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that it would lead to the migration of options currently trading in the OTC market to trading on the Exchange. Also, any migration to the Exchange from the OTC market would result in increased market transparency. Additionally, the Exchange believes the proposed rule change is designed to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest in that it should create greater trading and hedging opportunities and flexibility. The proposed rule change should also result in enhanced efficiency in initiating and closing out positions and heightened contra-party creditworthiness due to the role of OCC as issuer and guarantor of the proposed cash-settled options. Further, the proposed rule change would result in increased competition by permitting the Exchange to offer products that are currently available for trading only in the OTC market.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in cash-settled FLEX non-ETF Equity Options. Regarding the proposed cash settlement, the Exchange would use the same surveillance procedures currently utilized for the Exchange's other FLEX Options. For surveillance purposes, the Exchange would have access to information regarding trading activity in the pertinent underlying securities. The Exchange believes that limiting cash settlement to options on 50 non-ETF underlying securities that would currently be eligible to have cash-settlement as a contract term would minimize the possibility of manipulation due to the robust liquidity in both the equities and options markets. Further, the Exchange believes that assessing eligibility of qualifying securities using the highest average daily notional value, rather than with the highest average daily volume, ensures that cash settlement eligibility is tied to a more robust and meaningful measure of market activity that is less susceptible to manipulation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any

burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as all Floor Brokers and FLEX Market Makers that are authorized to trade FLEX Equity Options, including non-ETF options, in accordance with the Exchange's Rules will be able to trade cash-settled FLEX non-ETF Equity Options in the same manner. This includes that, for all FLEX Equity Options at least one of exercise style, expiration date, and exercise price must differ from options in the non-FLEX market. Additionally, positions in cash-settled FLEX non-ETF Equity Options of all OTP Holders will be subject to the same position limits, and such positions will be aggregated with positions in physically settled options on the same underlying in the same manner.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act, as the proposal is designed to increase competition for order flow on the Exchange in a manner that is beneficial to investors because it is designed to provide investors seeking to transact in FLEX non-ETF Equity Options with the opportunity for an alternative method of settling their option contracts at expiration. The Exchange believes the proposed rule change will encourage competition, as it may broaden the base of investors that use FLEX Equity Options to manage their trading and investment risk, including investors that currently trade in the OTC market for customized options, where settlement restrictions do not apply. The proposed rule change would give market participants an alternative to trading similar products in the OTC market. By trading a product in an exchange-traded environment (that is currently traded in the OTC market), the Exchange would be able to compete more effectively with the OTC market. The Exchange believes the proposed rule change may increase competition as it may lead to the migration of options currently trading in the OTC market to trading on the Exchange. Also, any migration to the Exchange from the OTC market would result in increased market transparency and thus increased price competition.

The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues who offer similar functionality. The Exchange believes the proposed rule change encourages competition amongst market participants to provide tailored cash-settled FLEX non-ETF Equity Option contracts.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 the 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-NYSEARCA-2026-68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEARCA-2026-68. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright

protection. All submissions should refer to file number SR-NYSEARCA-2026-68 and should be submitted on or before July 28, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-13651 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33-11428; 34-105832; IA-6977; IC-36237]

No Adjustment to Civil Monetary Penalty Amounts

AGENCY: Securities and Exchange Commission.

ACTION: Notice that maximum civil monetary penalties will not increase for inflation in the 2026 calendar year.

SUMMARY: The Securities and Exchange Commission (“Commission”) is publishing this notice (“Notice”) pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (“2015 Act”). This Act requires all agencies to annually adjust for inflation the civil monetary penalties that may be imposed under the statutes administered by the agency and publish the adjusted amounts in the **Federal Register**. This Notice informs the public that, in accordance with the April 17, 2026, guidance from the Office of Management and Budget (“OMB”), there will be no inflation adjustment for 2026. The maximum inflation-adjusted civil monetary penalty amounts published in January 2025 for penalties under the Securities Act of 1933 (“Securities Act”), the Securities Exchange Act of 1934 (“Exchange Act”), the Investment Company Act of 1940 (“Investment Company Act”), the Investment Advisers Act of 1940 (“Advisers Act”), and certain penalties under the Sarbanes-Oxley Act of 2002 will continue to apply to all civil monetary penalties imposed after January 15, 2025, for violations of the aforementioned statutes that occurred after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Stephen Ng, Senior Special Counsel, Office of the General Counsel, at (202) 551-7957, or Hannah Riedel, Senior Counsel, Office of the General Counsel, at (202) 551-7918.

SUPPLEMENTARY INFORMATION:

I. Background

This Notice is being published pursuant to the 2015 Act,¹ which amended the Federal Civil Penalties Inflation Adjustment Act of 1990.² The 2015 Act requires that agencies use a specific formula to calculate the maximum inflation-adjusted amounts of civil monetary penalties they administer on an annual basis and publish these new amounts in the **Federal Register** by January 15th of each year.³ The Commission published the first annual adjustment required by the 2015 Act on January 6, 2017 (“2017 Adjustment”).⁴

Since 2017, the Commission has published annual adjustments as required by the 2015 Act, the most recent of which was published on January 7, 2025 (“2025 Adjustment”).⁵ The annual adjustments apply to the civil monetary penalty provisions contained in four statutes administered by the Commission: the Securities Act, the Exchange Act, the Investment Company Act, and the Investment Advisers Act.⁶ In addition, the Sarbanes-Oxley Act provides the Public Company Accounting Oversight Board (“PCAOB”) authority to levy civil monetary penalties in its disciplinary proceedings.⁷ Penalties assessed by the PCAOB in its disciplinary proceedings are penalties “enforced” by the Commission for purposes of the 2015 Act.⁸

¹ Public Law 114-74 Sec. 701, 129 Stat. 599-601 (Nov. 2, 2015), codified at 28 U.S.C. 2461 note.

² Public Law 101-410, 104 Stat. 890-892 (1990), codified at 28 U.S.C. 2461 note. The Inflation Adjustment Act previously had been amended by the Debt Collection Improvement Act of 1996 (“DCIA”) to require that each Federal agency adopt regulations at least once every four years that adjust for inflation the civil penalties that may be imposed under the statutes administered by the agency. Public Law 104-134, Title III, Sec. 31001(s)(1), 110 Stat. 1321-373 (1996), codified at 28 U.S.C. 2461 note.

³ 28 U.S.C. 2461 note Sec. 4. The 2015 Act replaced the formula prescribed in the DCIA with a new formula for calculating the inflation-adjusted amount of relevant civil monetary penalties.

⁴ Release Nos. 33-10276; 34-79749; IA-4599; IC-32414 (effective Jan. 18, 2017). As part of the 2017 Adjustment, the Commission promulgated 17 CFR 201.1001(a) and Table I to Subsection 1001, which lists the penalty amounts for all violations that occurred on or before November 2, 2015. For violations occurring after November 2, 2015, Subsection 1001(b) provides that the applicable penalty amounts will be adjusted annually based on the formula set forth in the 2015 Act. Subsection 1001(b) further provides that these adjusted amounts will be published in the **Federal Register** and on the Commission’s website.

⁵ Release Nos. 33-11350; 34-102134; IA-6808; IC-35442 (effective Jan. 15, 2025).

⁶ See 28 U.S.C. 2461 note Sec. 3(2).

⁷ 15 U.S.C. 7215(c)(4)(D).

⁸ The Commission may by order affirm, modify, remand, or set aside sanctions, including civil monetary penalties, imposed by the PCAOB. See Sarbanes-Oxley Act of 2002, 15 U.S.C. 7217(c).

II. Cancellation of 2026 Penalty Inflation Adjustment

Since 2017, the Commission has, as provided in the 2015 Act, annually adjusted these maximum civil penalties for inflation by increasing them by a multiplier (“CPI-U Multiplier”) that represents the percentage change between the Consumer Price Index for all Urban Consumers (“CPI-U”) from the Bureau of Labor Statistics (“BLS”) for October of the prior year and October of the year directly preceding the January adjustment.⁹ OMB provides the CPI-U Multiplier to Federal agencies in an annual memorandum.¹⁰ The Commission adjusted civil monetary penalty amounts for 2025 Adjustment by multiplying the amounts in its previous adjustment by the CPI-U Multiplier and then rounding to the nearest dollar.¹¹

Due to a lapse in appropriations from October 1, 2025, until November 12, 2025, BLS was unable to produce the October 2025 CPI-U data. As a result, there was no inflation adjustment multiplier for 2026, which is needed to adjust civil monetary penalties for the 2026 calendar year under the 2015 Act. On April 17, 2026, OMB issued Memorandum M-26-11 informing agencies of the cancellation of the inflation adjustment for 2026.¹² Accordingly, the Commission will continue using the maximum civil monetary penalties as adjusted for inflation by the 2025 Adjustment for all penalties imposed after January 15, 2025, for violations that occurred after November 2, 2015.¹³ For violations that

⁹ See 28 U.S.C. 2461 note Sec. 5.

¹⁰ *Id.* Sec. 7(a) (requiring OMB to issue annual guidance to agencies on implementing the inflation adjustments required under the 2015 Act); OMB, M-16-06, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Feb. 24, 2016), at 4, available at https://www.whitehouse.gov/wp-content/uploads/legacy-drupal_files/omb/memoranda/2016/m-16-06.pdf (indicating that OMB will issue annual adjustment rate guidance).

¹¹ See Release Nos. 33-11350; 34-102134; IA-6808; IC-35442 (effective Jan. 15, 2025), at 5-7. The CPI-U Multiplier for the 2025 Adjustment was 1.02598. See OMB, M-25-02, Implementation of Penalty Inflation Adjustments for 2025, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Dec. 17, 2024), available at <https://www.whitehouse.gov/wp-content/uploads/2024/12/M-25-02.pdf>.

¹² See OMB, M-26-11, Cancellation of Penalty Inflation Adjustments for 2026, Regarding the Federal, Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Apr. 17, 2026), available at <https://www.whitehouse.gov/wp-content/uploads/2026/04/M-26-11-Cancellation-of-Penalty-Inflation-Adjustments-for-2026-Regarding-the-Federal-Civil-Penalties-Inflation-Adjustment-Act-Improvements-Act-of-2015.pdf>.

¹³ The maximum civil penalty amounts from the 2025 Adjustment are available in the **Federal Register**, 90 FR 2767 (published Jan. 13, 2025), and

²⁶ 17 CFR 200.30-3(a)(12).

occurred on or before November 2, 2015, the penalty amounts in Table I to 17 CFR 201.1001 continue to apply.¹⁴

By the Commission.

Dated: July 1, 2026.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-13629 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 36238; 812-16024]

Muzinich Aviation Income Fund (mAIR) and Muzinich & Co., Inc.

July 2, 2026.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).

ACTION: Notice.

Notice of an application under section 6(c) of the Investment Company Act of 1940 (the “Act”) for an exemption from sections 18(a)(2), 18(c) and 18(i) of the Act, under sections 6(c) and 23(c) of the Act for an exemption from rule 23c-3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d-1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end investment companies to issue multiple classes of shares and to impose asset-based distribution and/or service fees and early withdrawal charges.

APPLICANTS: Muzinich Aviation Income Fund (mAIR) and Muzinich & Co., Inc.

FILING DATE: The application was filed on May 8, 2026 and amended on June 18, 2026.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. The email should include the file number referenced above. Hearing requests should be received by the Commission by 5:30 p.m., Eastern time on July 27, 2026, and should be accompanied by proof of

service on the Applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*. Applicants: Alyssa M. Bernard, Muzinich Aviation Income Fund (mAIR), 615 East Michigan Street, Milwaukee, Wisconsin 53202, and *alyssa.bernard@usbank.com*; with copies to Deborah Bielicke Eades and Nathaniel Segal, Vedder Price P.C., 222 N LaSalle Street, Chicago, Illinois 60601, and *deades@vedder.com*, and *nsegal@vedder.com*.

FOR FURTHER INFORMATION CONTACT: Trace W. Rakestraw, Senior Special Counsel, at (202) 551-6825 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: For Applicants’ representations, legal analysis, and conditions, please refer to Applicants’ amended application, dated June 18, 2026, which may be obtained via the Commission’s website by searching for the file number at the top of this document, or for an Applicant using the Company name search field on the SEC’s EDGAR system. The SEC’s EDGAR system may be searched at <https://www.sec.gov/search-filings>.

You may also call the SEC’s Office of Investor Education and Assistance at (202) 551-8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026-13710 Filed 7-6-26; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-105845; File No. SR-FINRA-2026-004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Partial Amendment No. 1 to Proposed Rule Change To Amend FINRA Rule 2210 (Communications With the Public)

July 2, 2026.

I. Introduction

On February 10, 2026, the Financial Industry Regulatory Authority, Inc.

(“FINRA”) filed with the Securities and Exchange Commission (“SEC” or “Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Exchange Act”) ¹ and Rule 19b-4 thereunder, ² a proposed rule change to amend FINRA Rule 2210 (Communications with the Public) to allow a member to project the performance of, or provide a targeted return with respect to, a security, a securities portfolio, or an asset allocation or other investment strategy in its communications with the public, subject to certain conditions (hereinafter, the “Initial Rule Filing”).

The proposed rule change was published for comment in the **Federal Register** on February 25, 2026. ³ The public comment period closed on March 18, 2026. The Commission received comment letters in response to the Notice. ⁴ On April 7, 2026, FINRA consented to an extension of the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to May 26, 2026. ⁵ On May 18, 2026, the Commission received a letter from FINRA stating that it was considering comments on the proposed rule change and anticipated submitting a response to comments, as well as amendments to the proposed rule change, “in the near future.” ⁶ On May 20, 2026, the Commission published an order instituting proceedings to determine whether to approve or disapprove the proposed rule change (“OIP”). ⁷ The Commission received comment letters in response to the OIP. ⁸ On June 30, 2026, FINRA responded to the comment letters

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Exchange Act Release No. 104877 (Feb. 20, 2026), 91 FR 9308 (Feb. 25, 2026) (File No. SR-FINRA-2026-004) (“Notice”), <https://www.govinfo.gov/content/pkg/FR-2026-02-25/pdf/2026-03705.pdf>.

⁴ The comment letters received in response to the Notice are available at <https://www.sec.gov/rules-regulations/public-comments/sr-finra-2026-004>.

⁵ See letter from Joseph Savage, Vice President and Associate General Counsel, Office of General Counsel, FINRA (Apr. 7, 2026), <https://www.finra.org/sites/default/files/2026-04/SR-FINRA-2026-004-Extension-5-26-2026.pdf>.

⁶ Letter from David Driscoll, Associate General Counsel, Office of General Counsel, FINRA (May 18, 2026), <https://www.finra.org/sites/default/files/2026-05/SR-FINRA-2026-004-Response-to-Comments-20260518.pdf>.

⁷ See Exchange Act Release No. 105524 (May 20, 2026), 91 FR 30750 (May 26, 2026) (File No. SR-FINRA-2026-004), <https://www.govinfo.gov/content/pkg/FR-2026-05-26/pdf/2026-10365.pdf>.

⁸ The comment letters received in response to the OIP are available at <https://www.sec.gov/rules-regulations/public-comments/sr-finra-2026-004>.

on the Commission’s website, available at <https://www.sec.gov/files/civil-penalties-inflation-adjustments-011525.pdf>.

¹⁴ 17 CFR 201.1001(a).

received in response to the Notice⁹ and filed a partial amendment to the proposed rule change ("Partial Amendment No. 1").¹⁰

The Commission is publishing this notice to solicit comments on Partial Amendment No. 1 from interested persons.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Partial Amendment

A. Background

Among other things, FINRA Rule 2210 imposes restrictions on the content of members' communications with the public. For example, FINRA Rule 2210(d)(1) (General Standards) requires, among other things, that: (1) a communication prepared by a member be based on principles of fair dealing and good faith, be fair and balanced, and provide a sound basis for evaluating the facts in regard to any particular security or type of security, industry, or service;¹¹ and (2) the member preparing the communication: (a) not omit any material fact or qualification if the omission, in light of the context of the material presented, would cause the communication to be misleading;¹² (b) not make any false, exaggerated, unwarranted, promissory, or misleading statement or claim in the communication;¹³ and (c) consider the nature of the audience to which the communication will be directed and provide details and explanations appropriate to the audience.¹⁴ These standards also generally prohibit a communication prepared by a member from predicting or projecting performance, implying that past performance will recur, or making any exaggerated or unwarranted claim, opinion, or forecast.¹⁵ This general prohibition, however, does not preclude communications that contain: (1) certain hypothetical illustrations of mathematical principles;¹⁶ (2) certain investment analysis tools or written reports produced by such investment

analysis tools;¹⁷ and (3) certain price targets contained in research reports on debt or equity securities.¹⁸

The proposed rule change would adopt a fourth exception to FINRA Rule 2210(d)(1)(F) to permit the communication of projected performance or targeted returns in certain narrowly defined circumstances. Specifically, under the Initial Rule Filing, proposed FINRA Rule 2210(d)(1)(F)(iv) would have excluded from FINRA Rule 2210(d)(1)(F)'s general prohibition a member's communication that projects the performance of, or provides a targeted return with respect to, a security, a securities portfolio, or an asset allocation or other investment strategy, provided that the member: (1) adopts and implements written policies and procedures reasonably designed to ensure that the communication is relevant to the likely financial situation and investment objectives of the intended audience of the communication;¹⁹ (2) has a reasonable basis for the criteria used and assumptions made in calculating the projected performance or targeted return, and retains written records supporting the basis for such criteria and assumptions;²⁰ and (3) provides sufficient information to enable the intended audience to understand: (i) the criteria used and assumptions made in calculating the projected performance or targeted return, including whether the projected performance or targeted return is net of anticipated fees and expenses; and (ii) the risks and limitations of using the projected performance or targeted return in making investment decisions, including reasons why the projected performance or targeted return might differ from actual performance.²¹

In response to commenters, FINRA is proposing the following amendments to the proposed rule change as described in the Initial Rule Filing:

B. Proposed Amendment to FINRA Rule 2210(b)(4) (Recordkeeping)

FINRA is proposing to amend FINRA Rule 2210's recordkeeping requirement to require members to maintain information concerning the source of any projection of performance or targeted return. Specifically, Partial Amendment No. 1 would modify FINRA Rule 2210(b)(4)(A)(iv) to require that a member's records include information concerning the source of any projection of performance or targeted return.²² FINRA stated that requiring firms to keep records of information relating to projections and targeted returns would help members substantiate the basis for such performance presentations.²³

C. Proposed Amendments to Proposed FINRA Rule 2210(d) (Content Standards)

1. Proposed Amendment to Proposed FINRA Rule 2210(d)(1)(F)(iv)(b) (Reasonable Basis Standard)

FINRA is proposing to eliminate the Initial Rule Filing's proposed requirement that members: (1) have a reasonable basis for the criteria used and assumptions made in calculating a projected performance or targeted return in a communication with the public, and (2) retain written records supporting the basis for such criteria and assumptions.²⁴ Specifically, Partial Amendment No. 1 would eliminate proposed FINRA Rule 2210(d)(1)(F)(iv)(b) and renumber proposed FINRA Rule 2210(d)(1)(F)(iv)(c) as FINRA Rule 2210(d)(1)(F)(iv)(b).²⁵ FINRA stated that an express reasonable basis standard is unnecessary because FINRA Rule 2210's general content standards would preclude any unreasonable projections or targeted returns.²⁶

2. Proposed Amendments to Proposed FINRA Rule 2210(d)(1)(F)(iv)(c) (Disclosure)

FINRA is proposing to eliminate the Initial Rule Filing's proposed requirement that members expressly disclose: (1) whether any projected performance or targeted return appearing in a communication with the public is net of anticipated fees and expenses, and (2) the reasons why a projected performance or targeted return appearing in a communication with the

⁹ See letter from Joseph Savage, Vice President and Associate General Counsel, Office of General Counsel, FINRA (Jun. 30, 2026) ("FINRA Response Letter"), <https://www.sec.gov/comments/SR-FINRA-2026-004/srfinra2026004-913220-2799313.pdf>.

¹⁰ Partial Amendment No. 1 is available on FINRA's website at <https://www.finra.org/rules-guidance/rule-filings/sr-finra-2026-004>.

¹¹ FINRA Rule 2210(d)(1)(A).

¹² *Id.*

¹³ FINRA Rule 2210(d)(1)(B).

¹⁴ FINRA Rule 2210(d)(1)(E).

¹⁵ FINRA Rule 2210(d)(1)(F).

¹⁶ FINRA Rule 2210(d)(1)(F)(i) (stating that a member may communicate a hypothetical illustration of mathematical principles, provided that it does not predict or project the performance of an investment or investment strategy).

¹⁷ FINRA Rule 2210(d)(1)(F)(ii) (stating that a member may publish an investment analysis tool, or a written report produced by an investment analysis tool, that includes projections of performance provided it meets the requirements of FINRA Rule 2214 (Requirements for the Use of Investment Analysis Tools)).

¹⁸ FINRA Rule 2210(d)(1)(F)(iii) (stating that a member may communicate a price target contained in a research report on debt or equity securities, provided that the price target has a reasonable basis, the report discloses the valuation methods used to determine the price target, and the price target is accompanied by disclosure concerning the risks that may impede achievement of the price target).

¹⁹ Proposed FINRA Rule 2210(d)(1)(F)(iv)(a) as proposed in the Initial Rule Filing.

²⁰ Proposed FINRA Rule 2210(d)(1)(F)(iv)(b) as proposed in the Initial Rule Filing.

²¹ Proposed FINRA Rule 2210(d)(1)(F)(iv)(c) as proposed in the Initial Rule Filing.

²² See proposed FINRA Rule 2210(b)(4)(A)(iv) as proposed in Partial Amendment No. 1.

²³ FINRA Response Letter at 13.

²⁴ See proposed FINRA Rule 2210(d)(1)(F)(iv)(b) as proposed in the Initial Rule Filing.

²⁵ See proposed FINRA Rule 2210(d)(1)(F)(iv) as proposed in Partial Amendment No. 1.

²⁶ FINRA Response Letter at 12.

public might differ from actual performance.²⁷ Specifically, Partial Amendment No. 1 would modify proposed FINRA Rule 2210(d)(1)(F)(iv)(c) to delete the following clauses: (1) “including whether the projected performance or targeted return is net of anticipated fees and expenses”, and (2) “including reasons why the projected performance or targeted return might differ from actual performance.”²⁸ FINRA stated that FINRA Rule 2210’s general content standards, together with the remaining proposed disclosure requirements that are specific to projections of performance and targeted returns, would help ensure that investors receive information to consider the risks and limitations of relying on such performance in determining how to invest.²⁹

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change, as amended by Partial Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–FINRA–2026–004 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–FINRA–2026–004. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the filing will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–FINRA–2026–004 and should be submitted on or before July 28, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–13713 Filed 7–6–26; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

SBIC License Issuance

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Small Business Investment Company (SBIC) licenses.

SUMMARY: Pursuant to the authority granted to the United States Small Business Administration under section 301(c) of the Small Business Investment Act of 1958, as amended, to grant Small Business Investment Company licenses under the Small Business Investment Company Program, this notice satisfies the requirement effective August 17, 2023 under 13 CFR 107.501(a) to publish in the **Federal Register** the names of SBICs with date of licensure and Total Intended Leverage Commitments. The following SBICs received SBIC licenses as of the date indicated below:

SBIC fund name	Date of licensure	Leverage tiers ¹
Acequia Capital Origin SBIC, L.P	5/4/2026	1.25x.
Pelican Energy Partners Base Zero SBIC, L.P	5/12/2026	Non-Leveraged.
RSCF II SBIC, L.P	5/26/2026	2.00x.
Savory Fund III Financial Institutions Fund, L.P	5/27/2026	Non-Leveraged.
BSCP SBIC III, L.P	5/29/2026	2.00x.
New Canaan Funding Mezzanine VIII SBIC, L.P	6/9/2026	2.00x.
Navigate Capital Partners SBIC Fund II, L.P	6/11/2026	2.00x.
Aldine Capital Fund V, L.P	6/11/2026	2.00x.
Bayview Capital Partners V, L.P	6/15/2026	1.00x.

¹ Maximum amount of Leverage expressed as a multiple of Leverageable Capital pursuant to 13 CFR 107.1150.

Paul Van Eyl,

Director of Policy, Office of Investment and Innovation, U.S. Small Business Administration.

[FR Doc. 2026–13688 Filed 7–6–26; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice 13053]

30-Day Notice of Proposed Information Collection: Brokering Approval (License)

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for

approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments up to August 6, 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/

²⁷ See proposed FINRA Rule 2210(d)(1)(F)(iv)(c) as proposed in the Initial Rule Filing.

²⁸ See proposed FINRA Rule 2210(d)(1)(F)(iv) as proposed in Partial Amendment No. 1.

²⁹ FINRA Response Letter at 15.

³⁰ 17 CFR 200.30–3(a)(12).

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:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, Andrea Battista, who may be reached at BattistaAL@state.gov or 202–992–0973.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Brokering Approval.
- *OMB Control Number:* 1405–0142.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Directorate of Defense Trade Controls (DDTC), Defense Trade Controls Management.
- *Form Number:* DS–4294.
- *Respondents:* Respondents are U.S. and foreign persons who wish to engage in International Traffic in Arms Regulations (ITAR)-controlled brokering of defense articles and defense services.
- *Estimated Number of Respondents:* 170.
- *Estimated Number of Responses:* 170.
- *Average Time per Response:* 2 hours.
- *Total Estimated Burden Time:* 340 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

In accordance with part 129 of the ITAR, U.S. and foreign persons who

wish to engage in ITAR-controlled brokering activity of defense articles and defense services must first register with DDTC. Brokers must then submit a written request for approval to DDTC and receive DDTC’s approval prior to engaging in such activities, unless exempted. This information is currently used in the review of the brokering request submitted for approval and to ensure compliance with defense trade statutes and regulations. It is also used to monitor and control the transfer of sensitive U.S. technology.

Methodology

Applicants may submit a Brokering Approval Request electronically via DDTC’s Defense Export Control and Compliance System (DECCS), using the DS–4294.

Michael J. Vaccaro,

Deputy Assistant Secretary for Defense Trade Controls, U.S. Department of State.

[FR Doc. 2026–13664 Filed 7–6–26; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Public Notice: 13014]

Privacy Act of 1974; System of Records

AGENCY: Department of State.

ACTION: Notice of a modified system of records.

SUMMARY: This system of records documents the adjudication of grievance appeals and separation for cause actions recommended by an agency, as well as any other matters arising under the Foreign Service Grievance Board’s (FSGB) jurisdiction. These records may also be used to provide statistical data and other information for reports, member productivity, and other management functions.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this system of records notice is effective upon publication, with the exception of the routine uses (a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), and (p) that are subject to a 30-day period during which interested persons may submit comments to the Department. Please submit any comments by August 6, 2026.

ADDRESSES: Questions can be submitted by mail, email, or by calling Timothy J. Kootz, the Senior Agency Official for Privacy, on (202) 485–2051. If mail, please write to: Timothy J. Kootz, Senior Agency Official for Privacy; U.S. Department of State; Shared Knowledge Services, A/SKS; Room 4534, 2201 C St.

NW; Washington, DC 20520. If email, please address the email to the Senior Agency Official for Privacy, Timothy J. Kootz, at SORN@state.gov. Please write “Foreign Service Grievance Board Records, State-13” on the envelope or the subject line of your email.

FOR FURTHER INFORMATION CONTACT:

Timothy J. Kootz, Senior Agency Official for Privacy; U.S. Department of State; Shared Knowledge Services, A/SKS; Room 4534, 2201 C St. NW, Washington, DC 20520 or by calling (202) 485–2051.

SUPPLEMENTARY INFORMATION: The modified system of records notice includes revisions and additions to the following sections: Security Classification, System Location, System Manager(s), Authority for Maintenance of the System, Purpose(s) of the System, Categories of Individuals Covered by the System, Categories of Records in the System, Record Source Categories, Routine Uses, Policies and Practices for Storage of Records, Policies and Practices for Retrieval of Records, Policies and Practices for Retention and Disposal of Records, and Administrative, Technical, and Physical Safeguards. In addition, the Department is taking this opportunity to make minor administrative updates to the notice in the following sections: Record Access Procedures, Contesting Record Procedures, Notification Procedures, Exemptions, and History. This notice is being modified to reflect the Department’s move to digital storage solutions, new OMB guidance, access by contractors, and updated contact information.

SYSTEM NAME AND NUMBER:

Foreign Service Grievance Board Records, State-13.

SECURITY CLASSIFICATION:

Unclassified and Classified.

SYSTEM LOCATION:

SA–26, 8101 O’Dell Rd., Beltsville, MD 20705, and within a government cloud provided, implemented, and overseen by the Department’s Enterprise Server Operations Center (ESOC), 2201 C Street NW, Washington, DC 20520.

SYSTEM MANAGER(S):

Executive Secretary, Foreign Service Grievance Board, SA–15, 1800 N. Kent Street, Suite 3100S, Arlington, VA 22209. The Executive Secretary can be reached via email at FSGB@state.gov.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 2581 (General Authority of Secretary of State); 22 U.S.C. 2651a (Organization of the Department of

State); 22 U.S.C. 3921 (Administration by the Secretary of State); 22 U.S.C. 3901 (Foreign Service Act of 1980); 22 U.S.C. 3921 (Management of the Foreign Service) 22 U.S.C. 4135(e) (Foreign Service Grievance Board); 22 CFR 903.2 (Record of proceedings).

PURPOSE(S) OF THE SYSTEM:

This system of records is maintained to document and adjudicate grievance appeals and separation for cause actions recommended by an agency, as well as any other matters arising under the Board's jurisdiction. These records may also be used to provide statistical data and other information for reports, member productivity, and other management functions.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former Foreign Service personnel of the Department of State, the Department of Commerce U.S. & Foreign Commercial Service (FCS), the U.S. Agency for Global Media (USAGM), the Department of Agriculture Foreign Agricultural Service (FAS), the Peace Corps, and former Foreign Service personnel of the U.S. Agency for International Development (USAID) who are parties to, or mentioned in the parties' filings in grievance appeals, separation for cause cases, and other cases adjudicated by the Foreign Service Grievance Board. The Privacy Act defines an individual at 5 U.S.C. 552a(a)(2) as a United States citizen or lawful permanent resident.

CATEGORIES OF RECORDS IN THE SYSTEM:

The Foreign Service Grievance Board records covered include the Records of Proceedings; Board Orders and Decisions; and Court Case Files. The Records of Proceedings in the grievance appeal or separation for cause proceedings include all documents filed by the parties; exhibits; hearing transcripts; decisions, orders, and other communications issued by the Board; and any other materials received or obtained by the Board in connection with the case, except for materials the Board excludes from the Record of Proceedings under 22 CFR 903.3. Board Orders and Decisions are files that contain only those specific documents issued by the Board in a case. Court Case Files contain documents sent to the relevant court or administrative body when a Board decision is appealed, or an exception is filed; communications regarding those appeals or exceptions; and subsequent court actions. These records may contain employees' name, social security number, addresses, law

enforcement information, race, sex, national origin, disability status, and medical information.

RECORD SOURCE CATEGORIES:

The individual; the agency which employs the individual; the exclusive representative; other individuals or organizations from whom the FSGB has received testimony, affidavits, or other documents.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

Foreign Service Grievance Board Records may be disclosed:

(a) To appropriate agencies, entities, and persons when (1) the Department of State suspects or has confirmed that there has been a breach of the system of records; (2) the Department of State has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department of State (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department of State efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(b) To another Federal agency or Federal entity, when the Department of State determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(c) To members of the Board and staff of the Board, to conduct grievance reviews, carry out research related to the grievance or separation for cause proceeding, and for any other functions related to the adjudication of a grievance or a separation for cause proceeding.

(d) To the grievant or charged employee so that they can pursue a grievance appeal or defend themselves in a separation for cause proceeding and review the record of proceedings to ensure its accuracy.

(e) To the grievant representative(s), if any, so that they can pursue a grievance appeal or defend a client in a separation for cause proceeding and review the record of proceedings to ensure its accuracy.

(f) To the exclusive employee representative so that they can participate in any grievance or separation for cause proceeding and review the record of any proceeding to ensure its accuracy.

(g) To the Agency against which the grievance has been filed or any other Agency with equities in the grievance, so that the recipient or other Agency can: (i) defend itself in a grievance appeal, (ii) have access to material and relevant information in an appeal in which it has equities, and/or (iii) review the record of proceedings to ensure its accuracy.

(h) To an appropriate court or administrative body, which will be provided a copy of the Record of Proceedings when one of the parties files an appeal or exception of a Board decision.

(i) To the Department of Justice ("DOJ"), if it is representing an Agency in an appeal of a Board decision, so that the Department of Justice can defend the Agency in such an appeal.

(j) To the National Archives and Records Administration for records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

(k) To a contractor of the Department having need for the information in the performance of the contract but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

(l) To an agency, whether federal, state, local or foreign, where a record indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, so that the recipient agency can fulfill its responsibility to investigate or prosecute such violation or enforce or implement the statute, rule, regulation, or order.

(m) To the Federal Bureau of Investigation, the Department of Homeland Security, the National Counter-Terrorism Center (NCTC), the Terrorist Screening Center (TSC), or other appropriate federal agencies, for the integration and use of such information to protect against terrorism, if that record is about one or more individuals known, or suspected, to be or to have been involved in activities constituting, in preparation for, in aid of, or related to terrorism. Such Information may be further disseminated by recipient agencies to Federal, State, local, territorial, tribal, and foreign government authorities, and to support private sector processes as contemplated in Homeland Security Presidential Directive/HSPD-6 and

other relevant laws and directives, for terrorist screening, threat-protection and other homeland security purposes.

(n) To a congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

(o) To a court, adjudicative body, or administrative body before which the Department is authorized to appear when (a) the Department, (b) any employee of the Department in his or her official capacity; (c) any employee of the Department in his or her individual capacity where the DOJ or the Department has agreed to represent the employee; or (d) the Government of the United States, when the Department determines that litigation is likely to affect the Department, is a party to litigation or has an interest in such litigation, and the use of such records by the Department is deemed to be relevant and necessary to the litigation or administrative proceeding.

(p) To the DOJ for its use in providing legal advice to the Department or in representing the Department in a proceeding before a court, an adjudicative body, or other administrative body before which the Department is authorized to appear, where the Department deems DOJ's use of such information relevant and necessary to the litigation, and such proceeding names as a party or interests:

(1) The Department or any component of it;

(2) Any employee of the Department in his or her official capacity;

(3) Any employee of the Department in his or her individual capacity where DOJ has agreed to represent the employee; or

(4) The Government of the United States, where the Department determines that litigation is likely to affect the Department or any of its components.

In addition to the routine uses described above, redacted decisions and orders issued in grievances and separation for cause proceedings may be published on the Board's public website to inform the public about the Board's decisions and operations.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in both hard copy and in electronic media. A description of standard Department of State policies concerning storage of electronic records is found here <https://fam.state.gov/FAM/05FAM/05FAM0440.html>. All hard copies of records containing personal information are maintained in secured file cabinets and in restricted

areas, access to which is limited to authorized personnel only.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Case numbers and individual grievant names.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained in accordance with the following Records Disposition Schedule: DAA-0059-2013-0002.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All users are given cyber security awareness training which covers the procedures for handling Sensitive but Unclassified (SBU) information, including personally identifiable information (PII). Annual refresher training is mandatory. In addition, all Department OpenNet users are required to take the Foreign Service Institute distance learning course instructing employees on privacy and security requirements, including the rules of behavior for handling PII and the potential consequences if it is handled improperly. Before being granted access to Foreign Service Grievance Board Records, a user must first be granted access to the Department of State computer system.

Department of State employees and contractors may remotely access this system of records using non-Department owned information technology. Such access is subject to approval by the Department's access program and is limited to information maintained in unclassified information systems. Remote access to the Department's information systems is configured in compliance with OMB Circular A-130 multifactor authentication requirements and includes a time-out function.

All Department of State employees and contractors with authorized access to records maintained in this system of records have undergone a thorough background security investigation. Access to the Department of State, its annexes and posts abroad is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage. When it is determined that a user no longer needs access, the user account is disabled.

Information that conforms with Department-specific definitions for Federal Information Security Modernization Act (FISMA) low, moderate, or high categorization are permissible for cloud usage and must specifically be authorized by the Department's Cloud Program Management Office and the Department of State Authorizing Official. Specific security measures and safeguards will depend on the FISMA categorization of the information in a given cloud system. In accordance with Department policy, systems that process more sensitive information will require more stringent controls and review by Department cybersecurity experts prior to approval. Prior to operation, all Cloud systems must comply with applicable security measures that are outlined in FISMA, FedRAMP, OMB regulations, National Institute of Standards and Technology's (NIST) Special Publications (SP) and Federal Information Processing Standards (FIPS) and Department of State policies and standards.

All data stored in cloud environments categorized above a low FISMA impact risk level must be encrypted at rest and in-transit using a federally-approved encryption mechanism. The encryption keys shall be generated, maintained, and controlled in a Department data center by the Department key management authority. Deviations from these encryption requirements must be approved in writing by the Department of State Authorizing Official. High FISMA impact risk level systems will additionally be subject to continual auditing and monitoring, multifactor authentication mechanism utilizing Public Key Infrastructure (PKI) and NIST 800 53 controls concerning virtualization, servers, storage and networking, as well as stringent measures to sanitize data from the cloud service once the contract is terminated.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should submit a Privacy Act request to the U.S. Department of State Information Access Programs (IAP) directorate by following the guidance and procedures located at <https://foia.state.gov/request/request2.aspx>. Mailed requests can be addressed to U.S. Department of State, Information Access Programs Directorate (A/SKS/IAP); 2201 C Street NW Washington, DC 20520-0000. To request information under the Privacy Act, the individual should be a citizen of the United States, or an alien lawfully admitted for permanent residence. The Privacy Act permits access to an individual's own

records only if those records are within a system of records that are retrieved by an individual's name or personal identifier.

CONTESTING RECORD PROCEDURES:

Individuals who wish to contest the content of any record pertaining to him or her in the system should write to U.S. Department of State; Information Access Programs Directorate (A/SKS/IAP); 2201 C Street NW, Washington, DC 20520–0000.

NOTIFICATION PROCEDURES:

Individuals who wish to be notified if the system contains a record pertaining to him or her should write to the U.S. Department of State; Information Access Programs Directorate (A/SKS/IAP); 2201 C Street NW, Washington, DC 20520–0000.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(k)(1), records subject to the provisions of section 552(b)(1) are exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). Pursuant to 5 U.S.C. 552a(k)(5), records that consist of investigatory material compiled for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information are exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f).

HISTORY:

Previously published at 42 FR 49706.

Timothy J. Kootz,

Deputy Assistant Secretary, Shared Knowledge Services (A/SKS), U.S. Department of State.

[FR Doc. 2026–13634 Filed 7–6–26; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2026–5578]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: International Role of the Federal Aviation Administration

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 (OMB) approval to renew an information collection. The collection involves questioning, via email, telephone or other means, foreign entities to determine what collaborative opportunities exist. The information to be collected is necessary to accomplish the statutory requirements of Title 49 United States Code (49 U.S.C.) § 40104 to “provide technical assistance on any other aspect of aviation safety that the Administrator determines is likely to enhance international aviation safety.” The information collection will also inform the FAA’s International Strategy, which is the agency’s mechanism for fulfilling its international role. The information collection directly supports the International Strategy by enabling the FAA to adapt and strengthen its longstanding international presence in response to emerging opportunities and risks facing the U.S. aerospace industry from abroad.

DATES: Written comments should be submitted by September 8, 2026.

ADDRESSES: Please send written comments:

By Electronic Docket:
www.regulations.gov (Enter docket number into search field).

By mail: Nicholas DeLotell, Office of International Affairs, 800 Independence Ave. SW, Washington, DC 20591.

By fax: (202) 267–7198.

FOR FURTHER INFORMATION CONTACT:

Nicholas DeLotell by email at: 9-APL-API-Resources@faa.gov; phone: (202) 710–1163.

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: 2120–0818.

Title: Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: International Role of the Federal Aviation Administration.

Form Numbers: FAA Form 1240–6.

Type of Review: Clearance of a renewal of an information collection.

Background: 49 U.S.C. 40104 requires “the Administrator to promote and achieve global improvements in the safety, efficiency, and environmental effect of air travel by engaging with foreign counterparts, in the International Civil Aviation Organization (ICAO) and its subsidiary organizations, and other international organizations and fora, and with the private sector.” The statute further requires the Administrator to engage bilaterally and multilaterally on an ongoing basis to bolster international collaboration and to harmonize international aviation safety requirements, and to expand the technical assistance provided by the FAA in support of enhancing international aviation safety.

This information collection specifically facilitates work and training arrangements with foreign counterparts, ICAO and its subsidiary organizations, other international organizations and fora, and with private entities around the world; it identifies opportunities and unexpected changes; and it ultimately contributes to the fulfillment of the FAA’s mission to provide the safest, most efficient aerospace system in the world.

Foreign affairs specialists assigned to the FAA Office of International Affairs will collect information from respondents (foreign counterparts, ICAO and its subsidiary organizations, other international organizations and fora, or from private foreign entities) verbally, in-person or telephonically, or in writing via letter, email, or other electronic means.

Respondents: Information is collected from approximately 195 affected entities. Respondents are representatives from the FAA’s counterpart Civil Aviation Authorities and other aviation-related international organizations.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 0.5 hours (rounded up from 0.4103).

Estimated Total Annual Burden: 80 hours.

Issued in Washington, DC.

David S. Burkholder,

Acting Executive Director, Office of International Affairs.

[FR Doc. 2026–13678 Filed 7–6–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION**Federal Highway Administration****Federal Transit Administration****Notice of Final Federal Agency Actions on Proposed Interstate Bridge Replacement Program in Portland, Oregon and Vancouver, Washington**

AGENCY: Federal Highway Administration (FHWA) and Federal Transit Administration (FTA), USDOT.

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and FTA.

SUMMARY: This notice announces actions taken by FHWA and FTA that are final. The actions relate to a proposed multimodal project for the Interstate Bridge Replacement (IBR) Program for highway and high-capacity transit improvements between Portland, Oregon, and Vancouver, Washington, across the Columbia River in the Interstate 5 (I-5) corridor. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, FHWA and FTA are advising the public of final agency actions subject to 23 U.S.C. 139(l)(1). A claim seeking judicial review of the Federal agency actions on the subject project will be barred unless the claim is filed on or before December 4, 2026. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

ADDRESSES: The Final Supplemental Environmental Impact Statement (FSEIS), Record of Decision (ROD), and additional project documents can be viewed and downloaded from the project website at:

www.interstatebridge.org or by contacting the IBR Program, 500 East Broadway, Suite 200, Vancouver, WA 98660, during normal business hours of 8 a.m. to 5 p.m. (Pacific Standard Time), Monday through Friday, except State holidays.

FOR FURTHER INFORMATION CONTACT: For FHWA: Thomas Goldstein, PE, Federal Highway Administration, 530 Center Street NE, Suite 420, Salem, OR 97301; Telephone: (503) 316-2545.

For FTA: Jeff Horton, PE, Federal Transit Administration, Region 10, 915 Second Avenue, Suite 3142, Seattle, WA 98174; Telephone: (206) 220-4463.

For the IBR Program (Oregon Department of Transportation (ODOT)/ Washington Department of Transportation (WSDOT)): Chris Regan, IBR Environmental Manager, Interstate

Bridge Replacement Program, 500 East Broadway, Suite 200, Vancouver, WA 98660; Telephone: (360) 556-7135.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA and FTA have taken final agency action subject to 23 U.S.C. 139(l)(1) by issuing approvals for the IBR Program in the States of Oregon and Washington. The FHWA and FTA, as Federal joint lead agencies, ODOT, WSDOT, Metro, Southwest Washington Regional Transportation Council (RTC), Tri-County Metropolitan Transportation District of Oregon (TriMet), and Clark County Public Transportation Benefit Area Authority (C-TRAN), as local joint lead agencies, have signed a ROD for a Supplemental Environmental Impact Statement (SEIS) for the IBR Program for proposed highway and high-capacity transit improvements between Portland, Oregon, and Vancouver, Washington, across the Columbia River in the I-5 corridor. Federal cooperating agencies in the preparation of the SEIS were the National Oceanic and Atmospheric Administration National Marine Fisheries Service, National Park Service, U.S. Army Corps of Engineers, U.S. Coast Guard (USCG), and U.S. Environmental Protection Agency. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the FSEIS, published in the **Federal Register** on April 17, 2026, at 91 FR 20653. The IBR Program and project records are available by contacting FHWA, FTA, or the IBR Program at the addresses provided above. The FSEIS and ROD can be viewed and downloaded from the project website at <https://www.interstatebridge.org/library> or obtained from any contact listed above. This notice applies to all Federal agency decisions that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321 *et seq.*]; Federal-Aid Highway Act [23 U.S.C. 109, 139, and 128]; 23 CFR part 771.

2. *Air:* Clean Air Act [42 U.S.C. 7401-7671(q)].

3. *Land:* Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303; 23 U.S.C. 138]; 23 CFR part 774; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200301 *et seq.*]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

4. *Noise:* Noise Control Act of 1972 [42 U.S.C. 4901-4918]; 23 CFR part 772.

5. *Wildlife:* Endangered Species Act [16 U.S.C. 1531-1544 and 1536]; Marine

Mammal Protection Act [16 U.S.C. 1361-1423h]; Fish and Wildlife Coordination Act [16 U.S.C. 661-667d]; Anadromous Fish Conservation Act [16 U.S.C. 757(a)-757(f)]; Migratory Bird Treaty Act [16 U.S.C. 703-712]; Bald and Golden Eagle Protection Act [16 U.S.C. 668]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801-1891d], with Essential Fish Habitat requirements [16 U.S.C. 1855(b)(2)].

6. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended [54 U.S.C. 306101 *et seq.*]; Archaeological Resources Protection Act of 1979 [16 U.S.C. 470(aa)-470(mm)]; Archaeological and Historic Preservation Act [54 U.S.C. 312501-312508]; Native American Graves Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001-3013; 18 U.S.C. 1170].

7. *Social and Economic:* American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201-4209].

8. *Wetlands and Water Resources:* Clean Water Act (Section 319, Section 401, Section 404) [33 U.S.C. 1251-1387]; Land and Water Conservation Fund (LWCF) [54 U.S.C. 200301 *et seq.*]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300f-300j-26]; Rivers and Harbors Act of 1899 [33 U.S.C. 401-406]; Wild and Scenic Rivers Act [16 U.S.C. 1271-1287]; Emergency Wetlands Resources Act, [16 U.S.C. 3901, 3921]; Wetlands Mitigation [23 U.S.C. 119(g) and 133(b)(3)]; Flood Disaster Protection Act [42 U.S.C. 4012a, 4106].

9. *Hazardous Materials:* Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [42 U.S.C. 9601-9675]; Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*]; Resource Conservation and Recovery Act (RCRA) [42 U.S.C. 6901-6992(k)].

10. *Executive Orders:* The analysis pertaining to any applicable Executive Order considered during the environmental review process to the extent such analysis may be challenged in court. Such Executive Orders may include, E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(l)(1)

Keith Lynch,

Oregon Division Administrator, Federal Highway Administration.

Megan Blum,

Deputy Associate Administrator for Planning and Environment, Federal Transit Administration.

[FR Doc. 2026-13627 Filed 7-6-26; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Information Collection Activities; Comment Request on Information Return for Publicly Offered Original Issue Discount Instruments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of information collection; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the IRS is inviting comments on the information collection request outlined in this notice.

DATES: Written comments should be received on or before September 8, 2026 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Control No. 1545-0887" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT:

View the latest drafts of the tax forms related to the information collection listed in this notice at <https://www.irs.gov/draft-tax-forms>. Requests for additional information or copies of this collection should be directed to Marcus W. McCrary, 470-769-2001.

SUPPLEMENTARY INFORMATION: The IRS, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the IRS assess the impact and minimize the burden of its information collection requirements. Comments submitted in response to this notice will be summarized and/or

included in the request for OMB approval. All comments will become a matter of public record, and viewable on relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Title: Information Return for Publicly Offered Original Issue Discount Instruments.

OMB Control Number: 1545-0887.

Form Number: Form 8281.

Abstract: Form 8281 is filed by the issuer of a publicly offered debt instrument having OID. The information is used to update Pub. 1212, Guide to Original Issue Discount (OID) Instruments, to enable brokers and other middlemen to identify publicly traded OID obligations, which they may hold as nominees for the true owners, so that they can meet the requirement to file Forms 1099-INT and 1099-OID as required by section 6049.

Current Actions: There is no change to the previously approved information collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 2,500.

Estimated Time per Response: 6 hours, 22 minutes.

Estimated Total Annual Burden Hours: 15,917.

Dated: July 2, 2026.

Marcus W. McCrary,

Tax Analyst.

[FR Doc. 2026-13683 Filed 7-6-26; 8:45 am]

BILLING CODE 4831-GV-P

DEPARTMENT OF THE TREASURY

Interest Rate Paid on Cash Deposited To Secure U.S. Immigration and Customs Enforcement Immigration Bonds

AGENCY: Departmental Offices, Treasury.

ACTION: Notice.

SUMMARY: For the period beginning July 1, 2026, and ending on September 30, 2026, the U.S. Immigration and Customs Enforcement Immigration Bond interest rate is 3 per centum per annum.

DATES: Rates are applicable July 1, 2026, to September 30, 2026.

ADDRESSES: Comments or inquiries may be mailed to Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106-1328.

You can download this notice at the following internet addresses: <http://www.treasury.gov> or <http://www.federalregister.gov>.

FOR FURTHER INFORMATION CONTACT:

Ryan Hanna, Manager, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Service, Parkersburg, West Virginia 261006-1328 (304) 480-5120; Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106-1328, (304) 480-5117.

SUPPLEMENTARY INFORMATION: Federal law requires that interest payments on cash deposited to secure immigration bonds shall be "at a rate determined by the Secretary of the Treasury, except that in no case shall the interest rate exceed 3 per centum per annum." 8 U.S.C. 1363(a). Related Federal regulations state that "Interest on cash deposited to secure immigration bonds will be at the rate as determined by the Secretary of the Treasury, but in no case will exceed 3 per centum per annum or be less than zero." 8 CFR 293.2. Treasury has determined that interest on the bonds will vary quarterly and will accrue during each calendar quarter at a rate equal to the lesser of the average of the bond equivalent rates on 91-day Treasury bills auctioned during the preceding calendar quarter, or 3 per centum per annum, but in no case less than zero. [FR Doc. 2015-18545]. In addition to this Notice, Treasury posts the current quarterly rate in Table 2b—Interest Rates for Specific Legislation on the Treasury Direct website.

The Acting Fiscal Assistant Secretary, Gary Grippo, having reviewed and approved this document, is delegating the authority to electronically sign this

document to Heidi Cohen, Federal Register Liaison for the Department, for

purposes of publication in the **Federal Register**.

Heidi Cohen,
Federal Register Liaison.

[FR Doc. 2026–13670 Filed 7–6–26; 8:45 am]

BILLING CODE 4810–AS–P



FEDERAL REGISTER

Vol. 91

Tuesday,

No. 128

July 7, 2026

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 419, et al.

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 416, 419, 427, and 488

[CMS–1850–P]

RIN 0938–AV83

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2027 based on our continuing experience with these systems. We also describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment systems. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting Program and the Ambulatory Surgical Center Quality Reporting Program. There are no changes to the Rural Emergency Hospital Quality Reporting Program. We propose to expand the prior authorization requirement to include additional Botulinum Toxin Injection services. We also propose to implement certain provisions of the Consolidated Appropriations Act, 2026, for off-campus outpatient departments of a provider. In addition, this proposed rule announces notices of closure of teaching hospitals and opportunities to apply for available slots. This rule also requests information regarding potential approaches to improve comparability

and standardization, particularly for complex contracting methodologies, of the HPT information reported in machine-readable files and consumer-friendly displays. We propose hospital AOs with deeming authority to assess compliance with certain Emergency Medical Treatment and Labor Act (EMTALA) administrative requirements during accreditation and reaccreditation surveys. Finally, we are soliciting comments on a potential separate payment under the Inpatient Prospective Payment System (IPPS) for domestic procurement of personal protective equipment and essential medicines.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by August 31, 2026.

ADDRESSES: In commenting, please refer to file code CMS–1850–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov/docket/CMS-2026-2344>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1850–P, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1850–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Regulation coordination questions, contact Gina Aughenbaugh via email at OutpatientPPS@cms.hhs.gov.

Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA), contact Melissa Daly via email at Melissa.Daly@cms.hhs.gov.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at APCPanel@cms.hhs.gov.

Ambulatory Surgical Center Covered Procedures List (ASC CPL), contact

Abigail Cesnik via email at Abigail.Cesnik@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting Program measures, contact Marsha Hertzberg via email at Marsha.Hertzberg@cms.hhs.gov.

Ambulatory Surgical Center Quality Reporting Program policies, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Facilities, contact Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

Blood and Blood Products, contact Gil Ngan via email at Gil.Ngan@cms.hhs.gov.

Cancer Hospital Payments, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

CMS Web Posting of the OPPS and ASC Payment Files, contact Gil Ngan via email at Gil.Ngan@cms.hhs.gov.

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C–APCs), contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

Device-Intensive Status and No Cost/ Full Credit and Partial Credit Devices, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

Hospital Outpatient Quality Reporting Program measures, contact Kristina Rabarison via email at Kristina.Rabarison@cms.hhs.gov.

Hospital Outpatient Quality Reporting Program policies, contact Kimberly Go via email at Kimberly.Go@cms.hhs.gov.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

Hospital Price Transparency, contact Sarah Wheat via email at PriceTransparencyHospitalCharges@cms.hhs.gov.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at Abigail.Cesnik@cms.hhs.gov.

Medicare OPPS Drug Acquisition Cost Survey, contact Cory Duke via email at Cory.Duke@cms.hhs.gov or Gil Ngan at Gil.Ngan@cms.hhs.gov or Nate Vercauteren at Nathan.Vercauteren@cms.hhs.gov.

Method to Control Unnecessary Increases in the Volume of Outpatient Services, contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Cory Duke via email at

Cory.Duke@cms.hhs.gov or Nicole Marcos via email at Nicole.Marcos@cms.hhs.gov.

OPPS Brachytherapy, contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at Erick.Chuang@cms.hhs.gov or Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Gil Ngan via email at Gil.Ngan@cms.hhs.gov, Cory Duke via email at Cory.Duke@cms.hhs.gov, or Nate Vercauteren via email at Nathan.Vercauteren@cms.hhs.gov.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at NewTechAPCapplications@cms.hhs.gov.

OPPS Packaged Items/Services, contact Cory Duke via email at Cory.Duke@cms.hhs.gov.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at DevicePTapplications@cms.hhs.gov.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at Marina.Kushnirova@cms.hhs.gov or Tonya Gierke at Tonya.Gierke@cms.hhs.gov.

Outpatient Department Prior Authorization Requirements, contact Yuliya Cook via email at Yuliya.Cook@cms.hhs.gov.

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at PHPPaymentPolicy@cms.hhs.gov.

Potential Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines Issues, please contact DAC@cms.hhs.gov.

Provider-Based Attestation Requirements, please contact CAA_2026_Section_6225@cms.hhs.gov.

Rural Emergency Hospital Quality Reporting Program policies, contact Anita Bhatia via email at Anita.Bhatia@cms.hhs.gov.

Rural Emergency Hospital Quality Reporting Program measures, contact Melissa Hager via email at Melissa.Hager@cms.hhs.gov.

Skin Substitute Products, contact Nicole Marcos via email at Nicole.Marcos@cms.hhs.gov.

Software as a Medical Service, contact Nicole Marcos via email at Nicole.Marcos@cms.hhs.gov.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at OutpatientPPS@cms.hhs.gov.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at ASCPPS@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on [Regulations.gov](https://www.regulations.gov) public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the calendar year (CY) 2012 OPPS/ASC proposed rule, the addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these addenda are published and available only on the CMS website. The addenda relating to the OPPS are available at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. The addenda relating to the ASC payment system are available at <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notice>.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2026 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

I. Summary and Background

A. Executive Summary of this Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2027. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule announces the closure of a teaching hospital and the opportunity to apply for available slots. In addition, this proposed rule updates and refines requirements for the Hospital Outpatient Quality Reporting Program and the Ambulatory Surgical Center Quality Reporting Program. There are no changes to the Rural Emergency Hospital Quality Reporting Program. We propose to expand the prior authorization requirement to include additional Botulinum Toxin Injection services. This proposed rule also

includes proposals to implement certain provisions of the Consolidated Appropriations Act, 2026, for off-campus outpatient departments of a provider. This rule also requests information regarding potential approaches to improve comparability and standardization, particularly for complex contracting methodologies, of the information reported in machine-readable files and consumer-friendly displays. Additionally, we propose hospital AOs with deeming authority to assess compliance with certain EMTALA administrative requirements under 42 CFR 489.20 during accreditation and reaccreditation surveys. Finally, we are soliciting comments on a potential separate payment under the Inpatient Prospective Payment System (IPPS) for domestic procurement of personal protective equipment and essential medicines.

2. Summary of the Major Provisions

- **OPPS Update:** For CY 2027, we propose to increase the payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 2.4 percent. This increase factor is based on the proposed inpatient hospital market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), reduced by a proposed productivity adjustment of 0.8 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2027 will be approximately \$110.9 billion, an increase of approximately \$9.5 billion compared to estimated CY 2026 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services. Under the proposed 340B remedy offset, payments for services at hospitals subject to the 340B remedy offset will be reduced by 3 percentage points.

- **ASC Payment Update:** For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. In light of the impact of the COVID-19 public health emergency (PHE) on healthcare utilization, we extended our policy to update the ASC payment system using the hospital market basket

update an additional 2 years—through CYs 2024 and 2025. For CY 2026, we extended this interim period an additional year—through CY 2026. In this proposed rule, we are extending our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2027). Using the hospital market basket update, for CY 2027, we are increasing payment rates under the ASC payment system by 2.4 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a proposed hospital market basket percentage increase of 3.2 percent reduced by a final productivity adjustment of 0.8 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2027 will be approximately \$9.9 billion, an increase of approximately \$520 million compared to estimated CY 2026 Medicare payments.

- **Adjustment for Cost-of-Living in Alaska and Hawaii:** For CY 2027, we propose to establish a cost-of-living adjustment (COLA) for outpatient hospital services provided in Alaska and Hawaii that mirrors the COLA provided for inpatient hospital services provided in these States, including any changes finalized in the IPPS for FY 2027.

- **Device Pass-Through Payment Applications:** For CY 2027, we received 19 complete applications for device pass-through payments. We seek public comment on 13 applications (six applicants withdrew). We propose to approve device pass-through payment status for seven applications and deny device pass-through payment status for six applications. We will make final determinations on these applications in this final rule with comment period.

- **Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:** For CY 2027, we propose to continue to expand the ASC covered procedures list (CPL) by adding 618 codes to the ASC CPL that were recommended by stakeholders or are proposed for removal from the IPO list for CY 2027.

- **Changes to the Inpatient Only (IPO) List:** We are continuing to phase out the IPO list by proposing to remove 637 services from the auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory and urinary clinical families from the IPO list for CY 2027.

- **Cross-Program Updates for the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs:** We propose to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs.

- **Hospital Outpatient Quality Reporting Program:** In addition to the cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, we propose updates and refinements to validation and validation reconsideration procedures, including policies applicable to electronic clinical quality measures (eCQMs). We are also issuing a Request for Information on potentially including an Advance Care Planning measure specified for the Hospital Outpatient Department setting.

- **Rural Emergency Hospital Quality Reporting Program:** We are not proposing any updates to the Rural Emergency Hospital Quality Reporting Program in this proposed rule.

- **Ambulatory Surgical Center Quality Reporting Program:** In addition to the cross-program measure proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, we are soliciting information on potential stratification of the All-cause Transfer/Admission measure.

- **Expansion of Category for Hospital Outpatient Department Prior Authorization Process:** We are adding Botulinum Toxin Injection codes to the existing category of services subject to the Hospital Outpatient Department prior authorization process for dates of service on or after July 1, 2027.

- **Partial Hospitalization and Intensive Outpatient Programs:** We propose to update the Partial Hospitalization Program (PHP) and Intensive Outpatient Program (IOP) payment rates for CY 2027 using the methodology we finalized in CY 2026.

- **Payment Adjustment for 340B-Acquired Drugs Based on Results of the Medicare OPPS Drug Acquisition Cost Survey:** Section 1833(t)(14)(D)(ii) of the Act requires the Secretary to periodically conduct surveys of hospital acquisition costs for each specified covered outpatient drug for use in setting the payment rates for such drugs. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, “Lowering Drug Prices by Once Again Putting Americans First”. Section 5 of the E.O., “Appropriately Accounting for

Acquisition Costs of Drugs in Medicare”, which directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Accordingly, from January 1, 2026 through April 7, 2026, we conducted a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPSS. Taking the survey results into account, we propose for CY 2027 to pay ASP minus 33.4 percent for 340B acquired drugs. Statute requires that this policy be implemented in a budget neutral manner, so this proposal would increase OPSS payments for non-drug services by an equivalent amount, which is estimated to be an 8.44 percent increase to non-drug service payments for this proposed rule.

- *Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy.* The Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (88 FR 77150) codified an annual 0.5 percent reduction in the OPSS conversion factor applicable to non-drug items and services, excluding hospitals that enrolled in Medicare after January 1, 2018, until we estimated that the reduction had fully offset the additional \$7.8 billion in non-drug services payments made as part of the prior 340B drug payment policy. This reduction was effective January 1, 2026. For CY 2027, we propose to increase the annual percent reduction to the OPSS conversion factor used to determine the payment amounts for non-drug items and services for hospitals for whom this adjustment applies from 0.5 percent to 3 percent.

- *Request for Information (RFI) on Strengthening the Standardization and Comparability of Hospital Price Transparency Data:* We are requesting information regarding potential approaches to improve comparability and standardization of the HPT information reported in machine-readable files (MRFs) and consumer-friendly displays. We are particularly interested in comments regarding the reporting of contract mechanisms such as outlier payments, stop-loss provisions, rate tiering, and carve-outs. The RFI also seeks public comment on potential approaches to enhance the comparability and usefulness of the consumer-friendly display

requirements, including feedback on whether to modify or eliminate the current deemed compliance policy for internet-based price estimator tools, update the required list of shoppable services, and provide additional clarification regarding the items and services included in displayed prices, such as ancillary and bundled services.

- *Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs):* For CY 2027, we propose to use our authority under section 1833(t)(2)(F) of the Act to apply the Physician Fee Schedule equivalent rate for any Healthcare Common Procedure Coding System (HCPCS) codes assigned to the imaging without contrast APCs when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. We propose to exempt rural Sole Community Hospitals from this method to control the unnecessary volume of imaging without contrast services.

3. Summary of Costs and Benefits

In section XXVI. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPSS Changes

Table 88 in section XXVI.C. of this proposed rule displays the distributional impact of all the OPSS changes on various groups of hospitals and CMHCs for CY 2027 compared to all estimated OPSS payments in CY 2026. We estimate that the proposed policies in this proposed rule will result in a 1.9 percent increase in OPSS payments to providers for services. We estimate that total OPSS payments for CY 2027, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPSS (including general acute care hospitals, children’s hospitals, cancer hospitals, and CMHCs) will increase by approximately \$1.82 billion compared to CY 2026 payments due to the OPD update, excluding changes in enrollment, utilization, and case-mix. However, for providers subject to the 340B remedy offset, the 340B remedy offset is estimated to reduce payments by \$2.3 billion in CY 2027.

We estimated the isolated impact of our OPSS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPSS. Beginning CY 2024, they are also paid for IOP services under the OPSS. Based on our policy to calculate CMHC PHP and IOP costs based on 40

percent of the corresponding proposed hospital-based PHP and IOP costs, we estimate an 8.4 percent increase in CY 2027 payments to CMHCs relative to their CY 2026 payments.

b. Impacts of the Updated Wage Index

We estimate that our update of the wage indexes based on the fiscal year (FY) 2027 IPPS final rule wage indexes will result in no change for urban hospitals under the OPSS and a 0.5 percent increase for rural hospitals. These wage indexes include continued utilization of the Office of Management and Budget (OMB) labor market area delineations based on 2020 Decennial Census data, with updates, as discussed in section II.C. of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

For CY 2027, we propose to continue to provide additional payments to cancer hospitals so that a cancer hospital’s payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPSS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. For CY 2027, we propose a target PCR of 0.88 to determine the CY 2027 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

There are no significant impacts of our CY 2027 payment policies for hospitals that are eligible for the rural sole community hospital adjustment, as we propose to maintain the policy in the CY 2027 OPSS.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2027 OPSS/ASC, we are establishing an OPD fee schedule increase factor of 2.4 percent and applying that increase factor to the conversion factor for CY 2026. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 1.9 percent and that rural hospitals will experience an increase in payments of 6.4 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals will experience an increase in payments of 6.4 percent, minor teaching hospitals will experience an increase in payments of 3.9 percent, and major teaching

hospitals will experience a decrease in payments of 2.4 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 2.0 percent in payments, while hospitals with government ownership will experience a decrease of 0.8 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 10.6 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the proposed CY 2027 payment rates, compared to estimated CY 2026 payment rates, ranges between an increase of 35 percent and a decrease of 4 percent.

f. Impact of the Changes to the Hospital Outpatient Quality Reporting Program

Across 3,000 hospitals participating in the Hospital Outpatient Quality Reporting Program, we estimate that our proposed changes, if finalized, would result in a total information collection burden decrease of 16,985 hours at a cost savings of \$971,221 beginning with the CY 2029 reporting period/CY 2031 payment determination.

g. Impact of the Changes to the Ambulatory Surgical Center Quality Reporting Program

Across 5,149 ASCs participating in the Ambulatory Surgical Center Quality Reporting Program, we estimate that our proposed changes, if finalized, would result in a total information collection burden decrease of 16,753 hours at a cost savings of \$957,937 beginning with the CY 2027 reporting period/CY 2029 payment determination.

B. Legislative and Regulatory Authority for the Hospital OPSS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services.

The OPSS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPSS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPSS. The following Acts made additional changes to the OPSS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use Disorder- Prevention that Promotes Opioid Recovery and

Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation Reduction Act, 2022 (Pub. L. 117–169), enacted on August 16, 2022; the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), enacted December 29, 2022; and the Consolidated Appropriations Act, 2026 (CAA, 2026; Pub. L. 119–75), enacted on February 3, 2026.

Under the OPSS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPSS includes payment for most hospital outpatient services, except those identified in section I.C of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPSS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPSS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the “2 times rule”). In implementing this provision, we generally use the cost of

the item or service assigned to an APC group.

For new technology items and services, special payments under the OPSS may be made in one of two ways. section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as “transitional pass-through payments”, for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is generally temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPSS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPSS. While most hospital outpatient services are payable under the OPSS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPSS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section

1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPSS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPSS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- Indian Health Service (IHS) hospitals; and
- Rural emergency hospitals (REHs).

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPSS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPSS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPSS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and

advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPSS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPSS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital

outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2024, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html>.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 25, 2025. The recommendations of the Panel for the most recent meeting are available on the CMS website at <https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment>. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2022, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (87 FR 68499). We are currently accepting nominations at <https://mearis.cms.gov>.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of two subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The two current subcommittees include the following:

- **APC Groups and Status Indicator Assignments Subcommittee**, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made; and
- **Data Subcommittee**, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during

a scheduled Panel meeting, and the Panel recommended at the August 25, 2025, meeting that these subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPTS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at <https://facadatabase.gov>.

F. Public Comments Received on the CY 2026 OPPTS/ASC Final Rule With Comment Period

We received approximately 48 timely pieces of correspondence on the CY 2026 OPPTS/ASC final rule with comment period that appeared in the **Federal Register** on November 25, 2025 (90 FR 53448).

II. Proposed Updates Affecting OPPTS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000 OPPTS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000, for each APC group.

For the CY 2027 OPPTS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2027, and before January 1, 2028 (CY 2027), using the same basic methodology that we described in the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53455 through 53457), using CY 2025 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2027, we began with approximately 147 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2025 and before January 1, 2026, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing

changes, we used approximately 74 million final action claims to develop the proposed CY 2027 OPPTS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under “Downloads” for the CY 2027 OPPTS/ASC proposed rule on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>.

Addendum N to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>), includes the proposed list of bypass codes for CY 2027. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2025 and, therefore, includes codes that were in effect in CY 2025 and used for billing. We propose to retain these deleted bypass codes on the proposed CY 2027 bypass list because these codes existed in CY 2025 and were covered HOPD services in that period, and CY 2025 claims data were used to calculate proposed CY 2027 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more “pseudo” single procedure claims for ratesetting purposes. “Overlap bypass codes” that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we propose to add for CY 2027 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2027, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2027 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2025 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2024. For the proposed CY 2027 OPPTS payment rates, we used the set of claims processed during CY 2025. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a

hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2025 (the year of claims data we used to calculate the proposed CY 2027 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2025 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices> and included with every proposed and final OPPS rule.

In accordance with our longstanding policy, similar to our finalized policy for CY 2026 OPPS ratesetting, we propose to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including the data in OPPS ratesetting. For CY 2027 and future years, we propose not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2027. The Hospital OPPS page on the CMS website on which this proposed rule is posted (<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section

we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>, includes information about obtaining the “OPPS Limited Data Set,” which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2025 claims that are used to calculate the proposed payment rates for the CY 2027 OPPS/ASC proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2027 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier “PN,” which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment

period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier “PN” from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2027 OPPS, we propose to continue to remove claim lines with modifier “PN” from the ratesetting process.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (90 FR 53457), which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We propose to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR

for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, as it better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>) for the proposed CY 2027 payment rates for blood and blood products (which are generally identified with status indicator “R”).

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- The CY 2005 OPPS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- The CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- The CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 and 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C-APC.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy—cancer treatment through solid source radioactive implants—consisting of a seed or seeds (or radioactive source) (“brachytherapy sources”) separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2013 OPPS/ASC final rule with comment period (77 FR 68240 and 68241). As we have stated in prior OPPS updates, we believe that adopting the

general OPPS prospective payment methodology for brachytherapy sources is appropriate for several reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals’ charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals’ charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for most items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2027, except where otherwise indicated, we propose to continue our policy and use the costs derived from CY 2025 claims data to set the proposed CY 2027 payment rates for brachytherapy sources because we propose to use CY 2025 data to set the proposed payment rates for most other items and services that would be paid under the CY 2027 OPPS. With the exception of the proposed payment rates for brachytherapy sources A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie), C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D. of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose for CY 2027 and subsequent years to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). For CY 2027 and subsequent years, we propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise

specified, per source) and C2699 (Brachytherapy source, nonstranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2027 and subsequent years, we also propose to continue the policy we implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, for the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2027 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>) and identified with status indicator “U” (Brachytherapy Sources, Paid under OPPS; separate APC payment).”

For CY 2018, we assigned status indicator “U” to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at \$4.69 per mm² for the brachytherapy source’s APC—APC 2648 (Brachytx planar, p-103) (82 FR 59233 through 59234). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at \$4.69 per mm² for APC 2648 (Brachytx planar, p-103) (83 FR 58834 through 58836). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of \$1.02 per mm². In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of

\$1.02 per mm² may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CY 2020 (84 FR 61157 and 61158). Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, CY 2023, CY 2024, CY 2025, and CY 2026 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760 and 71761, 88 FR 81553, 89 FR 93925, and 90 FR 53458), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of \$4.69 per mm² for HCPCS code C2645 for CYs 2021 through 2026.

There were no CY 2025 claims available that reported HCPCS code C2645 for the CY 2027 OPPS/ASC proposed rule. Therefore, in the absence of claims data, we propose to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2026 payment rate of \$4.69 per mm² for HCPCS code C2645, which we propose be assigned to APC 2648 (Brachytx planar, p-103) for CY 2027. Similarly, there were no CY 2025 claims available for this proposed rule that reported HCPCS A9527 (Iodine i-125, sodium iodide solution, therapeutic, per millicurie), which is assigned to APC 2632, or HCPCS code C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), which is assigned to APC 2636. While both APC 2632 and 2636 have historically been designated as Low Volume APCs, which uses up to 4 years of claims data, we are concerned that 4 years of historical claims data would only yield 2 claims for each APC and that may not be reliable for ratesetting for these APCs for CY 2027. Therefore, we propose to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states in part that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2026 payment rates for APC 2632 and APC 2636 for CY 2027. Specifically, for CY 2027, we propose a payment rate of \$396.32 per

millicurie for APC 2632 and a payment rate of \$89.40 per 1 mm for APC 2636.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C. of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act in the case of APCs 2632, 2636, and 2648 as detailed above.

For CY 2027, we propose to designate five brachytherapy APCs as Low Volume APCs as these APCs met our criteria to be designated as Low Volume APCs.

We continue to invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to outpatientpps@cms.hhs.gov.

b. Comprehensive APCs (C-APCs) for CY 2027

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the costliest primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C-APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C-APC policy (79 FR 66798 through 66810).

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and

implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 and 66810). We have gradually added new C-APCs since the policy was implemented beginning in CY 2015, with the number of C-APCs now totaling 74 (80 FR 70332; 81 FR 79584 and 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; 87 FR 71769; 88 FR 81562; 89 FR 93926; and 90 FR 53448).

Under our C-APC policy, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator “J1”. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as “adjunctive services”) and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy, and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot, by statute, be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 and 66801). A list of services excluded from the C-APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website at

<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

The C-APC policy payment methodology set forth in the CY 2014 OPPTS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPTS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator “J1,”¹ excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPTS. Services and procedures described by HCPCS codes assigned to status indicator “J1” are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPTS/ASC final rule with comment period, we expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the “Comprehensive Observation Services” C-APC (C-APC 8011). Services within this APC are assigned status indicator “J2.”² Specifically, we make a payment through C-APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator “T3;”
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378

¹ Status indicator “J1” denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2027 Addendum D1 to this proposed rule.

² Status indicator “J2” denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2027 Addendum D1 to this proposed rule.

³ Status Indicator “T” is defined as a “Procedure or Service, Multiple Procedure Reduction Applies” the OPPTS payment status is “Paid under OPPTS; separate APC payment.” Definitions to all OPPTS payment status indicators are available in Addenda D1 to this proposed rule.

that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

- Does not contain services described by a HCPCS code to which we have assigned status indicator “J1.”

The assignment of status indicator “J2” to a specific set of services performed in combination with each other allows for all other OPPTS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPTS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components

reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPTS Change Request 9658 (Transmittal 3523)⁴ for further instructions on reporting these services in the context of a C-APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and self-administered drugs (SADs), unless they function as packaged supplies (78 FR 74868, 74869, and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15 of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.⁵

⁴ <https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3523cp.pdf>.

⁵ <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator “J1” as a single “J1” unit procedure claim (78 FR 74871 and 79 FR 66801). Line-item charges for services included on the C-APC claim are converted to line-item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator “J1” and later used to develop the geometric mean costs for the C-APC relative payment weights. (We note that we use the term “comprehensive” to describe the geometric mean cost of a claim reporting “J1” service(s) or the geometric mean cost of a C-APC, inclusive of all the items and services included in the C-APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C-APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator “J1” according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator “J1” or units thereof, we identify one “J1” service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple “J1” procedure claims to the C-APC to which the service designated as the primary service is assigned. If the reported “J1” services on a claim map to different C-APCs, we designate the “J1” service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple “J1” services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator “J1” to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and certain add-on codes (as described further below) from the originating C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form- or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this proposed rule, in the originating C-APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator “J1” (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of “J1” services (or combinations of “J1” services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described

above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary “J1” service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2027, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator “J1” and any number of units of a single add-on code for the primary “J1” service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C-APC within the same clinical family of C-APCs. As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C-APC. We list the proposed complexity adjustments for “J1” and add-on code combinations for CY 2027, along with all the other proposed complexity adjustments, in Addendum J to this proposed rule.

(which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the final geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C-APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C-APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPTS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on

the claim with a primary procedure, identified by OPPTS status indicator "J1," payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a "J1" service assigned to a C-APC. In the CY 2020 OPPTS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator "J2" when they are included on a claim with a "J2" service (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C-APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173), provides for payment under the OPPTS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPTS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs

or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPTS are considered covered ancillary services for which the OPPTS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies.

Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C-APC payment when these products appear on a claim with a primary C-APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C-APC service is consistent with our C-APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C-APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWP when payment for them is packaged with payment for a primary C-APC service. In order to ensure payment for new drugs and biologicals described by

HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug or biological described by HCPCS code C9399 from packaging when the drug or biological is included on a claim with a “J1” service, which is the status indicator assigned to a C–APC, and a claim with a “J2” service, which is the status indicator assigned to comprehensive observation services. See Addendum J for the proposed CY 2027 C–APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI., “CY 2023 OPPS Payment Status and Comment Indicators”, to add a new definition to status indicator “A” to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The current definition of status indicator “A”, as finalized in the CY 2023 OPPS/ASC final rule with comment period, can be found in Addendum D1. This change ensures the MAC prices claims for drugs or biologicals billed with HCPCS code C9399 at 95 percent of the drug or biological’s AWP and pays separately for the drug or biological under the OPPS when it appears on the same claim as a primary C–APC service.

(4) Exclusion of Cell and Gene Therapies From the C–APC Policy

As previously discussed in this section, and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), the C–APC policy packages payment for items and services that are typically integral, ancillary, supportive,

dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861), we finalized defining a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a comprehensive APC treats all individually reported codes as representing components of the comprehensive service, we make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), we generally treat all items and services reported on a C–APC claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a comprehensive service. Historically, items packaged for payment provided in conjunction with the primary C–APC service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually SADs, unless they function as supplies (78 FR 74868 through 74869 and 74909).

However, we recognized in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204) that there are rare instances in which cell and gene therapies appear on the same claim as a primary C–APC service and therefore, have their payment packaged with payment for the primary C–APC service. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938), given the unique nature of these therapies, we do not believe they function as integral, ancillary, supportive, dependent, or adjunctive to any of the current primary C–APC services. Additionally, we stated that when these products are administered, they are the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent, or adjunctive to any primary C–APC services.

Therefore, we finalized a policy for CY 2025 and subsequent years (89 FR 93932 through 93938), to not package payment for cell and gene therapies into C–APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C–APC service. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C–APC primary service, we will continue to add their product specific HCPCS codes, when created, to the C–APC exclusion list. The proposed list of qualifying products can be found in Table 1.

BILLING CODE 4169–69–P

TABLE 1: CELL AND GENE THERAPIES PROPOSED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2027

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
CARVYKTI	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Skysona	J3387	Injection, elivaldogene autotemcel, per treatment
Lenmeldy	J3391	Injection, atidarsagene autotemcel, per treatment
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5×10^{15} vector genomes
Ryoncil	J3402	Injection, remestemcel-l-rknd, per therapeutic dose
Hemgenix	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose

BILLING CODE 4169-69-C

We list all proposed C-APC exclusion categories for CY 2027 in Addendum J to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

(5) Exclusion of Non-Opioid Products for Pain Relief Under Section 4135 of the Consolidated Appropriations Act, 2023 From the C-APC Policy

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA,

2023, titled “Access to Non-Opioid Treatments for Pain Relief,” amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(iv) of the Act). In

particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount. As stated earlier in this section, our current policy is to exclude from the packaged C-APC payment those items

and services that are required by statute to be separately paid.

Accordingly, in the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under section 4135 of the CAA, 2023 from the C-APC policy to ensure payment is not packaged into any C-APC and that separate payment is made in accordance with the statute (89 FR 93938 through 93939).

(6) C-APCs for CY 2027

For CY 2027 and subsequent years, we propose to continue to apply the C-APC payment policy methodology. We

refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C-APC payment policy methodology- and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any standard APCs to C-APCs in CY 2027; thus, we propose that the number of C-APCs for CY 2027 (see Table 2) would be the same as the number for CY 2026, which is 74 C-APCs (91 FR 8384).

BILLING CODE 4169-69-P

TABLE 2: PROPOSED CY 2027 C-APCs

C-APC	CY 2027 APC Group Title	Clinical Family
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS
5112	Level 2 Musculoskeletal Procedures	ORTHO
5113	Level 3 Musculoskeletal Procedures	ORTHO
5114	Level 4 Musculoskeletal Procedures	ORTHO
5115	Level 5 Musculoskeletal Procedures	ORTHO
5116	Level 6 Musculoskeletal Procedures	ORTHO
5117	Level 7 Musculoskeletal Procedures	ORTHO
5153	Level 3 Airway Endoscopy	AENDO
5154	Level 4 Airway Endoscopy	AENDO
5155	Level 5 Airway Endoscopy	AENDO
5163	Level 3 ENT Procedures	ENTXX
5164	Level 4 ENT Procedures	ENTXX
5165	Level 5 ENT Procedures	ENTXX
5166	Cochlear Implant Procedure	COCHL
5182	Level 2 Vascular Procedures	VASCX
5183	Level 3 Vascular Procedures	VASCX
5184	Level 4 Vascular Procedures	VASCX
5191	Level 1 Endovascular Procedures	EVASC
5192	Level 2 Endovascular Procedures	EVASC
5193	Level 3 Endovascular Procedures	EVASC
5194	Level 4 Endovascular Procedures	EVASC
5200	Implantation Wireless PA Pressure Monitor	WPMXX
5211	Level 1 Electrophysiologic Procedures	EPHYS
5212	Level 2 Electrophysiologic Procedures	EPHYS
5213	Level 3 Electrophysiologic Procedures	EPHYS
5222	Level 2 Pacemaker and Similar Procedures	AICDP
5223	Level 3 Pacemaker and Similar Procedures	AICDP
5224	Level 4 Pacemaker and Similar Procedures	AICDP
5231	Level 1 ICD and Similar Procedures	AICDP
5232	Level 2 ICD and Similar Procedures	AICDP
5244	Level 4 Blood Product Exchange and Related Services	SCTXX
5302	Level 2 Upper GI Procedures	GIXXX
5303	Level 3 Upper GI Procedures	GIXXX
5313	Level 3 Lower GI Procedures	GIXXX
5331	Complex GI Procedures	GIXXX
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5361	Level 1 Laparoscopy and Related Services	LAPXX
5362	Level 2 Laparoscopy and Related Services	LAPXX
5372	Level 2 Urology and Related Services	UROXX
5373	Level 3 Urology and Related Services	UROXX
5374	Level 4 Urology and Related Services	UROXX
5375	Level 5 Urology and Related Services	UROXX
5376	Level 6 Urology and Related Services	UROXX
5377	Level 7 Urology and Related Services	UROXX
5378	Level 8 Urology and Related Services	UROXX

C-APC	CY 2027 APC Group Title	Clinical Family
5414	Level 4 Gynecologic Procedures	GYNXX
5415	Level 5 Gynecologic Procedures	GYNXX
5416	Level 6 Gynecologic Procedures	GYNXX
5431	Level 1 Nerve Procedures	NERVE
5432	Level 2 Nerve Procedures	NERVE
5433	Level 3 Nerve Procedures	NERVE
5461	Level 1 Neurostimulator and Related Procedures	NSTIM
5462	Level 2 Neurostimulator and Related Procedures	NSTIM
5463	Level 3 Neurostimulator and Related Procedures	NSTIM
5464	Level 4 Neurostimulator and Related Procedures	NSTIM
5465	Level 5 Neurostimulator and Related Procedures	NSTIM
5471	Implantation of Drug Infusion Device	PUMPS
5491	Level 1 Intraocular Procedures	INEYE
5492	Level 2 Intraocular Procedures	INEYE
5493	Level 3 Intraocular Procedures	INEYE
5494	Level 4 Intraocular Procedures	INEYE
5495	Level 5 Intraocular Procedures	INEYE
5496	Level 6 Intraocular Procedures	INEYE
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5627	Level 7 Radiation Therapy	RADTX
5881	Ancillary Outpatient Services When Patient Dies	N/A
8011	Comprehensive Observation Services	N/A

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy

AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.

BREAS = Breast Surgery

COCHL = Cochlear Implant

EBIDX = Excision/ Biopsy/Incision and Drainage

ENTXX = ENT Procedures

EPHYS = Cardiac Electrophysiology/

EVASC = Endovascular Procedures

EXEYE = Extraocular Ophthalmic Surgery

GIXXX = Gastrointestinal Procedures

GYNXX = Gynecologic Procedures

INEYE = Intraocular Surgery

LAPXX = Laparoscopic Procedures

NERVE = Nerve Procedures

NSTIM = Neurostimulators

ORTHO = Orthopedic Surgery

PUMPS = Implantable Drug Delivery Systems

RADTX = Radiation Oncology

SCTXX = Stem Cell Transplant

UROXX = Urologic Procedures

VASCX = Vascular Procedures

WPMXX = Wireless PA Pressure Monitor

BILLING CODE 4169-69-C

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high-quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241, 59242, and 59246 through 52950) for further background.

(1) Mental Health Services Composite APC

For CY 2027, we propose to continue our longstanding policy of limiting the aggregate payment for specified less resource intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services (88 FR 49572). We refer readers to the April 7, 2000, OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for further background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 and 33581 and 82 FR

59246 and 59247), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate for APC 5863, which was the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital would continue to be paid the payment rate for composite APC 8010. This policy applied in CYs 2018 through 2023.

In the CY 2024 OPPS/ASC proposed rule, we stated that APC 5863 was no longer the maximum partial hospitalization per diem payment rate for a hospital due to the creation of APC 5864, which is four or more hospital-based PHP services per day (88 FR 49572). We solicited comment on whether APC 5864 would be appropriate to use as the daily mental health cap, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital (88 FR 49572). Based on public comments received and our longstanding policy, in the CY 2024 OPPS/ASC final rule with comment period, we finalized APC 5864, four hospital-based PHP services per day, as the daily mental health cap (88 FR 81566).

We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource intensive of all outpatient mental health services. For CY 2027 and subsequent years, we propose to continue this policy that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for four partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010. In addition, we propose to continue to set the payment rate for composite APC 8010 at the same payment rate that we propose for APC

5864, which is a partial hospitalization per diem payment rate for four partial hospitalization services furnished in a day by a hospital.

Under the proposed policy, the Integrated OCE (I/OCE) would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5864 for all the specified mental health services furnished by the hospital on that single date of service by paying for the services through composite APC 5863.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569) we finalized a policy that effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the “with contrast” composite APCs as having at least one or more imaging procedures from the same family

performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the “with contrast” composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2027, we propose to continue to pay for all multiple imaging

procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2027, except where otherwise indicated, we propose to use the costs derived from CY 2025 claims data to set the proposed CY 2027 payment rates. Therefore, for CY 2027, the proposed payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2025 claims available for the CY 2027 OPPS/ASC proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the

proposed geometric mean costs, we used the same methodology that we used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as “overlap bypass codes” that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the internet on the CMS website <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>) and are discussed in more detail in section II.A.1.a. of this proposed rule.

BILLING CODE 4169–69–P

TABLE 3: OPPTS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2027 APC 8004 (Ultrasound Composite)	CY 2027 Approximate APC Geometric Mean Cost = \$326.30
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1 st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2027 APC 8005 (CT and CTA without Contrast Composite) *	CY 2027 Approximate APC Geometric Mean Cost = \$247.29
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2027 APC 8006 (CT and CTA with Contrast Composite)	CY 2027 Approximate APC Geometric Mean Cost = \$484.46
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye

70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
70471	Cta h&n c+ w/noncontrast img
70473	Ct cere prfu aly c+wo ct/cta
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1- regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2027 APC 8007 (MRI and MRA without Contrast Composite) *	CY 2027 Approximate APC Geometric Mean Cost = \$591.20
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye

70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2027 APC 8008 (MRI and MRA with Contrast Composite)	CY 2027 Approximate APC Geometric Mean Cost = \$954.20
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye

72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr

* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

BILLING CODE 4169–69–C

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items

and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals’ incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient

item that meets the patient’s needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary

services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payments because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Packaging encourages efficiency and is an essential component of a prospective payment system; therefore, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Proposed CY 2027 Policy on Packaged Items and Services

For CY 2027, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2027, we are not proposing any changes to the current overall packaging policy discussed in II.A.3.a. We propose to continue to conditionally

package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

c. Proposed Payment for Diagnostic Radiopharmaceuticals

(1) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in § 419.2(b), we refer to them as “policy-packaged” drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and, prior to CY 2025, all radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

In the CY 2008 OPPS/ASC final rule with comment period, we finalized the packaging status of diagnostic radiopharmaceuticals as part of our overall enhanced packaging approach for the CY 2008 OPPS and subsequent years (72 FR 66635 through 66641). Importantly, we noted that we believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, making it appropriate to package the payment for the diagnostic radiopharmaceutical into the payment for the related nuclear medicine procedure. Higher cost diagnostic radiopharmaceuticals were one specific type of product that, prior to CY 2025, was policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties raised concerns regarding policy packaging of diagnostic radiopharmaceuticals.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222) and CY 2025 OPPS/ASC final rule with comment period (89 FR 93950), we stated that we continue to believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, generally making it appropriate to package payment for them with payment for the related nuclear medicine procedure. However, we stated there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) we finalized a policy to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than \$630 for CY 2025. We also finalized a policy of applying similar methodology to that finalized in the CY 2025 OPPS/ASC final rule with comment period for determining the per day costs of drugs and biologicals in order to calculate the per day costs for diagnostic radiopharmaceuticals for CY 2026 and future years (89 FR 93953 through 93955). We noted that any diagnostic radiopharmaceutical with a per day cost at or below that threshold will continue to be policy packaged under our longstanding policy at § 419.2(b)(15) (89 FR 93962 to 93963). Additionally, we finalized the policy that starting in CY 2026 and for subsequent years, we will update the threshold amount of \$630 by a forecast of the Producer Price Index (PPI) for Pharmaceuticals for Human Use, Prescription (Bureau of Labor Statistics (BLS) series code WPUSI07003) from IHS Global, Inc (IGI) (89 FR 93955).

In the CY 2025 OPPS/ASC final rule with comment period, we also finalized a policy to pay for nonpass-through, separately payable diagnostic radiopharmaceuticals with per day costs above the designated threshold based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. As we found that the ASP data we had was not usable for the purpose of paying for diagnostic radiopharmaceuticals, we finalized a policy to pay for qualifying nonpass-through diagnostic radiopharmaceuticals with claims data based on mean unit cost data derived

from hospital claims. Additionally, we finalized corresponding modifications to the regulation text at § 419.2(b)(15) and § 419.41 to codify our finalized payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals. In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical refinement to the diagnostic radiopharmaceutical packaging threshold methodology and finalized the CY 2026 diagnostic radiopharmaceutical packaging threshold of \$655. For additional information regarding the policy finalized, please reference the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53482 through 53488).

(2) Proposed Diagnostic Radiopharmaceutical Packaging Threshold

For CY 2027, we propose to continue the policy finalized in CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963). Specifically, we propose to continue to calculate the per day cost of diagnostic radiopharmaceuticals based on the methodology described in section V.B.1.b. of this proposed rule, which relies on the methodology finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638).

As finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955), starting in the OPPS/ASC rulemaking for CY 2026 and for subsequent years, we stated we would update the proposed threshold amount of \$630 by a forecast of the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) from IHS Global, Inc (IGI) by using most recently available four-quarter moving average PPI levels to trend from the third quarter of the year 2 years prior to the applicable calendar year to the third quarter of the year prior to the applicable calendar year (for example, from the third quarter of 2024 to the third quarter of 2025 for CY 2026). In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 final threshold forward from the third quarter of the CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest \$5 increment (90 FR 53482 through 53483).

We believed using the most recently available four-quarter moving average PPI levels more appropriately updated the packaging threshold from CY 2025 for payment in CY 2026. For CY 2026 and subsequent updates, we finalized to trend the CY 2025 threshold of \$630 forward using the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription for CY 2025 (third quarter) forward using the PPI for Pharmaceuticals for Human Use, Prescription for the applicable payment year (third quarter) (90 FR 53482 through 53488). This is the same as the update factor used for the OPPS drug packaging threshold, where we originally used the four-quarter moving average PPI levels for Pharmaceutical Preparations, Prescription (BLS series code WPUSI07003, formerly BLS series code 32541DRX) to trend the \$50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of the applicable payment year (71 FR 68085 and 68086).

Therefore, for CY 2027, we propose to update the CY 2025 \$630 threshold amount by the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to trend the \$630 threshold forward. Specifically, we propose to use the most recently available forecast of the four-quarter moving average PPI levels for Pharmaceutical for Human Use, Prescription from the third quarter of 2025 to the third -quarter of 2027, and to round the resulting dollar amount to the nearest \$5 increment. Based on this methodology, we trended the \$630 threshold forward and rounded the resulting dollar amount (\$667.44) to the nearest \$5 increment, which yields a proposed figure of \$665 per day for CY 2027. Consistent with our methodology and practices listed in section V.B.1.b. of this proposed rule, we also propose that if more recent data are subsequently available (for example, a more recent estimate of the PPI for Pharmaceuticals for Human Use, Prescription), we would use such data, if appropriate, to determine the CY 2027 diagnostic radiopharmaceutical packaging threshold in the final rule.

(3) Amount of Separate Payment for Diagnostic Radiopharmaceuticals Exceeding the Threshold

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93959), once we determine that the per day cost of a nonpass-through diagnostic radiopharmaceutical exceeds the cost threshold, proposed to be \$665 per day for CY 2027, we will then assign that

radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. We propose to continue our current policy for CY 2027, and propose to pay for those nonpass-through, separately payable diagnostic radiopharmaceuticals based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. While, under this authority, we would ordinarily use the ASP methodology under section 1847A of the Act, we continue to find that the ASP data we had was not usable for payment purposes. We continue to believe that arithmetic mean unit cost (MUC) would be an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. Therefore, we propose to continue our current policy and propose for CY 2027 to pay for qualifying diagnostic radiopharmaceuticals with per day costs above the diagnostic radiopharmaceutical packaging threshold based on their arithmetic MUC, which would be derived from calendar year 2025 claims data.

Although we propose to base payment for qualifying radiopharmaceuticals on their arithmetic MUC for CY 2027, we continue to encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While we propose to continue to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2027, we note that manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2027, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPS. We encourage interested parties to submit comments regarding potential issues that may arise that prevent appropriate ASP reporting for diagnostic radiopharmaceuticals. We refer readers to the CY 2025 OPPS/ASC final rule with comment period as it discusses some of the known concerns regarding ASP reporting for diagnostic radiopharmaceuticals (89 FR 93948 through 93963) as well as the CY 2026 OPPS/ASC final rule with comment period (90 FR 53482 through 53488). We reiterate our stance from the CY 2025 OPPS/ASC final rule with comment period, that if we were to use average sales price as the basis of calculating a payment, we believe there must be more consistent, validated, and universal

reporting in order for ASP to be a viable payment methodology (89 FR 93961).

We also reiterate, as we stated in the CY 2025 and CY 2026 OPPS/ASC final rules with comment period (89 FR 93957 and 90 FR 53484), that there could be potential value in the use of ASP data for payment purposes for diagnostic radiopharmaceuticals when reported correctly and by all manufacturers who manufacture a product that is described by a given HCPCS code. We continue to believe that the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals, as well as for therapeutic radiopharmaceuticals. Previously, to facilitate potential future payment for diagnostic radiopharmaceuticals based on ASP, we sought comment from interested parties on how CMS could ensure more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology utilized in future rulemaking. For example, we sought comment on how CMS could update its past guidance, *Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status*,⁶ to reflect current clinical practices and to reflect ASP reporting for diagnostic radiopharmaceuticals. Based on our analysis, and input from interested parties, we will be publishing an ASP reporting Framework for Diagnostic Radiopharmaceuticals on the Medicare Hospital Outpatient PPS website at <https://www.cms.gov/medicare/>

⁶ https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf.

payment/prospective-payment-systems/hospital-outpatient.

Additionally, as discussed in section V.B.5. of this proposed rule (Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data), we propose to set the payment rate for new diagnostic radiopharmaceuticals that exceed the diagnostic radiopharmaceutical packaging threshold and with HCPCS codes, but which do not have pass-through status and are without claims data, at ASP plus 6 percent. If ASP data for these diagnostic radiopharmaceuticals are not available, we propose to pay WAC plus 3 percent during the product's initial sales period, consistent with our policy described in section V.B.2. of this proposed rule. If the WAC also is unavailable, we propose to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. Following the initial sales period, a payment rate of WAC plus 6 percent would apply, if ASP data for these diagnostic radiopharmaceuticals remained unavailable. We continue to believe the volume of products in this category would typically be very low; however, in these rare situations, we continue to believe it would continue to be appropriate to use ASP plus 6 percent, WAC plus 3 or 6 percent, or 95 percent of AWP until a MUC is available. As we stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93962), it is appropriate to use this payment hierarchy until a MUC is available. There is typically only one manufacturer for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, although reporting of ASP is not a condition of CMS approving a HCPCS

application, CMS has the opportunity to actively engage with the manufacturer, or sponsor of a HCPCS application, during the HCPCS application process. This allows for ongoing dialogue and education regarding the unique ASP reporting requirements that may be associated with a particular product, including how to ensure the reported ASP aligns with the dose descriptor for the newly assigned HCPCS code (89 FR 93958). We continue to believe the hierarchy previously specified is appropriate to determine the payment for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, as it is consistent with the typical hierarchy associated with payment for drugs and biologicals paid under the OPPS as discussed in sections V.A. and V.B. of this proposed rule.

(4) Qualifying Diagnostic Radiopharmaceuticals Above the Diagnostic Radiopharmaceutical Packaging Threshold

The HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that exceed the proposed diagnostic radiopharmaceutical packaging threshold are proposed to be assigned to a status indicator of "K", indicating separate payment to be paid based on that HCPCS code's arithmetic MUC. A proposed APC and a proposed payment rate are assigned as shown in Addendum B to this proposed rule. HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold are proposed to continue to be assigned to a status indicator of "N", indicating packaged payment.

The proposed list of diagnostic radiopharmaceuticals that we calculate as having per day costs that exceeded \$665 and their proposed status indicators can be found in Table 4.

BILLING CODE 4169-69-P

TABLE 4: PROPOSED QUALIFYING DIAGNOSTIC RADIOPHARMACEUTICALS WITH PER DAY COSTS EXCEEDING \$665

HCPCS Code	Short Descriptor	Proposed CY 2027 Status Indicator Assignment
A4642	In111 satumomab	K
A9507	In111 capromab	K
A9508	I131 iodobenguante, dx	K
A9515	Choline C 11, diagnostic	K
A9521	Tc99m exametazime	E1*
A9532	I125 serum albumin, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9551	Tc99m succimer	K
A9554	I125 iothalamate, dx	K
A9557	Tc99m bicsiate	K
A9569	Technetium TC-99m auto WBC	K
A9570	Indium In-111 auto WBC	K
A9572	Indium In-111 pentetreotide	K
A9582	Iodine I-123 iobenguane	K
A9584	Iodine I-123 ioflupane	K
A9586	Florbetapir F18	K
A9587	Gallium Ga-68	K
A9588	Fluciclovine F-18	K
A9591	Fluoroestradiol F 18	K
A9592	Copper cu 64 dotatate diag	K
A9593	Gallium ga-68 psma-11 ucsf	K
A9594	Gallium ga-68 psma-11, ucla	K
A9595	Piflu f-18, dia 1 millicurie	K
A9596	Gallium illuccix 1 millicure	K
A9601	Flortaucipir inj 1 millicuri	K
A9602	Fluorodopa f-18 diag per mci	K
A9608	Flotufolastat f18 diag 1 mci	K
A9800	Gallium locametz 1 millicuri	K
C9067	Gallium ga-68 Dotatoc	K
Q9982	Flutemetamol F18	K
Q9983	Florbetaben F18	K

*Proposed Status Indicator assignment is E1 until compliance with the Medicaid National Drug Rebate Agreement occurs. Once compliance is met, status indicator K would apply.

BILLING CODE 4169-69-C

Proposed definitions of status indicators can be found in Addendum D1 to this proposed rule. Addenda to this proposed rule can be found on the CMS OPPS web page.

4. Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that

term is defined in section 1833(t)(16)(G)(iv) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively.

The additional payments required under section 1833(t)(16)(G) of the Act began on January 1, 2025, based on the policy finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94361). In section XIII.E. of this proposed rule, we propose to continue the policy finalized in the CY 2025 OPPS/ASC final rule with comment period for CY 2027. We also propose non-opioid treatments for pain relief that would qualify under this policy for CY 2027 and seek public comment on those product evaluations.

We refer readers to section XIII.E. of this proposed rule for a summary of this proposal.

5. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53489 through 53490), we applied this policy and calculated the relative payment weights for each APC for CY 2026 that were shown in Addenda A and B of the CY 2026 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53455 through 53480). For CY 2027, as we did for CY 2026, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2027 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT Evaluation or Assessment and Management (E/M) codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2027, as we did for CY 2026, we propose to continue to standardize all the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For

CY 2027, as we did for CY 2026, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2027 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2026 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2027 unscaled relative payment weights.

For CY 2026, we multiplied the CY 2026 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2025 claims to calculate the total relative payment weight for each service (90 FR 53489). We then added together the total relative payment weight for each of these services to calculate an estimated aggregate weight for the year. For CY 2027, we propose to apply the same process using the estimated CY 2027 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2026 estimated aggregate weight by the unscaled CY 2027 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. Click on the link labeled “Hospital Outpatient Prospective Payment—Notice of Proposed Rulemaking” for 2027, which can be found under the heading “Hospital Outpatient Regulations and Notices” and open the claims accounting document link, which is labeled “2027 Proposed Rule OPPS Claims Accounting.”

We propose to compare the estimated unscaled relative payment weights in CY 2027 to the estimated total relative

payment weights in CY 2026 using CY 2025 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2027 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2027 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4582 to ensure that the proposed CY 2027 relative payment weights are scaled to be budget neutral. The proposed CY 2027 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the methodology for payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under section 1833(t)(9) of the Act but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this proposed rule) is included in the budget neutrality calculations for the CY 2027 OPPS.

B. Proposed Conversion Factor Update

1. OPD Fee Schedule Increase Factor

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges of the Act (or an amount that is computed and applied with respect to covered OPD services). In the FY 2027 IPPS/Long Term Care Hospital (LTCH) proposed rule (91 FR 19496), consistent with current law, based on IHS Global, Inc.’s (IGI’s) fourth quarter 2025 forecast, the proposed FY 2027 IPPS market basket percentage increase was 3.2 percent. We noted that under our regular process for the CY

2027 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2027 IPPS/LTCH PPS final rule. If that forecast is different than the IPPS market basket percentage increase used for this proposed rule, the CY 2027 OPPS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase.

For CY 2027, we propose to use the estimate of the hospital inpatient market basket percentage increase of 3.2 percent as one component to calculate the OPD fee schedule increase factor.

2. Productivity Adjustment

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity ((TFP) previously referred to as multifactor productivity).⁷ Please see <https://www.bls.gov/productivity/> for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>. In the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496), the proposed productivity adjustment for FY 2027 was 0.8 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2027 OPPS/ASC proposed rule would be a reduction of 0.8 percentage point. We also propose that if more recent data subsequently become available after the publication of the CY 2027 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the

productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 hospital inpatient market basket update and the productivity adjustment for the final rule with comment period, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2027 an OPD fee schedule increase factor of 2.4 percent for the CY 2027 OPPS/ASC proposed rule (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.2 percent, less the proposed 0.8 percentage point productivity adjustment).

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2027, we propose to increase the CY 2026 conversion factor of \$91.415 by 2.4 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose to further adjust the conversion factor for CY 2027 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to apply an overall budget neutrality factor of 1.0098 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2027 IPPS wage indexes to those payments using the CY 2026 OPPS wage indexes. We further propose to calculate an additional budget neutrality factor of 0.9951 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis and the CY 2027 proposed transitional exception for low wage index hospitals.

For CY 2027, we propose to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to calculate a CY 2027 budget neutrality adjustment factor for the cancer hospital payment adjustment. We previously finalized transitioning from the target PCR of 0.89 for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reducing

the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. We propose a CY 2027 target PCR equal to 0.88 for the cancer hospital payment adjustment, which includes the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act. The proposed CY 2027 estimated payments applying the proposed CY 2027 cancer hospital payment adjustment are greater than the estimated payments applying the CY 2026 final cancer hospital payment adjustment. Therefore, we propose to apply a budget neutrality adjustment factor of 0.9994 to the conversion factor for the cancer hospital payment adjustment.

We propose to establish a cost-of-living adjustment (COLA) for hospitals in Alaska and Hawaii in the CY 2027 OPPS. We propose a budget neutrality factor of 0.9993 to account for the CY 2027 proposed COLA by comparing proposed total estimated payments from our simulation model without a COLA policy to those with the proposed CY 2027 COLA.

For the CY 2027 OPPS/ASC proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2027 will equal approximately \$195.3 million, which represents 0.18 percent of total projected CY 2027 OPPS spending. Therefore, we state that the proposed conversion factor would be adjusted by the difference between the 0.30 percent estimate of pass-through spending for CY 2026 and the 0.18 percent estimate of proposed pass-through spending for CY 2027, resulting in a proposed increase to the conversion factor for CY 2027 of 0.12 percentage point.

We propose that estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2027. We estimate for this proposed rule that outlier payments would be approximately 1.19 percent of total OPPS payments in CY 2026; the 1.00 percent for proposed outlier payments in CY 2027 would constitute a 0.19 percentage point decrease in payment in CY 2027 relative to CY 2026.

In this proposed rule with comment period, we estimate an 8.44 percent increase to nondrug OPPS payment rates as a budget neutral adjustment for the \$4.85 billion reduction in OPPS drug payment as a result of the proposed 340B drug payment policy. As part of that proposed policy, we note

⁷ <https://www.bls.gov/productivity/notices/2021/mfp-to-tp-term-change.htm>.

that our adjustment in the final rule could potentially change as a result of changes such as updated data, modifications to the estimate methodology, and other factors. For additional discussion of the proposed 340B drug payment policy, please see section V.B.7 of this proposed rule.

For CY 2027, we propose to use a conversion factor of \$102.004 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 1.024 (2.4 percent for CY 2027), the required proposed wage index budget neutrality adjustment of approximately 1.0098, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment and the proposed transitional exception of approximately 0.9951, the proposed cost-of-living

adjustment of 0.9993, the proposed cancer hospital payment adjustment of 0.9994, the adjustment for drugs purchased under the 340B Program of 1.0844, and the proposed adjustment factor of 1.0012 (an increase of 0.12 percentage point) for the difference in pass-through spending, which results in a proposed conversion factor for CY 2027 of \$102.004.

For CY 2027, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above and apply an adjustment factor of 0.9805 to the proposed CY 2027 conversion factor of \$102.004. We propose that the hospitals that fail to meet the requirements of the

Hospital OQR Program will use a reduced OPD fee schedule update factor of 0.4 percent (that is, the proposed OPD fee schedule increase factor of 2.4 percent further reduced by 2.0 percentage points).

For CY 2027, as previously discussed in section V.B.7, we propose to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies with a 3 percentage point reduction to the OPD fee schedule increase factor. This would result in a proposed reduced conversion factor for CY 2027 of approximately \$99.015 for this group of hospitals. The calculations we performed to determine the CY 2027 proposed conversion factor are shown in Table 5.

BILLING CODE 4169-69-P

TABLE 5: CALCULATION OF CY 2027 PROPOSED OPPS CONVERSION FACTOR

<u>Start:</u> CY 2026 Final OPPS Conversion Factor = \$91.415
<u>Step 1a:</u> Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2026. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0030), the percentage of outlier spending (0.01) and the percentage of domestic NIOSH/N95 policy (0.0001) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2026. ➤ $1.0000 - (0.0030 + 0.01 + 0.0001) = 0.9869$
<u>Step 1b:</u> Divide \$91.415 by 0.9869 ➤ $\\$91.415 / 0.9869 = \textbf{\\$92.628}$
<u>Step 2:</u> Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 1.0098. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with \$92.628. ➤ $\\$92.628 * 1.0098 = \textbf{\\$93.536}$
<u>Step 3:</u> Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9951. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with \$93.536. ➤ $\\$93.536 * 0.9951 = \textbf{\\$93.078}$
<u>Step 4:</u> Adjust the conversion factor by cost-of-living adjustment (COLA) of 0.9993. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with \$93.078. ➤ $\\$93.078 * 0.9993 = \textbf{\\$93.013}$
<u>Step 5:</u> Adjust the conversion factor by the cancer hospital payment adjustment of 0.9994. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with \$93.013. ➤ $\\$93.013 * 0.9994 = \textbf{\\$92.957}$
<u>Step 6:</u> Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we propose to maintain our current policy, there is no impact on the conversion factor by this policy. ➤ $\\$92.957 * 1.0000 = \textbf{\\$92.957}$
<u>Step 7:</u> Adjust the conversion factor by the proposed 340B drug payment budget neutrality adjustment policy of 1.0844. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with \$92.957. $\\$92.957 * 1.0844 = \textbf{\\$100.802}$
<u>Step 8a:</u> Adjust the conversion factor by the OPD fee schedule increase factor of 0.024 for CY 2027. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2027 over CY 2026 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2026. ➤ $1.0000 + 0.024 = 1.0240$
<u>Step 8b:</u> Multiply \$100.802 by 1.0240.

➤ $\$100.802 \times 1.0240 = \$103.222$
<i>Step 9a:</i> Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2027. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0018) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2027.
➤ $1.0000 - (0.0018 + 0.01) = 0.9882$
<i>Step 9b:</i> Multiply \$103.222 by 0.9882 to get the CY 2027 proposed OPPS conversion factor. $\$103.222 \times 0.9882 = \$102.004$
<i>Finish:</i> CY 2027 proposed OPPS Conversion Factor = \$102.004
<i>* Reduction for Providers Subject to the 340B Remedy Offset</i>
<i>Step 8:</i> Multiply \$102.004 by 0.9707 to get the CY 2027 proposed OPPS conversion factor for the providers subject to the 340B remedy offset. $\$101.722 \times 0.9707 = \$99.015$

Please note rounding may affect the numbers in the calculations above.

BILLING CODE 4169-69-C

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified in regulation at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related portion or OPPS labor-related share. The scaled weight budget neutrality calculation methodology is discussed in section II.A.5. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for CY 2027. We refer readers to section II.C. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting

documentation under “Downloads” for this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2027 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount. Under §§ 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000, final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998, OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of

the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State, and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2027, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2026 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of “frontier States”

as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 and 53370; for FY 2014, 78 FR 50590 to 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; FY 2023, 87 FR 49006; FY 2024, 88 FR 58977; for FY 2025, 89 FR 69300; and for FY 2026, 90 FR 36851.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2027 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, an adjustment for occupational mix, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban States, an adjustment to the wage index based on commuting patterns of hospital employees (the out-migration adjustment), the 5 percent cap on any decrease to a hospital's wage index from its wage index in a prior FY, and the transitional payment exception for hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Beginning with FY 2024, we include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and we exclude "dual reclass" hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 58971 through 58973). We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) for a detailed discussion of all proposed changes to the FY 2027 IPPS wage indexes.

We note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index for FY 2027 would not be less than 95 percent of its final wage index for FY 2026. Except for newly opened hospitals, we apply the cap for a fiscal year using the final wage index

applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year (subject to any reclassification), and it would not receive a cap for that first year, because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted previously).

Consistent with the FY 2026 IPPS/LTCH PPS final rule (90 FR 36852 through 36854), we discontinued for CY 2026 and subsequent years the low wage index hospital policy under the OPPS (90 FR 53495 through 53496). Under the low wage index hospital policy that we previously adopted for the OPPS (84 FR 61186 through 61188), we increased the wage index for hospitals with a wage index value below the 25th percentile wage index value for a calendar year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2025 IFC (89 FR 80405 through 80421), FY 2026 IPPS/LTCH PPS final rule (90 FR 36852 through 36854) and CY 2026 OPPS/ASC final rule with comment period (90 FR 53495 through 53496) for a detailed discussion regarding the removal of the low wage index hospital policy from the IPPS for FYs 2025 and 2026 and the OPPS for CY 2026.

In the FY 2026 IPPS final rule (90 FR 36855 through 36857), using our authority under section 1886(d)(5)(I)(i) of the Act, we adopted a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. As indicated in that rule, we adopted this temporary payment exception "to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under prospective payment systems." To address these same concerns under the OPPS, we correspondingly adopted a transitional payment exception for CY 2026 under the OPPS using our equitable adjustment authority under section 1833(t)(2)(E) of the Act (90 FR 53496 through 53497). This authority allows the Secretary to establish, in a budget neutral manner, adjustments as determined to be necessary to ensure equitable payments.

The CY 2026 transitional exception policy under the OPPS applied to hospitals that benefited from the CY

2024 low wage index hospital policy. For those hospitals, we compared the hospital's proposed CY 2026 wage index to the hospital's CY 2024 wage index. If the hospital was significantly impacted by the discontinuation of the low wage index hospital policy, meaning the hospital's proposed CY 2026 wage index was decreasing by more than 9.75 percent from the hospital's CY 2024 wage index, then the transitional payment exception for CY 2026 for that hospital was equal to the additional CY 2026 amount the hospital would be paid under the OPPS if its CY 2026 wage index were equal to 90.25 percent of its CY 2024 wage index. This transitional payment exception was applied after the application of the 5-percent cap described at 42 CFR 412.64(h)(7). This policy was budget neutral under the OPPS through the second wage index budget neutrality adjustment applied to the OPPS conversion factor (which currently includes the 5 percent hold harmless cap policy).

In the FY 2027 IPPS/LTCH proposed rule (91 FR 19476 through 19478) we proposed, using our authority under section 1886(d)(5)(I)(i) of the Act, to continue to apply the narrow transitional payment exception to the calculation of FY 2027 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy that we adopted in CY 2026. As indicated in that rule, we proposed to continue this temporary payment exception because "[s]ome hospitals that previously benefitted from the low wage index hospital policy would continue to experience decreases of approximately 5 percent or more per year from their FY 2024 wage index (with the low wage index hospital policy applied)."⁸ To address these same concerns under the OPPS, we correspondingly propose to continue the transitional payment exception for CY 2027 under the OPPS that we adopted in CY 2026 using our equitable adjustment authority under section 1833(t)(2)(E) of the Act.

Core Based Statistical Areas (CBSAs) are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes

⁸ 91 FR 19477.

for purposes of the IPPS and OPPTS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at <https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html>. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPTS wage index, in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2027, under the OPPTS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2027 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPTS to determine the wage adjustments for both the OPPTS payment rate and the copayment rate for CY 2027. Therefore, any policies and adjustments that are finalized for the FY 2027 IPPS post-reclassified wage index would be reflected in the final CY 2027 OPPTS wage index beginning on January 1, 2027, if appropriate. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) and the proposed FY 2027 hospital wage index files posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipp-pps-proposed-rule-home-page>.

Regarding budget neutrality for the CY 2027 OPPTS wage index, we refer readers to section II.C. of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPTS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPTS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPTS, it is our

longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2027. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19459 through 19479) for a detailed discussion of the proposed changes to the FY 2027 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPTS to qualify for the out-migration adjustment if they are located in a "section 505 out-migration county" (that is, a county identified under section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPTS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2027, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPTS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA) (88 FR 49585 through 49586). Furthermore, we propose that the wage index that would apply for CY 2027 to non-IPPS hospitals paid under the OPPTS would continue to include the rural floor adjustment and any other policies and adjustments applied to the IPPS wage index. In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPPTS would include the 5 percent cap on wage index decreases and the previously described proposed transitional payment exception for hospitals significantly impacted by the discontinuation of the low wage index hospital policy.

For CMHCs, for CY 2027, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2027 would continue to include the rural floor adjustment and any other policies and adjustments applied to the IPPS wage index. In addition, the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases and proposed transitional exception. Also, we propose that the

wage index that would apply to CMHCs would not include the out-migration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2027 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2027-ipp-pps-proposed-rule-home-page>) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2027 IPPS/LTCH PPS proposed rule (available for download via the website noted previously) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2027. We are including the out-migration adjustment information from Table 2 associated with the FY 2027 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule, with the addition of non-IPPS hospitals that would receive the section 505 out-migration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPTS at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-regulations-notice>. At this link, readers will find a link to the proposed FY 2027 IPPS wage index tables and Addendum L, associated with this proposed rule.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB control number 0938–0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPTS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes new hospitals, defined for this purpose as entities that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate

status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using statewide average CCRs (also referred to as statewide average default CCRs), including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPTS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the Claims Accounting Narrative for this proposed rule, which is posted on the CMS website. We propose to calculate the default ratios for CY 2027 using the most recent cost report data.

The statewide average CCRs are available on our website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices>; click on the link on the left of the page titled “Annual Policy Files” and then select the relevant year to download the statewide CCRs and upper limits in the “Downloads” section of the web page.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2027

In the CY 2006 OPPTS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPTS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provides the Secretary the authority to make an adjustment to OPPTS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPTS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPTS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-

through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPTS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPTS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. As detailed in the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53499), we provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2026.

For CY 2027, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPTS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2027

1. Background

Since the inception of the OPPTS, which was authorized by the BBA, Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPTS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress added section 1833(t)(7) of the Act, “Transitional Adjustment to Limit Decline in Payment,” which requires the Secretary to determine OPPTS payments to cancer and children’s hospitals based on their pre-BBA payment amount (these hospitals are

often referred to under this policy as “held harmless” and their payments are often referred to as “hold harmless” payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPPTS and a “pre-BBA amount.” That is, cancer hospitals are permanently held harmless to their “pre-BBA amount,” and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPTS than the payment amount they would have received before implementation of the OPPTS, as set forth in section 1833(t)(7)(F) of the Act. The “pre-BBA amount” is the product of the hospital’s reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The “pre-BBA amount” and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB No. 0938–0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPTS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals’ costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPTS hospitals. For a

complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 and 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a

policy to provide additional payments to the cancer hospitals so that each cancer hospital’s final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the “target PCR”) for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment

adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 6 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2026.

TABLE 6: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2026

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89
2024	0.88
2025	0.87
2026	0.88

2. Proposed Policy for CY 2027

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage point less than the target PCR that would otherwise apply. Section 16002(b) of the 21st Century Cures Act also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, section 16002(b) of

the 21st Century Cures Act provides that the Secretary shall not consider the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital’s proposed PCR is equal to the weighted average PCR (or “target PCR”) for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act. As discussed further below, we are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2027.

To calculate the proposed CY 2027 target PCR, we propose to use the same extract of cost report data from HCRIS used to estimate costs for the CY 2027 OPPS which, in most cases, would be the most recently available hospital cost

reports. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital’s most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2025 claims data that we used to model the impact of the proposed CY 2027 APC relative payment weights (3,374 hospitals) because we believe it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2027 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2023 to 2025; however, the cost reporting periods were predominantly from fiscal years ending in 2024 and 2025. We then removed the cost report data of the 50 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the

calculation of hospital-weighted statistics. We also removed the cost report data of nine hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,315 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 89 percent of

reasonable cost (weighted average PCR of 0.89). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.88 for each cancer hospital.

Table 7 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2027, due to the cancer hospital payment adjustment policy. The actual, final

amount of the CY 2027 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2027 payments and costs from the settled CY 2027 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 7: ESTIMATED CY 2027 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2027 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	35.2%
050660	USC Norris Cancer Hospital	19.8%
100079	Sylvester Comprehensive Cancer Center	31.3%
100271	H. Lee Moffitt Cancer Center & Research Institute	16.3%
220162	Dana-Farber Cancer Institute	45.4%
330154	Memorial Sloan-Kettering Cancer Center	42.5%
330354	Roswell Park Cancer Institute	7.8%
360242	James Cancer Hospital & Solove Research Institute	27.1%
390196	Fox Chase Cancer Center	5.3%
450076	M.D. Anderson Cancer Center	52.9%
500138	Seattle Cancer Care Alliance	41.8%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the

OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2026, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus \$6,225 (the fixed-dollar amount threshold) (90

FR 53502 through 53504). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPSS. Our estimate of total outlier payments as a percent of total CY 2025 OPSS payments, using CY 2025 claims available for this proposed rule, is approximately 0.93 percent. Therefore, for CY 2025, we estimate that we did not meet the outlier target by 0.07 percent of total aggregated OPSS payments.

For the CY 2027 OPSS/ASC proposed rule, using CY 2025 claims data and CY 2026 payment rates, we estimate that the aggregate outlier payments for CY 2026 would be approximately 1.19 percent of the total CY 2026 OPSS payments. We provide estimated CY 2027 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

2. Proposed Outlier Calculation for CY 2027

For CY 2027, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPSS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPSS payments), would be allocated to CMHCs for partial hospitalization program (PHP) and intensive outpatient program (IOP) outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPSS outlier payments. We propose to continue our outlier policy that if a CMHC's cost for PHP and IOP services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2027 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPSS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds

the APC payment amount plus the fixed-dollar threshold.

We calculate the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2026 (90 FR 53502 through 53504). For purposes of estimating outlier payments for CY 2027, we used the hospital-specific overall ancillary CCRs available in the April 2026 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPSS Pricer to pay claims. The claims that we generally use to model each OPSS update lag by 2 years.

In order to estimate CY 2027 hospital outlier payments, we inflate the charges on the CY 2025 claims using the same proposed charge inflation factor of 1.15154 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809). We used an inflation factor of 1.07310 to estimate CY 2026 charges from the CY 2025 charges reported on CY 2025 claims before applying CY 2026 CCRs to estimate the percent of outliers paid in CY 2026. The proposed methodology for determining these charge inflation factors is discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809). As we stated in the CY 2005 OPSS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPSS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPSS/ASC final rule with comment period (71 FR 68011), we were concerned that we could systematically overestimate the OPSS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2027 IPPS outlier calculation to the CCRs used to simulate CY 2027 OPSS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2027, we propose to apply an adjustment factor of 0.977497 to the CCRs that were in the April 2026 OPSF to trend them forward from CY 2026 to CY 2027. The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19809).

To model hospital outlier payments for this CY 2027 OPSS/ASC proposed rule, we applied the overall CCRs from the April 2026 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.977497 to approximate CY 2027 CCRs) to charges on CY 2025 claims that were adjusted (using the proposed charge inflation factor of 1.15154 to approximate CY 2027 charges). We simulated aggregated CY 2027 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2027 OPSS payments. We estimate that a proposed fixed dollar- threshold of \$7,100 combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPSS payments to outlier payments for CY 2027. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we propose to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer

readers to section XV. of this proposed rule.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPSS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this proposed rule, the payment rate for most services and procedures for which payment is made under the OPSS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight described in section II.A. of this proposed rule. The national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available on the CMS website at “*Hospital Outpatient Regulations and Notices*”) and for most HCPCS codes to which separate payment under the OPSS has been assigned in Addendum B to this proposed rule (which is available on the CMS website, see link above) is calculated by multiplying the proposed CY 2027 scaled weight for the APC by the CY 2027 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPSS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status

indicator assignments: “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “Q4,” “R,” “S,” “T,” “U,” or “V” (as defined in Addendum D1 to this proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of “Q1” and “Q2”) qualify for separate payment. We note that, although blood and blood products with status indicator “R” and brachytherapy sources with status indicator “U” are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the “full” national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the “reduced” national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the “full” national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2027 OPSS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPSS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPSS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPSS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate}).$

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2027 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) “Lugar” hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. For CY 2027, we propose to apply for the CY 2027 OPSS wage index any adjustments for the FY 2027 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment and a wage index floor of 1.00 in frontier States, in accordance with section 10324 of the Affordable Care Act of 2010. For further discussion of the wage index we are applying for the CY 2027 OPSS, including the low wage index hospital policy, we refer readers to section II.C. of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2027 IPPS wage index, which are listed in Table 3 associated with the FY 2027 IPPS proposed rule and available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>. (Click on the link on the left side of the screen titled “FY 2027 IPPS Proposed Rule Home Page” and select “FY 2027 Proposed Rule Tables”.) This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) of the Act or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

$Y = 0.40 \times (\text{national unadjusted payment rate})$.

Step 6. If a provider is an sole community hospital (SCH), as set forth in the regulations at § 412.92, or an essential access community hospital (EACH), which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index

adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2027 full national unadjusted payment rate for APC 5071 is \$811.46. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is \$795.64. This reduced rate is calculated by multiplying the

reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the proposed full national unadjusted payment is approximately \$486.88 (0.60 * \$811.46). The labor-related portion of the proposed reduced national adjusted payment is approximately \$477.38 (0.60 * \$795.64).

Step 2 & 3. The FY 2027 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2027 wage index policies, is 1.3260.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately \$645.60 (\$486.88 * 1.3260). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately \$633.01 (\$795.64 * 1.3260).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately \$324.58 (0.40 * \$811.46). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately \$318.26 (0.40 * \$795.64).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the proposed full national unadjusted payment is approximately \$970.18 (\$645.60 + \$324.58). The sum of the portions of the proposed reduced national adjusted payment is approximately \$951.27 (\$633.01 + \$318.26) as shown in Table 8.

TABLE 8: PROPOSED FULL NATIONAL UNADJUSTED PAYMENT RATE AND PROPOSED REDUCED NATIONAL ADJUSTED PAYMENT RATE

Proposed Full national unadjusted payment rate	Proposed Reduced national adjusted payment rate
\$970.18	\$951.27

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment

rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPDS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted

copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011,

that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B. of the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amended section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section “X.B. Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests”, of the CY 2022 OPPTS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(C), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2027 through CY 2029 is 90 percent, with beneficiary coinsurance equal to 10 percent.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA were initially implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. On February 9, 2023 and December 14, 2023, we issued initial⁹ and revised¹⁰ guidance, respectively, implementing

the Medicare Part B Inflation Rebate Program, including the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act.¹¹ For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at <https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare>.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) of the Act requires under the ASC payment system that, in the case of a Part B rebatable drug for which payment is not packaged into a payment for a service, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPTS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPTS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the

inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug described under section 1192(c) of the Act.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and the OPPTS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. Consistent with the policy adopted in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance, the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152 (88 FR 79043).

In the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81594), we codified the OPPTS program payment and cost as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41, which cross-references the regulations adopted in the CY 2024 PFS final rule (§§ 410.152(m) and 489.30(b)(6)). We also amended the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. Similarly, we codified the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference

⁹ <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf>.

¹⁰ <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf>.

¹¹ In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies “inflation-adjusted coinsurance” in the “Notes” column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at <https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcparthdrugavgsalesprice>.

to 42 CFR 489.30(b)(6), which codified the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

In the CY 2025 PFS final rule (89 FR 98228 through 98275), we codified regulations implementing section 11101 of the IRA in newly added 42 CFR part 427, chapter IV, including new provisions at §§ 427.200 and 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined in § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. As finalized, § 427.201(a) establishes that CMS will use the methodology established in such section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage and incorporates references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). Section 427.201(c) provides that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Section 427.201(b) sets forth the calculation of the inflation-adjusted beneficiary coinsurance. We will compare the payment amount in paragraph (b)(3) of such section to the inflation-adjusted payment amount for an applicable calendar quarter; if the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is calculated by multiplying the inflation-adjusted payment amount by 0.20. Section 427.201(b)(3) specifies that CMS will use the published payment amount in quarterly pricing files^{12 13 14} to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance. If so, such adjusted beneficiary coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. This approach deviates from the rebate calculation approach set forth in § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published

payment amount in quarterly pricing files differ.

We note that the cost sharing amounts of rebatable drugs paid under the OPPS published in the quarterly Addendum A and B updates reflect the inflation-adjusted coinsurance applied as a percent of the payment amount that would otherwise apply in accordance with section 1847A(b)(1)(B) or (C) of the Act, as determined by the Secretary pursuant to 1847A(i)(5) of the Act using the methodology in § 427.201. As we explained in the CY 2025 PFS final rule (89 FR 98237), this policy is intended to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount, and we believe this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the “specified amount” used to determine rebate amounts. We refer readers to the full discussion at 89 FR 98237 and 98238 for additional details.

2. OPPS Copayment Policy

For CY 2027, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. We refer readers to the November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458). In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles. The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2027, are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2027, the Medicare beneficiary’s minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the

national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.

- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year’s rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year’s rate, the copayment amount is calculated as the product of the new payment rate and the prior year’s coinsurance percentage.

- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

- If HCPCS codes are added to an APC and, after recalibrating its relative

¹² See <https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>.

¹³ See <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates>.

¹⁴ See <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda>.

payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20 percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, \$162.29 is 20 percent of the full national unadjusted payment rate of \$970.18. For APCs with only a minimum unadjusted copayment in Addenda A and B to proposed rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service. *B* is the beneficiary payment percentage. *B* = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*.

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2027, are shown in Addenda A and B to this proposed rule (which are available via the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2027 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

We also note that the co-insurance for a separately payable drug under the OPPS shall not exceed the amount of inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding

System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for

these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section X.I. “Proposed CY 2027 Payment Status and Comment Indicators” of this proposed rule, we discuss the various status indicators and comment indicators used under the OPPS. We also provide a

complete list of the status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, 61 new HCPCS codes were established and made effective on April 1, 2026. Through the April 2026 OPPS quarterly update CR (Transmittal 13686, Change Request 14380, dated March 13, 2026), we recognized several new HCPCS codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 9 (New HCPCS Codes Effective April 1, 2026). The proposed status indicator, APC assignment, and payment rate for

each HCPCS code can be found in Addendum B to this proposed rule.

The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator “NP” in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment, and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

BILLING CODE 4169–69–P

TABLE 9: NEW HCPCS CODES EFFECTIVE APRIL 1, 2026

CY 2026 HCPCS Code	CY 2026 Long Descriptor
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
C8007 (retroactive to January 1, 2026)	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring a insertion of a separate distal respiratory sensor electrode or electrode array
C8008 (retroactive to January 1, 2026)	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009 (retroactive to January 1, 2026)	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8010	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
C8011 (retroactive to January 1, 2026)	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012 (retroactive to January 1, 2026)	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013 (retroactive to January 1, 2026)	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C9309	Injection, onasemnogene abeparvovec-brve, per treatment
C9818 (effective January 23, 2026)	suzetrigine, oral, 1 mg
G0680	Detection and quantification of coronary artery calcium and/or aortic valve calcification from algorithmic analysis of computed tomography of the chest with report
G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
J0463	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg
J1164	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	Injection, immune globulin (yimmugo), 100 mg
J3404	Injection, zopapogene imadenovec-drba suspension, per therapeutic dose
J8502	Injection, aprepitant (aponvie), 1 mg
J9003	Leuprolide injectable (camcevi etm), 1 mg
J9183	Gemcitabine intravesical system, 225 mg
J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
J9278	Injection, carboplatin (avyxa), 1 mg
J9601	Injection, linvoseltamab-gcpt, 1 mg
M0233	Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, first dose
M0234	Intravenous infusion, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, includes infusion and post administration monitoring, second dose
Q0238	Injection, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg
Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4419	Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4421	Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)

CY 2026 HCPCS Code	CY 2026 Long Descriptor
Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4425	Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)
Q4426	Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4427	Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4429	Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4435	Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Prelect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4439	Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5161	Injection, denosumab-kyqq (aukelso/bosaya), biosimilar, 1 mg
Q5162	Injection, denosumab-nxxp (bildyos/bilprevida), biosimilar, 1 mg
0614U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 4 enzyme complexes by stained blue native polyacrylamide gel electrophoresis (PAGE), frozen tissue (muscle, liver, heart, cultured skin fibroblasts), diagnostic qualitative result
0615U	Borrelia burgdorferi (Lyme disease), antibody detection of 26 recombinant protein groups, by immunoassay, IgM
0616U	Neurology (dementia), DNA methylation analysis of more than 30,000 sites, whole blood, algorithm reported as positive or negative risk
0617U	Cardiovascular (atherosclerotic cardiovascular disease [ASCVD]), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0618U	Psychiatry (bipolar disorder), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
0619U	Pulmonary (chronic obstructive pulmonary disease [COPD]), DNA methylation analysis of more than 18,000 sites, whole blood, algorithm reported as positive or negative risk
0620U	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0621U	Infectious disease (Lyme borreliosis), DNA methylation analysis of more than 10,000 sites, whole blood, algorithm reported as positive or negative risk
0622U	Psychiatry (major depressive disorder), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0623U	Autoimmune (multiple sclerosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0624U	Hepatology (nonalcoholic steatohepatitis [NASH]), DNA methylation analysis of 5,000 sites, whole blood, algorithm reported as positive or negative risk
0625U	Endocrinology (osteoporosis), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
0626U	Neurology (Parkinson disease), DNA methylation analysis of more than 20,000 sites, whole blood, algorithm reported as positive or negative risk
0627U	Psychiatry (schizophrenia), DNA methylation analysis of more than 15,000 sites, whole blood, algorithm reported as positive or negative risk

CY 2026 HCPCS Code	CY 2026 Long Descriptor
0628U	Nephrology (kidney disease-related genetic conditions), genomic analysis, renal disease panel, saliva, DNA, next-generation sequencing of 449 genes, reported as pathogenic or likely pathogenic variants of uncertain significance or risk alleles
0629U	Infectious disease (tuberculosis), DNA, analysis of 1 target by PCR with clustered regularly interspaced short palindromic repeat (CRISPR)-based probe detection, plasma or serum, qualitative report as detected or not detected
0630U	Oncology (breast), mRNA, gene expression profiling by microarray of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as an index that is diagnostic of a molecular subtype (luminal, basal, Her2)

2. July 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2026 update, 98 new codes were established and made effective July 1, 2026. Through the July 2026 OPPS quarterly update CR (Transmittal R13832CP Change Request 14477, dated June 16, 2026) we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the

proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective July 1, 2026). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator

“NP” in Addendum B to this proposed rule to indicate that the codes are assigned to interim APC assignments and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

TABLE 10: NEW HCPCS CODES EFFECTIVE JULY 1, 2026

CY 2026 HCPCS Code	CY 2026 Long Descriptor
A9574	Injection, ferumoxitol, 1 mg
C1609	Vertebral device, motion-preserving, with screw fixation
C8014	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)
C9310	Injection, leucovorin calcium (avyxa), 1 mg
G0572	Management of new patient with dementia residing in an eligible memory care unit, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible memory care unit, including specialized dementia care units within assisted living facilities or other qualifying memory care settings designed to provide specialized care for individuals with dementia and cognitive impairment)
G0573	Management of established patient with dementia residing in an eligible memory care unit, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible memory care unit, including specialized dementia care units within assisted living facilities or other qualifying memory care settings designed to provide specialized care for individuals with dementia and cognitive impairment)
G0574	Management of new patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)
G0575	Management of established patient with dementia residing in an eligible residential care community, for use only in a medicare-approved cmmi model (services must be furnished within a patient's eligible residential care community, including assisted living facilities, board and care homes, or other qualifying residential settings where dementia care services are provided)
G0669	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of early cardio-kidney-metabolic (eCKM) conditions (hypertension, or two or more of: dyslipidemia, obesity/overweight with central obesity marker, prediabetes); initial 12-month period; per month.
G0670	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of early cardio-kidney-metabolic (eCKM) conditions (hypertension, or two or more of: dyslipidemia, obesity/overweight with central obesity marker, prediabetes); follow-on 12-month period; per month.
G0671	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of cardio-kidney-metabolic (CKM) conditions (one or more of: diabetes mellitus, chronic kidney disease Stage 3a or 3b, atherosclerotic cardiovascular disease); initial 12-month period; per month.
G0672	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of cardio-kidney-metabolic (CKM) conditions (one or more of: diabetes mellitus, chronic kidney disease Stage 3a or 3b, atherosclerotic cardiovascular disease); follow-on 12-month period; per month.
G0673	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of musculoskeletal (MSK) conditions (chronic musculoskeletal pain); initial 12-month treatment period; per month.
G0674	Outcome-Aligned Payment (OAP) for technology-enabled chronic care management of behavioral health conditions (BH) conditions (one or more of: depression, anxiety); initial 12-month period; per month.
G0675	Outcome-Aligned Payment (OAP) for behavioral health (BH) conditions (one or more of: depression, anxiety); follow-on 12-month period; per month.
G0676	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing cardio-kidney-metabolic conditions (early cardio-kidney-metabolic [eCKM] or cardio-kidney-metabolic [CKM] track); per review.
G0677	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing musculoskeletal (MSK) conditions; per review.
G0678	Standard Co-Management service payment for documented review of clinical updates from ACCESS Participant managing behavioral health (BH) conditions (depression, anxiety); per review.

CY 2026 HCPCS Code	CY 2026 Long Descriptor
G0685	Algorithmic analysis for identification of new lesions and determination of change of existing lesions for advanced metastatic cancer using data sets from 2 or more previously acquired pet or pet/ct studies
J0528	Injection, fosfomycin disodium, 20 mg
J1289	Injection, narsoplimab-wuug, 1 mg
J1577	Injection, immune globulin (qivigy), 100 mg
J2361	Injection, depemokimab-ulaa, 1 mg
J2374	Apraclonidine hydrochloride ophthalmic, 1% solution, 0.1 mL
J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL
J3386	Injection, etuvetidigene autotemcel, per treatment
J3405	Injection, onasemnogene abeparvovec-brve, per treatment
J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj
J9232	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg
M0231	Intravenous infusion, tocilizumabbavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, includes infusion and post administration monitoring, first dose
M0232	Intravenous infusion, tocilizumabbavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, includes infusion and post administration monitoring, second dose
Q0234	Injection, tocilizumab-bavi, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation only, 1 mg
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg
Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg
Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg
Q5168	Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
Q5169	Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg
Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg
Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg
1026T	Transvaginal laser photobiomodulation therapy of pelvis, provided by a physician or other qualified health care professional
1027T	Percutaneous insertion or replacement of neurostimulation catheter via left subclavian or left jugular vein into the superior vena cava, with verification of capture of phrenic nerves, mapping and programming, and delivery of transvenous phrenic neurostimulation therapy in ventilated patients, with repositioning when performed, including imaging guidance
1028T	Mapping and programming of neurostimulation catheter with delivery of transvenous phrenic neurostimulation therapy in ventilated patients, with repositioning and verification of left phrenic nerve capture, per session
1029T	Mapping and programming of neurostimulation catheter with delivery of transvenous phrenic neurostimulation therapy in ventilated patients, without catheter repositioning, per session
1030T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; initial 30 minutes

CY 2026 HCPCS Code	CY 2026 Long Descriptor
1031T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1032T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) and digital simulation, cumulative time for up to 30 days; initial 60 minutes
1033T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1034T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; initial 90 minutes
1035T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
1036T	Noninvasive hemodynamic assessment with pulmonary pressures and ejection fraction when performed, including passive acquisition of acoustic and electrical signals, augmentative algorithmic analysis, and generation of a clinical report with review, interpretation, and clinical integration by a physician or other qualified health care professional
1037T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant pancreatic tissue, including imaging guidance
1038T	Autologous muscle cell therapy, injection(s) of muscle progenitor cells into the tongue, including esophagoscopy, when performed
1039T	Connectomic analysis of previously performed multi-modal brain magnetic resonance imaging (MRI) requiring physician or other qualified health care professional (QHP) analysis of software- and physician-generated structural and functional maps for integration of cortical grey matter correlation based on resting state functional MRI and mapping of white matter connectivity based on diffusion weighted MRI relative to brain regions, with physician or other QHP interpretation and report
1040T	Bronchoscopy, flexible, with bronchial cryotherapy, 1 lung, including trachea, when performed
1041T	Augmentative algorithmic analysis of encephalographic waveforms to identify the source and propagation of epileptiform activity, including artifact reduction with analysis of 3D localization of spike sources throughout the examination, 3D animations over time of high-amplitude event locations, high-frequency activity locations, and temporal relationships among locations, with interpretation and report by physician or other qualified health care professional, related to a previously performed electroencephalogram (EEG)
1042T	Implantation of absorbable urologic scaffold for prosthetic urethra restoration of reconstructed bladder neck and urethral anastomosis (List separately in addition to code for primary procedure)
1043T	Quantitative magnetic resonance, without imaging, for analysis of liver tissue, including assessment of 1 or more parameters (eg, proton density fat fraction [PDFF], water diffusion, T1-water relaxation time), with automatically generated report.
1044T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; first 5 sq cm or less
1045T	Harvest of full-thickness skin for autologous heterogeneous skin-construct graft, including direct closure of donor site; each additional 5 sq cm, or part thereof (List separately in addition to code for primary procedure)
1046T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; first 50 sq cm or less, or 0.5% of body area of infants and children
1047T	Autologous heterogeneous skin-construct graft application, trunk, arms, legs; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

CY 2026 HCPCS Code	CY 2026 Long Descriptor
1048T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 50 sq cm or less, or 0.5% of body area of infants and children
1049T	Autologous heterogeneous skin-construct graft application, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 50 sq cm, or each additional 0.5% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
1050T	Insertion, subcutaneous heart failure decompensation monitor, containing sensors that measure, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds
1051T	Removal of subcutaneous heart failure decompensation monitor
1052T	Interrogation device evaluation(s), (in person or remote) up to 30 days, insertable subcutaneous heart failure decompensation monitor, analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report, review and interpretation by a physician or other qualified health care professional
1053T	Programming device evaluation (in person or remote) of subcutaneous heart failure decompensation monitor, with analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report and review and interpretation by a physician or other qualified health care professional
0631U	Red blood cell antigen (fetal RhD gene analysis), multiplex polymerase chain reaction (PCR) and next-generation sequencing (NGS) of circulating cell-free DNA (cfDNA), plasma from pregnant individuals known to be RhD negative, reported as detected or not detected
0633U	Obstetrics (single-gene noninvasive prenatal test), cell-free DNA (cfDNA), nextgeneration sequencing (NGS) analysis of 1 or more targets (eg, CFTR, SMN1, HBB, HBA1, HBA2) to identify paternally inherited pathogenic variants and to determine fetal inheritance of maternal mutation, using maternal blood sample, algorithm reported as a fetal risk score
0634U	Oncology (breast cancer), cellfree DNA (cfDNA), evaluation of 11 ESR1 variants (E380Q, S463P, L536R, Y537C, Y537N, Y537S, D538G, V422del, L536H, L536P, Y537D) using droplet digital PCR (ddPCR), plasma, reported as positive or negative
0635U	Autoimmune (atopic dermatitis), mRNA, nextgeneration sequencing (NGS), gene expression profiling of 487 genes, noninvasive skin-surface scraping, algorithm reported as likelihood of response to therapy
0636U	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgG
0637U	Babesia (Babesiosis), antibody detection of 20 recombinant protein groups, by immunoassay, IgM
0638U	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgG
0639U	Bartonella (Bartonellosis), antibody detection of 32 recombinant protein groups, by immunoassay, IgM
0640U	Oncology (leptomeningeal metastases), tumor cell selection, identification, detection and enumeration based on differential CD318(CDCP1), SUSD2, CD340(erbB2/HER2), HGFR/cMET, FOLR1, EGFR, N cadherin, MUC1, EpCAM, and TROP2 antibody biomarkers, cerebrospinal fluid, reported as detection and quantification of tumor cells
0641U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment
0642U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level
0643U	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for singlenucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability
0644U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification

CY 2026 HCPCS Code	CY 2026 Long Descriptor
0645U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance
0646U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffinembedded (FFPE) tumor tissue DNA, baseline assessment
0647U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patientspecific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)
0648U	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from formalin-fixed paraffin-embedded (FFPE) tissue
0649U	Neurology (Alzheimer disease), DNA, targeted nextgeneration sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status
0650U	Drug metabolism (adverse drug reactions and drug response), genotyping of 9 genes (ie, CYP2D6, CYP2C19, G6PD, SLC01B1, HLA-B*58:01, NAT2, CYP2C9, VKORC1, ABCG2), reported as metabolizer status and transporter function
0651U	Oncology (hereditary cancer), genomic DNA, 55 hereditary cancer pre-dispositioned genes, next-generation sequencing (NGS) and digital multiplex ligation-dependent probe amplification for variants, small indels (<40 base pairs), using saliva, whole blood or nail clipping, interpretive clinical report with variant classification
0652U	Drug metabolism (adverse drug reactions), DNA analysis of 13 genes by targeted genotyping, using saliva or buccal swab, reported as diplotype and metabolizer status
0653U	Nephrology (inherited kidney disorders), DNA, analysis of approximately 700 genes associated with inherited kidney diseases by exome sequencing, using whole blood, saliva, or nail clipping, reported as an interpretive clinical report classifying pathogenic and likely pathogenic variants
0654U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by western blot analysis, using cultured skin fibroblasts, diagnostic qualitative result
0655U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by spectrophotometric kinetic assay, using cultured skin fibroblasts, diagnostic quantitative result
0656U	Inborn error of metabolism (primary mitochondrial disease), mitochondrial analysis of 1 enzyme complex by radioactive activity assay, using cultured skin fibroblasts, diagnostic quantitative result
0657U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of comparator nuclear and mitochondrial DNA by nextgeneration sequencing (NGS), using blood or buccal sample, relevant variants reported with proband results
0658U	Rare diseases (constitutional/heritable disorders), rapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for singlenucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
0659U	Rare diseases (constitutional/heritable disorders), ultrarapid whole genome sequence analysis of nuclear and mitochondrial DNA by next-generation sequencing (NGS) for singlenucleotide variants (SNVs), insertions/deletions, copy number variants, uniparental disomy, and repeat expansions, using blood or buccal sample, identification and categorization of genetic variants
90616	Influenza virus vaccine, trivalent (tIRV), mRNA, 37.5 mcg/0.38 mL dosage, for intramuscular use
90639	Influenza virus vaccine, quadrivalent (qIRV), mRNA; 50 mcg/0.5 mL dosage, for intramuscular use

BILLING CODE 4169-69-C

3. October 2026 HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2026, in the CY 2027 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2027 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2026 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2027, we propose to continue our established policy of assigning comment indicator “N1” in Addendum B to this proposed rule for those new HCPCS codes that will be effective October 1, 2026, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2027 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

4. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2027, in the CY 2027 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2028 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2027, we propose to include the new Level II HCPCS codes effective January 1, 2027, in Addendum B to the CY 2027 OPPS/ASC final rule with comment period, which would be incorporated in the January 2027 OPPS quarterly update CR. Specifically, for CY 2027, we propose to continue our established policy of assigning comment indicator “N1” in Addendum B to the OPPS/ASC

final rule with comment period to the new HCPCS codes that will be effective January 1, 2027, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2027 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

b. New CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA’s CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year’s rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule with comment period, and to finalize the specific APC and status indicator

assignments for those codes in the following year’s rule.

For the CY 2027 OPPS update, we received the CPT codes that will be effective January 1, 2027, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator “NP” in Addendum B to the proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator.

Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2027 CPT codes in Addendum O, specifically under the column labeled “CY 2027 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.” The final HCPCS code numbers will be included in the CY 2027 OPPS/ASC final rule with comment period. In summary, we solicit public comments on the proposed CY 2027 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2027. The CPT codes listed in Addendum B appear with short descriptors only; therefore, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2027 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

Finally, in Table 11 (Comment and Finalization Timeframes for New and Revised OPPS-Related HCPCS Codes),

we summarize our current process for updating codes through our OPPTS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPTS.

TABLE 11: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPTS-RELATED HCPCS CODES

OPPTS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2026	HCPCS (CPT and Level II Codes)	April 1, 2026	CY 2027 OPPTS/ASC proposed rule	CY 2027 OPPTS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II Codes)	July 1, 2026	CY 2027 OPPTS/ASC proposed rule	CY 2027 OPPTS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II Codes)	October 1, 2026	CY 2027 OPPTS/ASC final rule with comment period	CY 2028 OPPTS/ASC final rule with comment period
January 2027	CPT codes	January 1, 2027	CY 2027 OPPTS/ASC proposed rule	CY 2027 OPPTS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	CY 2027 OPPTS/ASC final rule with comment period	CY 2028 OPPTS/ASC final rule with comment period

B. Proposed OPPTS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. In addition, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs,

biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group, the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPTS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2027, we propose that each APC relative payment weight represents the hospital cost of

the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to consider changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also

known as the HOP Panel or the Panel) recommendations for specific services for the CY 2027 OPPS update will be discussed in the relevant specific sections throughout the CY 2027 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable regarding the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest median cost (or mean cost if so elected) for an item or service within the same group (referred to as the “2 times rule”).

The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2027, we propose to make exceptions to this limit on the variation of costs within each

APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2027 OPPS update, we identified the APCs with violations of the 2 times rule, and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we have proposed a 2 times rule exception) in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this proposed rule. Rather, it is published and made available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we have not proposed a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2027 included in this proposed rule are related to changes in costs of services that were observed in the CY 2025 claims data available for CY 2027 ratesetting. Addendum B to this proposed rule identifies with a comment indicator “CH” those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2026, OPPS Addendum B Update, which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-update>.

3. Proposed APC Exceptions to the 2 Times Rule

While considering the APC changes that we propose for CY 2027, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;

- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2025 claims data available for this proposed rule, we found 27 APCs with violations of the 2 times rule. We applied the criteria as described previously in this section to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2027 and found that all of the 27 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2025 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 12. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 12 lists the 27 APCs for which we propose to make an exception under the 2 times rule for CY 2027 based on the criteria cited above and claims data submitted between January 1, 2025, and December 31, 2025, and Cost-to-Charge Ratios (CCRs), if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

TABLE 12: PROPOSED CY 2027 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5054	Level 4 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5613	Level 3 Therapeutic Radiation Treatment Preparation
5671	Level 1 Pathology
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5722	Level 2 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5735	Level 5 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5742	Level 2 Electronic Analysis of Devices
5791	Pulmonary Treatment
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by

an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc> on the CMS website and then follow the instructions to access the MEARIS™ system for

OPPS New Technology APC applications.¹⁵

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of “S” (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of “T” (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2026, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC

¹⁵ Currently approved under OMB control number 0938–0860; expires October 31, 2027.

1491 (New Technology—Level 1A (\$0–\$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 (\$145,001–\$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from \$10 to \$14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for APC 1507 (New Technology—Level 7 (\$501–\$600)) is made at \$550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is intended to be budget neutral in comparison to what would have been paid under the previous reasonable-cost payment system, and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and continue to be adequate to ensure access to services. For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer

readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have low annual volume, which we consider to be fewer than 100 claims in the year of claims data used for ratesetting (86 FR 63528). Where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access of new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy in the CY 2019 OPPS/ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. However, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the now-ended New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Despite the universal low volume APC policy, we continued to see payment instability for services with very low claims volume of fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. For CY 2025, we finalized a policy to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period used for the universal low volume policy. Instead of assigning these services to a different New

Technology APC based on the very few claims available, we maintained the New Technology APC assignment for each service from the prior year, CY 2024. We refer readers to the CY 2025 OPPS/ASC final rule with comment period for a discussion on the policy (89 FR 94016 through 94018). Consistent with our overall policy regarding use of updated claims data in the final rule with comment period, we finalized our proposal to perform a similar analysis for the final rule with comment period using updated claims data, including determining whether specific HCPCS codes continue to meet the criteria for our universal low volume APC policy or would be subject to our proposed policy to continue exempting services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain the New Technology APC assignment from the previous year.

In the CY 2026 OPPS/ASC final rule with comment period we finalized a continuation of the policy to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from the universal low volume policy moving forward. We finalized to continue this policy in future years, until, or unless, an alternative policy was finalized. We refer readers to the CY 2026 OPPS/ASC final rule with comment period for a discussion on the policy (90 FR 53530 through 53531).

In addition to the universal low volume policy and the policy to exempt services with fewer than 10 claims in the 4-year lookback period, it has been our policy to maintain the New Technology APC assignment for services with zero claims in the claims year used for rulemaking. For CY 2027, since we propose CY 2027 OPPS payment rates based on CY 2025 claims data, if a service has no CY 2025 claims, we propose to maintain the same New Technology APC assignment for CY 2027. We continue to believe this approach is appropriate because, in the absence of new claims data, there is no additional information upon which to base a reassignment. This policy ensures consistency and stability in payment until sufficient claims data become available to support a reassignment to a different New Technology APC or appropriate clinical APC.

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with

the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPSS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new

procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

For CY 2027, the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 are provided in Addendum A to this proposed rule (which is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices>).

2. Services in New Technology APCs With Zero Claims for the Rulemaking Period or Under 10 Claims in the 4-Year Lookback Period

For CY 2027, there are several services that have either zero claims for CY 2027 rulemaking (based on CY 2025 claims) or fewer than 10 claims in the previous 4-year lookback period. For CY 2027, we propose to maintain the New Technology APC assignments for services listed in Table 13.

TABLE 13: SERVICES WITH FEWER THAN 10 CLAIMS IN THE LOOKBACK PERIOD OR ZERO CLAIMS FOR CY 2027 RATESETTING

Name of Service	HCPCS Code	# of Single Frequency Claims	Final CY 2026 OPPS FR APC & SI Assignments	Proposed CY 2027 OPPS NPRM APC & SI Assignments
Blinded Procedure for NYHA Class III/IV Heart Failure	C9758	9 claims	1590, T	1590, T
CardiAMP	C9782	3 claims	1590, T	1590, T
Corvia Medical Interatrial Shunt	C9760	2 claims	1592, T	1592, T
DARI Motion Procedure	0693T	0 claims	1505, S	1505, S
Implantable Glucose Monitoring System	0446T	0 claims	1563, T	1563, T
Implantable Glucose Monitoring System	0448T	9 claims	1563, T	1563, T
Magnetic Resonance Imaging With Inhaled Hyperpolarized Xenon-129 Contrast Agent	C9791	6 claims	1551, T	1551, T
Surfacor Inside-Out Access Catheter	C9780	7 claims	1534, S	1534, S
Transcatheter Atrial Shunt System (TASS)	C9792	1 claim	1537, S	1537, S

3. Procedures Assigned to New Technology APC Groups for CY 2027

As we described in the CY 2002 OPSS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained

sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best

information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource

utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2027, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1564)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 (\$3001–\$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 (\$3001–\$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.¹⁶ This therapy is administered through a subretinal injection, which interested parties

describe as an extremely delicate and sensitive surgical procedure. The FDA-approved package insert describes one of the steps for administering Luxturna as, “after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana”.

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.¹⁷ However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself. CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC final rule with comment period, we established a new HCPCS code, C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process (85 FR 85940). For CY 2021, we assigned HCPCS code C9770 to APC 1561 (New Technology—Level 24 (\$3001–\$3500)) using the geometric mean cost of CPT code 67036 (86 FR 63532).

CY 2023 was the first year that claims data were available for HCPCS code C9770; therefore, we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule with comment period, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated

using this methodology fell within the cost band for APC 1562 (New Technology—Level 25 (\$3501–\$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023 (87 FR 71810).

For CY 2024, we proposed and finalized that we would delete HCPCS code C9770 effective December 31, 2023 and recognize CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) starting January 1, 2024 (88 FR 81617 through 81619). We determined the payment rate for CPT code 0810T using the claims data for HCPCS code C9770 and designated CPT code 0810T as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC. For CY 2024, we finalized assignment of CPT code 0810T to APC 1563 (New Technology—Level 26 (\$4001–\$4500)) (88 FR 81618). For 2025, claims data for CPT code 0810T was not yet available. Therefore, we continued to use claims data for HCPCS code C9770 to determine the appropriate APC for CPT code 0810T and finalized to continue to assign CPT code 0810T to APC 1563 for CY 2025 (89 FR 94018 and 94019).

CY 2026 was the first year that we had claims data available for CPT code 0810T, and there were 7 claims available. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we used the available combined 43 claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2026, we designated CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 43 combined claims available. Therefore, we used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data from a 4-year lookback period to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC, which was the arithmetic mean cost of \$4,327. This fell within the cost band for APC 1563 (New Technology—Level 26 (\$4001–\$4500)), therefore, we continued to assign CPT code 0810T to APC 1563 for CY 2026 (90 FR 53532).

For CY 2027, there are nine claims available for CPT code 0810T, with a

¹⁶ Luxturna. FDA Package Insert. Available: <https://www.fda.gov/media/109906/download>.

¹⁷ LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. <https://mysparkgeneration.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf>.

geometric mean cost of \$4,183. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we propose to use the available combine claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2027, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there were only 39 combined claims available. This is below the threshold of 100 claims for a service within a year required to designate a service as a low volume service and apply our universal low volume APC policy. Using all available claims for CPT code 0810T

and HCPCS code C9770 from the 4-year lookback period, based on 39 claims, we determined the geometric mean cost to be approximately \$4,239, the arithmetic mean cost to be \$4,587, and the median cost to be \$4,502. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean of \$4,587 falls within the cost band for APC 1564 (New Technology—Level 27 (\$4501–\$5000)). Therefore, we propose to reassign CPT code 0810T to APC 1564 for CY 2027. Additionally, we propose to perform a similar analysis using updated claims data, including determining if CPT code 0810T

continues to meet the criteria for our universal low volume APC policy, in the CY 2027 OPPS/ASC final rule with comment period and update the APC assignment as needed.

Refer to Table 14 for the final CY 2026 and proposed CY 2027 New Technology APC and status indicator assignment for CPT code 0810T. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 14: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0810T

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS, SI APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	1563, T	1564, T

b. BgRT (APC 1518 and 1523)

Biology Guided Radiation Therapy (BgRT) uses positron-emitting radiopharmaceuticals to control delivery of radiation therapy to treat primary and metastatic lung or bone tumors. During radiation treatment delivery, the same system applies these firing filters to the real-time positron emission tomography (PET) data collected by the radiation treatment delivery machine. Effective January 1, 2024, CMS created HCPCS codes C9794 (Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (*i.e.*, modeling) and C9795 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions) to describe the modeling and treatment delivery portions of the BgRT service. We assigned HCPCS code C9794 to APC 1521 (New Technology—Level 21 (\$1901–\$2000)) and HCPCS code C9795 to APC 1525 (New Technology—Level 25 (\$3501–\$4000)) for CY 2024.

For CY 2025, we continued to assign HCPCS code C9794 to APC 1521 (New Technology—Level 21 (\$1901–\$2000)) with a payment rate of \$1,950.50 and HCPCS code C9795 to APC 1525 (New Technology—Level 25 (\$3501–\$4000)) with a payment rate of \$3,750.50 because we did not have any claims data for the service.

Effective January 1, 2025, HCPCS codes C9794 and C9795 were replaced by HCPCS codes G0562 and G0563, respectively. For CY 2026, we utilized available claims data for HCPCS codes C9794 and C9795 to propose payment rates for HCPCS codes G0562 and G0563. Due to concerns given the extremely limited number of claims and the substantial decrease that would occur if the proposed rates were finalized, we did not finalize the proposed payment rate changes (90 FR 53533 and 53534). For CY 2026, we finalized the assignment of HCPCS code G0562 to APC 1521 and status indicator “S” and HCPCS code G0563 to APC 1524 (New Technology—Level 24 (\$3001–\$3500)) and status indicator “S” (90 FR 53534).

Since HCPCS code G0562 and G0563 were made effective January 1, 2025, and the proposed OPPS payment rates for CY 2027 are based on available CY 2025 claims data, this is the first time

that we have available claims for HCPCS codes G0562 and G0563, specifically, for ratesetting. For CY 2027, we propose to designate HCPCS codes G0562 and G0563 as low volume procedures under our universal low volume APC policy, given that there are 24 single frequency claims for G0562 and 47 claims for G0563 during the claims period. For HCPCS code G0562, we determined the arithmetic mean cost to be approximately \$1,461, the median cost to be approximately \$1,601, and the geometric mean cost to be approximately \$1,398. Because the median cost is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The median cost of \$1,601 falls within the cost band for APC 1518 (New Technology—Level 18 (\$1601–\$1700)). Therefore, we propose to assign HCPCS code G0562 to APC 1518 (New Technology—Level 18 (\$1601–\$1700)) with a payment rate of \$1,650.50 for CY 2027. For HCPCS code G0563, we determined the arithmetic mean cost to be approximately \$2,644; the median cost to be approximately \$2,218, and the geometric mean cost to be approximately \$2,467. The arithmetic mean cost is the statistical methodology

that estimated the highest cost for the service; therefore, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean cost of \$2,644 falls within the cost band for APC 1523 (New Technology—Level 23 (\$2501–\$3000)). Therefore, we propose to assign HCPCS code G0563 to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2750.50 for CY 2027.

Additionally, we propose to perform a similar analysis using updated claims data, including determining if HCPCS codes G0562 and G0563 continue to meet the criteria for our universal low volume APC policy, in the CY 2027 OPPTS/ASC final rule with comment period and update the APC assignments as needed.

Refer to Table 15 for the final CY 2026 and proposed CY 2027 OPPTS New Technology APC and status indicator

assignment for HCPCS codes G0562 and G0563. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPTS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 15: FINAL CY 2026 AND PROPOSED CY 2027 OPPTS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS Code	Long Descriptor	Final CY 2026 OPPTS APC, SI	Proposed CY 2027 OPPTS APC, SI
G0562	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	1521, S	1518, S
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	1524, S	1523, S

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APC 5594).

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. We have explained previously that services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. In the CY 2026 OPPTS/ASC final rule we noted that, over the past several years, the claims volumes for CPT codes 78431 and 78433 have increased significantly while the geometric mean costs of the codes have remained relatively stable. We explained that, although we had seen stability in the claims data for CPT codes 78431 and 78433, CPT code 78432, which is closely related to CPT codes 78431 and 78433, continued to have low claims frequency and fluctuating geometric mean costs. We explained that, due to our concerns regarding CPT code 78432 and the lack

of an appropriate clinical APC for CPT codes 78431 and 78433 at the time based on resource cost similarity, we finalized to continue to assign CPT codes 78431 through 78433 to New Technology APCs for CY 2026 (90 FR 53536 and 53537). While we believe that cardiac PET/CT services, such as those described by CPT codes 78431 through 78433, are clinically similar to services assigned to the Nuclear Medicine and Related Services APC series, such as CPT codes 78429 and 78430, we previously had concerns that the resource costs for the APC series did not align with the resource costs reflected in the claims data for CPT codes 78431 through 78433. As a result, we previously maintained CPT codes 78431 through 78433 in New Technology APCs.

For CY 2027, we propose changes to APCs 5591–5594 (Nuclear Medicine and Related Services) that includes the shifting of the APC assignments for several codes in that APC series. We refer readers to section III.E. Proposed APC-Specific Policies of this proposed

rule for a discussion of the policy proposal. As a result of these proposed changes, the proposed geometric mean costs of the Nuclear Medicine and Related Services APC series have also shifted. We believe that the new geometric mean costs of the proposed Nuclear Medicine and Related Services APC series more closely align with the costs reflected in the claims data for CPT codes 78431 through 78433. Therefore, we propose to assign CPT codes 78431 through 78433 to APC 5594 (Level 4 Nuclear Medicine and Related Services). Refer to Table 16 for the final CY 2026 and proposed CY 2027 OPPTS New Technology APC and status indicator assignment for CPT codes 78431 through 78433. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPTS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 16: FINAL CY 2026 AND PROPOSED CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	1522, S	5594, S
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	1517, S	5594, S
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	1522, S	5594, S

d. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent Into Renal Pelvis (APC 1550)

Effective October 1, 2023, CMS established HCPCS code C9789 (Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed) and assigned it to APC 1559 (New Technology—Level 22 (\$2001–\$2500)), with a payment rate of \$2,250.50 based on our review of the clinical and resource characteristics of this service.

This code may be used to describe the unique procedure associated with the administration of the drug described by HCPCS code J9281 (Mitomycin pyelocalyceal instillation, 1 mg) or similar products. HCPCS code J9281 may be used to describe the product, JELMYTO® (mitomycin for pyelocalyceal solution). The FDA approved JELMYTO® in 2020, and the FDA approved indication and usage for JELMYTO® is as an alkylating drug indicated for the treatment of adult

patients with low-grade Upper Tract Urothelial Cancer (LG–UTUC).¹⁸

For CY 2025, the OPPS payment rates were based on available CY 2023 claims data. Because we created HCPCS code C9789 effective October 1, 2023, we had limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only had six claims available for ratesetting, so we maintained the New Technology APC assignment of APC 1559 (New Technology—Level 22 (\$2001–\$2500)) with a payment of \$2,250.50 for CY 2025, based on our CY 2025 policy to maintain the New Technology APC assignment for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy (89 FR 94034).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. HCPCS code C9789 had 222 single frequency claims in CY 2024, which exceeded the 100 claims threshold generally used for the universal low volume APC policy. The geometric mean cost for HCPCS code C9789 was

approximately \$1,211. Therefore, for CY 2026, we assigned HCPCS code C9789 to APC 1551 (New Technology—Level 14 (\$1201–\$1300)) with a payment rate of \$1,250.50 (90 FR 53542 and 53543).

For CY 2027, the proposed OPPS payment rates are based on available CY 2025 claims data. HCPCS code C9789 has 235 single frequency claims in CY 2025 and the geometric mean cost for HCPCS code is \$1,173. Therefore, for CY 2027, we propose to assign HCPCS code C9789 to APC 1550 (New Technology—Level 13 (\$1101–\$1200)) with a payment rate of \$1,150.50.

Refer to Table 17 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignment for HCPCS code C9789. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

¹⁸ Jelmlyto Package Insert, Revised January, 2021.

TABLE 17: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	1551, T	1550, T

e. LimFlow TADV Procedure, CPT Code 0620T (APC 1581)

The LimFlow TADV procedure which is described by CPT code 0620T (Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed) is an endovascular procedure that is used to treat patients with chronic limb-threatening ischemia. According to the developer, these patients are no longer eligible for conventional endovascular or open bypass surgery to treat their artery blockage, and without this procedure, they are likely to face limb amputation.

CPT code 0620T was established in January 2021 and was assigned to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of approximately \$17,400, which is the highest-paying APC for endovascular procedures. While we proposed to continue to assign CPT code 0620T to APC 5194 for CY 2024, we finalized a reassignment from a clinical APC to a New Technology APC with a higher payment rate based on comments received expressing concern that the low payment rate of the procedure would discourage providers from performing the procedure and deny access to the procedure. For CY 2024, the procedure was assigned to APC 1578 (New Technology—Level 41 (\$25,001–\$30,000)) (88 FR 81694). For CY 2025 ratesetting, there were 11 single frequency claims for CPT code 0620T in the CY 2023 claims data. As this is below the threshold of 100 claims for a service within a year, we applied our universal low volume APC policy and used the highest of the geometric mean

cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims and the application of the universal low volume APC policy, we assigned HCPCS code 0620T to APC 1579 (New Technology—Level 42 (\$30,001–\$40,000)) with a payment rate of \$35,000.50 based on the median cost of approximately \$36,400 (89 FR 94034 through 94036).

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. There were 19 single frequency claims for 0620T in the CY 2024 claims data. As this is below the threshold of 100 claims for a service within a year, we proposed to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims and the application of the universal low volume APC policy, for CY 2026, we assigned HCPCS code 0620T to APC 1580 (New Technology—Level 43 (\$40,001–\$50,000)) with a payment rate of \$45,000.50 based on the arithmetic mean cost of approximately \$43,748 (90 FR 53543 and 53544).

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. There were 28 single frequency claims for 0620T in the CY 2025 claims data. As this is below the threshold of 100 claims for a service within a year, we propose to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, we have determined that the arithmetic mean is approximately \$51,748; the median is approximately \$46,455; and the geometric mean cost is

approximately \$47,513. Of these, the arithmetic mean is the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for APC 1581 (New Technology—Level 44 (\$50,001–\$60,000)). Therefore, for CY 2027, we propose to designate this service as a low volume service under our universal low volume APC policy and to assign HCPCS code 0620T to APC 1581 (New Technology—Level 44 (\$50,001–\$60,000)) with a payment rate of \$55,000.50.

f. Liver Histotripsy Service (APC 1575)

CPT code 0686T (Histotripsy (*i.e.*, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.¹⁹ When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed (absent the cost of the device) each time it is reported on a claim. On March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, payment for CPT code 0686T in CY 2024

¹⁹ *ClinicalTrials.gov*. “The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER).” Accessed May 10, 2022. <https://clinicaltrials.gov/ct2/show/study/NCT04573881>.

reflected payment for both the service that was performed and the device used each time it was reported on a claim. For CY 2024, we assigned CPT code 0686T to APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) with a payment rate of \$17,500.50 (88 FR 81631 through 81633). For CY 2025, we continued to assign CPT code 0686T to APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) due to our CY 2025 policy to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, and based on the fact that there were only three claims for CPT code 0686T in the prior 4-year period (89 FR 94036 and 94037).

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. For the CY 2026 OPPS/ASC proposed rule, we identified 94 claims for CPT code 0686T within this period. As this was below the threshold of 100 claims for a service within a year, we proposed to apply our universal low volume APC policy and used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 0686T to the

appropriate New Technology APC. We identified \$32,307.41 as the arithmetic mean, \$20,577.77 as the median, and \$21,264.91 as the geometric mean. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT code 0686T. However, six additional claims were processed since the CY 2026 OPPS/ASC proposed rule, bringing the total number of claims to 100. Since the total number of CY 2024 single-frequency claims for CPT code 0686T surpassed the 99-claim threshold for the universal low-volume APC policy, we used the geometric mean cost (\$16,008) of the CY 2024 claims data for CPT code 0686T to set the payment rate for CY 2026 under our standard ratesetting methodology, rather than the highest of the three statistical methodologies over a 4-year lookback period. Due to the updated claims data available for the CY 2026 OPPS/ASC final rule with comment period, we finalized a New Technology APC assignment for CPT code 0686T to APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) with a payment rate of around \$17,500.50, which was the same APC to which the service was assigned in CY 2025 (90 FR 53544 and 53545).

For CY 2027, the OPPS payment rates are proposed to be based on available

CY 2025 claims data. We have identified 166 single claims for CPT code 0686T within this period. As this surpasses the 99-claim threshold for the universal low volume APC policy for a service within a year, we propose to assign CPT code 0686T using our standard ratesetting methodology using the geometric mean cost to set the payment rate for CPT code 0686T. The geometric mean cost of CPT code 0686T is approximately \$14,311. The geometric mean falls within APC 1575 (New Technology—Level 38 (\$10,001–\$15,000)). Therefore, for CY 2027, we propose to assign CPT code 0686T to APC 1575 (New Technology—Level 38 (\$10,001–\$15,000)) with a payment rate of \$12,500.50.

Refer to Table 18 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignments for CPT code 0686T. The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 18: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	1576, S	1575, S

g. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1518)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant,²⁰ for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-

²⁰ Subsequently, the FDA approved a prior approval supplemental new drug application (sNDA) providing for the following labeling modification: expansion of the indication to include monotherapy of Spravato™ (esketamine) for treatment resistant depression (TRD). See https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2025/211243Orig1s016ltr.pdf.

resistant depression (TRD)). This is the first FDA approval of esketamine for any use.

Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation and respiratory depression

caused by esketamine nasal spray administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The Spravato™ REMS program requires, among other requirements, that the esketamine nasal spray be dispensed and administered to enrolled patients in health care settings that are certified in

the REMS. See www.fda.gov for more information regarding the Spravato™ REMS program requirements.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of at least 2 hours post-administration observation of the patient under direct supervision of a health care professional in the certified health care setting. Refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105); see also the Spravato REMS document and Spravato labeling available on the FDA website.²¹

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient who requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and

includes two hours of post-administration observation. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine.

For CY 2025, HCPCS code G2082 was assigned to APC 1513 (New Technology—Level 13 (\$1101–\$1200)) with a payment rate of \$1,150.50 and HCPCS code G2083 was assigned to APC 1516 (New Technology—Level 16 (\$1401–\$1,500)) with a payment rate of \$1,450.50.

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2027, we propose to assign HCPCS codes G2082 and G2083 to New Technology APCs based on each of the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to APC 1513 (New Technology—Level 13 (\$1101–\$1200)) with a payment rate of \$1,150.50 based on its approximate geometric mean cost of \$1,181, which was calculated using

the available 742 single frequency claims from CY 2025 claims data. We also propose to maintain the APC assignment for HCPCS code G2083 (APC 1518 (New Technology—Level 18 (\$1601–\$1700)) with a payment rate of \$1,650.50 based on its approximate geometric mean cost of \$1,648, which was calculated using the available 5,741 single frequency claims from CY 2025 claims data. As we continue to gather adequate claims data on these codes, we invite public comment on the appropriate clinical APC assignments for HCPCS codes G2082 and G2083.

Please refer to Table 19 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignments for HCPCS code G2082 and G2083. The proposed CY 2027 payment rates for these CPT codes can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 19: FINAL CY 2026 AND PROPOSED CY 2027 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	1512, S	1513, S
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	1517, S	1518, S

²¹ The REMS document is available at <https://www.fda.gov/drugs/drug-safety-and-availability/>

[risk-evaluation-and-mitigation-strategies-rems](https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems), and labeling can be found at <https://www.fda.gov/drugs/drug-safety-and-availability/>

www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

h. SAINT Neuromodulation System (APCs 1511, 1520, 1521 and 1523)

The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex to treat major depressive disorder (MDD). The patient first receives structural MRI and functional MRI scans that are analyzed by the provider to identify and localize the personalized stimulation target in the patient's dorsolateral prefrontal cortex. Once the areas targeted for treatment are identified, the patient receives non-invasive magnetic stimulation in the targeted area. The patient has 10 treatment sessions per day with each treatment session lasting 10 minutes followed by 50 minutes of rest before another treatment session occurs. The treatment is administered over 5 days for a total of 50 sessions of non-invasive magnetic stimulation therapy. There are four CPT codes listed below that describe the MRI scans that are used to target the treatment and describe the administration of the non-invasive magnetic stimulation therapy.

- 0889T—Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation.

- 0890T—Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day.

- 0891T—Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation,

including neuronavigation, delivery and management, subsequent treatment day.

- 0892T—Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day.

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. However, CPT codes 0889T, 0890T, 0891T, and 0892T did not become effective until July 1, 2024, which means there were no claims data for the procedures described these CPT codes. We assigned our proposed rates for these services based on our evaluation of the resources needed to perform these services.

Because we only had a partial year of data for CY 2026 rulemaking, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the current APCs assignments for CPT codes 0889T, 0890T, 0891T, and 0892T.

For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. We note that this is the first year that we have a full year of claims data. We identified 74 single frequency CY 2025 claims for ratesetting for CPT code 0889T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0889T is \$673, the median cost is \$971, and the arithmetic mean cost is \$776. The median is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0889T to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50.

We identified 73 single frequency CY 2025 claims for ratesetting for CPT code 0890T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0890T is \$1,750, the median cost is \$1,868, and the arithmetic mean cost is \$1,955. The arithmetic mean is the statistical methodology that estimates the highest

cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0890T to APC 1521 (New Technology—Level 21 (\$1901–\$2000)) with a payment rate of \$1950.50.

We identified 19 single frequency CY 2025 claims for ratesetting for CPT code 0892T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0892T is approximately \$2,649, the median cost is approximately \$2,193 and the arithmetic mean cost is approximately \$2,719. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0892T to APC 1523 (New Technology—Level 23 (\$2501–\$3000)) with a payment rate of \$2,750.50.

For CPT code 0891T, the OPPS payment rate is proposed based on available CY 2025 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2027, we propose to assign CPT code 0891T to a New Technology APC based on the code's geometric mean costs. Specifically, we propose to assign CPT code 0891T to APC 1520 (New Technology—Level 20 (\$1801–\$1900)) with a payment rate of \$1,850.50 based on its approximate geometric mean cost of \$1,885, which is calculated using the available 241 single frequency claims from CY 2025 claims data. Please refer to Table 20 for the final CY 2026 and proposed CY 2027 OPPS New Technology APC and status indicator assignments for CPT codes 0889T, 0890T, 0891T, and 0892T.

The proposed CY 2027 payment rates for these CPT codes can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

TABLE 20: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0889T, 0890T, 0891T, AND 0892T

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation	1511, S	1511, S
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	1525, S	1521, S
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	1525, S	1520, S
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	1525, S	1523, S

i. Skin Cell Suspension Autograft (SCSA) Procedures (CPT Codes 15X19 Through 15X22) (APC 1575)

Effective January 1, 2025, both CPT code 15013 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin) and HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)) describe the preparation step of a skin cell suspension autograft (SCSA) procedure to treat acute thermal burn injuries. Both codes describe the preparation step of a three-step SCSA procedure: harvesting, preparation, and application. The difference between the codes is that CPT code 15013 describes the manual preparation of the SCSA, and HCPCS code C8002 describes the automated preparation of the SCSA. Due to the similarities between the procedures, in the CY 2025 OPPS/ASC final rule with comment period, we

assigned both CPT code 15013 and HCPCS code C8002 to APC 1567 (New Technology—Level 30 (\$6,001–\$6,500)) with a payment rate of \$6,250.50 and status indicator “T”. In the CY 2025 OPPS/ASC final rule with comment period, we noted that we believed the sum of the payment rates for the three-step process should approximate \$10,000. However, because of the effect of the multiple procedure reduction, the total payment for the skin cell suspension autograft furnished using the RECELL System would have been approximately \$8,000, contrary to the intended target of \$10,000 as stated in the CY 2025 OPPS/ASC final rule with comment period. To correct this error, in the CY 2025 OPPS/ASC Correction Notice, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 (\$7,001–\$7,500)) with a payment rate of \$7,250.50 and status indicator “S” (Procedure or service, not discounted when multiple, paid under OPPS; separate APC payment).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims

data. Since CPT code 15013 and HCPCS code C8002 were not effective until January 1, 2025, we did not have any claims for either code for CY 2024. Therefore, for CY 2026, we finalized to continue to assign CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 (\$7,001–\$7,500)) with a payment rate of \$7,250.50.

Effective January 1, 2027, CPT codes 15011 through 15018 will be deleted and replaced with a bundled four code structure: CPT code 15X19 through 15X22:

- CPT 15X19: Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1 percent of body area of infants and children
- CPT 15X20: each additional 100 sq cm, or each additional 1 percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
- CPT 15X21: Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1 percent of body area of infants and children

• CPT 15X22: Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1 percent of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Unlike CPT codes 15011 through 15018, which provide a three step-based coding structure with each procedural

step billed separately, CPT codes 15X19 through 15X22 provide a simplified bundled coding structure based on anatomic size.

In light of these coding changes, we propose for CY 2027 to maintain overall payment rates for the SCSA procedure, as we do not believe that changes in coding structure alone warrant changes in payment for a procedure that remains clinically unchanged. The proposed APC and status indicator assignments

for CPT Codes 15X19 through 15X22 are provided in Table 21. Due to the new bundled coding structure, for CY 2027 we also propose to delete HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)), which describes the automated preparation step of the SCSA procedure.

TABLE 21: PROPOSED CY 2027 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NEW CPT CODES 15X19 THROUGH 15X22 EFFECTIVE JANUARY 1, 2027

CPT Code	Long Descriptor	Proposed CY 2027 OPps APC, SI
15X19	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	1575, S
15X20	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A, N
15X21	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	1575, S
15X22	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)	N/A, N

The proposed CY 2027 payment rates for CPT codes 15X19 through 15X22 can be found in Addendum B to this proposed rule via the internet on the CMS website.

j. Renal Histotripsy Service (APC 1534)

HCPCS code C9790 (Histotripsy (that is, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) was created October 1, 2023, and was used to describe the Medicare approved Category B IDE (investigational device exemption) clinical study involving the renal histotripsy procedure associated with the use of the HistoSonics Edison System. CPT code 0888T (Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) replaced HCPCS code C9790 effective July 1, 2024.

Renal histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy solid renal tumors and is currently in a prospective, multi-center, single-arm pivotal trial designed to

evaluate the effectiveness and safety of the device for the destruction of kidney tissue by treating primary solid renal tumors. Because the renal histotripsy clinical study is designated as a Category B (non-experimental/investigational) IDE study, the Medicare payment for CPT code 0888T reflects payment for both the service that is performed, and the device used each time it is reported on a claim. For CY 2025 we assigned CPT code 0888T to APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) with a payment rate of \$17,500.50 based on the previous APC and status indicator assignments for HCPCS code C9790.

For CY 2026, the proposed OPps payment rates were based on available CY 2024 claims data. We had identified one single frequency claim for HCPCS code C9790 and eight single frequency claims for CPT code 0888T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we

finalized maintaining the APC assignment for CPT code 0888T to APC 1576 (New Technology—Level 39 (\$15,001–\$20,000)) with a payment rate of \$17,500.50.

For CY 2027, the proposed rates are based on available CY 2025 claims data. We identified 14 single frequency CY 2025 claims for ratesetting for CPT code 0888T. Using this claims data from CY 2025, our analysis found the geometric mean cost of CPT 0888T is approximately \$5,940, the median cost is approximately \$6,740 and the arithmetic mean cost is approximately \$8,145. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2027, to assign CPT code 0888T to APC 1534 (New Technology—Level 34 (\$8001–\$8500)) with a payment rate of \$8,250.50.

Refer to Table 22 for the final CY 2026 and proposed CY 2027 OPps New Technology APC and status indicator assignment for CPT code 0888T. The proposed CY 2027 payment rates for this CPT code can be found in

Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum

D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum

D1 can also be found via the internet on the CMS website.

TABLE 22: FINAL CY 2026 AND PROPOSED CY 2027 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE RENAL HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC
0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	1576, S	1534, S

4. CY 2027 Proposals for SaMS Procedures Currently Assigned to New Technology APCs

For CY 2027, we propose an interim payment policy for software-based medical services with algorithmic analyses, which is detailed in section X.B. of this proposed rule. Since this CY 2027 proposal involves services assigned to New Technology APCs, this section specifically addresses the interaction between software-based services with algorithmic analyses that are currently assigned to new technology APCs for CY 2026, including the CY 2027 proposed changes to terminology and status indicator assignments. For the full discussion on proposed CY 2027 policies on software-based medical services with algorithmic analyses, including services that are currently assigned to clinical APCs for CY 2026 and analyses currently paid under the Clinical Lab Fee Schedule (CLFS), we refer readers to section X.B. of this proposed rule with comment period.

For CY 2027, we propose three changes regarding software-based medical services with algorithmic analyses. First, we propose to change the terminology from SaaS (Software as a Service), which is how we have referred to these services in prior rulemaking, to Software as a Medical Service (SaMS). For a detailed discussion on the rationale for this proposed terminology change from SaaS to SaMS, we refer readers to section X.B. of this proposed rule with comment period.

Second, for SaMS that are currently assigned to new technology APCs for CY 2026, we propose to maintain the current new technology APC assignments under our equitable adjustment authority at section 1833(t)(2)(E) of the Act for CY 2027. While we typically apply our standard rate-setting methodologies for all

services assigned to new technology APCs, such as the universal low-volume policy or making adjustments based on geometric mean cost using available claims data, we are not proposing to do so for SaMS because this is an interim policy. As discussed in section X.B. of this proposed rule, we propose to use CY 2027 as a transitional period to take an incremental step toward developing a more comprehensive and appropriate payment methodology for services we propose to identify as SaMS. In light of this broader policy objective, we believe it is important to minimize potential disruptions in payment for SaMS during this period. Additionally, given the evolving nature of these types of services and anticipated potential policy changes in the future, we believe maintaining current payment levels for CY 2027 is a reasonable step while we continue to refine a more comprehensive payment framework for these services. We note that this approach of maintaining payment is not unusual for SaMS services, as we have historically used our equitable adjustment authority to maintain the new technology APC assignments for some SaMS when there have been concerns regarding low volume and limited claims data. Consistent with this approach, we propose to maintain the existing new technology APC assignments for SaMS rather than assign payment rates based on current claims data. Third, we propose to assign SaMS assigned to new technology APCs to a proposed new status indicator “O1”—Software as a Medical Service, paid under OPPS; separate APC payment. We refer readers to section XI. of this proposed rule with comment period for the payment status of status indicator “O1.”

We refer readers to section X.B. of this proposed rule for a full discussion on our CY 2027 proposals for SaMS.

(1) Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) (APC 1511)

Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) is a software-based service with algorithmic analysis that assesses the extent of coronary artery disease severity. This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

- 0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report.

- 0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.

- 0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.

- 0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

Of these four CPT codes, only CPT code 0625T was determined to be separately payable in the OPPS and was assigned to status indicator “S” (Procedure or Service, Not Discounted When Multiple) starting October 1, 2022. We assigned CPT code 0625T to a separately payable status indicator based on the technology and its potential utilization in hospital outpatient departments, our evaluation of the service, as well as input from our medical advisors. The procedure was assigned to APC 1511 (New Technology—Level 11 (\$900–\$1000)) with a payment rate of \$950.50 for CY 2023.

For CY 2024, the OPPS payment rates were based on available CY 2022 claims data. There were 37 claims for CPT code 0625T during this time period. As this was below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0625T as a low volume service under our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately \$3.70, the arithmetic mean cost to be approximately \$4.10, and the median cost to be approximately \$3.50. Under our universal low volume new technology APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology Level 1A—(0–\$10)) with a payment rate of \$5.00. However, we acknowledged that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the CY 2022 claims available only reflected 2 months of data, we were concerned that we did not have sufficient claims data to justify reassignment to another new technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within new technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 69902), for CY 2024, we finalized our proposal to maintain CPT code 0625T’s assignment to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50 rather than applying the universal low volume APC policy (88 FR 81649).

For CY 2025, there were only three available claims for 0625T. We continued to have concerns that we did not have sufficient claims data to justify reassignment to another New

Technology APC based on the CY 2023 geometric mean cost of \$180. Therefore, we used our authority under section 1833(t)(2)(E) for CY 2025 to continue to assign CPT code 0625T to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50 (89 FR 94039).

Effective January 1, 2026, the AMA CPT Editorial Panel created a new Category I CPT code for AI–QCT: CPT code 75577 (Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified healthcare professional). CPT codes 0623T–0626T were deleted and replaced with CPT code 75577. Since CPT code 75577 was effective on January 1, 2026, we will not have claims data available for ratesetting for this code until the CY 2028 rulemaking cycle. However, as CPT code 0625T was still in use until December 31, 2025, we determined the payment rate for CY 2026 for CPT code 75577 using the available CY 2024 claims data for CPT code 0625T.

For the CY 2026 OPPS/ASC proposed rule, there were 22 separately payable claims in the CY 2024 data reported for CPT code 0625T with a geometric mean cost of approximately \$496 (90 FR 53539). We continued to have concerns that we did not have sufficient claims data to justify reassignment to another APC based on the 4-year lookback period, which determined the highest value to be the arithmetic mean of \$243. Therefore, we used our authority under section 1833(t)(2)(E) of the Act for CY 2026 to assign CPT code 75577 to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50 (90 FR 53540).

For CY 2027, we propose to designate the AI–QCT procedure as a SaMS procedure, as such term is provided in section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT code 75577 using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignment, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignment for CPT code 75577 to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50. Additionally, we propose to assign CPT code 75577 to proposed new

status indicator “O1” to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(2) LiverMultiScan Service (APC 1511)

CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.*, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) during the same session; single organ) and 0649T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.*, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) became effective July 1, 2021 and are associated with the LiverMultiScan service.

LiverMultiScan is a software-based service with algorithmic analysis that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients’ providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient’s liver fibrosis and inflammation. In accordance with our add-on codes policy for SaaS²² (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes.

²² We note that at the time that the add-on code policy was created (87 FR 72032 through 72033), we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

Thus, CPT code 0649T, the add-on code for LiverMultiScan, is assigned to the identical APC and status indicator as CPT code 0648T, the standalone code for the same service.

For CY 2024, CY 2025, and CY 2026, we used our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0648T and 0649T to APC 1511 (New Technology—Level 11 (\$901–\$1,000) with a payment rate of \$950.50 (90 FR 53545 and 53546)).

For CY 2027, we propose to designate the LiverMultiScan service as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT codes 0648T and 0649T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignment for CPT codes 0648T and 0649T to APC 1511 (New Technology—Level 11 (\$901–\$1000) with a payment rate of \$950.50).

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(3) Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP is a software-based service with algorithmic analysis that applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine

what the next management step should be for the patient (for example, CT surveillance versus invasive procedure). In accordance with our SaaS add-on codes policy²³ (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0722T, the add-on code for the Optellum LCP service, is assigned to the identical APC and status indicator as CPT code 0721T, the standalone code for the same service.

For CY 2024, we assigned CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 (\$601–\$700)) (88 FR 81640 and 81641).

For CY 2025, we continued to assign CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 (\$601–\$700)) with a payment rate of \$650.50 based on our CY 2025 policy to maintain new technology APC assignments for CY 2025 for new technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy (89 FR 94039 through 94041).

For CY 2026, we finalized OPPS payment rates for CPT codes 0721T and 0722T based on CY 2024 claims data, which would have resulted in assignment to APC 1502 (New Technology—Level 2 (\$51–\$100)). However, due to limited claims data, the resulting approximate 90 percent reduction in payment, and questions we had regarding potential adjustments to our payment methodologies to reflect the underlying value of SaMS, we instead used our authority under section 1833(t)(2)(E) of the Act to maintain the APC assignment. Therefore, for CY 2026, we continued to assign CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 (\$601–\$700)) with a payment rate of \$650.50 (90 FR 53546 and 53547).

For CY 2027, we propose to designate the Optellum LCP service as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT codes 0721T and 0722T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for

this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignments for CPT codes 0721T and 0722T to APC 1508 (New Technology—Level 8 (\$601–\$700) with a payment rate of \$650.50. Additionally, we propose to assign CPT codes 0721T and 0722T to proposed new status indicator “O1” to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(4) Quantitative Magnetic Resonance (QMR) for Analysis of Tissue Composition (APC 1511)

Effective January 1, 2022, CPT codes 0697T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; multiple organs) and 0698T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)) are associated with the CoverScan, which is a software-based service with algorithmic analyses. This service is a medical image management and processing software package that analyzes MR data and provides quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas, and kidney. For CY 2024, we assigned CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 (\$900–\$1,000)).

For CY 2025, there were fewer than 100 claims for ratesetting and because we recognized that the number of claims used to apply our universal low volume policy (using the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data) may not have represented the cost of this SaaS, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act to

²³ We note that when the add-on code policy was created in the CY 2023 OPPS/ASC final rule with comment period, we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

continue to assign CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 (\$900–\$1,000)) with a payment of \$950.50. In accordance with our SaaS add-on codes policy²⁴ (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0698T, the add-on code for CoverScan was assigned to the identical APC and status indicator as CPT code 0697T, the standalone code for the same service (89 FR 94041 to 94043).

For CY 2026, the OPPS payment rates were based on available CY 2024 claims data. We identified 55 single frequency claims for CPT code 0698T and no claims for CPT code 0697T in CY 2024. Because the standalone service and add-on services are identical, we believed it was important for purposes of ratesetting to use the data that is available, whether it was associated with the standalone code or the add-on code, to determine appropriate payment. As the 55 single frequency claims were below the threshold of 100 claims for a service within a year, we would have proposed applying our universal low volume APC policy and would have used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0697T and 0698T to the appropriate New Technology APC. Our analysis of the combined data, zero claims for CPT code 0697T and 137 claims for CPT code 0698T, yielded a geometric mean cost of approximately \$422, an arithmetic mean cost of approximately \$600, and a median cost of approximately \$777. The median cost was the statistical methodology that estimated the highest cost for CPT codes 0697T and 0698T. Based on the median cost, we would have proposed to assign CPT codes 0697T and 0698T to APC 1509 (New Technology—Level 9 (\$701–\$800)) with a payment of \$750.50.

For CY 2026 OPPS/ASC final rule with comment period (90 FR 53547 to 53549), we recognized that the few claims available for CPT codes 0697T and 0698T may not have truly represented the cost of this SaMS. We recognized that software-based technologies, like those described by CPT codes 0697T and 0698T, are unique

and rapidly evolving and that a significant fluctuation in payment may hinder patient access to these new services. For CY 2026, we finalized continuing to assign CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 (\$900–\$1,000)) with a payment of \$950.50 which we believe best reflected the cost of the service at the time.

For CY 2027, we propose to identify the CoverScan procedure as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignment for CPT codes 0697T and 0698T using our authority under section 1833(t)(2)(E). By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignment for CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment rate of \$950.50. Additionally, we propose to assign CPT codes 0697T and 0698T to proposed new status indicator “O1” to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(5) Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP, a software-based service with algorithmic analysis. The service performs quantitative assessment of the biliary tree and gallbladder. It uses a

proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. In accordance with our SaaS add-on codes policy²⁵ (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Consistent with our SaaS add-on codes policy, CPT code 0724T, the add-on code for QMRCP is assigned to the identical APC and status indicator as CPT code 0723T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 (\$900–\$1,000)). For CY 2025, we continued to assign CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 (\$900–\$1,000)) based on there being fewer than 10 claims in the 4-year lookback period and the exception from the universal low-volume APC policy.

For CY 2026, the OPPS payment rates were proposed to be based on available CY 2024 claims data. There were only four new claims for HCPCS code 0724T and no claims for CPT code 0723T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period due to an exception from the universal low-volume APC policy, we proposed, for CY 2026, to continue to assign CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 (\$901–\$1000)), with a payment rate of \$950.50.

For CY 2027, we propose to designate the QMRCP procedure as a SaMS procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignments for CPT codes 0723T and 0724T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignments for CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 (\$901–\$1000)) with a payment

²⁴ We note that when the add-on code policy was created in the CY 2023 OPPS/ASC final rule with comment period, we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

²⁵ We note that when the add-on code policy was created in the CY 2023 OPPS/ASC final rule with comment period, we referred to these services as SaaS. We will continue to refer to the policy as the SaaS add-on code policy as provided in rulemaking. However, when we refer to these services generally, we will use the term SaMS, as explained in this proposed rule. The SaaS and SaMS terms are interchangeable.

rate of \$950.50. Additionally, we propose to assign CPT codes 0723T and 0724T to proposed new status indicator “O1” to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

(6) Fibresolve, 0877T and 0878T (APC 1508)

Effective July 1, 2024, the AMA CPT Editorial Panel established the following CPT codes to describe the software-based service with algorithmic analysis medical technology used for the non-invasive assessment of interstitial lung disease and idiopathic pulmonary fibrosis utilizing data from chest computed tomography (CT) images. The CPT codes, their long descriptors, and their current payment assignments are listed below that describe Fibresolve.

- 0877T—Augmentative analysis of chest CT imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging. CPT code 0877T is assigned to New Technology APC 1508 New Technology—Level 8 (\$601–\$700) and a status indicator of “S” (Procedure or Service, Not Discounted When Multiple; Paid under OPPS) with a payment of \$650.50.

- 0878T—Augmentative analysis of chest CT imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure. CPT code 0878T is assigned to New Technology APC 1508 New Technology—Level 8 (\$601–\$700) and a status indicator of “S” (Procedure or Service, Not Discounted When Multiple; Paid under OPPS) with a payment of \$650.50.

For CY 2027, we propose to designate the Fibresolve procedure as a SaMS

procedure, as such term is provided section X.B. of this proposed rule, and maintain the existing new technology APC assignments for CPT codes 0877T and 0878T using our authority under section 1833(t)(2)(E) of the Act. By maintaining the existing APC assignments, we hope to minimize potential disruptions in payment for this service while we continue to evaluate longer-term payment approaches. Therefore, for CY 2027, we propose to maintain the APC assignments for CPT codes 0877T and 0878T to APC 1508 (New Technology—Level 8 (\$601–\$700) with a payment rate of \$650.50. Additionally, we propose to assign CPT codes 0877T and 0878T to proposed new status indicator “O1” to designate the service as SaMS.

The proposed CY 2027 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website. In addition, we refer readers to Addendum D1 to this proposed rule for the status indicator meanings for all codes reported under the OPPS. Addendum D1 can also be found via the internet on the CMS website.

D. Proposed Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2026 OPPS/ASC proposed rule, CY 2024 claims were generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2024 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100

single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for the CY 2027 OPPS/ASC proposed rule, we proposed to designate five brachytherapy APCs and four clinical APCs as low volume APCs under the OPPS. The five brachytherapy APCs and four clinical APCs meet our criteria of having fewer than 100 single claims in the claims’ year used for ratesetting (CY 2025 for the CY 2027 OPPS/ASC proposed rule). Nine of the 10 APCs were designated as low volume APCs in CY 2025. Based on data for the CY 2026 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) has 87 single claims and now meets our criteria to be designated as a low volume APC. Table 23 includes the CY 2025 claims available for ratesetting for each of the APCs we propose to designate as a low volume APC for CY 2027. The proposed cost statistics for our CY 2027 low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this proposed rule on the CMS website. We refer readers to our website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>; click on the relevant regulation to download the low volume APC cost statistics under the comprehensive (OPPS) ratesetting methodology in the downloads section of the web page.

TABLE 23: PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2027

APC	APC Description	CY 2025 Claims Available for Ratesetting
2635	Brachytx, non-str, HA, p-103	28
2642	Brachytx, stranded, c-131	41
2643	Brachytx, non-stranded, c-131	78
2645	Brachytx, non-stranded, gold-198	87
2647	Brachytx, NS, Non-HDR Ir-192	13
5244	Level 4 Blood Product Exchanges and Related Services	40
5495	Level 5 Intraocular Procedures	94
5496	Level 6 Intraocular Procedures	35
5881	Ancillary Outpatient Services When Patient Dies	34

*E. Proposed APC-Specific Policies***1. Nuclear Medicine and Related Services APC Series (APC 5591 Through 5594)**

The Nuclear Medicine and Related Services APC series was created as part of the broader APC restructuring and consolidation in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70392 through 70397). The APC series was developed from what were previously separate APC groupings primarily organized by anatomy and imaging modality. Since the initial establishment of the Nuclear Medicine and Related Services series in the CY 2016 OPPS/ASC final rule with comment period, we have maintained the four-level APC structure for the series.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy of paying separately for diagnostic radiopharmaceuticals with estimated per day costs higher than a packaging threshold specific to diagnostic radiopharmaceuticals (89 FR 93948 through 93963). Because certain diagnostic radiopharmaceuticals are paid separately under the policy, the nuclear medicine and other services these diagnostic radiopharmaceuticals would otherwise be packaged into would no longer include those costs. As a result, based on the associated changes to the ratesetting process, we observed impacts on the estimated cost of services assigned to the Nuclear Medicine and Related Services APC series such that the range of cost significant codes across the various APC levels became less distinct, in particular between Levels 3 and 4.

As part of our standard process of reviewing updated claims and cost

report data, we continue to observe in the CY 2027 OPPS data that the differences between the four levels of APC geometric means are less distinct than they were previously, in part due to the policy of paying separately for diagnostic radiopharmaceuticals. Specifically, under a four level APC structure using the NPRM claims data and maintaining the same APC assignments as in the CY 2026 OPPS/ASC final rule with comment period, the geometric mean cost of the Level 3 APC would be \$1,367.99 while the geometric mean cost of the Level 4 APC would be \$1,497.06. The range of cost significant codes in the Level 3 APC would be from \$812 to \$1,404, while the range for the Level 4 APC would be from \$1,024 to \$1,676; indicating a high degree of overlap in the estimated costs of the services assigned to those APC levels. Given the relative proximity of the APC geometric mean costs and the clinical and cost similarities of the services between the APCs in the Nuclear Medicine and Related Services series, we believe that it is appropriate to reorganize the Nuclear Medicine and Related Services APC series for the CY 2027 OPPS.

Additionally, we note that CPT codes 78431 (Myocardial imaging, positron emission tomography (pet), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan), 78432 (Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed),

dual radiotracer (e.g., myocardial viability);), and 78433 (Myocardial imaging, positron emission tomography (pet), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan) have sufficient CY 2025 claims data available to be appropriate assigned to clinical APCs for CY 2027 OPPS ratesetting. We believe the restructuring of the series now makes it appropriate to propose to assign these codes to APC 5594 (Level 4 Nuclear Medicine and Related Services) and we propose to assign these three CPT codes to APC 5594 for CY 2027.

Based on our review of the updated claims data, we propose to reassign a number of services to revised levels in the Nuclear Medicine and Related Services APC series for CY 2027 and to assign CPT codes 78431, 78432, and 78433 to APC 5594 (Level 4 Nuclear Medicine and Related Services) in the CY 2027 OPPS. Please see the APC-sorted Two Times Listing for this proposed rule on the CMS website or Addendum B to this proposed rule to see the Nuclear Medicine APC we have proposed to assign each HCPCS code in the series.

2. Breast/Lymphatic Surgery and Related Procedures APC Series (APC 5091 Through 5093)

The Breast/Lymphatic Surgery and Related Procedures APC series was initially created as part of the broader APC restructuring and consolidation in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70379 through 70380). The APC series was reorganized

from what were previously separate APC groupings for breast and skin surgery. In the CY 2017 OPPS/ASC final rule with comment period, we created an additional level 4 APC to the Breast/Lymphatic Surgery and Related Procedures APC series (81 FR 79584). Since that time, we have maintained the four-level APC structure for the series.

In the CY 2026 OPPS/ASC final rule with comment period, we observed that certain complexity adjustments in the APC series were being promoted up by two APC levels (90 FR 53466) due to cost inversion between the Level 2 and 3 APCs. This data anomaly occurred as a combined result of the APC levels having cost ranges that were not sufficiently distinct, and the contribution of the complexity adjustment claims data contributing to the APC geometric means. In the CY 2026 OPPS/ASC final rule with comment period, we were able to recalibrate the APCs to address these concerns, and, as part of our standard practice, would continue to monitor the claims data as available.

In reviewing the claims data available for ratesetting for the CY 2027 OPPS proposed rule, we continue to observe data anomalies due to the APC cost ranges not being sufficiently distinct, in particular between the Level 2 and 3 APCs for the Breast/Lymphatic Surgery and Related Procedures APC series. While APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures) has a cost significant range from approximately \$7,131.27 to \$8,734.72, the single cost significant code currently assigned to the Level 3 APC, that is not a complexity adjustment, has an estimated geometric mean cost of \$8,219.71, falling well within the Level 2 cost significant range. As a result of the cost ranges overlapping and based on the cost and payment anomalies that would otherwise occur as a result, we believe that it is appropriate to consolidate the current Level 2 and 3 APCs in the Breast/Lymphatic Surgery and Related Procedures APC series into a single Level 2 APC. Accordingly, the current Level 4 Breast/Lymphatic Surgery and Related Procedures APC would then

become the Level 3 Breast/Lymphatic Surgery and Related Procedures APC. We note that while there would be changes in the naming and structure of the levels, the APC geometric means, and resulting payment rates, would likely not be significantly different relative to where they otherwise would have been absent this proposal.

Based on our review of the updated claims data, for CY 2027, we propose to establish a 3 level Breast/Lymphatic Surgery and Related Procedures APC series by consolidating the current Level 2 and 3 APCs into a single Level 2 APC, and remapping the current Level 4 APC as the level 3 APC.

Please see the APC-sorted Two Times Listing for this proposed rule on the CMS website, or Addendum B to this proposed rule, to see the reconfigured Breast/Lymphatic Surgery and Related Procedures APC series and the APC placement and payment rate for each HCPCS code within the reconfigured APC series.

3. Hypoglossal Nerve Neurostimulator (HGNS) Procedures (APCs 5465, 5463, and 5432)

Effective January 1, 2022, the AMA's CPT Editorial Panel created three new codes to describe the open implantation of hypoglossal nerve neurostimulator (HGNS) array with an implanted pulse generator and a separate distal respiratory sensor, the revision or replacement of the HGNS, and the removal of the HGNS for the treatment of obstructive sleep apnea (OSA). The codes, their long descriptors, and APC and status indicators are listed below.

- 64582—*Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array.* CPT code 64582 is assigned to APC 5465 (Level 5 Neurostimulator and Related Procedures) and status indicator “J1” (Hospital Part B Services Paid Through a Comprehensive APC).

- 64583—*Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator.* CPT code 64583 is assigned to APC 5463 (Level 3

Neurostimulator and Related Procedures) and status indicator “J1” (Hospital Part B Services Paid Through a Comprehensive APC).

- 64584—*Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array.* CPT code 64584 is assigned to APC 5432 (Level 2 Nerve Procedures) and status indicator “Q2” (T-Packaged Codes).

As the technology has evolved, we realize that the current HGNS CPT codes do not accurately describe newer hypoglossal nerve neurostimulators that are on the market. As a result, some providers are utilizing CPT code 64568 (Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator) to describe the implantation of hypoglossal nerve neurostimulators that are not described by the current hypoglossal nerve neurostimulator implantation code.

To address the questions and concerns regarding coding and billing for the implantation, revision or replacement, or removal of hypoglossal nerve neurostimulators that are not described by existing coding, we created six new C-codes. These new C-codes describe the implantation, revision or replacement, and removal of hypoglossal nerve neurostimulators that do not contain a separate implantable respiratory sensor electrode or electrode array, and systems that do not contain an implanted battery or pulse generator. We used the current HGNS CPT codes as the crosswalk codes for the new C-codes. These new HCPCS codes and their APC and status indicator assignments were published in the April 2026 quarterly update CR (Transmittal 13686, Change Request 14380, dated March 13, 2026), and are retroactive to January 1, 2026. The proposed APC and status indicator assignments for HCPCS codes C8007–C8009 and C8011–C8013, along with their long descriptors are shown in Table 24. The proposed CY 2027 rates for these codes can be found in Addendum B to this proposed rule via the internet on the CMS website.

**TABLE 24: PROPOSED CY 2027 OPPS APC AND STATUS INDICATOR
ASSIGNMENTS FOR THE HYPOGLOSSAL NERVE NEUROSTIMULATOR C-CODES**

HCPCS Code	Long Descriptor	Proposed CY 2027 OPPS SI	Proposed CY 2027 OPPS APC
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring insertion of a separate distal respiratory sensor electrode or electrode array	J1	5465
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator.	J1	5463
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator.	Q2	5432
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components.	J1	5465
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver.	J1	5463
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and Receiver.	Q2	5432

4. Permanent Prostatic Urethral Stent, CPT Code 52282 (APC 5375)

The ProVee® System is indicated to treat obstructive lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH) in men with prostatic urethral lengths greater than or equal to 3.75 cm and prostatic volumes between 30 cc and 80 cc. The insertion of a permanent prostatic urethral stent procedure, represented by CPT code 52282 (Cystourethroscopy, with insertion of permanent urethral stent), became effective January 1, 1998, and describes the insertion of a permanent urethra stent using an endoscope. This procedure offers another therapy option for select patients with lower urinary tract symptoms (LUTS) secondary to BPH.

For CY 2026, we assigned CPT code 52282 to APC 5374 (Level 4 Urology and Related Services) with a payment rate of \$3,601.33 based on its geometric mean cost of approximately \$3,775, which was calculated using the available 115 single frequency claims from the CY 2024 claims data.

For this CY 2027 OPPS/ASC proposed rule, we reviewed the CY 2025 claims submitted between January 1, 2025 through December 31, 2025, that were processed on or before December 31, 2025, for CPT code 52282 and found 109 single frequency claims available for ratesetting, with a resulting

geometric mean cost of \$4,005. Additionally, for this CY 2027 OPPS/ASC proposed rule, we examined the claims reported for CPT code 52282. We noted that there has not been an FDA approved permanent prostatic urethral stent on the US market for approximately 9 years until a permanent prostatic urethral stent received their FDA PMA approval in late 2025. Therefore, we believe the report claims for CPT code 52282 do not accurately represent the device and service cost associated with inserting a permanent prostatic urethral stent. Based on our examination of device and service costs associated with a permanent prostatic urethral stent, we believe it is appropriate to move CPT code 52282 to APC 5375 (Level 5 Urology and Related Services) from APC 5374 (Level 4 Urology and Related Services) because CPT code 52282 shares more resource cost and clinical homogeneity with procedures in APC 5375. Specifically, we believe CPT code 52282 shares resource and clinical homogeneity with HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants). Therefore, for CY 2027, we propose to reassign CPT code 52282 from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services).

5. Integrated Sacral Neurostimulator, CPT Code 0786T (APC 5464)

Effective January 1, 2024, the CPT Editorial Panel separated integrated from non-integrated (*i.e.*, traditional) sacral neurostimulator procedures by establishing new CPT code, 0786T to report procedures using integrated sacral neurostimulator devices, while CPT code 64590 was updated to reflect the use of traditional technology. We assigned CPT code 0786T to status indicator “E1” (Not covered by any outpatient benefit category) because the device associated with this CPT code did not have FDA approval. The long descriptors for CPT codes 0786T and 64590 are listed below:

- 0786T—*Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed.*
- 64590—*Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver.*

On June 17, 2025, Neuspera received FDA approval for their implanted sacral neurostimulator for urge urinary incontinence (UUI). At the August 2025 HOP Panel meeting, the manufacturer requested that we assign CPT code 0786T to APC 5464 (Level 4 Neurostimulator and Related

Procedures). The HOP Panel agreed with the presenter and made that recommendation.

In the CY 2026 OPPS/ASC final rule with comment period, we assigned CPT code 0786T to APC 5463 (Level 3 Neurostimulator and Related Procedures) and status indicator “J1” based on what we believed were the costs and resources required to perform the procedure with an integrated device.

For CY 2027, proposed OPPS payment rates are based on available CY 2025 claims data. Because 0786T was not assigned to a clinical APC before January 1, 2026, we do not have any

claims data. Based on our examination of the procedures assigned to the Level 3 and Level 4 Neurostimulator and Related Procedures APCs, we believe it is appropriate to reassign CPT code 0786T from APC 5463 (Level 3 Neurostimulator and Related Procedures) to APC 5464 (Level 4 Neurostimulator and Related Procedures) because CPT code 0786T shares more resource cost and clinical homogeneity with procedures in APC 5464, specifically, with the other sacral and tibial neuromodulation procedures for bladder dysfunction that are

assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). Therefore, for CY 2027, we propose to reassign CPT code 0786T from APC 5463 (Level 3 Neurostimulator and Related Procedures) to APC 5464 (Level 4 Neurostimulator and Related Procedures). The proposed APC and status indicator assignment for CPT code 0786T is shown in Table 25. The proposed CY 2027 payment rates for CPT code 0786T can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 25: FINAL CY 2026 AND PROPOSED CY 2027 OPPS APC AND STATUS INDICATOR ASSIGNMENT FOR THE INTEGRATED NEUROSTIMULATOR PROCEDURE

CPT Code	Long Descriptor	Final CY 2026 OPPS APC, SI	Proposed CY 2027 OPPS APC, SI
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed.	5463, J1	5464, J1

6. C-Codes Describing Percutaneous Coronary Intervention (PCI) With Drug-Eluting Stents, C-codes C9601, C9603, C9605, and C9608

Effective January 1, 2013, CMS created several HCPCS C-codes to describe certain percutaneous coronary intervention (PCI) procedures utilizing

drug eluting stents to mirror those PCI CPT codes that do not utilize drug eluting stents. The AMA CPT Editorial Board deleted several of those CPT codes effective January 1, 2026. For CY 2027, we propose to delete the C-codes that mirrored the deleted CPT codes, specifically revising the status

indicators for C9601, C9603, C9605, and C9608 to “D” (Discontinued Codes) indicating that they are no longer active codes. The C-codes, long descriptors, status indicators, and their corresponding CPT code (listed below each C-code) are shown in Table 26.

BILLING CODE 4169-69-P

**TABLE 26: FINAL CY 2026 AND PROPOSED CY 2027 STATUS INDICATOR
REVISIONS FOR C9601, C9603, C9605, C9608**

HCPCS Code (Corresponding CPT Code)	Long Descriptor	Final CY 2026 SI	Proposed CY 2027 SI
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N	D
(92929)	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	D	N/A
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N	D
(92934)	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	D	N/A
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N	D
(92938)	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	D	N/A
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N	D

HCPCS Code (Corresponding CPT Code)	Long Descriptor	Final CY 2026 SI	Proposed CY 2027 SI
(92944)	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	D	N/A

BILLING CODE 4169-69-C

7. Electrophysiologic Evaluation of Cardiac Contractility Modulation Systems, CPT Code 0930T

CPT code 0930T (*Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator*) became effective January 1, 2025 and is used to describe the electrophysiologic evaluation of a

cardiac contractility modulation system at the time of initial implantation or replacement of the system. This code is currently assigned to APC 5211 (Level 1 Electrophysiologic Procedures) and status indicator “J1” (Hospital Part B Services Paid Through a Comprehensive APC). There are currently no claims data for CPT 0930T.

After review of the service and other like services, we believe this service is always performed with the initial implantation or replacement of the system and therefore, we believe that the electrophysiologic evaluation is integral, ancillary, supportive, dependent, and adjunctive to the

primary service (the implantation or replacement of the system) and should therefore be packaged into the CPT code describing the initial implantation or replacement of the cardiac contractility modulation-defibrillator pulse generator.

Therefore, for CY 2027, we propose to revise the status indicator for CPT 0930T to “N”. The proposed status indicator assignment for CPT code 0930T is shown in Table 27. The proposed CY 2027 payment rate for this HCPCS code can be found in Addendum B to the CY 2027 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 27: FINAL CY 2026 AND PROPOSED CY 2027 STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0930T

CPT Code	Long Descriptor	Final CY 2026 APC, SI	Proposed CY 2027 SI
0930T	Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator	5211, J1	N

8. Endovenous Femoral-Popliteal Arterial Revascularization With Placement of Stent Graft, CPT Code 0505T

CPT code 0505T (*Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete*

the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion) became effective January 1, 2018 and is used to treat patients with advanced peripheral vascular disease, specifically those with long complex femoropopliteal artery stenoses and occlusions resulting in lifestyle limiting claudication or severe lower limb threatening ischemia.

The DETOUR™ System is a graft system used with the service described

by CPT 0505T. It restores arterial blood flow to the lower limb around the blocked femoral artery and allows for venous return, which reduces the signs and symptoms of lower limb ischemia and prevents amputation. We created HCPCS code C1604 (*Graft, transmural transvenous arterial bypass (implantable), with all delivery system components*) when the DETOUR™ System was approved for transitional device pass-through payment under OPPS effective January 1, 2024. The pass-through payment for this device

expires December 31, 2026. Once the pass-through payment period expires, payment for the device is packaged into the OPPS payment rate for the associated procedure(s).

We review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data and review of the clinical characteristics of the procedure. For CY 2027, the OPPS payment rates are proposed based on available CY 2025 claims data. CPT code 0505T is currently assigned to APC 5193 (Level 3 Endovascular Procedures)

with a payment of approximately \$11,800. We note that CPT code 0505T has a geometric mean cost (GMC) of \$41,123 based on 46 single frequency claims. We considered reassigning CPT 0505T to APC 5194 (Level 4 Endovascular Procedures) with a payment of approximately \$18,700 but we do not believe this APC is appropriate after incorporating the costs of the expiring pass-through device. Given the low volume of claims data for this procedure and the absence of a clinical APC in terms of clinical and resource similarity, we propose to

reassign CPT 0505T to APC 1580 (New Technology—Level 43 (\$40,001–\$50,000)) with a payment of \$45,000.50. As we continue to gather adequate claims data on this code, we invite public comment on the appropriate clinical APC for CPT code 0505T.

Please refer to Table 28 for the proposed APC and status indicator assignment for CPT code 0505T. The proposed payment rate for this HCPCS code can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 28: FINAL CY 2026 AND PROPOSED CY 2027 STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0505T

CPT Code	Long Descriptor	Final CY 2026 APC, SI	Proposed CY 2027 APC, SI
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	5193, J1	1580, S

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, OPPS transitional pass-through payment status for a device category are limited to a period of not less than 2 years but not more than 3 years.

In the CY 2017 OPPS/ASC final rule with comment period, in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category (81 FR 79654). In addition, in the CY 2017 OPPS/ASC final rule with comment period, we finalized a policy to allow for quarterly expiration of pass-through payment status for devices to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices (81 FR 79655). We also established a policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set

the payment rates (67 FR 66763). We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.²⁶

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, 21 device categories are eligible for pass-through payment. These devices are listed in Table 29 where we detail the expiration dates of pass-through payment status for each of the 21 devices currently receiving device pass-through payment.

BILLING CODE 4169–69–P

²⁶ To apply for OPPS transitional device pass-through status, applicants complete an application

that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This collection

(CMS–10052) has an OMB control number of 0938–0857 and an expiration date of June 30, 2029.

TABLE 29: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2026, IN 2027, IN 2028, OR IN 2029

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (<i>i.e.</i> disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (<i>i.e.</i> disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	09/30/2027
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components	01/01/2025	12/31/2027
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components	01/01/2025	12/31/2027
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)	01/01/2025	12/31/2027
C1738	Powered, single-use (<i>i.e.</i> disposable) endoscopic ultrasound-guided biopsy device	01/01/2025	12/31/2027
C1739	Tissue marker, uniquely detectable and identifiable with probe/sensor, any method (implantable), with delivery system	01/01/2025	12/31/2027
C9610	Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)	01/01/2025	12/31/2027

HCPSC Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1740	Leadless electrode, transmitter, battery (all implantable), for sequential left ventricular pacing	10/01/2025	09/30/2028
C1741	Anchor/screw for bone fixation, absorbable (implantable)	10/01/2025	09/30/2028
C1742	Pressure monitoring system, compartmental intramuscular (implantable), continuous, including all components (e.g., introducer, sensor), excludes mobile (wireless) software application	10/01/2025	09/30/2028
C1607	Neurostimulator, integrated (implantable), rechargeable with all implantable and external components including charging system	01/01/2026	12/31/2028
C1608	Prosthesis, total, dual mobility, first carpometacarpal joint (implantable)	01/01/2026	12/31/2028
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)	04/01/2026	03/31/2029
C1609	Vertebral device, motion-preserving, with screw fixation	07/01/2026	06/30/2029

BILLING CODE 4169–69–C**2. New Device Pass-Through Applications for CY 2027****a. Background**

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories to determine the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we continue to believe that pass-through payments for devices that offer substantial clinical improvement are important to ensure hospitals can provide Medicare beneficiaries with access to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPTS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically

implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

As finalized in CY 2026 OPPTS/ASC final rule with comment period, skin substitutes with an approved Biologics License Application (BLA) will be considered under transitional drug pass-through payment status, and skin substitutes with FDA Premarket approval (PMA) or FDA 510(k) clearance will continue to be evaluated under transitional device pass-through payment status (90 FR 53636).

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, under § 419.66(c), to determine whether a new category of pass-through payment devices should be established.

The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not “insignificant” relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)).

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. We generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test (69 FR 65775), and we calculate the device offset amount at the HCPCS/CPT code level (81 FR 79657); and

- Demonstrate a substantial clinical improvement, that is, the device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA’s Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

In the CY 2016 OPPS/ASC final rule, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications preliminarily approved during quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while applicants whose submissions are not approved during quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2023 OPPS/ASC final rule, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 OPPS/ASC proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

In the CY 2020 OPPS/ASC final rule with comment period, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered

by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle.

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19457 to 19459), we have proposed to repeal the alternative pathway for new technology add-on payment and OPPS device pass-through applications and require all applicants for new technology add-on payments and OPPS device pass-through payments to demonstrate that they meet the same eligibility requirements to receive add-on payments and/or pass-through payments. Specifically, we proposed that all applications received for OPPS device pass-through payment status on or after October 1, 2026, including all applications received through the remainder of the CY 2028 OPPS application cycle ending on March 1, 2027, and applications received for subsequent calendar years would have to demonstrate that the technology met the requirements currently reflected at § 419.66(c)(2)(i). OPPS device pass-through payment applications submitted as of September 30, 2026, for devices that are part of the FDA’s Breakthrough Devices Program and received FDA marketing authorization for the indication covered by the Breakthrough Device designation would be evaluated and could be approved under the alternative pathway, provided that all other criteria have been met. Existing device category codes established based on the approval, either preliminary or via a final determination made in an OPPS/ASC final rule, including any device category codes established for approved alternative pathway applications received as of September 30, 2026, would continue to be eligible for device pass-through payment status and would remain in effect for at least 2 years, but no more than 3 years, consistent with § 419.66(g). Previously existing device category codes that were no longer eligible for device pass-through payment status would remain unchanged. We proposed to revise paragraph § 419.66(c)(2)(ii) to reflect this proposed policy. If finalized as proposed, the change would go into effect on October 1, 2026 (91 FR 19458).

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html, in the “Downloads” section.

b. Applications Received for Device Pass-Through Status for CY 2027

We received 19 applications by the March 2, 2026, quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2027 OPPS/ASC proposed rule. Six applications subsequently withdrew. Discussions of the 13 complete applications, 10 under alternative pathway and 3 under traditional pathway, we received by the March 2, 2026 deadline are included following section IV.2.b. of this proposed rule. Of the applications, we received five in the second quarter of 2025, eight in the third quarter of 2025, one in the fourth quarter of 2025, and five in the first quarter of 2026. Seven of the applications were preliminarily approved for device pass-through payment status during the quarterly review process: The MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE® CRT System, SetPoint System, TOUCH® CMC 1 Prosthesis, Espirit™ BTK Everolimus Eluting Resorbable Scaffold System, and TOPS™ System.

Applications received after the March 2026 deadline for the remaining 2027 quarters (the quarters beginning June 1, September 1, and December 1 of 2026) through March 1, 2027, if any, will be discussed in the CY 2028 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because

of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf>.

(1) Alternative Pathway Device Pass-Through Applications

We received 10 device pass-through applications by the March 2026 application deadline for devices that were eligible to apply under the alternative pathway.

(a) Altius® Direct Electrical Nerve Stimulation System

Neuros® Medical, Inc. submitted an application for a new device category for transitional pass-through payment status for the Altius® Direct Electrical Nerve Stimulation System (the Altius® System) for CY 2027. According to the applicant, the Altius® System is an implantable neuromodulation system that provides continuous, high frequency, high amplitude nerve stimulation to either the sciatic nerve or both the tibial and common peroneal nerves by directly stimulating targeted nerves via implanted cuff electrode leads that are wrapped circumferentially around target nerves in the amputated leg. The applicant stated that the Altius® System consists of the (1) Altius® Implantable Pulse Generator (IPG), which is implanted in the abdomen; (2) Altius® Cuff Electrode Leads; (3) Altius® Battery Charger and alternating current (AC) adapter; (4) Altius® Patient Controller, which allows the patient to activate the IPG to initiate therapy; (5) Programming Wand, which

is used by the provider to program and set stimulus therapy parameters; and (6) Programmer Application Personal Computer (PAPC), which includes physician programming software. The applicant is seeking a new device category for transitional pass-through payment status for only the Altius® IPG and the Altius® Cuff Electrode Lead components of the Altius® System. The applicant stated that the Altius® IPG is a rechargeable neurotransmitter device that is implanted in the abdomen and when activated, generates a continuous high frequency, high amplitude alternating current electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s). Per the applicant the “alternating” nature of the delivered electrical stimulus refers to the direct electrical stimulation of the circumferential electrodes within a lead distributed in an alternating fashion across these electrodes.

Table 30 provides an overview of the transitional device pass-through payment status application for the Altius® System and CMS’s preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP250530FMCYD>.

BILLING CODE 4169–69–P

²⁷ The applicant conducted cost calculations for both the Altiusr IPG with one Altiusr Cuff Electrode Lead (\$41,000.00) and the Altiusr IPG with two Altiusr Cuff Electrode Leads (\$52,000.00). We consider both costs as the estimated reasonable cost to assess whether the Altiusr System meets the cost significance requirements.

TABLE 30: ALTIUS® SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> PMA approval - August 26, 2024 <i>Application submitted to CMS:</i> May 30, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> Altius® System is an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees. <i>Breakthrough Device designation:</i> Altius® System is an aid in the management of chronic intractable pain of the lower limb of adult amputees. This device received FDA Breakthrough Device designation under the trade name Altius® High Frequency Nerve Block System. The trade name was later updated to the Altius® Direct Electrical Nerve Stimulation System.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is surgically implanted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), C1778 (Lead, neurostimulator (implantable)), C1767 (Generator, neurostimulator (implantable), non-rechargeable), C1787 (Patient programmer, neurostimulator), C1816 (Receiver and/or transmitter, neurostimulator (implantable)), C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads), C1825 (Generator, neurostimulator (implantable), non-rechargeable, with carotid sinus baroreceptor stimulation lead(s)), C1826 (Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system), C1827 (Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller), and C1883 (Adapter/extension, pacing lead or neurostimulator lead (implantable) do not describe the device.	See following discussion.
Cost Criteria	The cost for eligible device components of Altius® System (the Altius® IPG and Altius® Cuff Electrode Lead(s)) is \$41,000.00 or \$52,000.00, depending on whether the patient requires one or two cuff electrodes. ²⁶ The cost of the Altius® IPG is \$30,000.00 and the cost of each Altius® Cuff Electrode Lead is \$11,000.00. For cost significance requirements: ²⁷ HCPCS code: 64575 APC code: 5463 CY 2026 device offset amount: \$7,697.89 CY 2026 APC payment rate: \$11,384.04 The Altius® IPG with one Altius® Cuff Electrode Lead:	No concerns.

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
	Requirement #1: $(\$41,000.00 / \$11,384.04) \times 100 = 360.15\%$. Requirement #2: $(\$41,000.00 / \$7,697.89) \times 100 = 532.61\%$ Requirement #3: $((\$41,000.00 - \$7,697.89) / \$11,384.04) \times 100 = 292.53\%$ The Altius® IPG with two Altius® Cuff Electrode Leads: Requirement #1: $(\$52,000.00 / \$11,384.04) \times 100 = 456.78\%$. Requirement #2: $(\$52,000.00 / \$7,697.89) \times 100 = 675.51\%$ Requirement #3: $((\$52,000.00 - \$7,697.89) / \$11,384.04) \times 100 = 389.16\%$	

BILLING CODE 4169-69-C

We are inviting public comment on whether the Altius® System meets the newness criterion at § 419.66(b)(1) and whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the eligibility criteria at § 419.66(b)(3) and (b)(4).²⁸

Regarding the device category eligibility criterion at § 419.66(c)(1), with respect to the Altius® IPG and Altius® Cuff Electrode Lead components, the applicant stated that no existing (current or previous) device pass-through payment categories appropriately describe the nominated device components. Per the applicant, the existing pass-through codes C1778 (Lead, neurostimulator (implantable)) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system) do not describe the Altius® IPG and the Altius® Cuff Electrode Lead components because these codes (1) are not specifically indicated for treating chronic intractable lower limb amputation pain; (2) are not capable of delivering continuous, high amplitude, high frequency alternating current; (3) do not use circumferentially wrapped and anchored cuff electrode leads to provide direct energy delivery to the targeted nerves; and (4) do not allow for physician-pre-programmed therapy delivery controlled by the patient using the patient stimulation controller. The applicant also stated that devices described by C1778 do not make direct contact with the target nerve; instead they deliver stimulation to the general

region of the pain, unlike the Altius® Cuff Electrode Leads. The applicant added that existing devices described by C1822 deliver low-amplitude, rectangular pulses per second to general or peripheral areas to increase nerve activity and produce pain relief, whereas the Altius® IPG provides continuous, high-amplitude sinusoidal waveform stimulation to decrease target nerve activity and produce on-demand pain relief. The applicant asserted that the Altius® System, including the Altius® IPG and Altius® Cuff Electrode Lead components, is the only FDA-authorized neuromodulation system indicated as an aid in the management of chronic intractable phantom and residual lower limb post-amputation pain in adult amputees.

Based on the description the applicant provided, the Altius® IPG is a rechargeable neurotransmitter device that generates a continuous high frequency, high amplitude alternating electrical stimulus (5kHz and 10kHz) via the Altius® Cuff Electrode Leads, which are circumferentially wrapped, anchored, and implanted around the nerve(s), and therefore, could be appropriately described by C1778 (Lead, neurostimulator (implantable)) and C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), respectively. Specifically, we believe that the pass-through payment category C1778 may appropriately describe the Altius® Cuff Electrode Lead component because the pass-through payment category describes any device that is an implantable neurostimulator lead. Additionally, we believe the pass-through payment category C1822 may appropriately describe the Altius® IPG because the category includes implantable neurostimulator pulse generators that deliver high-frequency stimulation (including approximately 10 kHz) and are rechargeable using an external charging system. Further, C1822 does not describe the amplitude, pulse frequency, or waveform of the stimulation generated by the device. We note that CMS does not establish pass-through device categories for the purpose of describing specific devices, but rather, device categories are intended to encompass all devices that can be appropriately described by a

category. In this context, we believe the Altius® IPG and the Altius® Cuff Electrode Lead components may be appropriately described by C1778 and C1822.

We are inviting public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criterion at § 419.66(c)(1).

We are also inviting public comment on whether the Altius® IPG and the Altius® Cuff Electrode Lead components meet the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components meet the device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the Altius® System, inclusive of the Altius® IPG and the Altius® Cuff Electrode Lead components for CY 2027.

(b) Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

Abbott Laboratories submitted an application for a new device category for transitional pass-through payment status for the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK) for CY 2027. According to the applicant, the Esprit™ BTK is a temporary, balloon-expandable resorbable polymer scaffold with a drug (everolimus) and resorbable polymeric coating, delivered via a balloon dilatation catheter, that is designed to resorb over time and is intended to improve luminal diameter in infaroplateal lesions in patients with chronic limb-threatening ischemia.

Table 31 provides an overview of the transitional device pass-through payment status application for the Esprit™ BTK and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ptp/DEP250829XYFGP>.

BILLING CODE 4169-69-P

²⁸ For its cost calculations, the applicant selected HCPCS code 64590 in APC 5464 and based its calculations on CY 2026 data. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). For our calculations, we used APC 5463, which we believe has the lowest applicable APC payment rate (\$11,384.04) related to the HCPCS codes provided by the applicant, and HCPCS code 64575 in APC 5463, which has a device offset amount of \$7,697.89, at the time the application was received. Based on our initial assessment for this proposed rule, using the APC payment rate of \$11,384.04 and the device offset amount of \$7,697.89, we believe the Altius® System meets the cost significance requirements.

TABLE 31: ESPRIT™ BTK APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> Premarket Approval (PMA) - April 26, 2024 <i>Application submitted to CMS:</i> August 29, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with Chronic Limb Threatening Ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm. <i>Breakthrough Device Designation Indication:</i> The Absorb GT1 BVS is a temporary scaffold that will fully resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with critical limb ischemia (CLI). In all cases, the treated lesion length should be less than the total scaffolding length with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm. Note: This device received FDA Breakthrough Device designation through the Expedited Access Pathway (EAP) on June 28, 2017, under the trade name Absorb GT1 BVS System. The trade name was later updated to Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System).	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically implanted in a patient's infrapopliteal artery.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1874 (Stent, coated/covered, with delivery system), C1875 (Stent, coated/covered, without delivery system), C1876 (Stent, non-coated/non-covered, with delivery system), C1877 (Stent, non-coated/non-covered, without delivery system), C2625 (Stent, non-coronary, temporary with delivery system), and C2617 (Stent, non-coronary, temporary without delivery system) do not describe the Esprit™ BTK.	No concerns.
Cost Criteria	The cost of the Esprit™ BTK is \$10,650.00. Per the applicant, the Esprit™ BTK includes two one-time-use individual components: Esprit™ BTK scaffold and Esprit™ BTK delivery system. The cost of each Esprit™ BTK is \$3000.00. A range of one to six scaffolds are implanted depending on the length of the lesion being treated and the corresponding healthy-to-healthy clinical need of the patient, with an average of 3.55 scaffolds used per case. Therefore, the average cost per case is \$10,650. For cost significance requirements: HCPCS code: 37284 APC code: 5194 CY 2026 device offset amount: \$8,208.78 CY 2026 APC payment rate: \$18,728.69 Requirement #1: $(\\$10,650.00 / \\$18,728.69) \times 100 = 56.86\%$. Requirement #2: $(\\$10,650.00 / \\$8,208.78) \times 100 = 129.74\%$. Requirement #3: $((\\$10,650.00 - \\$8,208.78) / \\$18,728.69) \times 100 = 13.03\%$.	No concerns.

BILLING CODE 4169–69–C

The Esprit™ BTK was preliminarily approved for device pass-through payment status effective April 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the Esprit™ BTK under the alternative pathway for devices that have an FDA

Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the Esprit™ BTK meets all applicable device pass-through payment status criteria as specified in regulations at

§ 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the Esprit™ BTK for device pass-through payment status for CY 2027.

(c) MY01 Continuous Compartmental Pressure Monitor

MY01 Inc. submitted an application for a new device category for transitional pass-through payment status for the MY01 Continuous Compartmental Pressure Monitor for CY 2027. According to the applicant, the MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle

compartment pressure to aid in the diagnosis of acute and chronic compartment syndrome. The nominated device consists of an introducer and a pressure monitor which are used in conjunction with the MY01 Mobile Application. The applicant stated that it is only seeking a new device category for transitional pass-through payment status for the MY01 Continuous Compartmental Pressure Monitor component.

Table 32 provides an overview of the transitional device pass-through payment status application for the MY01 Continuous Compartmental Pressure Monitor and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP250602XAAW9>.

BILLING CODE 4169-69-P

TABLE 32: MY01 CONTINUOUS COMPARTMENTAL PRESSURE MONITOR APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> 510(k) clearance - March 13, 2025 <i>Application submitted to CMS:</i> June 2, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments. <i>Breakthrough Device designation:</i> (June 20, 2021) The MY01 device is used for real-time and continuous measurement of muscle pressures. The measured muscle pressure can be used as an aid in the diagnosis of acute compartment syndrome (ACS). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically inserted into the muscle compartment for continuous pressure monitoring.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	No similar device category codes.	No concerns.
Cost Criteria	The cost of the MY01 Continuous Compartmental Pressure Monitor is \$3,250.00. Per the applicant, the MY01 Mobile Application (included in the system) is available to be downloaded and accessed free of charge with the corresponding MY01 Continuous Compartmental Pressure Monitor. For cost significance requirements: HCPCS code: 20950 APC code: 5071 CY 2025 device offset amount: \$0.00 CY 2025 APC payment rate: \$703.59 Requirement #1: $(\$3,250.00 / \$703.59) \times 100 = 461.02\%$. Requirement #2: \$3,250.00 exceeds \$0.00 by at least 25%. Requirement #3: $((\$3,250.00 - \$0.00) / \$703.59) \times 100 = 461.02\%$.	No concerns.

BILLING CODE 4169–69–C

The MY01 Continuous Compartmental Pressure Monitor was preliminarily approved for device pass-through payment status effective October 1, 2025. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the MY01 Continuous Compartmental Pressure Monitor under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the MY01 Continuous Compartmental Pressure Monitor meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the

information available at the time of this proposed rule, we propose to finalize approval for the MY01 Continuous Compartmental Pressure Monitor for device pass-through payment status for CY 2027.

(d) ProSense® Cryoablation System

IceCure™ Medical Ltd. submitted an application for a new device category for transitional pass-through payment status for the ProSense® Cryoablation System for CY 2027. According to the applicant, the ProSense® Cryoablation System is designed to destroy tissue by the application of extreme cold temperatures utilizing liquid nitrogen for the treatment of breast cancer for patients with low-risk tumors. The applicant stated that the ProSense® Cryoablation System is comprised of (1) the ProSense® Chassis, (2) an adjustable touch screen, and (3) external

accessories, including introducers, liquid nitrogen dewar, holder, foot pedal, and Prosense® Cryoprobes. The applicant is seeking a new device category for transitional pass-through payment status for only the ProSense® Cryoprobe component of the ProSense® Cryoablation System. Per the applicant, the ProSense® Cryoprobe is a rigid probe with a tip that creates ice balls to destroy target tissue through cycles of freezing and thawing.

Table 33 provides an overview of the transitional pass-through payment status application for the ProSense® Cryoablation System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP251226K6A1C>.

BILLING CODE 4169–69–P

TABLE 33: PROSENSE® CRYOABLATION SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> De Novo authorization - October 3, 2025 <i>Application submitted to CMS:</i> December 26, 2025	See following discussion.
Breakthrough Device Designation	<i>FDA Indication:</i> The ProSense® Cryoablation System is indicated for the local treatment of breast cancer in patients ≥70 years of age with biologically low-risk tumors ≤1.5 cm in size and treated with adjuvant endocrine therapy, including patients not suitable for surgery for breast cancer treatment. Biologically low-risk breast cancer is defined as unifocal tumor, size ≤1.5 cm, estrogen receptor (ER)-positive, progesterone receptor (PR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, Ki-67<15%, and/or genomic testing indicative of low-risk breast cancer, infiltrating ductal carcinoma (excluding lobular carcinoma, extensive intraductal component, or evidence of lymphovascular invasion), and clinically negative lymph node (N0). <i>Breakthrough Device designation:</i> The IceCure ProSense® Cryoablation System is intended for cryogenic destruction of tissue during surgical procedures by the application of extreme cold temperatures. It is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ear, nose, and throat (ENT), gynecology, oncology, proctology, and urology. The system is designed to destroy tissue by the application of extreme cold temperatures including breast cancer, prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications: • Urology (ablate prostate tissue in cases of prostate cancer and benign prostatic hyperplasia (BPH)). • Oncology (ablation of cancerous or malignant tissue and benign tumors and palliative intervention). • Dermatology (ablation or freezing of skin cancers and other cutaneous disorders. Palliation of tumors of the skin. Destruction of warts or lesions). • Gynecology (ablation of malignant neoplasia or benign dysplasia of the female genitalia). ENT (Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth). General Surgery (ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocoele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions). • Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions. Destruction of warts or lesions. Palliation of tumors of the oral cavity, rectum, and skin). • Thoracic Surgery (ablation of arrhythmic cardiac tissue and cancerous lesions). • Proctology (ablation of benign or malignant growths of the anus and rectum and hemorrhoids). • Breast Cancer: The ProSense® is indicated for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer.	No concerns.
§ 419.66(b)(3)	Device is single-use, is an integral part of the cryoablation procedure, is used in one patient only, is surgically inserted, and comes into contact with human tissue.	No concerns.
§ 419.66(b)(4)	Device is not equipment for which depreciation and financing expenses are recovered as depreciable assets and is not a supply furnished incident to the service.	No concerns.
Device Category	Device category code C2618 (Probe, cryoablation) does not describe the ProSense® Cryoprobe.	See following discussion.
Cost Criteria	The cost of the ProSense® Cryoprobe is \$2,550.00. For cost significance requirements:	No concerns.

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
	HCPCS code: 0581T APC code: 5091 CY 2025 device offset amount: \$1,816.99 CY 2025 APC payment rate: \$3,829.28 Requirement #1: $(\$2,550.00 / \$3,829.28) \times 100 = 66.59\%$. Requirement #2: $(\$2,550.00 / \$1,816.99) \times 100 = 140.34\%$. Requirement #3: $((\$2,550.00 - \$1,816.99) / \$3,829.28) \times 100 = 19.14\%$.	

BILLING CODE 4169-69-C

As stated previously, with respect to the newness criterion at § 419.66(b)(1), the device must have received FDA approval or clearance (that is, FDA marketing authorization), and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization. In the CY 2016 OPPS/ASC final rule with comment period, we clarified that we intended to convey that the 3-year timeframe for submitting a device pass-through payment application would be triggered by the initial FDA approval or clearance, and not by any subsequent FDA approvals or clearances. We specified “initial” FDA clearance or approval in § 419.66(b)(1) because, in some cases, FDA will provide supplemental approvals or clearances for a device after the initial approval or clearance (80 FR 70420). We received a pass-through payment status application for the ProSense® Cryoablation System on December 26, 2025, which we do not believe is within 3 years of the initial FDA marketing authorization.

The ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, was previously cleared on December 20, 2019, in K183213, the 510(k) clearance for the IceCure Family Cryoablation System (IceSense™3, ProSense®, MultiSense).²⁹ The predicate device described in K183213, the IceSense™3 System, was previously cleared on November 29, 2010, in K102360,³⁰ and the preceding predicate device, the Galil Medical SeedNet Family was cleared on November 18, 2005, in K052530.³¹ We

note that K183213 states that cryoablation is the fundamental technological principle for both the subject IceCure Family of cryotherapy devices and the predicate IceSense™3 System cleared in K102360 and the Galil Medical SeedNet Family cleared in K052530. Finally, according to K183213, the ProSense® Cryoablation System is a mere rebranding of the cleared IceSense™3 single-probe system cleared in K102360, and the ProSense® Cryoablation System has the same hardware and software components as the IceSense™3 System. K183213 also states that the hardware and software changes introduced since the device was originally cleared on November 29, 2010, in K102360, were analyzed and determined not to require new 510(k) premarket notifications and that the K183213 submission includes the current configuration of the system.

While the October 3, 2025, FDA decision summary for De Novo classification for the ProSense® Cryoablation System includes a new indication for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer, based on the information in K183213, we believe that the initial FDA marketing authorization date for the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe component, may be as early as November 18, 2005, or as recent as December 20, 2019. The applicant submitted the pass-through payment application on December 26, 2025, which is more than 3 years after either November 18, 2005, or December 20, 2019; therefore, we do not believe that the ProSense® Cryoablation System, inclusive of the nominated ProSense® Cryoprobe, meets the newness criterion.

We are inviting public comment on whether the ProSense® Cryoablation System meets the newness criterion at § 419.66(b)(1).

We also are inviting public comment on whether the ProSense® Cryoprobe meets the eligibility criteria at § 419.66(b)(3) and (b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), with respect to the ProSense® Cryoprobe, the applicant stated that the existing pass-through code C2618 (Probe, cryoablation) does not appropriately describe the ProSense® Cryoprobe. According to the applicant, the ProSense® Cryoprobe is currently included in this existing category only because that category is old, extremely broad, and does not allow for appropriate recognition of innovative new technologies or include those that have received FDA Breakthrough Device designation. The applicant also stated that since C2618 was established, CMS has created other categories for ablation catheters that are specific to use in specific anatomic locations, such as non-cardiac endovascular (C1888) and extravascular (C1886). Further, the applicant stated that the ProSense® Cryoprobe is the only device cleared under product code QXW as a cryoablation device for local low-risk breast cancer treatment.

Based on the description the applicant provided, the ProSense® Cryoprobe is a probe used for cryoablation, and therefore, could be appropriately described by C2618 (Probe, cryoablation). Specifically, we believe that the pass-through payment category C2618 may appropriately describe the ProSense® Cryoprobe because C2618 describes any probe used for cryoablation and is not specific to an anatomical location. We note that we do not establish pass-through device categories for the purpose of describing specific devices, rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we believe the ProSense® Cryoprobe may be appropriately described by C2618.

We are inviting public comment on whether the ProSense® Cryoprobe meets the device category eligibility criterion at § 419.66(c)(1).

We are also inviting public comment on whether the ProSense® Cryoprobe meets the cost criterion at § 419.66(d)(3).

²⁹ U.S. Food and Drug Administration. (2019, December 20). *Decision Summary for K183213 [IceCure Family Cryoablation System (IceSense™3, ProSense®, MultiSense)]*. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183213.pdf.

³⁰ U.S. Food and Drug Administration. (2010, November 29). *510(k) Summary for K102360 [IceCure's IceSense™3 device]*. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/cdrh_docs/pdf10/K102360.pdf.

³¹ U.S. Food and Drug Administration. (2005, November 18). *510(k) Summary for K052530 [SeedNet Family]*. U.S. Department of Health and Human Services. https://www.accessdata.fda.gov/cdrh_docs/pdf5/K052530.pdf.

After reviewing the information provided by the applicant, we are unable to determine that the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe, meets the new device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for the ProSense® Cryoablation System, inclusive of the ProSense® Cryoprobe for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the ProSense® Cryoablation System,

inclusive of the ProSense® Cryoprobe, for CY 2027.

(e) RemeOs™ Screw LAG Solid

Bioretec, Inc. submitted an application for a new device category for transitional pass-through payment status for the RemeOs™ Screw LAG Solid for CY 2027. According to the applicant, the RemeOs™ Screw LAG Solid is an absorbable, magnesium-based alloy screw intended for the use in traumatic and orthopedic surgery for the fixation of bone fractures and for fixation after osteotomies, such as for the correction of deformities or

malalignments. The absorbable implant provides temporary fixation and stabilization through osteosynthesis of bone fractures and osteotomies until bony fusion has occurred.

Table 34 provides an overview of the transitional device pass-through payment status application for the RemeOs™ Screw LAG Solid and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP2506023YUR4>.

BILLING CODE 4169-69-P

TABLE 34: REMEOS™ SCREW LAG SOLID APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> De Novo classification - March 29, 2023 <i>Application submitted to CMS:</i> June 6, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The RemeOs™ Screw LAG Solid is intended for the use in traumatic and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and for the fixation after osteotomies, e.g., for the correction of deformities or malalignments. The absorbable implants serve as temporary fixation and stabilization by osteosynthesis of bone fractures and osteotomies until bony fusion has occurred. The RemeOs™ Screw LAG Solid is intended to be used for skeletally mature adults. The RemeOs™ Screw LAG Solid is indicated for the fixation of the medial malleolus. <i>Breakthrough Device designation:</i> (March 8, 2021) The RemeOs™ Screw LAG Solid products are intended for use in traumatic surgery/traumatology and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and osteotomies, and for the correction of deformities or malalignments. The implants serve as temporary fixation and stabilization by osteosynthesis of bones and fragments until bony fusion has occurred.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically inserted/implanted into the body for the fixation of bone fractures (osteosynthesis) and for fixation after osteotomies.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not describe the device.	No concerns.
Cost Criteria	The cost of the RemeOs™ Screw LAG Solid is \$2,999.00. For cost significance requirements: ³¹ HCPCS code:27766 APC code: 5114 CY 2025 device offset amount: \$1,639.49 CY 2025 APC payment rate: \$7,143.73 Requirement #1: $(\$2,999.00 / \$7,143.73) \times 100 = 41.98\%$. Requirement #2: $(\$2,999.00 / \$1,639.49) \times 100 = 182.92\%$. Requirement #3: $((\$2,999.00 - \$1,639.49) / \$7,143.73) \times 100 = 19.03\%$.	No concerns.

BILLING CODE 4169-69-C

The RemeOs™ Screw LAG Solid was preliminarily approved for device pass-through payment status effective

October 1, 2025. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the RemeOs™ Screw

LAG Solid under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing

authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the RemeOs™ Screw LAG Solid meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the RemeOs™ Screw LAG Solid for device pass-through payment status for CY 2027.

(f) SetPoint System

SetPoint Medical submitted an application for a new device category for transitional pass-through payment status for the SetPoint System for CY 2027. According to the applicant, the SetPoint System is a non-pharmacological treatment for rheumatoid arthritis (RA) and is a fully integrated neuroimmune modulation therapy for adults with moderately to severely active RA. The system consists of a rechargeable neuroimmune stimulator implanted on the left cervical vagus nerve during a 60–90-minute

procedure which subsequently delivers one minute of stimulation per day to activate the body's innate neuroimmune pathway.

Table 35 provides an overview of the transitional device pass-through payment status application for the SetPoint System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ptp/DEP2508042W2C1>.

BILLING CODE 4169–69–P

TABLE 35: SETPOINT SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> Premarket Approval (PMA) - July 30, 2025 <i>Application submitted to CMS:</i> August 4, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The SetPoint System is indicated for use in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response, loss of response, or intolerance to one or more biological or targeted synthetic disease modifying antirheumatic drugs (DMARDs). <i>Breakthrough Device designation:</i> (March 15, 2024) The SetPoint System is indicated for the treatment of adult patients with moderate to severe RA who have had an inadequate response, loss of response or intolerance to one or more biological or targeted synthetic DMARDs.	No concerns.
§ 419.66(b)(3)	Device is integral to the service(s) furnished, used for one patient only, comes in contact with tissue, and is surgically implanted in the patient.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category codes C1820 (Generator, neurostimulator (implantable), with rechargeable battery and charging system), C1822 (Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system), and C1826 (Generator, neurostimulator (implantable), do not describe the device.	No concerns.
Cost Criteria	The cost of the SetPoint System is \$59,500.00. Per the applicant, the SetPoint System is packaged and sold as a single kit to hospitals, with the Implant, Charger and Docking Station included in a singular kit. As a result, no separate components or partial systems are sold to hospitals. For cost significance requirements: HCPCS code: 0908T APC code: 5465 CY 2026 device offset amount: \$25,904.96 CY 2026 APC payment rate: \$31,526.06 Requirement #1: $(\$59,500.00 / \$31,526.06) \times 100 = 188.73\%$. Requirement #2: $(\$59,500.00 / \$25,904.96) \times 100 = 229.69\%$. Requirement #3: $((\$59,500.00 - \$25,904.96) / \$31,526.06) \times 100 = 106.56\%$.	No concerns.

The SetPoint System was preliminarily approved for device pass-through payment status effective January 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the SetPoint System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the

indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the SetPoint System meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the SetPoint System for

device pass-through payment status for CY 2027.

(g) TIDAL™ Fusion Cage System (Ossera™ AFX)

restor3d submitted an application for a new device category for transitional pass-through payment status for the TIDAL™ Fusion Cage System for CY 2027. According to the applicant, the TIDAL™ Fusion Cage is a single, continuous, porous piece of titanium

alloy containing a circular window for an intramedullary nail used during salvage procedures to restore bone length due to bone void, absent bone or surgical resection. The TIDAL™ Fusion Cage System is composed of the TIDAL™ Fusion Cage and a Disposable Instrument Kit, which includes size

trials, cannulated reamers, and inserters. The applicant stated that the TIDAL™ Fusion System is not for standalone use and is intended for use as an accessory to the DynaNail® TTC Fusion System and with an autograft and/or allogenic bone graft.

Table 36 provides an overview of the device category for transitional pass-

through payment status application for TIDAL™ Fusion Cage System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ptp/DEP250529B0B27>.

TABLE 36: TIDAL™ FUSION CAGE SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> 510(k) clearance - March 24, 2025 <i>Application submitted to CMS:</i> May 29, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The TIDAL™ Fusion Cage System is intended for use as part of a tibiototalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss. The TIDAL™ Fusion Cage System is intended for use as an accessory to the DynaNail® TTC Fusion System. The TIDAL™ Fusion Cage System is not intended for standalone use. The TIDAL™ Fusion Cage System is intended for use with autograft and/or allogenic bone graft. <i>Breakthrough Device designation:</i> The restor3d Fusion Cage System is intended for tibiototalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft in procedures such as: post-traumatic and degenerative arthritis; post-traumatic or primary arthrosis involving both ankle and subtalar joints; revision after failed ankle arthrodesis with subtalar involvement; failed total ankle arthroplasty; non-union ankle arthrodesis; rheumatoid hindfoot; talectomy; avascular necrosis of the talus; neuroarthropathy; neuromuscular disease and severe deformity; osteoarthritis; Charcot foot; and previously infected arthrosis, second degree. The restor3d Fusion Cage System is intended to provide stabilization in long bones of skeletally mature patients, including tibia, femur and humerus, in the presence of critical sized bone defects in lieu of bulk allograft, bone transport or other treatment for segmental defects in procedures such as: stabilization of fractures of the diaphyseal or metaphyseal regions of long bones; malunions and nonunion; osteomyelitis; and periprosthetic fractures. Note: FDA granted Breakthrough Device designation to this device under the trade name restor3d Fusion Cage System, which the applicant later changed to TIDAL™ Fusion Cage System (Ossera™ AFX).	See following discussion.
§ 419.66(b)(3)	Device is integral to the service furnished, used for one patient only, comes in contact with human tissue, and is surgically implanted into the ankle joint for permanent implantation.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1776 (Joint device (implantable)) and C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) do not describe the device.	See following discussion.
Cost Criteria	The TIDAL™ Fusion Cage System's total device cost is \$32,995.00, consisting of a Fusion Cage (\$27,995.00) and a Disposable Instrument Kit (\$5,000.00). For cost significance requirements: HCPCS code: 27871 APC code: 5115 CY 2026 device offset amount: \$5,973.37 CY 2026 APC payment rate: \$13,116.76 Requirement #1: $(\\$27,995 / \\$13,116.76) \times 100 = 213.43\%$. Requirement #2: $(\\$27,995 / \\$5,973.37) \times 100 = 468.66\%$. Requirement #3: $((\\$27,995 - \\$5,973.37) / \\$13,116.76) \times 100 = 167.89\%$.	See following discussion.

BILLING CODE 4169-69-C

Regarding the Breakthrough Device designation, we note that restor3d submitted a new technology add-on payment application for FY 2026 for the TIDAL™ Fusion Cage under the

alternative pathway, as discussed in the FY 2026 IPPS/LTCH PPS proposed and final rules (90 FR 18200 through 18202; 36817 through 36819). In the final rule, we stated that because the Disposable Instrument Kit was not included in the

Breakthrough Device designation, only the TIDAL™ Fusion Cage was eligible for new technology add-on payments under the alternative pathway. Consistent with our decision regarding new technology add-on payment

eligibility, we will not consider the Disposable Instrument Kit for transitional pass-through payment status under the alternative pathway because it is not included in the Breakthrough Device designation. We will only be discussing the TIDAL™ Fusion Cage in the following paragraphs.

We are inviting public comment on whether the TIDAL™ Fusion Cage meets the newness criterion at § 419.66(b)(1).

We also are inviting public comment on whether the TIDAL™ Fusion Cage meets the eligibility criteria at § 419.66(b)(3) and (b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), the applicant stated that no existing (current or previous) device pass-through payment categories appropriately describe the TIDAL™ Fusion Cage. Per the applicant, the existing pass-through code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the TIDAL™ Fusion Cage because C1713 is typically used to represent fixation components, such as an intramedullary nail or other fixation screws, but does not represent the TIDAL™ Fusion Cage.

Based on the description the applicant provided, the TIDAL™ Fusion Cage is a porous cage used as part of a limb salvage arthrodesis construct to bridge bone loss or a critical bone defect in the ankle and restore length due to bone void, absent bone, or surgical resection and therefore, could be described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-

to-bone (implantable)). Specifically, we believe that the pass-through payment category C1713 may appropriately describe the TIDAL™ Fusion Cage because C1713 is defined as implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact and may include orthopedic plates with accompanying washers or nuts as well as synthetic bone substitutes that may be used to fill bony voids or gaps.³³ In this context, we believe that the TIDAL™ Fusion Cage may be appropriately described by C1713.

We are inviting public comment on whether the TIDAL™ Fusion Cage meets the device category eligibility criterion at § 419.66(c)(1).

We are also inviting public comment on whether the TIDAL™ Fusion Cage meets the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the TIDAL™ Fusion Cage meets the new device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for the TIDAL™ Fusion Cage for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the TIDAL™ Fusion Cage for CY 2027.

³³ Centers for Medicare & Medicaid Services. (2024). *Medicare Claims Processing Manual* (CMS Pub. 100–04), Chapter 4: Part B Hospital (including inpatient hospital part B and OPPS). U.S. Department of Health and Human Services. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf>.

(h) TOPS™ System

Premia Spine, Inc. submitted an application for a new device category for transitional pass-through payment status for the TOPS™ System for CY 2027. According to the applicant, the TOPS™ System is a motion preserving device comprised of a titanium construct with an interlocking polycarbonate urethane (PcU) articulating core that is inserted into the lumbar vertebral joint after open posterior decompression and anchored using pedicle screws, preserving normal spinal motion and providing stabilization of the lumbar intervertebral segment. According to the applicant, the TOPS™ System replaces anatomical structures, such as the lamina and facet joints removed during spinal decompression treatment to alleviate pain, while preserving normal spinal motion and stabilizing the lumbar intervertebral segment. Per the applicant, unlike lumbar fusion, the TOPS™ System preserves normal biomechanical motion allowing relative motion in axial rotation, lateral bending, flexion, and extension while blocking sagittal translation, and stabilizing the spine after a decompression.

Table 37 provides an overview of the transitional device pass-through payment status application for the TOPS™ System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP2602261DX3J>.

BILLING CODE 4169–69–P

TABLE 37: TOPS™ APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> Premarket Approval (PMA) - June 15, 2023 <i>Application submitted to CMS:</i> February 27, 2026	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The TOPS™ System is a motion-preserving spinal implant that is inserted into the lumbar spine via pedicle screws. The TOPS™ System is intended to stabilize the spine following a lumbar decompression without rigid fixation. The TOPS™ System is indicated for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5. The date of the TPT application is within three years of FDA approval of the TOPS™ System <i>Breakthrough Device designation:</i> (October 26, 2020) The proposed indications for use includes patients between 35 and 80 years of age suffering from neurogenic claudication resulting from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum or scarring facet joint capsule at one level from L2 to L5.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically implanted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)), C1741 (Anchor/screw for bone fixation, absorbable, metallic (implantable)), C1821 (Interspinous process distraction device (implantable)), C1831 (Interbody cage, anterior, lateral or posterior, personalized (implantable)), C1737 (Joint fusion and fixation device(s), sacroiliac and pelvis, all system components (implantable)), and C1776 (Joint device (implantable)) do not encompass the device.	No concerns.
Cost Criteria	The cost of the TOPS™ System is \$16,500.00. Per the applicant, to complete the implant procedure of the TOPS™ System, the following components are required: one TOPS™ Implant (\$13,900.00), four TOPS™ Pedicle Screws (\$600.00 each), and four TOPS™ Set Screws (\$50.00 each). No partial systems are created by components. For cost significance requirements: HCPCS code: 0202T APC code: 5115 CY 2026 device offset amount: \$8,065.50 CY 2026 APC payment rate: \$13,116.76 Requirement #1: $(\$16,500.00 / \$13,116.76) \times 100 = 125.79\%$. Requirement #2: $(\$16,500.00 / \$8,065.50) \times 100 = 204.58\%$. Requirement #3: $((\$16,500.00 - \$8,065.50) / \$13,116.76) \times 100 = 64.30\%$.	No concerns.

BILLING CODE 4169–69–C

The TOPS™ System was preliminarily approved for device pass-through payment status effective July 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the TOPS™ System under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the TOPS™ System meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the TOPS™ System for device pass-through payment status for CY 2027.

(i) TOUCH® CMC 1 Prosthesis

Medartis submitted an application for a new device category for transitional pass-through payment status for the TOUCH® CMC 1 Prosthesis for CY 2027. According to the applicant, the TOUCH® CMC 1 Prosthesis is a cementless, ball-and-socket dual-mobility, total first carpometacarpal (CMC 1) joint prosthesis composed of a metacarpal implant (stem), trapezial implant (cup), and junction implant (neck), and has multiple sizes and

variants to fit patient anatomy. According to the applicant, the TOUCH® CMC 1 Prosthesis is the first total joint prosthesis for the CMC 1 joint and enables functional improvement,

pain reduction, and improvements in patient quality of life.

Table 38 provides an overview of the transitional device pass-through payment status application for the TOUCH® CMC 1 Prosthesis and CMS's

preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP250829G4VEC>.

TABLE 38: TOUCH® CMC 1 PROSTHESIS APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> Premarket Approval (PMA) - July 10, 2025 <i>Application submitted to CMS:</i> August 29, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The TOUCH® CMC 1 Prosthesis is indicated for 1 st carpometacarpal (CMC) primary total joint replacement (arthroplasty) in patients with symptomatic Eaton-Littler stage II or III osteoarthritis (OA). <i>Breakthrough Device designation:</i> The TOUCH® CMC 1 Prosthesis is indicated for replacement of the trapeziometacarpal joint due to rheumatoid arthritis, traumatic arthritis, osteoarthritis, and post-fracture deformation or bone loss. The TOUCH® CMC 1 Prosthesis received FDA Breakthrough Device Designation under the name TOUCH® Dual Mobility Trapeziometacarpal Prosthesis on November 10, 2021.	No concerns.
§ 419.66(b)(3)	Device is integral to the service furnished (1003T), used for one patient only, comes in contact with tissue, and is surgically implanted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category code C1776 Joint Device (implantable) does not encompass the device.	No concerns.
Cost Criteria	The cost of the TOUCH® CMC 1 Prosthesis is \$8,985.00. Per the applicant, the TOUCH® CMC 1 Prosthesis includes three one-time-use components: Cementless TOUCH® Cup (\$3,095.00), TOUCH® Neck + HR Liner (\$2,995.00), and Cementless TOUCH® Stem (\$2,895.00). The applicant stated that there are no partial systems created, and all three components are essential to creating a total joint arthroplasty prosthesis. For cost significance requirements: HCPCS code: 1003T APC code: 5115 CY 2026 device offset amount: \$5,895.98 CY 2026 APC payment rate: \$13,116.76 Requirement #1: $(\$8,985.00 / \$13,116.76) \times 100 = 68.50\%$. Requirement #2: $(\$8,985.00 / \$5,895.98) \times 100 = 152.39\%$. Requirement #3: $(\$8,985.00 - \$5,895.98) / \$13,116.76 \times 100 = 23.55\%$.	No concerns.

The TOUCH® CMC 1 Prosthesis was preliminarily approved for device pass-through payment status effective January 1, 2026. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the TOUCH® CMC 1 Prosthesis under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

After review of the information provided by the applicant, we agree that the TOUCH® CMC 1 Prosthesis meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the TOUCH® CMC 1 Prosthesis for device pass-through payment status for CY 2027.

(j) WiSE® (Wireless Stimulation of the Endocardium Technology) CRT System

EBR Systems, Inc. submitted an application for a new device category for transitional pass-through payment status for the WiSE® CRT System for CY 2027. According to the applicant, the WiSE® CRT System is an implantable, cardiac device capable of pacing the heart without a lead. It includes a subcutaneously implanted transmitter that generates ultrasonic pulses that

travel to a receiver implanted in the heart. The receiver, also known as the electrode, converts ultrasonic waves into electrical energy to stimulate cardiac tissue. The WiSE® CRT System uses leadless technology to stimulate the endocardial surface of the LV. Working in conjunction with a standard commercially available pacemaker (with

or without leads) or defibrillator already implanted in the patient, the WiSE® CRT System replaces the pacing function of a coronary sinus (CS) lead to achieve cardiac resynchronization therapy (CRT).

Table 39 provides an overview of the transitional device pass-through payment status application for the

WiSE® CRT System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP250429663YG>.

BILLING CODE 4169-69-P

TABLE 39: WISE® CRT SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> Premarket Approval - April 11, 2025 <i>Application submitted to CMS:</i> April 29, 2025	No concerns.
Breakthrough Device Designation	<i>FDA Indication:</i> The WiSE® CRT System is indicated for adult patients who are at least 22 years of age, are indicated for cardiac resynchronization therapy (CRT), have an existing or are eligible for an implanted right ventricular pacing system, and are in one of the following two categories: 1) Patients in whom previous coronary sinus (CS) lead implantation was unsuccessful, or where an implanted lead has been turned off, referred to as "previously untreatable" 2) Patients with previously implanted pacemakers or Implantable Cardioverter-Defibrillators (ICDs) in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation, referred to as "high risk upgrades". <i>Breakthrough Device designation:</i> (July 18, 2019) The WiSE® CRT System is indicated for adult patients at least 22 years of age who are indicated for cardiac resynchronization therapy (CRT), have an existing implanted right ventricular pacing system, and are either patients in whom previous coronary sinus lead implantation was unsuccessful or an implanted lead has been turned off ("previously untreatable"), or in patients with previously implanted pacemakers or ICDs in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation ("high risk upgrades").	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with tissue, and is surgically inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service	No concerns.
Device Category	Device category codes C1605 (Pacemaker, leadless, dual chamber (right atrial, right ventricular implantable components), C2621 (Pacemaker, other than single or dual chamber (implantable)), C2619 (Pacemaker, dual chamber, non-rate responsive (implantable)), C1785 (Pacemaker, dual chamber, rate responsive (implantable)), C1786 (Pacemaker, single chamber, rate-responsive (implantable)), and C2620 (Pacemaker, single chamber, non-rate responsive (implantable)) do not describe the device.	No concerns.
Cost Criteria	The cost of WiSE® CRT System is \$63,300.00. Per the applicant, the WiSE® CRT System consists of single-use components electrode and catheter (\$21,970.00), delivery sheath (\$2,590.00), transmitter (\$22,870.00) and battery (\$15,870.00) that are eligible for device pass-through payment, and a reusable controller (\$6,000.00). For cost significance requirements: ³⁴ HCPCS code: 0515T APC code: 5231 CY 2025 device offset amount: \$15,487.87 CY 2025 APC payment rate: \$22,446.19 Requirement #1: $(\$63,300.00 / \$22,446.19) \times 100 = 282.01\%$. Requirement #2: $(\$63,300.00 / \$15,487.87) \times 100 = 408.71\%$. Requirement #3: $((\$63,300.00 - \$15,487.87) / \$22,446.19) \times 100 = 213.01\%$.	No concerns.

BILLING CODE 4169–69–C

The WiSE® CRT System was preliminarily approved for device pass-through payment status effective October 1, 2025. We are inviting public comment on whether we should finalize approval for device pass-through payment status for the WiSE® CRT System under the alternative pathway

for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

³⁴ We note that the applicant selected the APC level device offset amount of \$15,312.79 for APC 5231 found in CY 2025 NFRM APC Offset File. Beginning in CY 2017, we calculate the device

offset amount at the HCPCS code level instead of the APC level (81 FR 79657). We note the HCPCS code level device offset amounts for the HCPCS codes provided by the applicant are available in the Addendum P to the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912). For our calculation, we selected the HCPCS level device offset amount of \$15,487.87 related to HCPCS 0515T in APC 5231 found in the Addendum P. Based on our initial assessment for this proposed rule, using the device offset amount of \$15,487.87

After review of the information provided by the applicant, we agree that the WiSE® CRT System meets all applicable device pass-through payment status criteria as specified in regulations at § 419.66. Therefore, based on the information available at the time of this proposed rule, we propose to finalize approval for the WiSE® CRT System for device pass-through payment status for CY 2027.

(2) Traditional Device Pass-Through Applications

(a) EndoForce™ Connector for Endovascular Venous Anastomosis

Phraxix Inc. submitted an application for a new device category for

would result in WiSE® CRT System meeting the cost significance requirement.

transitional pass-through payment status for the EndoForce™ Connector for Endovascular Venous Anastomosis (the EndoForce™ System) for CY 2027. According to the applicant, the EndoForce™ System provides an endovascular method for attachment of a non-autogenous arteriovenous graft (AVG) to a vein in the upper arm in patients with end stage renal disease (ESRD) requiring hemodialysis. Per the applicant, the EndoForce™ System is provided as a sterile, single-use EndoForce™ Connector Delivery System with a pre-mounted EndoForce™ Connector that is attached endovascularly at the venous anastomosis, in conjunction with a standard 6mm expanded polytetrafluoroethylene (ePTFE)

vascular access graft, to establish an end-to-end endovascular anastomotic conduit designed to help absorb the shear forces of blood flow at the AVG-vein junction and to provide a physical barrier to the ingress of neointimal hyperplasia.

Table 40 provides an overview of the transitional pass-through payment status application for the EndoForce™ System and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ntp/DEP260228AHPFT>.

TABLE 40: ENDOFORCE™ SYSTEM APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization: PMA approval - May 15, 2025.</i> <i>Application submitted to CMS: February 28, 2026.</i>	No concerns.
FDA Indication	The EndoForce™ System is indicated to provide an endovascular method for attachment of an AVG to a vein in the upper arm in patients with ESRD requiring hemodialysis. The EndoForce™ Connector is used together with conventional suturing of the graft to the artery during the implantation procedure. The graft is then used for vascular access during hemodialysis.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is surgically inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category codes C1768 (Graft, vascular), C1874 (Stent, coated/covered, with delivery system), C1875 (Stent, coated/covered, without delivery system), C1876 (Stent, non-coated/non-covered, with delivery system), C1877 (Stent, non-coated/non-covered, without delivery system), and C8000 (Support device, extravascular, for arteriovenous fistula (implantable)) do not describe the device.	No concern.
Cost Criteria	The cost of the EndoForce™ System is \$5,000.00. For cost significance requirements: HCPCS code: 36830 APC code: 5184 CY 2026 device offset amount: \$1,474.69 CY 2026 APC payment rate: \$5,685.01 Requirement #1: $(\$5,000.00 / \$5,685.01) \times 100 = 87.95\%$. Requirement #2: $(\$5,000.00 / \$1,474.69) \times 100 = 339.05\%$. Requirement #3: $((\$5,000.00 - \$1,474.69) / \$5,685.01) \times 100 = 62.01\%$.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: Improved Patency, Reduced Intervention Burden, and Reduced AVG Abandonment at 6 months. Claim #2: Improved Patency and Reduced AVG Abandonment. Claim #3: Sustained Patency and Fewer Interventions to Maintain Patency. Claim #4: Improved Cumulative (Secondary Patency) Compared to Sutured AVGs. Claim #5: Improved Cumulative (Secondary Patency) Compared to Mature AV Fistulas. Claim #6: Improved Cumulative Patency Compared to WaveLinQ™. Claim #7: Improved Cumulative Patency Compared to Ellipsys™. Claim #8: Reduced Interventions Compared to Traditional AVGs. Applicant provided one published study assessing the technology, two unpublished studies assessing the technology, and six background documents.	See following discussion.

We are inviting public comments on whether the EndoForce™ System meets the newness criterion at § 419.66(b)(1), the eligibility criteria at § 419.66(b)(3) and (b)(4), and the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we have the following concerns regarding whether the EndoForce™ System meets the

substantial clinical improvement criterion.

In support of claims one through four, eight, and nine, the applicant submitted a single published study evaluating the EndoForce™ System: Burgess et al. (2024), two un-published studies assessing the EndoForce™ System: Kramer et al. (n.d.) and Astor et al. (n.d.), and three background studies: Halbert et al. (2020), Harms et al. (2016), and Woodside et al. (2021) which did

not assess the nominated device. In support of claims five through seven the applicant submitted three background articles (Pisoni et al. (2021); Berland et al. (2019); Hull et al. (2018)) which did not assess the nominated device.^{35 36 37}

³⁵ Pisoni, R. L., Zepel, L., Zhao, J., Burke, S., Lok, C. E., Woodside, K. J., Wasse, H., Kawanishi, H., Schaubel, D. E., Zee, J., & Robinson, B. M. (2021). International Comparisons of Native Arteriovenous Fistula Patency and Time to Becoming Catheter-Free: Findings From the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American journal*

The Burgess et al. (2024) study is a single-arm, non-randomized study that analyzed the use of the EndoForce™ System in 158 patients aged 18 and older diagnosed with ESRD scheduled to have an AVG for hemodialysis placed in their upper arm in 10 U.S. institutions between 2018 and 2021 after a 6-month follow-up period.³⁸ We have several concerns with this study.

First, we are concerned that the study does not provide a comparison to a control group, such as patients treated with standard graft-to-vein sutured anastomosis. Without a comparison to currently available treatments, particularly in the clinical setting where it is most likely to be used, we are unable to assess whether the EndoForce™ System demonstrates substantial clinical improvement over currently available treatments. To demonstrate substantial clinical improvement, we consider supporting evidence, preferably published peer-reviewed clinical trials, that show improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to other currently available treatments.

Second, we are concerned that the smaller patient population and study design of Burgess et al. (2024), and the lack of stratification by key clinical factors known to affect AVG outcomes, may limit both the reliability of the cumulative patency findings and the generalizability of results to the Medicare population. Stratification factors, such as coronary artery disease, hypertension status, and ipsilateral access placement, which have all been shown to be associated with thrombosis, need for intervention, and cumulative

patency would be helpful to assess the outcomes.

In addition, it is unclear to what extent any improvement in cumulative patency is due to use of the EndoForce™ Connector versus the less invasive endovascular procedure used for implantation. We would welcome additional information on differentiating how the EndoForce™ System's connection to AVG versus the less invasive nature of the endovascular procedure leads to improvements in cumulative patency.

Furthermore, we note that, in Burgess et al. (2024), the authors compared results to three background studies, Halbert et al. (2020) (submitted in support of claim 4), Harms et al. (2016) (submitted in support of claim 8), and Woodside et al. (2021) (submitted in support of claim 8), none of which directly address the EndoForce™ System.^{39 40 41} We question the appropriateness of comparing cumulative patency, intervention rates, and AVG abandonment in Burgess et al. (2024) to outcomes reported in the three background studies, as observed differences may be influenced by variations in study design, study location, patient population and characteristics, and study period. Specifically, Burgess et al. (2024) reports a 6-month cumulative patency of 92 percent in its patient population and compares it to the 80 percent rate reported in Halbert et al. (2020). However, Halbert et al. (2020) is a meta-analysis of 32 studies conducted across 14 countries between 2007 and 2019, representing 3,381 AVGs placed in patients with chronic kidney disease or ESRD undergoing or preparing for hemodialysis using ePTFE grafts. In contrast, Burgess et al. (2024) analyzed ESRD patients between 2018 and 2021. Thus, we question whether the results in Halbert et al. (2020), which included studies dating back more than a decade, reflect current operative techniques and perioperative care in the U.S. and

therefore whether they are an appropriate comparator to Burgess et al. (2024). Similarly, Harms et al. (2016) is a retrospective study of 599 patients treated between January 2006 and December 2011, and Woodside et al. (2021) is an observational cohort study of 73,027 patients using data from July 2012 to December 2014. These studies reflect earlier clinical practices and patient populations that differ from those in Burgess et al. (2024), which evaluated patients between 2018 and 2021. Burgess et al. (2024) compared its reported intervention rate of 1.22 per patient-year to higher rates reported in Harms et al. (2016) and Woodside et al. (2021), 1.58 and 1.87 respectively; however, these comparisons may not be appropriate given the significant differences in study design, time periods and patient populations. These earlier studies do not adequately account for changes in clinical practice over time and any observed differences in outcomes are likely confounded by these factors rather than attributable to the technology itself. As such, these studies may not provide a valid basis for comparison to Burgess et al. (2024).

Moreover, we note patient populations varied across studies, and it is unclear how these differences may have affected intervention rates per patient-year. For example, Burgess et al. (2024) included patients with two or fewer previous vascular accesses in the treatment arm, while Woodside et al. (2021) included patients undergoing a first-time AVG placement between dialysis initiation and 1 year. We note that patients who have had previous hemodialysis access points experience damage to the blood vessels regardless of whether the access point is a central venous catheter, AVG, or AVF.^{42 43} Further, having prior vascular access points in the ipsilateral arm has been shown to decrease cumulative patency in Harms et al. (2016). We welcome additional studies that control for patients with comparable vascular access placement histories, to more accurately quantify the contributions of the EndoForce™ System to improvements in interventions per patient-year.

Finally, we are concerned that differences in vascular location for

of kidney diseases: the official journal of the National Kidney Foundation, 77(2), 245–254. <https://doi.org/10.1053/j.ajkd.2020.06.020>.

³⁶ Berland, T. L., Clement, J., Griffin, J., Westin, G. G., & Ebner, A. (2019). Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4 Fr Device: Clinical Experience from the EASE Study. *Annals of vascular surgery*, 60, 182–192. <https://doi.org/10.1016/j.avsg.2019.02.023>.

³⁷ Hull, J. E., Jennings, W. C., Cooper, R. I., Waheed, U., Schaefer, M. E., & Narayan, R. (2018). The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *Journal of vascular and interventional radiology: JVIR*, 29(2), 149–158.e5. <https://doi.org/10.1016/j.jvir.2017.10.015>.

³⁸ Burgess, J. S., Beaver, J. D., London, M., Rohan, V., Orland, P., Yevzin, A., Setum, C., Ross, J., & InterGraft Study Investigators. (2024). Prospective multicenter study of a novel endovascular venous anastomotic procedure and device for implantation of an arteriovenous graft for hemodialysis. *The Journal of Vascular Access*, 25(4), 1244–1251. <https://doi.org/10.1177/11297298231159691>.

³⁹ Halbert, R. J., Nicholson, G., Nordyke, R. J., Pilgrim, A., & Niklason, L. (2020). Patency of ePTFE Arteriovenous Graft Placements in Hemodialysis Patients: Systematic Literature Review and Meta-Analysis. *Kidney360*, 1(12), 1437–1446. <https://doi.org/10.34067/kid.0003502020>.

⁴⁰ Harms, J. C., Rangarajan, S., Young, C. J., Barker-Finkel, J., & Allon, M. (2016). Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use. *Journal of Vascular Surgery*, 64(1), 155–162. <https://doi.org/10.1016/j.jvs.2016.02.033>.

⁴¹ Woodside, K. J., Repeck, K. J., Mukhopadhyay, P., Schaubel, D. E., Shahinian, V. B., Saran, R., & Pisoni, R. L. (2021). Arteriovenous Vascular Access-Related Procedural Burden Among Incident Hemodialysis Patients in the United States. *American Journal of Kidney Diseases*, 78(3), 369–379.e1. <https://doi.org/10.1053/j.ajkd.2021.01.019>.

⁴² Harms, J. C., Rangarajan, S., Young, C. J., Barker-Finkel, J., & Allon, M. (2016). Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use. *Journal of Vascular Surgery*, 64(1), 155–162. <https://doi.org/10.1016/j.jvs.2016.02.033>.

⁴³ Lok, C. E., Huber, T. S., Orchanian-Cheff, A., & Rajan, D. K. (2024). Arteriovenous access for hemodialysis: A review. *Journal of American Medical Association*, 331(15), 1307–1317. <https://doi.org/10.1001/jama.2024.0535>.

patients in the Burgess et al. (2024) compared to patients in the background studies may influence outcomes and adversely impact comparability of results. Specifically, while Burgess et al. (2024) evaluated patients with upper arm AVGs consistent with the EndoForce™ System's FDA indication, this varied across the comparator studies: Halbert et al. (2020) excluded studies that exclusively assessed lower extremity AVGs, Harms et al. (2016) included patients who had AVGs in the chest and thigh in addition to the upper extremity, and Woodside et al. (2021) did not specify the anatomical location of AVGs. It is unclear whether some of the studies included patient populations with upper extremity, lower extremity, and chest AVGs. As discussed in greater detail later in this section for the second claim, it is unclear whether upper extremity and upper arm are used interchangeably. We question whether vascular access location influences clinical outcomes, and as such, the results in these background studies may be confounded by inclusion of patients with additional graft locations that could adversely impact the comparability of the results to Burgess et al. (2024).

With regard to the second claim that the EndoForce™ System improves patency and reduces AVG abandonment, the applicant submitted one unpublished analysis (Astor et al. (n.d.)) that compared the primary patency (defined as the time interval from initial implantation until first intervention) and cumulative patency (defined as the time interval between implantation of the graft to abandonment) results from Burgess et al. (2024) to pooled results from a meta-analysis of 34 studies of AVGs implanted using traditional surgical techniques.⁴⁴ We are concerned that Astor et al. (n.d.) may not demonstrate that the EndoForce™ System substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. Astor et al. (n.d.) reported a high degree of variability among the comparator studies included in the meta-analysis (primary patency $I^2=99.44$; cumulative patency $I^2=99.36$), many of which showed similar or higher primary patency (60.21 percent; 95 percent confidence interval (CI): 50.84, 69.59) and cumulative patency (92.08 percent; 95 percent CI: 86.98, 97.18)

compared to results from Burgess et al. (2024). We note that 19 of the 31 studies that provided data on cumulative patency in Astor et al. (n.d.) did not specifically report 6-month patency outcomes in tables or text; the studies only provided data in survival curves from which the authors of Astor et al. (n.d.) derived 6-month patency measurements. The estimated 6-month cumulative patency including all 31 studies was 83.23 percent (95 percent CI: 80.18, 86.28), whereas the 6-month cumulative patency estimated from the 12 studies reporting numerical values was 86 percent (95 percent CI: 81.78, 90.22). Astor et al. (n.d.) did not state whether the difference between the 6-month cumulative patency rates of 92 percent in Burgess et al. (2024) and 86 percent was statistically significant. However, we note the lower 95 percent CI bound reported in Burgess et al. (2024) was 86.98 percent, lower than the upper 95 percent CI bound of 90.22 percent for the 12 studies in Astor et al. (n.d.) providing numerical data. We also note that Astor et al. (n.d.) states that the primary patency for the EndoForce™ System is similar to pooled results from comparator studies (60.21 percent vs 60.35 percent; $p=0.75$). Additionally, we note that the 20 percent AVG abandonment rate used as a baseline by Astor et al. (n.d.) which they report was reduced to 8 percent, comes from a single meta-analysis (Halbert) based on 32 studies from 14 countries conducted between 2007 and 2019. We question whether this is an appropriate comparator to the 158 patients treated between 2018 and 2021 in 10 U.S. institutions reported in Burgess et al. (2024).

We also note that the criteria for comparator studies included in the meta-analysis in Astor et al. (n.d.) excluded those studies which only assessed lower extremity or chest AVGs. However, it is unclear whether some of the studies included patient populations with upper extremity AVGs as well as lower extremity and chest AVGs. As previously discussed, vascular access location may influence outcomes, therefore, the results in these background studies may be confounded by inclusion of patients with additional graft locations that could adversely impact the comparability of the results to Burgess et al. (2024). Additionally, because of the EndoForce™ System's FDA indication for use in the upper arm, we question whether the comparison is appropriate. Further, we note it is unclear in the application whether the upper arm means the entire upper extremity, including the forearm

(distal to the elbow) or only a portion of the arm (proximal to the elbow). We are interested in additional information clarifying the meaning of upper arm to help us evaluate the evidence provided in support of substantial clinical improvement and determine if it is applicable.

With regard to the third claim that the EndoForce™ System sustains patency and requires fewer interventions to maintain patency, the applicant submitted one unpublished, extended follow-up study (Kramer et al. (n.d.)) of 37 patients from Burgess et al. (2024), that evaluates the number of interventions performed to achieve cumulative patency for an additional 6 months beyond the most recent intervention.⁴⁵ Similar to our concerns regarding Burgess et al. (2024), we are concerned that Kramer et al. (n.d.) does not provide a control group for comparison. We note that the authors in Kramer et al. (n.d.) stated that, since both the EndoForce™ System's pivotal trial (Burgess et al. (2024)) as well as this extended follow-up study do not directly compare outcomes to sutured AVGs, a meta-analytic approach to compare endovascular anastomosis of an AVG with a traditional sutured anastomosis may be warranted. We would welcome additional information directly comparing endovascular anastomosis of an AVG with a traditional sutured anastomosis.

Like Burgess et al. (2024), the authors of Kramer et al. (n.d.) compared results to two background studies, Harms et al. (2016) and Woodside et al. (2021), neither of which directly address the EndoForce™ System. As mentioned previously, we question whether the comparison of rates of interventions per patient-year in Kramer et al. (n.d.) to Harms et al. (2016) and Woodside et al. (2021) are appropriate and reflect true improvements or are attributable to differences in study design, patient population, and study period. Kramer et al. (n.d.) reported a rate of 1.32 interventions per patient-year in its patient population using the nominated technology and compared it to rates of 1.58 and 1.87 reported in Harms et al. (2016) and Woodside et al. (2021). However, as previously noted in our discussion of the first claim that the EndoForce™ System improves patency, reduces intervention burden, and reduces AVG abandonment at 6 months, due to the differences in study periods between Kramer et al. (n.d.) and Harms

⁴⁴ Astor, B.C., Moorthi, K., Grant, L., Litchfield, T. (Pre-publication). Endovascular AVG venous anastomosis improves cumulative patency compared to traditional sutured anastomosis: a meta-analysis.

⁴⁵ Kramer, A., Moorthi, K., Grant, L., Litchfield, T. (Pre-publication). Extended Follow-Up of an Endovascular Venous Anastomotic Connector for Arteriovenous Graft Creation in Hemodialysis: A Multicenter Study.

et al. (2016) and Woodside et al. (2021), we question whether the results in the comparator studies, some of which are over a decade old, reflect current operative techniques and latest perioperative care in the U.S. Also, as previously noted in our discussion of the first claim, the extent of variance in vascular access locations of the patient populations assessed in these three studies is unclear. As such, we are concerned that the results in these background studies may be confounded by inclusion of patients with additional graft locations which could adversely impact the comparability of the results to Kramer et al. (n.d.).

We are also concerned about whether the patient population in Kramer et al. (n.d.), which included 29 active patients at the end of the study period from the 37 patients initially assessed, is powered sufficiently to assess statistical significance, especially compared to Burgess et al. (2024), which included 134 active patients at the end of the study period from the 158 patients initially assessed. We note that when a study is not adequately powered for the statistical analysis, the statistics may appear artificially inflated and do not reflect confounding effects. Further, we are concerned that the cohort in Kramer et al. (n.d.) was selected and analyzed post-hoc, rather than identified as a variable of interest at the initiation of Burgess et al. (2024), and question whether quality of the study was diminished due to selection bias.

Additionally, we question whether Kramer et al. (n.d.) conclusively demonstrates that the EndoForce™ System provides a substantial clinical improvement compared to other available treatments. Kramer et al. (n.d.) estimated a cumulative patency of 78.4 percent at 180 days into the extended follow-up period (12 months from AVG implant at the start of Burgess et al. (2024)). In comparison, Halbert et al. (2020) reported a 12-month cumulative patency of 70 percent (95 percent CI: 64, 75). We also note the high degree of variability ($I^2=91$) among the comparator studies in Halbert et al. (2020), many of which showed similar or higher cumulative patency compared to Kramer et al. (n.d.). Therefore, we are unable to conclusively attribute the

difference in outcomes to the nominated device.

Lastly, we question the appropriateness of comparing measures of cumulative patency that are not equally defined. Kramer et al. (n.d.) compared cumulative patency between participants with and without graft interventions within the 6-month study period discussed in Burgess et al. (2024) and stated that the cumulative patency at 6 months was nearly identical (91.79 percent versus 91.80 percent, respectively). In Kramer et al. (n.d.), for patients without an intervention, time to loss of patency was measured from the date of implant, while for patients with interventions, time to loss of patency was measured from the date of first intervention. We question the appropriateness of comparing cumulative patency between AVGs used at first hemodialysis without intervention and those that required intervention prior to first hemodialysis use. As Harms et al. (2016) notes, intervention prior to first hemodialysis use is associated with a shortened cumulative patency. As such, we question if making such comparisons could be potentially misleading.

In support of claims five through seven, that the EndoForce™ System improves cumulative (secondary) patency compared to mature AV fistulas (AVFs), and devices used for AVF creation, including WaveLinQ™, and Ellipsys™, the applicant submitted three background articles (Pisoni et al. (2021); Berland et al. (2019); Hull et al. (2018)) which did not assess the nominated device.^{46 47 48} The applicant stated that improvement in AVG patency is comparable to the 6-month cumulative patency associated with mature AVFs (71 to 93 percent) (Liu, P. et al. (2023)). However, we note that the EndoForce™ System is indicated for attachment of an AVG to a vein, not for the creation of an AVF. An AVF involves a direct anastomosis between an artery and a vein, whereas an AVG uses a graft as a conduit between the artery and the vein. Therefore, we question whether it is clinically appropriate to compare the EndoForce™ System, a device used for AVG attachment, to mature AVFs and devices used for AVF creation,

including WaveLinQ™ and Ellipsys™. Given these fundamental differences in mechanism and clinical use, we question whether these claims demonstrate a substantial clinical improvement over existing technologies.

We are inviting public comment on whether the EndoForce™ System meets the device category criterion at § 419.66(c)(2) and the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the EndoForce™ System meets the new device category eligibility criteria, and therefore, we propose to deny the transitional pass-through payment status for the EndoForce™ System for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the EndoForce™ System for CY 2027.

(b) LINK™ External Fixator

Metric Medical Devices, Inc. submitted an application for a new device category for transitional pass-through payment status for the LINK™ External Fixator for CY 2027. According to the applicant, the LINK™ External Fixator is a dynamic percutaneous bone external fixator that provides continuous compression during the healing of bony fractures, fusions, and osteotomies. The applicant stated that the LINK™ External Fixator is composed of the (1) LINK™, a stainless steel box-shaped spring that applies forces to wires or pins inserted in the bone to either actively pull together and compress or distract the bones; (2) LINK™ Cover, a silicone cap that covers the bone pins or wire; and (3) LINK™ Bone Pins, which are inserted in a patient's bones and to which the LINKÔ attaches.

Table 41 provides an overview of the transitional pass-through payment status application for the LINK™ External Fixator and CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at <https://mearis.cms.gov/public/publications/device-ptp/DEP250902M814F>.

⁴⁶ Pisoni, R. L., Zepel, L., Zhao, J., Burke, S., Lok, C. E., Woodside, K. J., Wasse, H., Kawanishi, H., Schaubel, D. E., Zee, J., & Robinson, B. M. (2021). International Comparisons of Native Arteriovenous Fistula Patency and Time to Becoming Catheter-Free: Findings From the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American journal of kidney diseases: the official journal of the*

National Kidney Foundation, 77(2), 245–254. <https://doi.org/10.1053/j.ajkd.2020.06.020>.

⁴⁷ Berland, T. L., Clement, J., Griffin, J., Westin, G. G., & Ebner, A. (2019). Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4 Fr Device: Clinical Experience from the EASE Study. *Annals of vascular surgery*, 60, 182–192. <https://doi.org/10.1016/j.avsg.2019.02.023>.

⁴⁸ Hull, J. E., Jennings, W. C., Cooper, R. I., Waheed, U., Schaefer, M. E., & Narayan, R. (2018). The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access. *Journal of vascular and interventional radiology: JVIR*, 29(2), 149–158.e5. <https://doi.org/10.1016/j.jvir.2017.10.015>.

TABLE 41: LINK™ EXTERNAL FIXATOR APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization: 510(k) clearance - May 29, 2024</i> <i>Application submitted to CMS: September 2, 2025</i>	No concerns.
FDA Indication	Indications for use: 1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis, 2) fixation of proximal tibial metaphysis osteotomy and 3) adjunctive fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude LINK™ bone pin placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.	No concerns.
§ 419.66(b)(3)	Device is integral to the service(s) furnished, used for one patient only, comes in contact with human tissue, and is surgically inserted/implanted/applied in or on a wound or other skin lesion.	See following discussion.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category code C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not describe the device.	See following discussion.
Cost Criteria	The cost of the LINK™ External Fixator is \$4,800. This cost includes the 4-pin LINKÔ and the corresponding LINKÔ Cover (\$4,500) as well as two LINKÔ Bone Pin packages (2 pins in each package) (\$300). ⁴⁹ For cost significance requirements: ⁵⁰ HCPCS code: 28899 APC code: 5111 CY 2025 device offset amount: \$50.18 CY 2025 APC payment rate: \$239.88 Requirement #1: $(\$4,800 / \$239.88) \times 100 = 2,001.00\%$. Requirement #2: $(\$4,800 / \$50.18) \times 100 = 9,565.56\%$. Requirement #3: $((\$4,800 - \$50.18) / \$239.88) \times 100 = 1,980.08\%$.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: The LINK™ External Fixator offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, such as those patients with infected sites, metal allergies, anesthesia sensitivity, skin pathology, or other co-morbidities such as diabetes, neuropathy or immunocompromised patients, due to the minimally invasive nature of the bone fixation the LINK™ External Fixator provides. Claim #2: The LINK™ External Fixator significantly improves clinical outcomes for a patient population as compared to currently available treatments because of its ability to percutaneously fixate fractures, osteotomies, or arthrodesis, thus protecting the soft tissue envelope, vascular, and neural structures, which historically result in a more robust healing response and a shorter time to function. Two documents describing the nominated technology and its fundamental principles were provided. No published or unpublished studies assessing the technology were provided.	See following discussion.

BILLING CODE 4169-69-C

We are inviting public comment on whether the LINK™ External Fixator meets the newness criterion at § 419.66(b)(1).

⁴⁹Per the applicant, the LINKT is the shape changing force creating bridging element between bone pin implants with the fracture or site of fusion

between the pins. The cost and components listed in the table are for a 4-pin LINKT External Fixator. According to the applicant, a 2-pin LINKT External Fixator is available and would cost \$3,650 for the 2-pin LINKT and LINKT Cover (\$3,500) as well as one LINKT Bone Pin package (2 pins in each package) (\$150). Each LINKT package includes a cover to protect it from the environment. Additional LINKT Covers can be purchased in a separate

package if a replacement cover is needed (\$300 for a 2-pin cover or \$350 for a 4-pin cover). Per the applicant, all components (LINKT, LINKT Bone Pins, and LINKT Cover) are required, and there are no partial systems. The applicant stated that multiple LINKT units may be used for higher level musculoskeletal procedures, such as five LINKT units for a Lisfranc dislocation, complex fractures, or Charcot foot fixation.

Regarding the eligibility criterion at § 419.66(b)(3), we are concerned that the LINK™ External Fixator components may not be integral to the service furnished, come in contact with human tissue, or be surgically inserted or implanted.

With respect to whether the LINK™ Bone Pins and LINK™ Cover are integral to the service furnished, based on the information provided by the applicant, we question whether the components are necessary to furnish or deliver the primary procedure with which it is used. We note that, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005), we stated that we have interpreted the term “integral” to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. According to the applicant, the LINK™ uses a single-use external fixator consisting of a stainless-steel bridge spring formed into a box shape, with holes that are held in alignment by surgical needle drivers during pin placement. When released, the bridge shortens to apply forces and the side elements swing outward to create moments on bone fixation pins or wires embedded in bone, pulling together and compressing or distracting bony structures. While the LINK™ External Fixator may include LINK™ Bone Pins, per the applicant, other commercially available bone pins, k-wires, or Steinmann pins (hereinafter referred to collectively as “bone fixation pins or wires”) may be compatible with the LINK™ External Fixator, and we therefore question whether the LINK™ Bone Pins are integral to the service furnished as they may be replaced with other commercially available bone fixation pins or wires. We further question whether the LINK™ Bone Pins are integral to the service furnished as it is unclear, based on the information provided in the application, whether any LINK™ Bone Pins are included in the LINK™ External Fixator packaging,

or if they are packaged and sold separately from the LINK™ External Fixator. With respect to the LINK™ Cover, because the applicant stated that the LINK™ Cover is a separate removable silicon elastomer cover that protects the LINK™ and the patient from the pin and wire ends and does not play a role in providing compression, as such, we also question if the LINK™ Cover is integral to the service furnished. We are interested in additional information about these components of the LINK™ External Fixator, including whether the components are required to furnish or deliver the primary procedure with which it is used and if the components can be substituted with other commercially available products.

With respect to whether the LINK™ External Fixator comes in contact with human tissue and is surgically inserted or implanted, we note that, per the applicant, the LINK™ Bone Pins (or other bone pins or wires) are the only components that come in contact with human tissue and are surgically implanted or inserted into the patient. Per the applicant, the LINK™ component remains outside the body and acts like a spring on skin penetrating bone fixation pins to reduce and provide continuous compression at the bone healing interface. We further note that, according to the applicant, the LINK™ Cover is a separate, removable cover that does not come in contact with and is not surgically implanted or inserted into the patient. Therefore, we believe the LINK™ and the LINK™ Cover components of the LINK™ External Fixator do not come into contact with human tissue and are not surgically inserted or implanted as required by § 419.66(b)(3).

We are inviting public comment on whether the LINK™ External Fixator meets the eligibility criterion at § 419.66(b)(3).

Regarding the eligibility criterion at § 419.66(b)(4), based on the applicant's description, we question whether the LINK™ Bone Pins could be considered a supply furnished incident to a service. First, we question the role of LINK™ Bone Pins in creating surgical openings for access to bone to accomplish the fixation provided by the LINK™. In the CY 2001 OPPS interim final rule (65 FR 67804 through 67805), we stated that we consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. Based on the information provided on the application, we are

unclear if the LINK™ Bone Pins (or other bone fixation pins or wires) are placed through a previously created surgical opening or if they are directly inserted through skin and soft tissue to access bone. We would welcome information regarding whether, when, and how an incision is created during placement of the LINK™ External Fixator. Second, as discussed previously with respect to criteria at § 419.66(b)(3), we note that it is unclear whether the LINK™ Bone Pins may be replaced with other commercially available bone fixation pins or wires. We are seeking clarification about whether the LINK™ Bone Pins can be substituted with other commercially available products. We question whether LINK™ Bone Pins may be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

We are inviting public comment on whether the LINK™ External Fixator meets the eligibility criterion at § 419.66(b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), the applicant stated that the existing pass-through code of C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)) does not appropriately describe the LINK™ External Fixator because the category does not include fixators with the LINK™'s shape-changing, spring-like design that stores elastic mechanical energy allowing it to provide continuous dynamic compression, which pulls bones together and closes gaps formed by bone resorption or inadvertent mechanical loading and stimulates mesenchymal stem cells to differentiate along an osteogenic pathway to form bone and cartilage. In contrast, the applicant stated that traditional external fixators included in C1713 are static, and therefore, do not readjust or impart compression or distraction forces to enhance bone healing as the LINK™ does.

Based on the description the applicant provided, the LINK™ External Fixator is an external fixator that attaches to pins inserted into the bone principally with the intent to facilitate stabilization or oppose bone-to-bone contact, and therefore, could be appropriately described by C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)). Further, C1713 does not describe the type of fixation or specify the type of compression created by the device. Specifically, we believe that the pass-through payment category C1713 may appropriately describe the LINK™ External Fixator because C1713

⁵⁰ We note that the applicant selected the APC level device offset amount of \$0.19 for APC 5111 found in CY 2025 NFRM APC Offset File. Beginning in CY 2017, we calculate the device offset amount at the HCPCS code level instead of the APC level (81 FR 79657). We note the HCPCS code level device offset amounts for the HCPCS codes provided by the applicant are available in Addendum P to the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912). For our calculation, we selected the HCPCS level device offset amount of \$50.18 related to HCPCS 28899 in APC 5111 found in Addendum P. Based on our initial assessment for this proposed rule, using the device offset amount of \$50.18 would result in the LINK™ External Fixator meeting the cost significance requirements.

describes implantable pins and/or screws inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone contact, which is consistent with the LINK™ External Fixator description. We note that we do not establish pass-through device categories for the purpose of describing specific devices, rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we believe that the LINK™ External Fixator may be appropriately described by C1713.

We are inviting public comment on whether the LINK™ External Fixator meets the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we have the following concerns regarding whether the LINK™ External Fixator meets the substantial clinical improvement criterion. Specifically, we are concerned that the applicant did not (1) clearly identify the patient population that is unresponsive to, or ineligible for, currently available treatments that can only be treated with the LINK™ External Fixator and provide corresponding supporting evidence; (2) provide sufficient evidence of the LINK™ External Fixator's effect on recovery time, adverse events, pain, or any other clinical outcomes; or (3) submit evidence that the LINK™ External Fixator substantially improves the diagnosis or treatment of an illness when compared to other available treatments.

First, the applicant asserted that the LINK™ External Fixator offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, but did not identify a patient population that can only be treated with the LINK™ External Fixator. Instead, the applicant stated that bone fixation for those who have infected sites, metal allergies, anesthesia sensitivity, skin pathology, or other co-morbidities (such as diabetes, neuropathy, or a compromised immune system) can be treated with the LINK™ External Fixator due to the minimally invasive nature of bone fixation the nominated device provides. While, according to the applicant, these patients can be treated with the LINK™ External Fixator, the applicant did not explain why other available devices, such as the nitinol bone staple, mini-rail external fixator, and Genxfix External Fixation (the LINK™ External Fixator's predicate device), would not be available

treatment options for this patient population. We welcome additional information and supporting evidence regarding a patient population that can only be treated with the LINK™ External Fixator and not with another existing device.

Further, we note that no evidence was provided to support the applicant's claim that the LINK™ External Fixator significantly improves clinical outcomes compared to currently available treatments. We note that the applicant provided one document that describes the LINK™ External Fixator's uses and technical features and a second document that summarizes the principles of minimizing surgical trauma, application of continuous dynamic compression, and avoidance of permanent implants, which the applicant asserted are benefits associated with the nominated device, but did not provide any studies assessing the clinical outcomes of using the LINK™ External Fixator. Additionally, while the LINK™ External Fixation Independent Clinical Research Support document provided with the application includes citations that appear to represent studies related to internal and external fixation approaches, we cannot evaluate sources that are cited but not included as part of the application.

Moreover, we note that the applicant did not provide any evidence comparing the LINK™ External Fixator's clinical outcomes to those of other available treatment options, such as the Genxfix External Fixator (the predicate device), nitinol bone staple, Mini-Rail™ External Fixator, Hoffman® External Fixator System, or MaxFrame™. Specifically, FDA determined that the LINK™ External Fixator is substantially equivalent to a legally marketed device, the Genxfix External Fixator (the LINK™ External Fixator's predicate device), which received 510(k) clearance on December 28, 2016. The LINK™ External Fixator's FDA 510(k) summary indicated that the two devices share similar technological characteristics and that the LINK™ External Fixator differs only in its fixator utilizing a shape-changing spring rather than a shape-changing power screw and clamps to act on pins and wires as the Genxfix External Fixator does. We believe that further investigation with comparators would be helpful to determine whether the device demonstrates substantial clinical improvement over currently available treatments in the clinical setting where it is most likely to be used. To demonstrate substantial clinical improvement over currently available

treatments, we consider supporting evidence, preferably published, peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

We further note that dynamic digital external fixators made from readily available hardware (such as k-wires and dental rubber bands) have been in use for decades.⁵¹ Since these external fixators appear to apply dynamic forces in the treatment of hand bone fractures, we question whether these devices may treat some of the same conditions in a similar manner and clinical setting as the LINK™ External Fixator, and therefore, whether the LINK™ External Fixator represents a substantial clinical improvement over these longstanding treatment options.

We are inviting public comment on whether the LINK™ External Fixator meets the substantial clinical improvement category criterion at § 419.66(c)(2).

We also are inviting public comment on whether the LINK™ External Fixator meets the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the LINK™ External Fixator meets the new device category eligibility criteria, and therefore, we propose to deny transitional pass-through payment status for the LINK™ External Fixator for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the LINK™ External Fixator for CY 2027.

(c) Santreva™-ATK Endovascular Revascularization Catheter

AngioSafe®, Inc. submitted an application for a new device category for transitional pass-through payment status for the Santreva™-ATK Endovascular Revascularization Catheter (Santreva™-ATK Catheter) for CY 2027. According to the applicant, the Santreva™-ATK Catheter is an energy and wire-free platform for simultaneous intraplaque crossing and revascularization of complex occlusive peripheral artery disease, intended for facilitating intraluminal placement of guidewires beyond stenotic lesions.

⁵¹ Chauhan, A., Sikora-Klak, J., & Abrams, R. (2018). Dynamic "homemade" digital external fixators for proximal interphalangeal joint injuries: Surgical technique. *The Journal of Hand Surgery*, 43(9), 875.E1–875.E12. [https://www.jhandsurg.org/article/S0363-5023\(17\)31675-1/fulltext/](https://www.jhandsurg.org/article/S0363-5023(17)31675-1/fulltext/).

Table 42 provides an overview of the device category for the transitional pass-through payment status application for the Santreva™-ATK Catheter and

CMS's preliminary assessment. For additional details provided by the applicant, please refer to the online application posting available at [https://](https://mearis.cms.gov/public/publications/device-ntp/DEP260302QH9AE)

mearis.cms.gov/public/publications/device-ntp/DEP260302QH9AE.
BILLING CODE 4169-69-P

TABLE 42: SANTREVA™-ATK CATHETER APPLICATION OVERVIEW

Device Pass-through Criteria	Applicant Statements	Preliminary CMS Assessment
Newness Criterion	<i>FDA Marketing Authorization:</i> 510(k) clearance - September 22, 2025 <i>Application submitted to CMS:</i> March 2, 2026	No concerns.
FDA Indication	The Santreva™-ATK Endovascular Revascularization Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including Chronic Total Occlusions (CTOs), in the femoropopliteal (arterial) peripheral vasculature.	No concerns.
§ 419.66(b)(3)	Device is integral, used for one patient only, comes in contact with human tissue, and is percutaneously inserted.	No concerns.
§ 419.66(b)(4)	Device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets, and is not a material or supply furnished incident to a service.	No concerns.
Device Category	Device category code C1887 (catheter, guiding (may include infusion/perfusion capability)) does not describe the device.	See following discussion.
Cost Criteria	The cost of the Santreva™-ATK Catheter is \$3,000.00. For cost significance requirements: HCPCS code: 37263 APC code: 5192 CY 2026 device offset amount: \$2,314.89 CY 2026 APC payment rate: \$5,814.84 Requirement #1: $(\$3,000.00 / \$5,814.84) \times 100 = 51.59\%$. Requirement #2: $(\$3,000.00 / \$2,314.89) \times 100 = 129.60\%$. Requirement #3: $((\$3,000.00 - \$2,314.89) / \$5,814.84) \times 100 = 11.78\%$.	No concerns.
Substantial Clinical Improvement Criterion	Claim #1: Substantially improved mechanism; simultaneous crossing and revascularization Claim #2: Substantially improved safety: no periprocedural injury and reduced need for adjunctive plaque modification interventions with known adverse events Claim #3: Substantially improved complex lesion crossing Claim #4: Substantially improved crossing success in severely calcified lesions Claim #5: Substantial lumen gain while crossing complex lesions, delivering positive outcomes of multiple currently reimbursed maneuvers Claim #6: Predominantly intraplaque crossing and recanalization, preserving vessel wall integrity Claim #7: Substantial improvement in clinical condition and quality of life of patients Claim #8: Substantial improvement for physicians in day-to-day clinical practice Provided 1 published study assessing the technology, 19 published studies and articles assessing comparator technologies, and 31 background documents.	See following discussion.

BILLING CODE 4169-69-C

We are inviting public comment on whether the Santreva™-ATK Catheter meets the newness criterion at § 419.66(b)(1) and the eligibility criteria at § 419.66(b)(3) and (b)(4).

Regarding the device category eligibility criterion at § 419.66(c)(1), per the applicant, the existing pass-through code C1887 (Catheter, guiding (may include infusion/perfusion capability)) does not appropriately describe the Santreva™-ATK Catheter, because C1887 does not reflect the full scope of the device's function or the significant clinical improvement associated with the Santreva™-ATK Catheter, which facilitates the placement of guidewires beyond stenotic lesions by laterally cutting and then compressing plaque, to form an intraluminal channel to restore blood flow.

Based on the description the applicant provided, the Santreva™-ATK Catheter is intended to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including CTOs, in the femoropopliteal (arterial) peripheral vasculature, and therefore, may be appropriately described by C1887 (Catheter, guiding (may include infusion/perfusion capability)). Specifically, we believe the pass-through payment category C1887 may describe the Santreva™-ATK Catheter because the pass-through payment category includes guiding catheters and the Santreva™-ATK Catheter's primary function of crossing peripheral stenotic lesions to establish a revascularization pathway appears to be the same function performed by device described in C1887. In addition, per the applicant, the Santreva™-ATK Catheter is introduced and removed prior to final treatment, which is also consistent with the use of the guiding catheters described in C1887. We note that we do not establish pass-through device categories for the purpose of describing specific devices; rather, device categories are intended to encompass all devices that can be appropriately described by a given category. In this context, we believe the Santreva™-ATK Catheter may be appropriately described by C1887. We are inviting public comment on whether the Santreva™-ATK Catheter meets the device category eligibility criterion at § 419.66(c)(1).

Regarding the substantial clinical improvement criterion at § 419.66(c)(2), after reviewing the information provided by the applicant, we have the following concerns regarding whether the Santreva™-ATK Catheter meets the substantial clinical improvement criterion. First, we note that the applicant submitted a single study

evaluating the Santreva™-ATK Catheter in support of all eight substantial clinical improvement claims: Banerjee et al. (2026)⁵². The applicant provided an additional study, Saratzis et al. (2026),⁵³ which we consider to be reference material established by experts to define vessel preparation, core aims, and usage. We therefore do not believe this evidence directly supports the claims of improved mechanism compared to other existing devices or techniques that facilitate wire crossing.

The Banerjee et al. (2026) study analyzed the use of the Santreva™-ATK Catheter in 74 patients with Rutherford class 2 through 5 peripheral arterial disease and de novo femoropopliteal CTOs less than or equal to 30 centimeters in length. The primary outcome of the study was clinical success, defined as device-facilitated guidewire placement into the distal true lumen of the femoropopliteal CTO without device-related major adverse events through hospital discharge or within 24 hours post-procedure (whichever occurred first). We have several concerns with this study.

First, we are concerned about the study's small sample size of 74 patients. Peripheral artery disease (with or without CTO) affects approximately 12 million adults over the age of 40 in the U.S.⁵⁴ Based on the small sample size compared to the disease prevalence, we question whether the results of the study are generalizable to the broader Medicare population. Also, the study is single-arm with no comparator group, which limits the ability to assess whether the Santreva™-ATK Catheter demonstrates improved outcomes compared to other available technologies. In addition, we note that the Banerjee et al. (2026) study included

patients with Rutherford classifications 2 (moderate claudication) through 5 (minor tissue loss), a measure which represents clinically distinct disease severities, but did not stratify outcomes by Rutherford class. As a result, it is difficult to interpret performance across clinically relevant severity subgroups, and to assess whether the Santreva™-ATK Catheter substantially improved complex lesion crossing, lumen gain while crossing complex lesions, and clinical condition and quality of life of patients. Furthermore, we note that the study's 30-day follow-up period limits our ability to evaluate periprocedural injury, predominant intraplate crossing and recanalization, and clinical condition and quality of life of patients. Specifically, the 30-day follow-up in Banerjee et al. (2026) is insufficient to assess vessel wall integrity and recanalization outcomes. These outcomes may require a minimum of 12 months of follow-up to evaluate meaningfully as existing evidence demonstrates that femoropopliteal CTO interventions are associated with higher rates of reintervention at 12 months compared to non-CTO femoropopliteal interventions, indicating that clinically meaningful vessel wall outcomes continue to emerge beyond the 30-day periprocedural period.⁵⁵ Lastly, we are concerned that the study reports procedural success, focusing on safety and effectiveness, but does not isolate the contribution of simultaneous crossing from that of revascularization to patient outcomes. This limits our ability to evaluate the claims of improved mechanism of crossing and revascularization, improved safety with no periprocedural injury and reduced need for adjunctive plaque modification interventions with known adverse events, and improved complex lesion crossing. We note that the Santreva™-ATK Catheter is designed to facilitate the intraluminal placement of guidewires beyond stenotic lesions, including CTOs, but requires a subsequent intervention, such as stent placement, atherectomy, or balloon angioplasty to achieve clinical improvement. Given that it is only a step in a larger revascularization procedure, it is unclear how the Santreva™-ATK Catheter

⁵² Banerjee, S., Metzger, C., Thatipelli, M., Ramaiah, V.G., Sayfo, S., Das, T., Tsai, S., Hyder, O., Shammas, N. W., Bunte, M., Nseir, G., Thomas, A., Beasley, R., Bosarge, C., Gagne, P., Kwolek, C., Rao, S., Novak, S., Pershad, A., Walker, C., & Soukas, P. (2026). Safety and effectiveness of the Santreva™-ATK endovascular revascularization catheter in the RESTOR-1 peripheral CTO crossing pivotal study. *The American Journal of Cardiology*. Advance online publication. <https://doi.org/10.1016/j.amjcard.2026.01.007>.

⁵³ Saratzis, A., Patrone, L., Secemsky, E.A., Dua, A., Zayed, H., Torsello, G., Van Herzeele, I., Stavroulakis, K., & VPAD collaborators (2026). Use of Vessel Preparation in Endovascular Peripheral Arterial Disease (PAD) Interventions: A Global Qualitative Analysis. *Journal of endovascular therapy: an official journal of the International Society of Endovascular Specialists*, 15266028261424732. Advance online publication. <https://doi.org/10.1177/15266028261424732>.

⁵⁴ Cleveland Clinic. (n.d.). *Peripheral artery disease (PAD)*. Cleveland Clinic. <https://my.clevelandclinic.org/health/diseases/17357-peripheral-artery-disease-pad>.

⁵⁵ Tsai, S., Liu, Y., Hoang, L., Vu, M., Lu, H., Ramanan, B., Fernandez Vazquez, D., Rosol, Z., Sayfo, S., Alaiti, M.A., Koutakis, P., Brilakis, E.S., Shishehbor, M.H., & Banerjee, S. (2023). Comparative outcomes of interventions for femoropopliteal chronic total occlusion versus non-chronic total occlusion lesions from the multicenter XLPAD registry. *Journal of the American Heart Association*, 12(12), e028425. <https://www.ahajournals.org/doi/10.1161/JAHA.122.028425>.

independently contributes to the clinical outcomes asserted.

Additionally, we believe that the Santreva™-ATK Catheter may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to other available treatments. We note that there are currently available treatments for facilitating the intraluminal placement of conventional guidewires across stenotic lesions in the femoropopliteal peripheral vasculature, including the Crosser™ Catheter S6 and the Viance™ Crossing Catheter.⁵⁶ While the applicant included these existing treatments in comparator tables, the applicant did not explain how the Santreva™-ATK Catheter's improves patient-centered outcomes compared to other currently available CTO crossing devices. In addition, the applicant submitted three articles as comparator evidence, two publications on restenosis after directional atherectomy for lower-extremity peripheral artery disease (Krishnan et al., 2012; Tarricone, et al., 2015),⁵⁷ and one report evaluating FlowCardia's Crosser device for CTO recanalization in the PATRIOT study (Endovascular Today, 2009).⁵⁹ However, we believe the Krishnan and Tarricone articles would be more appropriately characterized as background literature as they do not establish a performance benchmark against which the Santreva™-ATK Catheter can be meaningfully compared. Furthermore, the source cited in a trade magazine that references the PATRIOT study is not the actual peer-reviewed study. As such, we believe that this evidence has limited value for the purposes of comparison. We would

welcome additional information that includes longer follow-up periods and comparator evidence that includes prospective studies of lesion-specific crossing devices that establish a meaningful performance benchmark for crossing success, safety, and durability.

Additional information about how the Santreva™-ATK Catheter leads to significantly improved patient-centered outcomes compared with currently available CTO crossing devices would help our assessment of whether the Santreva™-ATK Catheter demonstrates substantial clinical improvement over existing technologies. To demonstrate substantial clinical improvement over existing technologies, we consider supporting evidence, preferably published, peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or more rapid beneficial resolution of the disease process, compared to the standard of care.

With regard to the second and third claims, the applicant provided slide decks with comparative tables, however, the tables do not identify the specific studies or datasets from which the comparator values originated. Without access to the underlying sources, we are unable to evaluate study methodologies, patient selection, lesion characteristics, endpoint definitions, or follow-up duration, and therefore cannot determine whether any observed differences reflect true improvements attributable to the Santreva™-ATK Catheter.

With respect to the fifth claim, the applicant asserted that the Santreva™-ATK Catheter is a substantial clinical improvement over current crossing devices and algorithms, which require adjunct debulking or plaque modification devices for lumen gain. However, all patients in Banerjee et al. (2026) subsequently underwent a definitive revascularization procedure, making it difficult to isolate the clinical contribution of luminal gain achieved during crossing. Additionally, the supporting evidence does not demonstrate how the reported luminal gain represents an improvement over, or translates to better clinical outcomes than, other plaque modifying devices or techniques that achieve comparable luminal gain.

Regarding the seventh claim that the Santreva™-ATK Catheter substantially improves the clinical condition and quality of life of patients, the applicant submitted the Banerjee et al. (2026) study but provided no comparator data.

We are concerned that the submitted evidence does not differentiate device use outcomes from the overall revascularization procedure outcomes. Specifically, the Santreva™-ATK Catheter requires a subsequent intervention, such as stent placement, atherectomy, or balloon angioplasty, to achieve clinical improvement, and it is, therefore, unclear how the Santreva™-ATK Catheter independently contributes to the clinical outcomes asserted in this claim. We are also concerned that the 30-day follow-up in Banerjee et al. (2026) may not be sufficient to comprehensively assess clinical condition and quality of life outcomes, which may require longer assessment. We would be interested in additional information to determine whether the Santreva™-ATK Catheter independently contributes to downstream, patient-level clinical outcomes independent of the overall revascularization procedure.

With regard to the eighth claim that the Santreva™-ATK Catheter offers a substantial improvement for physicians in day-to-day clinical practice, we note that this is a matter of physician workflow rather than measurable clinical outcomes for patients. We therefore question whether the evidence provided, which primarily focuses on the lack of device-related major adverse events and lesion crossing time, supports the applicant's claim of substantial clinical improvement, and request clarification on how the evidence provided directly relates to the applicant's claims of improved clinical outcomes.

We also note the applicant included supplemental information in which the applicant described atheroplasty as a novel paradigm that integrates intraplaque traversal, lateral plaque compression, channel creation, and immediate distal perfusion. This information was not linked to a specific claim of substantial clinical improvement. To the extent the application includes materials that are not tied to a specific substantial clinical improvement claim, we are unable to evaluate that content under the substantial clinical improvement criteria.

We are inviting public comment on whether the Santreva™-ATK Catheter meets the device category criterion at § 419.66(c)(2).

We also are inviting public comment on whether the Santreva™-ATK Catheter meets the cost criterion at § 419.66(d)(3).

After reviewing the information provided by the applicant, we are unable to determine that the

⁵⁶ EV Today. (n.d.). CTO crossing devices. <https://evtoday.com/device-guide/us/cto-crossing-devices>.

⁵⁷ Krishnan, P., Baber, U., Purushothaman, K.R., Purushothaman, M., Wiley, J., Tarricone, A., Mehran, R., Kovacic, J., Kim, M., Moreno, P., Kini, A., Dangas, G., & Sharma, S. (2012). Histopathologic evidence of adventitial cuts predicts restenosis after directional atherectomy of lower extremity peripheral arterial disease: Results from a randomized, open label, investigator initiated trial comparing intravascular ultrasound guided atherectomy to angiography guided atherectomy in peripheral vascular interventions for TASC's A, B lesions (UTOPIA) pilot study [Abstract]. *Journal of the American College of Cardiology*, 59(13), E2083.

⁵⁸ Tarricone, A., Ali, Z., Rajamanickam, A., Gujja, K., Kapur, V., Purushothaman, K.R., Purushothaman, M., Vasquez, M., Zalewski, A., Parides, M., Overbey, J., Wiley, J., & Krishnan, P. (2015). Histopathological evidence of adventitial or medial injury is a strong predictor of restenosis during directional atherectomy for peripheral artery disease. *Journal of Endovascular Therapy*, 22(5), 712–715. <https://doi.org/10.1177/1526602815597683>.

⁵⁹ Endovascular Today. (2009, October 22). PATRIOT evaluates FlowCardia's Crosser to mediate CTO recanalization. http://evtoday.com/2009/10/eNews102909_07.htmwhy.

Santreva™-ATK Catheter meets the new device category eligibility criteria; therefore, we propose to deny transitional pass-through payment status for the Santreva™-ATK Catheter for CY 2027.

We are inviting public comments on our proposal to deny transitional pass-through payment status for the Santreva™-ATK Catheter for CY 2027.

B. Device-Intensive Procedures

1. Background

Under the OPPTS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40 percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4. of the CY 2026 OPPTS/ASC proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3. of the CY 2026 OPPTS/ASC proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria as listed. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the

APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPTS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b. of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3. and IV.C.4. of this proposed rule.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether

procedures qualify as device-intensive in the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPTS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Proposed Device-Intensive Procedure Policy

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to

30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believed allowing these additional procedures to qualify for device-intensive status would help ensure these procedures receive more appropriate payment in the ASC setting, which would help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, or has received an FDA IDE and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:
 - ++ Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the

implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 83 FR 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the

associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946).

Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94214

through 92419), we finalized a change to our methodology for applying default device offset percentages for new device-intensive procedures. Under our previous policy, if a new CPT/HCPCS code did not have available claims data, either from the new HCPCS code or any predecessor code or clinically-similar code that uses the same device, and the CPT/HCPCS code otherwise met our criteria for device-intensive status, we would apply a default device offset percentage of 31 percent. However, we were aware of certain situations where the default device offset amount might not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. A potential large difference between the default device offset amount and the device portion of similar devices might impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPPTS and to set payment rates for device-intensive procedures under the ASC payment system. Therefore, for CY 2025 and subsequent CYs, we finalized our proposal to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new CPT/HCPCS codes that both describe a procedure that requires the surgical implantation or insertion of a single-use device that exceeds 30 percent of the procedure's cost and that meets our requirements of a device as described here and lack claims data (from either the new HCPCS code or any predecessor code or clinically-similar code that uses the same device), we would apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We stated that we still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data, we believe the APC-wide average device offset percentage is, in many cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we finalized our modification to our default device offset percentage for new device-intensive procedures. This methodological change was finalized for

both the OPPTS and ASC Payment System for CY 2025 and subsequent CYs and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs.

Additionally, in the CY 2025 OPPTS/ASC final rule with comment period (89 FR 92414 through 92419), we stated that we were persuaded by commenters that the lack of a device edit for device-intensive procedures, particularly new technologies, might lead to an underreporting of device costs and total procedure costs and potentially impede beneficiary access to such new technologies over time. Therefore, in addition to finalizing a modification to our device edits policy for CY 2025, we finalized a modification to our device offset percentage calculation. For procedures subject to our modified device edits policy for CY 2025 that cannot report modifier "CG" to bypass this claims processing edit, the device offset percentages calculated (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. We stated that we believed that hospital outpatient claims that report a device code with such procedures provide, in general, a more accurate representation of the procedures' total costs. We also finalized, for purposes of determining device offset percentages, that we will not use claims data from procedures that had a status indicator of "E1" during the calendar year we are using for ratesetting and determining device offset percentages. Lastly, we refined our process for applying device offset percentages to use available claims data from predecessor codes annually, rather than the first year of the successor code's activation date, until we have available claims data from the successor code. In the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53673 through 53679), we finalized our proposal to continue these policies for CY 2026.

We propose to continue these policies for CY 2027. Specifically, we propose to continue use of HCPCS code-level device-intensive determination and three criteria to designate device-intensive procedures, in accordance with existing policies. We also propose to continue our device-intensive procedure policy, our proposed use of CY 2025 claims information for determining device offset percentages and assigning device-intensive status, and our proposed default device offset policy for determining device offset percentages in the absence of claims data for device-intensive procedures. As we indicated in the CY 2019 OPPTS/ASC

proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent (or the APC-wide default offset percentage) for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care electronically at outpatientpps@cms.hhs.gov. Additional information can be submitted prior to issuance of an OPPTS/ASC proposed rule or as a public comment in response to an issued OPPTS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2027 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2027 OPPTS/ASC proposed rule on our website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

3. Device Edit Policy

In the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPTS/ASC final rule with comment period (the CY 2015 device-dependent APCs) was reported on the claim. In addition, in the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device assigned to a device-intensive APC. In the CY 2016 OPPTS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70422)), will satisfy the edit.

In the CY 2017 OPPTS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy

for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is “Implantable/insertable device, not otherwise classified”.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81758 through 81759), we finalized our proposal to establish a procedure-to-device edit for the procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures—CPT codes 0308T and 0616T, 0617T, and 0618T. (We note that CPT codes 0617T and 0618T were deleted effective January 1, 2025 and CPT code 0616T was deleted effective January 1, 2025 and replaced with new CPT code 66683.) We have noted that interested parties have previously recommended in past rulemaking that we reestablish all our previous procedure-to-device edits, but we do not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). This APC represents a unique situation—the APC (which was the Level 5 Intraocular APC in previous years) had been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than \$15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. In the CY 2025 OPPS/ASC final rule with comment period, we finalized to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent years.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 92419

through 92422), we finalized a modification to our device edits policy. While historically our device edits policy has only applied to procedures that are device-intensive based on the most recent claims data available, commenters had raised concerns about hospitals underreporting device costs in years when certain device-intensive procedures had lost device-intensive status because the device portion of a procedure can fluctuate above and below our device-intensive threshold of 30 percent. Commenters indicated to us that the presence of the device edit requirement can have a significant impact on the device portion and geometric mean cost of a procedure, particularly for newer technologies. Therefore, for CY 2025 and subsequent CYs, we finalized a policy to apply our device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, we finalized a policy to reinstate our device edits policy for procedures that have been device-intensive since we began assigning device-intensive status at the HCPCS code level on January 1, 2017. We believed that by applying our device edit policy to procedures that were device-intensive on or after January 1, 2017, we might continue to receive device cost information for relatively new procedures with limited claims data, which may have been impacted by our policy to require that only existing device-intensive procedures be subject to our device edits policy.

We are not proposing any changes to our device edit policy for CY 2027.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the “FB” modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than \$1.01. In cases in which the device being

inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital’s usual charge for the device being implanted and the hospital’s usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the “FC” modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the “FB” and “FC” modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code “FD” (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the “FD” value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining

the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code “FD” when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including chapter 4, section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2027.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act (42 U.S.C. 1395l(t)(6)) provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biologicals. A “biological” as used in this proposed rule, and as codified at 42 CFR 414.802 and 414.902 includes a “product licensed under section 351 of the PHS [Public Health Service] Act”. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. “Current” refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain “new” drugs and biologicals that were not being paid for as a Hospital Outpatient Department (HOPD) service as of December 31, 1996, and whose cost is “not insignificant” in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as “drugs.” As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Drugs and biologicals pass-through applications are accepted and approved on a quarterly basis in which pass-through payments for approved applications could begin on the next available OPPS quarterly update. Furthermore, our current policy, which was finalized in CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), is to allow for quarterly expiration of pass-through payment

status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible to allow, on a prospective basis, for the maximum pass-through payment period without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals. Proposed CY 2027 pass-through drugs and biologicals and their designated APCs are assigned status indicator “G” in Addenda A and B to this proposed rule (which are available on the CMS website).⁶⁰

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act (42 U.S.C. 1395u(o)) for the drug or biological exceeds the portion of the otherwise applicable Medicare Outpatient Department (OPD) fee schedule that the Secretary determines is associated with the drug or biological. The regulations at 42 CFR 419.64(d) specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the Ambulatory Payment Classification (APC) payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act (42 U.S.C. 1395w–3a) establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term “ASP methodology” and “ASP-based” are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at <https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price>.

The pass-through application⁶¹ and review process for drugs and biologicals

⁶⁰ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

⁶¹ To apply for OPPS transitional Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC), applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This information collection (CMS–10008) is currently approved under OMB control number of 0938–0802 and has an expiration date of July 31, 2027.

is described on our website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc>.

2. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2026

There are 49 drugs and biologicals for which pass-through payment status expires by December 31, 2026, as listed in Table 43. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2023 through December 31, 2026. In accordance with the policy finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662) and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always

packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals⁶² that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year, which is proposed to be \$140 for CY 2027 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for high-cost diagnostic radiopharmaceuticals, we would provide separate payment when their

⁶² In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period for more information regarding this policy.

per day cost is greater than the threshold we propose to adopt of \$665). These policies are discussed further in section V.B.1. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2. of this proposed rule.

We welcome public comments on the status indicator for expiring pass-through drugs and biologicals, in accordance with our existing policies on packaged drugs, biologicals, and radiopharmaceuticals, including the threshold packaging policy.

BILLING CODE 4169-69-P

TABLE 43: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9145	Injection, aprepitant, (apovivie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026
J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Injection, pegfilgrastim-pbbk (fynetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026
J2329	Injection, ublituximab-xiyy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	Fecal microbiota, live - jslm, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	Injection, sodium thiosulfate, 100 mg	G	9119	07/01/2023	6/30/2026
J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026
J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0184	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026
J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy	G	0732	10/01/2023	9/30/2026
J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy	G	0733	10/01/2023	9/30/2026
J9321	Injection, epcoritamab-bysp, 0.1 mg	G	9250	10/01/2023	9/30/2026
A9608	Flotufolostat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
J1304	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
J2799	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026
J7353	Anacaulase-bcdb, 8.8% gel, 1 gram	G	0742	01/01/2024	12/31/2026
J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5×10^9 pfu/mL vector genomes, per 0.1 mL	G	0716	01/01/2024	12/31/2026
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)	G	0707	01/01/2024	12/31/2026
A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie	G	0709	01/01/2024	12/31/2026
J0177	Injection, aflibercept hd, 1 mg	G	0704	01/01/2024	12/31/2026
J2782	Injection, avacincaptad pegol, 0.1 mg	G	0705	01/01/2024	12/31/2026
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	G	0703	01/01/2024	12/31/2026
J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	G	0714	01/01/2024	12/31/2026
J1323	Injection, elranatamab-bcmm, 1 mg	G	0708	01/01/2024	12/31/2026
J9286	Injection, glofitamab-gxbm, 2.5 mg	G	0720	01/01/2024	12/31/2026
J0174	Injection, lecanemab-irmb, 1 mg	G	9157	01/01/2024	12/31/2026
J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg	G	0715	01/01/2024	12/31/2026
J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity	G	0702	01/01/2024	12/31/2026
J0349	Injection, rezafungin, 1 mg	G	9267	01/01/2024	12/31/2026
J9333	Injection, rozanolixizumab-noli, 1 mg	G	0721	01/01/2024	12/31/2026

CY 2026 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J3055	Injection, talquetamab-tgvs, 0.25 mg	G	0706	01/01/2024	12/31/2026
J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2×10^{13} vector genomes	G	0713	01/01/2024	12/31/2026
J0217	Injection, velmanase alfa-tycv, 1 mg	G	0710	01/01/2024	12/31/2026
J9029	Intravesical instillation, nadofaragene firadenovect-vncg, per therapeutic dose	G	0717	01/01/2024	12/31/2026

BILLING CODE 4169-69-C

3. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in or Continuing Through CY 2027

We propose to end pass-through payment status in CY 2027 for 28 drugs and biologicals. These products, listed in Table 44, were initially approved for pass-through payment status between April 1, 2024 and January 1, 2025. We also propose to continue pass-through payment status through CY 2027 for 45 drugs and biologicals, listed in Table 45, which were initially approved for pass-through payment status between April 1, 2025 and April 1, 2026. The APCs and Healthcare Common Procedure Coding System (HCPCS) codes for pass-through drugs and biologicals are assigned status indicator “G” (Pass-Through Drugs and Biologicals) in Addenda A and B to this proposed rule (which are available on the CMS website).⁶³ The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator “G” only for the duration of their pass-through status.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2027, we are continuing our policy to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP, as applicable. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in

the physician’s office setting in CY 2027. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, a \$0 pass-through payment amount will continue to be paid for pass-through drugs and biologicals under the CY 2027 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is generally ASP plus 6 percent, is \$0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals⁶⁴ below the applicable cost threshold that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount will continue to be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate will generally continue to be ASP plus 6 percent for CY 2027, minus a payment offset for the portion of the otherwise applicable OPPS payment that the Secretary determines is associated with the drug or biological. We note that if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure

and therefore, there are associated OPPS payment amounts for them.

We note that in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we modified the regulation text at 42 CFR 419.2(b)(15) to specify that only those diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year are policy-packaged. Meaning, for those diagnostic radiopharmaceuticals that are below the diagnostic radiopharmaceutical packaging threshold, for purposes of pass-through co-insurance calculations, they are treated like policy packaged drugs. For those diagnostic radiopharmaceuticals above the diagnostic radiopharmaceutical packaging threshold, they are not packaged, and are not considered policy packaged; therefore, for purposes of pass-through co-insurance calculations, they are treated like separately payable drugs assigned to an APC. Accordingly, a \$0 pass-through payment amount is assigned consistent with our policy described previously in this section for separately payable drugs assigned to an APC.

We will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY 2027 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2027, consistent with our CY 2026 policy for diagnostic and therapeutic radiopharmaceuticals, we will continue to provide payment for both diagnostic and therapeutic

⁶³ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

⁶⁴ In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period for more information regarding this policy.

radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2027, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs

receive under section 1842(o) of the Act, which is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we will continue to provide pass-through payment at WAC plus 3 or 6 percent, the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 or 6 percent payment policy can be found in section V.B.2.a. of this proposed rule. If WAC

information also is not available, we will continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 44 for the list of drugs and biologicals with pass-through payment status expiring during CY 2027 and Table 45 for the list of drugs and biologicals with pass-through payment status continuing through CY 2027.

BILLING CODE 4169-69-P

**TABLE 44: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT
STATUS EXPIRING IN CY 2027**

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass- Through Payment Effective Date	Pass-Through Payment End Date
J7171	J7171	Injection, adams13, recombinant-krhn, 10 iu	G	0727	04/01/2024	03/31/2027
J9248	J9248	Injection, melphalan (hepzato), 1 mg	G	0730	04/01/2024	03/31/2027
J2267	J2267	Injection, mirikizumab- mrkz, 1 mg	G	0728	04/01/2024	03/31/2027
J2277	J2277	Injection, motixafortide, 0.25 mg	G	0729	04/01/2024	03/31/2027
J3247	J3247	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment	G	0748	07/01/2024	06/30/2027
J3393	J3393	Injection, betibeglogene autotemcel, per treatment	G	0746	07/01/2024	06/30/2027
J3263	J3263	Injection, toripalimab- tpzi, 1 mg	G	0745	07/01/2024	06/30/2027
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	G	0744	07/01/2024	06/30/2027
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram	G	0749	07/01/2024	06/30/2027
A9506	A9506	Graphite crucible for preparation of technetium Tc 99m- labeled carbon aerosol, each	G	0760	07/01/2024	06/30/2027
J9028	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram	G	0767	10/01/2024	09/30/2027
J9345	J9345	Injection, retifanlimab- dlwr, 1 mg	G	9280	10/01/2024	09/30/2027
Q5133	Q5133	Injection, tocilizumab- bavi (tofidence), biosimilar, 1 mg	G	0786	10/01/2024	09/30/2027

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	G	0784	10/01/2024	09/30/2027
J9026	J9026	Injection, tarlatamab-dlle, 1 mg	G	0768	10/01/2024	09/30/2027
J9172	J9172	Injection, docetaxel (docivyx), 1 mg	G	0757	10/01/2024	09/30/2027
J9324	J9324	Injection, pemetrexed (pemrydi rtu), 10 mg	G	0782	10/01/2024	09/30/2027
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg	G	0761	10/01/2024	09/30/2027
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg	G	0737	10/01/2024	09/30/2027
A9615	A9615	Injection, pegulicianine, 1 mg	G	0772	10/01/2024	09/30/2027
J2601	J2601	Injection, vasopressin (baxter), 1 unit	G	0778	01/01/2025	12/31/2027
A9697	A9697	Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose	G	0814	01/01/2025	12/31/2027
J0175	J0175	Injection, donanemab-azbt, 2 mg	G	0765	01/01/2025	12/31/2027
Q5148	Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram	G	0811	01/01/2025	12/31/2027
J2468	J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms	G	0815	01/01/2025	12/31/2027
J0870	J0870	Injection, imetelstat, 1 mg	G	0813	01/01/2025	12/31/2027
J9329	J9329	Injection, tislelizumab-jsgr, 1mg	G	0816	01/01/2025	12/31/2027

**TABLE 45: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT
STATUS CONTINUING THROUGH CY 2027**

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass- Through Payment Effective Date	Pass- Through Payment End Date
J0138	J0138	Injection, acetaminophen 10 mg and ibuprofen 3 mg	G	2075	04/01/2025	03/31/2028
J3300	J3300	Injection, triamcinolone acetanide, preservative- free, 1 mg	G	1253	04/01/2025	03/31/2028
A9611	A9611	Flurpiridaz f 18, diagnostic, 1 millicurie	G	2065	04/01/2025	03/31/2028
Q5147	Q5147	Injection, aflibercept- ayyh (pavblu), biosimilar, 1 mg	G	2068	04/01/2025	03/31/2028
J9072	J9072	Injection, cyclophosphamide (avyxa), 5 mg	G	0719	04/01/2025	03/31/2028
J9292	J9292	Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg	G	2076	04/01/2025	03/31/2028
J9054	J9054	Injection, bortezomib (boruzu), 0.1 mg	G	2066	04/01/2025	03/31/2028
Q2058	Q2058	Obecabtagene autoleucel, up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2061	04/01/2025	03/31/2028
Q2057	Q2057	Afamitresgene autoleucel up to 10 billion mage-a4 tcr positive t-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2067	04/01/2025	03/31/2028
J9276	J9276	Injection, zanidatamab- hrii, 2 mg	G	2062	04/01/2025	03/31/2028
J1326	J1326	Injection, zolbetuximab- clzb, 1 mg	G	2063	04/01/2025	03/31/2028
J7172	J7172	Injection, marstacimab- hncq, subcutaneous, 0.5 mg	G	2064	04/01/2025	03/31/2028
J9174	J9174	Injection, docetaxel (beizray), 1 mg	G	0841	07/01/2025	06/30/2028

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass- Through Payment Effective Date	Pass- Through Payment End Date
J9382	J9382	Injection, zenocutuzumab-zbco, 1 mg	G	0853	07/01/2025	06/30/2028
Q5152	Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg	G	0846	07/01/2025	06/30/2028
J9011	J9011	Injection, datopotamab deruxtecan-dlnk, 1 mg	G	0835	07/01/2025	06/30/2028
J0614	J0614	Injection, treosulfan, 50 mg	G	0837	07/01/2025	06/30/2028
J9249	J9249	Injection, melphalan (apotex), 1 mg	G	0842	07/01/2025	06/30/2028
J9038	J9038	Injection, axatilimab-csfr, 0.1 mg	G	0839	07/01/2025	06/30/2028
J9289	J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy	G	0848	07/01/2025	06/30/2028
Q5100	Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg	G	0857	07/01/2025	06/30/2028
J9220	J9220	Injection, indigotindisulfonate sodium, 1 mg	G	0821	07/01/2025	06/30/2028
J0458	J0458	Injection, aztreonam/avibactam, 7.5 mg/2.5 mg (10 mg)	G	0878	10/01/2025	09/30/2028
J9256	J9256	Injection, nipocalimab-aahu, 3 mg	G	0893	10/01/2025	09/30/2028
J9326	J9326	Injection, telisotuzumab vedotin-tllv, 1 mg	G	0894	10/01/2025	09/30/2028
J3403	J3403	Revakinagene taroretsel-lwey, per implant	G	0897	10/01/2025	09/30/2028
Q5151	Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg	G	0852	10/01/2025	09/30/2028
A9616	A9616	Gallium ga-68 gozetotide (gozellix), diagnostic, 1 millicurie	G	0876	10/01/2025	09/30/2028
J7174	J7174	Injection, fitusiran, 0.04 mg	G	0889	10/01/2025	09/30/2028

CY 2026 HCPCS Code	CY 2027 HCPCS Code	Long Descriptor	CY 2026 Status Indicator	CY 2026 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q9998	Q9998	Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg	G	0859	10/01/2025	09/30/2028
Q9999	Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg	G	0895	10/01/2025	09/30/2028
J0681	J0681	Injection, ceftobiprole medocartil sodium, 3 mg	G	0879	10/01/2025	09/30/2028
C9307	C9307	Injection, linvoseltamab-gcpt, 1 mg	G	0916	01/01/2026	12/31/2028
C9308	C9308	Injection, carboplatin (avyxa), 1 mg	G	0917	01/01/2026	12/31/2028
J1737	J1737	Injection, meloxicam (azurity), 1 mg	G	0898	01/01/2026	12/31/2028
J9184	J9184	Injection, gemcitabine hydrochloride (avyxa), 200 mg	G	0909	01/01/2026	12/31/2028
J9275	J9275	Injection, cosibelimab-ipdl, 2 mg	G	0915	01/01/2026	12/31/2028
J9282	J9282	Mitomycin, intravesical instillation, 1 mg	G	0913	01/01/2026	12/31/2028
Q5158	Q5158	Injection, denosumab-bnht (bomyntra/conexence), biosimilar, 1 mg	G	0892	01/01/2026	12/31/2028
Q5160	Q5160	Injection, bevacizumab-nwgd (jobevnc), biosimilar, 10 mg	G	0918	01/01/2026	12/31/2028
C9309	C9309	Injection, onasemnogene abeparvovec-brve, per treatment	G	0922	04/01/2026	03/31/2029
J3404	J3404	Injection, zopapogenc imadenovec-drba suspension, per therapeutic dose	G	0924	04/01/2026	03/31/2029
J9183	J9183	Gemcitabine intravesical system, 225 mg	G	0926	04/01/2026	03/31/2029
J9277	J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph	G	0930	04/01/2026	03/31/2029
Q5162	Q5162	Injection, denosumab-nxxp (bildyos/bilprevda), biosimilar, 1 mg	G	0934	04/01/2026	03/31/2029

packaged drugs, biologicals, and radiopharmaceuticals, including the threshold packaging policy.

B. OPPTS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to \$50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the \$50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest \$5 increment to determine the CY 2007 threshold amount of \$55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPTS/ASC final rule with comment period (71 FR 68085 through 68086), we set the packaging threshold for establishing separate APCs for drugs and biologicals at \$140 for CY 2026 (90 FR 53698).

Following the CY 2007 methodology, for the CY 2027 OPPTS/ASC proposed rule, we propose to use the most recently available four quarter moving average PPI levels to trend the \$50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2027 and round the resulting dollar amount (\$142.40) to the nearest \$5 increment, which yields a figure of \$140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IGI. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations, we propose a packaging threshold for CY 2027 of \$140 for drugs, biologicals, and therapeutic radiopharmaceuticals. We also propose that if more recent data subsequently become available after the publication of the CY 2027 OPPTS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 OPPTS drug packaging threshold

amount in the CY 2027 OPPTS/ASC final rule with comment period.

We finalized in section II.A.3.c. of the CY 2025 OPPTS/ASC final rule with comment period (89 FR 94238 through 94241) to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the packaging threshold for CY 2025 of \$630. We also finalized that starting in CY 2026 and subsequent years, we would update this threshold by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). For the diagnostic radiopharmaceutical packaging threshold, we finalized using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPTS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPTS drug packaging threshold. Specifically, we finalized that, starting with the CY 2026 rulemaking cycle, we would use the most recently available four quarter moving average PPI levels to trend the CY 2025 threshold amount forward from the third quarter of the data year (CY 2024) to the third quarter of the payment year (CY 2025) and round the resulting dollar amount to the nearest \$5 increment. In the CY 2026 OPPTS/ASC final rule, we finalized a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 threshold amount of \$630 forward from the third quarter of CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest \$5 increment. We believed using the most recently available forecast of the four quarter moving average PPI levels more appropriately updates the packaging threshold amount from CY 2025 to the current payment year moving forward. For this proposed rule, we propose to use the most recently available four quarter moving average PPI levels to trend the final CY 2025 \$630 diagnostic radiopharmaceutical packaging threshold forward from the third quarter of CY 2025 to the third quarter of CY 2027 and round the resulting dollar amount (\$667.44) to the nearest \$5 increment, which yields a proposed radiopharmaceutical packaging threshold amount of \$665 for CY 2027. We also propose that if more recent data subsequently become available after the publication of the CY 2027 OPPTS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2027 diagnostic radiopharmaceutical packaging

threshold amount in the CY 2027 OPPTS/ASC final rule with comment period.

b. Proposed Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Radiopharmaceuticals Under the Cost Thresholds

To determine the proposed CY 2027 packaging status for all nonpass-through drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2025 and were paid (via packaged or separate payment) under the OPPTS. We used data from CY 2025 claims processed through December 31, 2025, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2027: anesthesia drugs; drugs, biologicals, and contrast agents and other drugs that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. Consistent with our policy described in section V.B.5. of this proposed rule, in situations where we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

To calculate the per day costs for drugs, biologicals, diagnostic radiopharmaceuticals, and therapeutic radiopharmaceuticals to determine their proposed packaging status for CY 2027, we used the methodology that was described in detail in the CY 2006 OPPTS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPTS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we estimated payment rates for CY 2027 using the ASP methodology, (ASP plus 6 percent, which is the payment rate we proposed for separately payable drugs and biologicals), as discussed in more detail in section V.A.1. and V.B.2. of this proposed rule to calculate the proposed CY 2027 per day costs. We used the manufacturer-submitted ASP

data from the fourth quarter of CY 2025 (data that were used for payment purposes in the physician's office setting, effective April 1, 2026) to determine the proposed CY 2027 OPPS/ASC per day costs.

As is our standard methodology, for CY 2027, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2025 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2027 OPPS/ASC proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2026. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, and do not have an ASP-based payment rate, we did not use a payment rate based on WAC or AWP for those items, consistent with our policy described in section V.B.3.a. of this proposed rule. Instead, we used their arithmetic mean unit cost derived from the CY 2025 hospital claims data to determine their per day cost.

- For diagnostic radiopharmaceuticals that do not have pass-through status as of April 1, 2026, we used their arithmetic mean unit cost derived from the CY 2025 hospital claims data to determine their per day cost. We did not use an ASP-based, WAC-based, or AWP-based payment rate for those items unless there was no arithmetic mean unit cost reported for the product, consistent with our proposed policy described in section V.B.3. of this proposed rule.

- For items other than diagnostic or therapeutic radiopharmaceuticals that did not have either an ASP-based payment rate, a payment rate based on WAC, or a payment rate based on AWP, we used the arithmetic mean unit cost of the items derived from the CY 2025 hospital claims data to determine their per day cost.

We propose to package drugs, biologicals, and therapeutic radiopharmaceuticals with a per day cost less than or equal to \$140 and identify items with a per day cost greater than \$140 as separately payable unless they are policy packaged. For diagnostic radiopharmaceuticals, we propose to package those items with a per day cost less than or equal to \$665 and identify items with a per day cost greater than \$665 as separately payable.

Consistent with our past practice (72 FR 667580), we cross-walked historical OPPS claims data from the CY 2025 HCPCS codes that were reported to the CY 2024 HCPCS codes that we display in Addendum B to this proposed rule (which is available on the CMS website)⁶⁵ for proposed payment in CY 2027.

Our policy during previous cycles of OPPS rulemaking has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period (71 FR 68086; 78 FR 75022; 89 FR 94238). We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year (71 FR 68086). Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2025, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2026, along with updated hospital claims data from CY 2025. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

We propose that payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the CY 2027 OPPS/ASC final rule with comment period would be based on ASP data from the second quarter of CY 2026. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2026. These payment rates would then be updated in the January 2027 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2027. For drugs and biologicals that do not currently have a payment rate based on ASP, WAC, or AWP, for therapeutic radiopharmaceuticals that do not currently have an ASP payment rate, and for all diagnostic radiopharmaceuticals, we will calculate their arithmetic mean unit cost from all of the CY 2025 claims data and updated

cost report information available for the CY 2027 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the CY 2027 OPPS/ASC final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS final rule with comment period (69 FR 65780) is in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2027 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2027. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2027 and subsequent years, consistent with our historical practice, we propose to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2026 and that are proposed for separate payment in CY 2027, and that then have per day costs equal to or less than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule, would continue to receive separate payment in CY 2027.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2026 and that are proposed for separate payment in CY 2027, and that then have per day costs equal to or less than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2027 final rule with comment period, would remain packaged in CY 2027.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2027 but that then have per-day costs greater than the CY 2027 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs

⁶⁵ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

and hospital claims data used for the CY 2027 final rule, would receive separate payment in CY 2027.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPSS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as “policy-packaged” drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPSS and are currently as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure including, but not limited to products, excluding skin substitutes, that aid wound healing; (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than the policy at § 419.2(b)(14). As we stated in the CY 2015 OPSS/ASC final rule with comment period: “We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the

surgery for purposes of our drug and biological surgical supply packaging policy” (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals that have a per day cost below the finalized diagnostic radiopharmaceutical packaging threshold that we discuss in section II.A.3. of this proposed rule, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) currently includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPSS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2027.

To propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of

the same drug or biological, we aggregated both our CY 2025 claims data and our pricing information, which is based on the ASP methodology, generally ASP plus 6 percent, across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the arithmetic mean unit cost available from the CY 2025 claims data to make the proposed packaging determinations for them: HCPCS 3471 (injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40,500 ml); and HCPCS code J7110 (Infusion, dextran 75,500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP methodology based payment rate, which is generally ASP plus 6 percent, per-unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2027 drug packaging threshold of \$140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2027 drug packaging threshold of \$140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2027 is displayed in Table 46.

BILLING CODE 4169-69-P

TABLE 46: PROPOSED HCPCS CODES TO WHICH THE CY 2027 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2027 HCPCS Code	CY 2027 Long Descriptor	Proposed CY 2027 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	E2
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	E2
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N

BILLING CODE 4169-69-C

We propose that our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2027 would also apply to diagnostic radiopharmaceuticals. This is because, as with drugs and biologicals, we believe that adopting standard HCPCS code-specific packaging determinations for radiopharmaceutical codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. To propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same diagnostic radiopharmaceutical, we would aggregate our CY 2025 claims data across all the HCPCS codes that describe each distinct diagnostic radiopharmaceutical to determine the mean units per day of the diagnostic radiopharmaceutical in terms of the HCPCS code with the lowest dosage descriptor. We would then analyze the aggregate per day cost of the diagnostic radiopharmaceutical to determine if the

per day cost is less than or equal to the proposed CY 2026 diagnostic radiopharmaceutical packaging threshold of \$665 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed CY 2027 diagnostic radiopharmaceutical packaging threshold of \$665 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be separately payable). There are currently no diagnostic radiopharmaceuticals that this policy would apply to.

2. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a “specified

covered outpatient drug” (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the

Secretary, subject to any adjustment for overhead costs and considering the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of the Act. We refer to this alternative methodology as the “statutory default”. Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to consider overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to consider the findings of the MedPAC study.⁶⁶

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we finalized a policy to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs; but we also are applying this provision to other separately payable

drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2025.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3 percent add-on in place of the 6 percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately

payable drugs, biologicals, and certain radiopharmaceuticals. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug, biological, or radiopharmaceutical under section 1847A(c)(4) of the Act. When WAC-based pricing is used for a drug, biological, or radiopharmaceutical, but not under section 1847A(c)(4) of the Act, the payment of WAC plus 6 percent would apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs, biologicals, and radiopharmaceuticals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not applied in determining payments for these separately payable drugs and biologicals.

Separately payable drug, biological, and radiopharmaceutical payment rates were listed in Addenda A and B to this proposed rule (available on the CMS website).⁶⁷ These addenda provide the proposed CY 2027 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals, with exceptions for certain radiopharmaceuticals previously discussed, and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for certain radiopharmaceuticals, these rates were based either on ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician’s office setting effective April 1, 2026, or WAC, AWP, or the arithmetic mean unit cost from CY 2025 claims data and updated cost report information available for the proposed rule. For nonpass-through therapeutic radiopharmaceuticals, payment rates were based on ASP data or the arithmetic mean unit cost. We propose to pay separately at the arithmetic mean unit cost for diagnostic radiopharmaceuticals with per day costs above the proposed threshold; the

⁶⁶ Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/june05_ch6.pdf.

⁶⁷ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

payment rates proposed for qualifying diagnostic radiopharmaceuticals are entirely the arithmetic mean unit cost if available (see section II.A.3.c.(3) of this proposed rule, regarding payment policy of qualifying diagnostic radiopharmaceuticals). In general, these published proposed payment rates will not be the same as the actual January 2027 payment rates. This is because payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals with ASP information for January 2027 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2026 (July 1, 2026, through September 30, 2026) will be used to set the payment rates that are released for the quarter beginning in January 2027 in December 2026. In addition, in Addenda A and B to this proposed rule, payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals for which there was no ASP, WAC, or AWP information available for April 2026, as well as all separately payable diagnostic radiopharmaceuticals, were based on the arithmetic mean unit cost in the available CY 2025 claims data.

If new pricing information becomes available for payment for the quarter beginning in January 2026, we will price payment for these drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals based on their newly available information. Finally, there may be drugs, biologicals and therapeutic radiopharmaceuticals that had ASP, WAC, or AWP information available for the proposed rule (reflecting April 2026 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2027. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on the arithmetic mean unit cost data derived from CY 2025 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2027 payment purposes and were only illustrative of the CY 2027 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2027 OPPS/ASC proposed rule.

We note that payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on.

In CY 2025, we clarified that only ASP data or, if ASP data are not available, the arithmetic mean unit cost

data, would be used to set payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals under the OPPS. For CY 2027, we are not proposing any changes to our policies for payment for separately payable therapeutic or diagnostic radiopharmaceuticals.

For CY 2027, we are not proposing any additional changes to our policies for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

b. Biosimilar Biological Products

In the CY 2024 OPPS/ASC final rule with comment period, we finalized the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid (88 FR 81783 through 81785). This policy allows for separate payment for biosimilars even if the biosimilar's per-day cost is below the packaging threshold if the biosimilar's reference product is separately paid. This policy removes the financial incentive to use a more expensive separately payable biological and promotes biosimilar use as a lower cost alternative to higher cost reference products.

Payment rates for drugs and biologicals (including biosimilars) under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the ASP plus a statutorily mandated 6 percent add-on. Additionally, section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment (88 FR 81783). These payment rates are published in the quarterly release of Addendum B or ASP pricing files.

c. Invoice Drug Pricing for CY 2027

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94243 to 94244), we finalized that, for separately payable drugs or biologicals for which CMS does not provide a payment rate in Addendum B, which would indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and arithmetic mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, the MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. We generally expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under section 1847A of the Act. For drug products that are not required to report ASP under section 1847A of the Act (for example, radiopharmaceuticals), invoice pricing may be used on a longer-term basis until an arithmetic mean unit cost (MUC) can be calculated. We finalized the invoice pricing policy for drugs to be effective January 1, 2026, with the intent to make technical updates to outpatient hospital claims and to allow providers time to prepare for any operational changes. We noted that the National Uniform Billing Committee (NUBC) created a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals, effective January 2026 for the purpose of this policy. The NUBC value code created is 92 (Drug/Biologic Invoice Cost), with the definition of: "Invoice Cost of drug/biologic. For use with Revenue Category 0636 when required by federal regulation." In the CY 2026 OPPS/ASC final rule with comment period, we finalized a technical clarification to this policy and clarified that CMS will determine whether the drug is not policy packaged; however, the MAC will continue to determine whether the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above

threshold packaging amount, as applicable (90 FR 53704). We reiterate that the drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. We acknowledge any rebates, chargebacks, or post-sale concessions may not be immediately available after treatment but hospital providers have 12 months from date of service to submit claims for payment and allowing providers to adjust submitted claims when the price concession is available.

For CY 2027, we are not proposing any additional changes to our invoice pricing policy for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We propose to continue our payment policy if CMS does not have pricing information (specifically, that ASP, WAC, AWP, and arithmetic mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices.

3. Payment Policy for Radiopharmaceuticals

For a complete history of the OPPTS payment policy for radiopharmaceuticals, we refer readers to the CY 2005 OPPTS final rule with comment period (69 FR 65811), the CY 2006 OPPTS final rule with comment period (70 FR 68655), and the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60524).

a. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPTS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, this payment policy for therapeutic radiopharmaceuticals will continue to apply in CY 2027.

Specifically, our policy of paying for separately payable pass-through therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals described in section V.A.1. of this proposed rule will continue to apply for CY 2027. We will pay for separately payable nonpass-through therapeutic radiopharmaceuticals through a modified ASP methodology where we pay at ASP plus 6 percent if ASP data are available. However, if ASP information is unavailable for a separately payable nonpass-through therapeutic radiopharmaceutical, we will continue to base the payment rate on arithmetic mean unit cost data derived from hospital claims. Our

policy not to use WAC or AWP to establish payment for separately payable nonpass-through therapeutic radiopharmaceuticals if ASP is not available will continue for CY 2027. We explained our rationale in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60524 through 60525) when we first adopted our policy to apply the principles of separately payable drug pricing to therapeutic radiopharmaceuticals.

For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60520 through 60521). We will rely on CY 2025 arithmetic mean unit cost data derived from hospital claims data for payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals for which ASP data are unavailable and update the payment rates for these products according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information becomes available.

The CY 2027 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).⁶⁸

b. Payment Policy for Diagnostic Radiopharmaceuticals Without Claims Data

For CY 2025, we finalized, as described in the CY 2025 OPPTS/ASC final rule with comment period (89 FR 93948 through 93963), to pay separately at arithmetic mean unit cost for diagnostic radiopharmaceuticals with a per day cost above our diagnostic radiopharmaceutical packaging threshold (proposed at \$665 for CY 2027). We also finalized our policy to pay for pass-through diagnostic radiopharmaceuticals based on ASP, WAC, and AWP.

We continue to believe that paying for nonpass-through diagnostic radiopharmaceuticals using the arithmetic mean unit cost would appropriately pay for the average price of a nonpass-through separately payable diagnostic radiopharmaceutical, as discussed in section II.A.3.c. of this proposed rule. In our view, the arithmetic MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average

costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. As we stated in the CY 2010 OPPTS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPTS payment for radiopharmaceuticals because these pricing methodologies do not include discounts. Specifically, the absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Additionally, in the CY 2025 OPPTS/ASC final rule with comment period (89 FR 93948 through 93963), we finalized to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status or claims data on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. To further clarify, these products will be paid based on ASP plus 6 percent, and at WAC plus 3 or 6 percent according to the policy in section V.B.2.a. of this proposed rule if ASP data are not available.

If the WAC also is unavailable, we proposed to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would be appropriate to use ASP, WAC, or AWP until an arithmetic MUC is established for new diagnostic radiopharmaceuticals with HCPCS codes that do not have passthrough status or claims data.

Please refer to section II.A.3.c. of this proposed rule for information regarding our broader payment policies for diagnostic radiopharmaceuticals, including our policy to pay for separately payable diagnostic radiopharmaceuticals with claims data based on the arithmetic mean unit cost data derived from hospital claims, and a list of the proposed qualifying diagnostic radiopharmaceuticals with per day costs exceeding the \$665 threshold for CY 2027 in Table 4 of this proposed rule. The proposed CY 2027 payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).

⁶⁸ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>.

4. Proposed Payment for Blood Clotting Factors

For CY 2027, we propose to continue our established policy to provide payment for blood clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPIs and to continue to pay a furnishing fee, authorized under section 1842(o)(5) of the Act. For a full discussion of our established payment policy for blood clotting factors, please refer to the CY 2023 OPPIs/ASC final rule with comment period (87 FR 71969 through 71970). In accordance with our policy as finalized in the CY 2008 OPPIs/ASC final rule with comment period (72 FR 66765), we will announce the actual figure of the percent change in the CPI for medical care for the 12-month period ending with June of the previous year. The updated CY 2027 furnishing fee calculation based on that figure through the applicable program instructions will be posted on the CMS website at <https://www.cms.gov/medicare/payment/part-b-drugs/asp-billing-resources>.

5. Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPI Hospital Claims Data

In the CY 2023 OPPIs/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPI hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2027, this policy will continue to apply. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPIs/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our policy, because we have no claims data and must determine if these products, drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals, exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the payment rate for the product, typically the ASP methodology, to determine whether their payment will be packaged as well as their payment status indicators.

6. CY 2027 Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy

a. Overview

Under the OPPIs, we generally set payment rates for separately payable drugs and biologicals (hereinafter referred to collectively as “drugs” in this section) under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data are not available, the payment amount is the average price for the drug in a year established under sections 1842(o), 1847A, or 1847B of the Act, as the case may be. Payment rates for drugs have usually been established under section 1847A of the Act, which generally sets a default rate of the average sales price (ASP) plus 6 percent. Section 1833(t)(14)(A)(iii)(II) of the Act also provides that the average price for the drug in the year as established under section 1847A of the Act, is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14).

In the CY 2018 OPPIs/ASC final rule with comment period (82 FR 59353 through 59371), CMS reexamined the appropriateness of paying the ASP plus 6 percent for drugs acquired through the 340B Drug Pricing Program (hereinafter referred to as the “340B Program”), a Health Resources and Services Administration (HRSA)-administered program that allows covered entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers. Based on findings of the Government Accountability Office (GAO),⁶⁹ the HHS Office of the Inspector General (OIG),⁷⁰ and the Medicare Payment Advisory Commission (MedPAC)⁷¹ that 340B hospitals were acquiring drugs at a significant discount under the 340B

Program, CMS adopted a policy beginning in 2018 generally to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B Program. This adjustment amount was based on our concurrence at the time with an analysis by MedPAC that concluded that the estimated average minimum discount of 22.5 percent of ASP adequately represented the average minimum discount that a 340B participating hospital received for separately payable drugs under the OPPIs (82 FR 59354 through 59371). Our intent in implementing this payment reduction was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340B drugs. We stated our belief that such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnished drugs to Medicare beneficiaries that were purchased under the 340B Program (82 FR 59353 through 59371).

b. Payment for 340B Drugs and Biologicals in CYs 2018 Through 2022

From January 1, 2018 through September 27, 2022, under the OPPIs we generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5 percent. In the CY 2018 OPPIs/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal to adjust the payment rate for separately payable drugs (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. For ease of reference, the OPPIs 340B drug payment adjustment policy is hereinafter referred to as the “340B Payment Policy” and refers both to the adjustments made to payment rates for 340B-acquired drugs described here and the corresponding rate adjustment for non-drug services and items described later in section V.B.6.c. of this proposed rule. We note that rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals were exempted from the adjustments made to payment rates for 340B-acquired drugs primarily due to these hospitals receiving special payment adjustments under the OPPIs. In addition, as stated in the CY 2018 OPPIs/ASC final rule with comment period, this policy change did not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which were excluded from the 340B Program. We also noted that

⁶⁹ Government Accountability Office. “Medicare Part B Drugs: ‘Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.’” June 2015. Available at <https://www.gao.gov/assets/gao-15-442.pdf>.

⁷⁰ Office of Inspector General. “Part B Payment for 340B Purchased Drugs. OEI-12-14-00030”. November 2015. Available at: <https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf>.

⁷¹ Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at <https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/>.

critical access hospitals are not paid under the OPPTS and therefore were not subject to the OPPTS 340B drug payment adjustment policy. Finally, in CY 2018, we did not initially apply the 340B Payment Policy to 340B-acquired drugs furnished in non-excepted off-campus provider-based departments (PBDs).

In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and made a series of refinements to the 340B Payment Policy, including a policy to pay for non-pass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than minus 22.5 percent of the reference biological product's ASP. Additionally, in the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy for CY 2019 and subsequent years.

During the CY 2019 OPPTS/ASC rulemaking cycle, we also clarified that the 340B payment adjustment applied to drugs priced using either wholesale acquisition cost (WAC) or average wholesale price (AWP), and since the policy was first adopted, we applied the 340B payment adjustment to 340B-acquired drugs priced using these pricing methodologies. We made this clarification because inquiries from interested parties following the finalization of the 340B Payment Policy in 2018 demonstrated that there was confusion as to whether drugs receiving WAC or AWP pricing were subject to the 340B payment adjustment (83 FR 33632). WAC is the drug manufacturer's list price for wholesalers or direct purchasers in the U.S., not including prompt payment or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or other publications of drug pricing data. AWP is set using industry-recognized AWP reference sources.⁷² The 340B payment

adjustment for WAC-priced drugs was WAC minus 22.5 percent. 340B-acquired drugs that were priced using AWP were paid an adjusted amount of 69.46 percent of AWP (83 FR 37125).⁷³

As discussed further in section V.B.6.f. of this proposed rule, the results of this policy meant that hospitals received an estimated \$10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B Payment Policy not been implemented (88 FR 77162). These reduced payments are detailed in Table 47 and are derived from Addendum AAA⁷⁴ published with the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 final rule with comment period (hereinafter referred to as the “Final Remedy rule”) (88 FR 77150).

TABLE 47: APPROXIMATE IMPACT IN REDUCED OPPTS PAYMENT FOR 340B-ACQUIRED DRUGS 2018 THROUGH 2022

	2018	2019	2020	2021	2022
Approximate Reduced OPPTS Drug Payment (including beneficiary cost sharing) (billions)	\$1.9	\$2.2	\$2.3	\$2.4	\$1.8*
* Amount January 1 to September 27, 2022. Reduced payments under the 340B Payment Policy were not in effect after September 27, 2022.					

For more detailed descriptions of our OPPTS payment policy for drugs acquired under the 340B Program during this timeframe, we refer readers to the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2020 OPPTS/ASC final rule with comment period (84 FR 61321 through 61327); the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63640 through 63649); the CY 2023 OPPTS/ASC

final rule with comment period (87 FR 71972 through 71973); the CY 2024 OPPTS/ASC final rule with comment period 88 FR 81789 through 81792; and the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53707 through 53722).

c. Payment for Non-Drug Items and Services in CY 2018 Through CY 2022

In the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59216, 59258), to comply with the statutory budget neutrality requirements under sections 1833(t)(9)(B) and (t)(14)(H) of the Act, we finalized our proposal to

redistribute our original, estimated reduction in payments for separately payable drugs as a result of the 340B Payment Policy by increasing the conversion factor used to determine the payment amounts for non-drug items and services. As further described in the CY 2018 OPPTS/ASC final rule with comment period, we used updated CY 2016 claims data and a list of 340B-eligible providers to calculate an estimated impact of \$1.6 billion based on the final CY 2018 policy to pay for OPPTS 340B-acquired drugs at a payment rate of generally ASP minus 22.5 percent. To effectuate the budget

⁷² www.cms.gov/files/document/part-b-drug-payment-limits-overview.pdf.

⁷³ The 69.46 percent of AWP was calculated by first dividing the original 95 percent of AWP price by 6 percent to generate a value that is similar to

ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which was similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

⁷⁴ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1793-f>.

neutrality provisions of the OPPS for CY 2018, we redistributed an estimated \$1.6 billion in reduced drug payments from adoption of the final 340B payment methodology to all hospitals paid under the OPPS by increasing the payment rates by 3.19 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018. We carried through this conversion factor adjustment from CYs 2019 through 2022, increasing payments for non-drug items and services in these CYs. This resulted in approximately \$7.769 billion, which for ease of reference in this proposed rule we hereafter refer to as \$7.8 billion, in additional spending on non-drug items and services from CYs 2018 through 2022.

d. Litigation History of the 340B Payment Policy

The 340B Payment Policy was the subject of significant litigation. See the Proposed Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (hereinafter referred to as the “proposed remedy rule”) for a more comprehensive summary of the litigation history (88 FR 44079 through 44080).

On June 15, 2022, the Supreme Court held that because HHS had not previously conducted a survey of hospitals’ acquisition costs, we could not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass’n v. Becerra*, 596 U.S. 724, 739 (2022). The Supreme Court declined to opine on the appropriate remedy, *see id.*, and on September 28, 2022, the district court vacated the prospective portion of the CY 2022 reimbursement rate for 340B-acquired drugs, *see Am. Hosp. Ass’n v. Becerra*, No. 1:18–cv–2084–RC, 2022 WL 4534617, at *5 (D.D.C.).⁷⁵ On January 10, 2023, the district court remanded without vacatur to give the agency the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for CY 2018 through CY 2022. *See Am. Hosp. Ass’n v. Becerra*, No. 1:18–cv–2084–RC, 2023 WL 143337, at *6 (D.D.C.).⁷⁶

e. Payment for 340B-Acquired Drug Claims for September 28, 2022 Through CY 2026

The agency complied with the district court’s September 28, 2022 decision by uploading revised OPPS drug files to

pay the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970), we finalized a policy reversing the 340B Payment Policy so that going forward we would pay for 340B-acquired drugs no differently than we pay for drugs that are not acquired through the 340B Program. To do so, we first provided that drugs acquired through the 340B Program would be paid at the statutory default rate (generally ASP plus 6 percent) for CY 2023. Second, to ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, we finalized a reduction of 3.09 percent to the 2023 OPPS conversion factor. This one-time adjustment to the conversion factor removed the effect of this aspect of the 340B Payment Policy, as originally adopted in CY 2018, for CY 2023 and subsequent years. This adjustment reduced the conversion factor to the conversion factor that would have been in place in CY 2023 if the 340B Payment Policy had never been implemented. For more detail on the payment rate for drugs acquired under the 340B Program for CY 2023 and the corresponding adjustment to the conversion factor to maintain budget neutrality as a result of reversing the 340B adjustment and paying for all separately payable drugs at ASP plus 6 percent (or WAC plus 3 or 6 percent or 95 percent of AWP), we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71973 through 71976).

For CYs 2024 through 2026, consistent with our policy finalized for CY 2023, we continued to pay the statutory default rate for 340B-acquired drugs (88 FR 81789 through 81791).

f. Remedy Payment Adjustment for 340B-Acquired Drugs From CY 2018 Through September 27, 2022

The agency complied with the district court’s January 10, 2023, remand order by issuing the Final Remedy rule on November 8, 2023 (88 FR 81540). The purpose of this rule was to address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPPS.

To address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022, CMS made one-time lump sum payments to affected 340B covered entity hospitals,

calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs from CY 2018 through September 27, 2022 and what they would have received for those drugs if the 340B adjustment had not been in place. These one-time lump sum payments were issued in early 2024. For more information on the calculation and distribution of the one-time lump sum payments, see the Final Remedy rule (88 FR 77156 through 77170).

g. Prospective Adjustment to Payments for Non-Drug Items and Services To Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022

As we described under section I.A.3. of the Final Remedy rule (88 FR 77151), to comply with statutory budget neutrality requirements, the decreased payments made to 340B hospitals for drugs in CY 2018 through September 27, 2022, were budget neutralized by corresponding increased payments to all hospitals for non-drug items and services starting in CY 2018 through CY 2022. When the past payments for these drugs were subsequently increased through the one-time lump sum payments in 2024, the same budget neutrality requirements obligated us to decrease the non-drug item and services payments made from CY 2018 through CY 2022.

To reduce the burden on providers of immediately offsetting the estimated \$7.8 billion of increased non-drug item and services payments made from CY 2018 through CY 2022, we finalized a policy to implement the offset prospectively over the course of several years. As we explained in the Final Remedy rule (88 FR 77172), this approach was similar to the original budget neutrality adjustment in the 340B Payment Policy that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the downward adjustment in the payment rate for drugs acquired under the 340B Program. We finalized in the Final Remedy rule that, beginning in CY 2026, we would reduce the conversion factor for non-drug items and services to all OPPS providers—except any hospital that enrolled in Medicare after January 1, 2018 (as described further below)—by 0.5 percent each year until the total offset was reached (which we estimated would take approximately 16 years (88 FR 77181)).

As we stated in the Final Remedy rule, we believed an annual reduction in the conversion factor was appropriate because it balanced the need to address the past payments for non-drug items

⁷⁵ https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.

⁷⁶ https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.

and services to ensure budget neutrality while also ensuring that the offset was not immediately financially burdensome on impacted entities, which we believed would be the case if we were to apply an adjustment for the full offset amount in a single year (88 FR 77170).

Accordingly, the Final Remedy rule finalized changes to the calculation of the OPSS conversion factor applicable to non-drug items and services beginning in CY 2026. Specifically, we codified a 0.5 percent reduction in the OPSS conversion factor applicable to non-drug items and services in the regulations as codified at § 419.32 (b)(1)(iv)(B)(12). As currently implemented, this 0.5 percent reduction remains in effect until the estimated payment reduction reaches \$7.8 billion, which we estimated will occur in CY 2041. For a full discussion of the CY 2026 adjustment to the conversion factor for non-drug items and services, see the Final Remedy rule (88 FR 77156 through 77170).

In finalizing our policy to apply a prospective adjustment, we recognized that any hospital that enrolled in Medicare after January 1, 2018 (hereinafter referred to as a “new provider”) received less than the full amount of the increased non-drug item and service payments made during that time than they otherwise would have received if enrolled prior to that date (88 FR 44080). We therefore exempted these providers from the prospective rate reduction, which was predominantly designed to account for non-drug item and service payments made during CY 2018 through CY 2022. As we explained, that means we calculate payment rates for new providers using the conversion factor before applying the 0.5 percent annual reduction to the conversion factor for non-drug items and services that apply to hospitals that are not “new providers” for purposes of this policy. For the purpose of designating a new provider, we define the date of enrollment in Medicare as the provider’s CMS certification number (CCN) effective date. We codified the exclusion of these new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(12) to § 419.32.

The providers that were determined to be subject to the payment reduction based on our review of provider enrollment and OPSS billing records were listed in Addendum R–340B Remedy Offset Providers to the CY 2026 OPSS/ASC final rule with comment period. We indicated in the CY 2026

OPSS/ASC final rule with comment period that providers not included on this list (providers that began billing Medicare under the OPSS after January 1, 2018) would not be subject to the payment reduction. For a complete discussion of our exclusion of new providers from the prospective payment adjustment, we refer readers to the Final Remedy rule (88 FR 77182 through 77185) and the CY 2026 final OPSS/ASC rule with comment period (90 FR 53709 through 53710).

h. CY 2026 Prospective Payment Adjustment

In the CY 2026 OPSS/ASC proposed rule, we proposed to revise the annual reduction to the OPSS conversion factor under § 419.32(b)(1)(iv)(B)(12) used to determine the payment amounts for non-drug items and services from 0.5 to 2 percent effective January 1, 2026 (90 FR 33634). Under this revised rate, we expected it would take approximately 6 years to reach the total offset of \$7.8 billion. As we explained in the CY 2026 OPSS/ASC proposed rule, while we continued to believe that a reduction to the OPSS conversion factor was the best way to effectuate budget neutrality, we questioned whether a 0.5 percentage point annual reduction for approximately 16 years best achieved the goal of the Final Remedy rule, which was to restore hospitals to as close to the financial position they would have been in had the 340B Payment Policy never been implemented as is reasonably feasible. Specifically, we noted that the further away from CY 2018 through CY 2022 the conversion factor adjustments extend, the less likely it is that hospitals’ relative utilization patterns of non-drug items and services would align with the relative utilization patterns of non-drug items and services from CY 2018 through CY 2022.

Because applying an annual reduction to the conversion factor for all non-drug items and services does not directly identify and recoup the specific amount owed by each hospital, but rather seeks to recoup the aggregate increased payments made to all hospitals for non-drug items and services starting in CY 2018 through CY 2022, it is important to apply the annual reduction to the OPSS conversion factor to the payment for non-drug items and services furnished during calendar years in which hospitals’ utilization patterns for such non-drug items and services most closely resemble their utilization patterns during CYs 2018 through 2022. Doing so helps to ensure that each hospital repays an amount that best approximates the excess payments it

received under the 340B Payment Policy.

We explained in the CY 2026 OPSS/ASC proposed rule (90 FR 53710) that a hospital’s utilization of non-drug items and services would likely diverge more from CY 2018 utilization in CY 2041 than it would in CY 2031 or CY 2026. The longer the recovery timeframe, the more each hospital’s utilization of non-drug items and services will likely diverge from what the hospital’s utilization of non-drug items and services was during the 2018–2022 timeframe the 340B Payment Policy was in place. Consequently, under the current recovery timeframe, the cumulative reduction applied to each hospital is less likely to reflect the amount of payment the hospital received for increased non-drug services from 2018 through 2022. As a result, it is less likely that each hospital will be restored to the financial position it would have occupied had the 340B Payment Policy in effect from 2018 to 2022 not been implemented.

Another factor that caused us to question the appropriateness of a 16 year recovery timeframe was the fact that by beginning the decrease to non-drug item and service payments in CY 2026, there was already an 8-year delay between the first year of the OPSS 340B Payment Policy and the first year of the prospective offset. (90 FR 53710). Thus, we observed, the longer it takes for us to fully recover the \$7.8 billion, the less suited the relative burden on hospitals from the adjustments would be to the relevant benefits those hospitals previously received. We also recognized the possibility that at least some hospitals that benefited from the increased payments from CY 2018 through CY 2022 would leave the market before 2041, increasing the risk that the remaining hospitals might ultimately account for a larger share of the payment reductions than they would have if the annual reduction to the OPSS conversion factor concluded sooner. We additionally noted that the \$7.8 billion dollar figure calculated in the Final Remedy rule (88 FR 77150) does not, and will not, account for inflation and does not contain interest even though the prospective offset is occurring many years after both the start of the 340B Payment Policy in CY 2018 as well as the lump sum remedy payments made in CY 2024.

We acknowledged in the CY 2026 OPSS/ASC proposed rule (90 FR 33635) that revising the annual reduction from 0.5 percent to 2 percent would be a change to the approach we finalized in the Final Remedy rule and that, at the time of the Final Remedy rule, we

considered but did not adopt a suggestion from a commenter requesting that we recover the amount over a shorter timeframe than 16 years. (88 FR 77179.) We indicated that our basis for not accepting the suggestion in the Final Remedy rule was that the 0.5 percent rate/16-year timeframe “properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities” (90 FR 33635). We stated in the CY 2026 OPPS/ASC proposed rule that this balancing insufficiently accounted for the main premise of the Final Remedy rule, which is to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. We explained that, for the reasons described above, we believed that a 6-year time frame better achieved that main goal and better balanced that goal and our budget neutrality obligations against hospital burden and reliance interests. We noted that the 16-year timeframe was more than three times longer than the 5-year period the 340B Payment Policy was in place. The 6 years we expected that the revised policy would be in effect, by contrast, would be closer to the timeframe the 340B Payment Policy was in place, and that a 2 percent payment reduction was still well below the 3.19 percent payment increase hospitals received for that time period (82 FR 52624 through 52625). We also indicated that because we proposed this policy in advance of CY 2026 and before any rate reductions went into effect for OPPS and Medicare Fee for Service payments, any reliance interests hospitals had in a policy that had not been implemented yet for these payment systems would be minimal and outweighed by the other considerations discussed in the CY 2026 OPPS/ASC proposed rule (90 FR 33635).

We did not finalize our proposal to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(12) in the CY 2026 OPPS/ASC final rule and the 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services finalized in the Final Remedy rule went into effect on January 1, 2026. The decision not to finalize an increased reduction for CY 2026 was made in response to concerns brought forth by some commenters. Specifically, we said “[w]hile we disagree with many of the

arguments these commenters raise, we are persuaded by the commenters to the extent that we will not finalize in CY 2026 our proposal to increase to 2 percent the 0.5 percent adjustment in 42 CFR 419.32(b)(1)(iv)(B)(12). We currently anticipate delaying a change for just 1 year. Thus, while we will retain the original 0.5 percent adjustment in the conversion factor in CY 2026, hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027—We do so based on the unique circumstances here.” (90 FR 53714).

i. CY 2027 Proposed Prospective Payment Adjustment

Effective January 1, 2027, we propose to increase the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(12) used to determine the payment amounts for non-drug items and services from 0.5 percent to 3 percent. Specifically, we propose to revise § 419.32(b)(1)(iv)(B)(12) to limit the 0.5 percent reduction to CY 2026 and add a new paragraph (13) implementing an annual 3.0 percent reduction (excluding new providers with a CMS certification number (CCN) effective date of January 2, 2018, or later) starting in CY 2027 and continuing until the estimated payment reductions made in accordance with paragraphs (12) and (13) for all applicable hospital outpatient items and service reaches \$7.769 billion. Under this revised rate, we expect we will reach this total by the end of CY 2029 (see Table 48). We recognize that this proposed annual reduction is greater than the 2 percent annual reduction we originally proposed for CY 2026. As further discussed below, we considered the following in establishing this proposal:

First, a 3 percent reduction is necessary to achieve the outcome for which we originally proposed the 2 percent annual reduction in CY 2026. That is, to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. By recovering the funds during a timeframe that aligns with the period in which the funds were originally paid out and applying the reduction in calendar years for which a hospital's utilization of non-drug items and services is more likely to align with its utilization during the period when the 340B Payment Policy was in effect, CMS will better ensure that the reduction in

payments to each hospital approximates the amount by which that hospital was overpaid. A total recoupment timeframe of roughly 6 years after the 340B remedy payments were made in CY 2024 more closely aligns with the 5 year timeframe the 340B Payment Policy was in place, as compared to the 8 years from CY 2024 that we estimate a 2 percent recoupment would require (see Table 48). Based on our analysis, we believe that, as additional time elapses following the period during which the 340B Payment Policy was in effect, hospitals' utilization of non-drug items and services is increasingly likely to diverge from their utilization patterns during that period. Since CMS is recouping the increased payments made for nondrug items and services while the 340B Payment Policy was effective by applying a reduced conversion factor to nondrug items and services furnished during the calendar years following the 340B Payment Policy's end date, the farther out these reductions apply, the less likely it is that the total recoupment for each hospital will align with the amount each hospital was overpaid. For example, if a hospital's utilization rate of non-drug items and services is three times greater in 2030 than it was in 2020, then a reduced conversion factor applied to the items and services furnished in 2030 could result in CMS recouping more than what the hospital was initially paid in 2020. Consequently, it is less likely that the hospital would be restored to the financial position they would have been in had the 340B Payment Policy never been in effect. A total recoupment timeframe of 6 years would recover the funds in a manner that limits this divergence in utilization while avoiding the burden on providers that would result from a shorter recovery timeframe.

Second, a 3 percent payment reduction is the most logical and appropriate percentage to apply as it closely approximates the 3.19 percent payment increase hospitals received for non-drug items and services from CYs 2018 through 2022 to budget neutralize the reduced drug payments resulting from the 340B Payment Policy. This approach is also consistent with the approach we adopted in CY 2023 (87 FR 71975) to maintain budget neutrality when we returned to our policy of paying ASP plus 6 percent for 340B acquired drugs.

With respect to implementing a 3 percent reduction in CY 2027 versus delaying implementation until a later CY to provide hospitals with additional time to prepare, we determined that implementing this payment reduction

starting CY 2027 would be appropriate. We have repeatedly emphasized that shorter recoupment windows would be considered and/or proposed in CY 2027. In the CY 2026/ASC final rule with comment period, we expressly stated “hospitals should anticipate that we will implement a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) beginning in CY 2027” (90 FR 53714). Elsewhere in that rule we stated that “we anticipate

implementing a larger adjustment (such as 2 percent or other adjustment greater than 0.5 percent) in next year’s rulemaking” (90 FR 53718). We communicated this same message in the Medicare Fact Sheets and Press Releases for the CY 2026 OPPTS/ASC final rule with comment period to ensure that hospitals were aware of the likely increase in the offset percentage in CY 2027.⁷⁷ Because hospitals have been aware that we would likely propose an

increased payment reduction in CY 2027 rulemaking, we do not believe hospitals need additional time to prepare for this repayment schedule.

We seek comment on our proposal to increase the annual percent reduction to 3 percent. We also specifically seek comment on the advisability of increasing the annual percent reduction to 2 percent.

TABLE 48: ILLUSTRATION OF THE PROPOSED 3 PERCENT AND ALTERNATIVE 2 PERCENT CONVERSION FACTOR ANNUAL REDUCTION TO THE OPPTS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2027 TO MAINTAIN BUDGET NEUTRALITY IN THE CY 2027 OPPTS/ASC PROPOSED RULE

	CY 2024	CY 2025	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
Total Applicable OPPTS Non-Drug Item and Service Spending (millions)	Remedy Payments Made in Q1 of CY 2024	No Remedy Offset Applied	67.5	77.0	83.6	90.6	97.7	105.1
			Alternative 2 Percent Payment Reduction					
Amount (millions)			300	1,500	1,700	1,800	2,000	500*
Estimated Total Cumulative Offset (millions)			300	1,800	3,500	5,300	7,300	7,769
			Proposed 3 Percent Payment Reduction					
Amount (millions)			300	2,300	2,500	2,700*		
Estimated Total Cumulative Offset (millions)			300	2,600	5,100	7,769		

* Note, the final year’s offset is estimated to be less than 2 or 3 percent in order to meet the total estimated offset of \$7.769 billion. The amounts illustrated in Table 48 reflect the total amount of reduced spending, which includes both Medicare and Beneficiary cost-sharing. Note, the figures in the table are rounded, which may create some display discrepancies, but all figures are calculated with the final recoupment amount being \$7.769 billion.

7. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

a. Background

In the CY 2000 OPPTS final rule (65 FR 18434), CMS implemented the PPS for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In the CY 2000 OPPTS final rule, we noted that the OPPTS applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We

identified one of these exceptions as “outpatient services provided by hospitals of the Indian Health Service (IHS).” We stated that these services would “continue to be paid under separately established rates which are published annually in the **Federal Register**” and, in the CY 2002 OPPTS/ASC final rule (66 FR 59856), we finalized a revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4), which specifies that hospitals of the IHS are excluded from the OPPTS.

In the intervening years, IHS and tribal facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates.⁷⁸ Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2026, the Medicare Outpatient per visit rate is \$733 for the lower 48 States (hereinafter referred to as “the lower 48 AIR”) and \$1,233 for Alaska.⁷⁹

In the CY 2025 OPPTS/ASC final rule with comment period (89 FR 94280

⁷⁷ <https://www.cms.gov/newsroom/fact-sheets/calendar-year-2026-hospital-outpatient-prospective-payment-system-opps-ambulatory-surgical-center>.

⁷⁸ <https://www.ihs.gov/BusinessOffice/reimbursement-rates/>.

⁷⁹ 91 FR 2787 (January 22, 2026); <https://www.federalregister.gov/documents/2026/01/22/>

[2026-01178/reimbursement-rates-for-calendar-year-2026](https://www.federalregister.gov/documents/2026/01/22/2026-01178/reimbursement-rates-for-calendar-year-2026).

through 94286), we finalized a policy to separately pay IHS and tribal hospitals for high-cost drugs, biologicals, and radiopharmaceuticals (hereinafter referred to as “drugs” for the purpose of this section) furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the AIR is calculated.⁸⁰ We finalized a continuation of this policy, without modification, in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53722 through 53723). We note that the AIR and the add-on payment are paid out of the Part B trust fund and are not subject to OPPS budget neutrality.

We defined high cost drugs (that is, drugs qualifying for the add-on payment) for the purpose of the policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS whose per day cost exceeds two times the lower 48 AIR amount in effect at the time of the release of each year’s OPPS/ASC final rule with comment period. In the CY 2026 OPPS/ASC final rule with comment period, this amount was identified as \$1,436 (2 times the CY 2025 lower 48 AIR of \$718).

To determine the calculated per day cost for each drug HCPCS code, we employed a methodology similar to our longstanding methodology used to calculate the per day cost of drugs for OPPS payment purposes. Specifically, to calculate the per day cost for CY 2026, we used an estimated payment rate based on the ASP methodology payment rate, which for purposes of the policy was generally ASP plus 0 percent (which is the payment rate for separately payable IHS drugs under the policy). We then used the manufacturer-submitted ASP data from the fourth quarter of CY 2024 to determine the per day cost. For drugs that did not have either an ASP-based payment rate or a payment rate based on WAC, we used arithmetic MUC of the items derived from the CY 2024 hospital claims data to determine their per day cost. For HCPCS codes for drugs that were proposed for separate payment in the CY 2026 OPPS/ASC proposed rule with comment period but then had per day costs equal to or less than \$1,436 (2 times \$718) in the CY 2026 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2026 OPPS/ASC final rule with comment period,

those drugs received separate payment in CY 2026.

We finalized that the amount of the add-on payment for a high-cost drug would be the ASP for the drug with no additional payment (that is, ASP plus 0 percent). We note that this add-on payment was implemented on a per-dose basis. In the event ASP pricing information was not available for a particular drug, we paid the WAC plus 0 percent and if WAC pricing information was not available, we paid 89.6 percent of AWP. If AWP was not available, we paid the arithmetic MUC. We also adopted a drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

To implement this policy, we finalized in the CY 2025 OPPS/ASC final rule with comment period a recurring annual process in which the lower 48 AIR in effect at the time of the release of each year’s OPPS/ASC final rule with comment period would be used to create a list of drugs qualifying for the add-on payment for the following calendar year. Once the drugs qualifying for the add-on payment were determined, the payment rate for a unit of the drug would be determined in accordance with the above described pricing hierarchy. The results of that process for CY 2025 were displayed in Addendum Q to the CY 2025 OPPS/ASC final rule with comment period. We additionally finalized that during the calendar year, the list of drugs would be modified on a quarterly basis (January, April, July, October) to add new-to-market drugs with per-day costs that exceeded two times the lower 48 AIR and to update qualifying drugs’ ASPs.

We finalized a continuation of this annual process, without modification, in the CY 2026 OPPS/ASC final rule and the results of that process for CY 2026 were displayed in Addendum Q to the CY 2026 OPPS/ASC final rule. For a full discussion of the AIR add-on payment policy for high cost drugs provided by IHS and tribal hospitals, we refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280 through 94286) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53722 through 53723).

b. AIR Add-On Payment for High-Cost Drugs Provided by IHS and Tribal Facilities Policy for CY 2027

For CY 2027, we propose to continue the policy as described in the CY 2025 and CY 2026 OPPS/ASC final rules.

Consequently, for CY 2027, we propose to continue to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authorities under which the AIR is calculated.

We propose to continue to define high cost drugs (that is, drugs qualifying for the add-on payment) for the purpose of the policy as any drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS which have per day costs exceeding two times the lower 48 AIR amount in effect at the time of the release of the CY 2027 OPPS/ASC final rule with comment period. For CY 2027, we propose that if the CY 2026 lower 48 AIR amount is in effect at the time of the release of the CY 2027 OPPS/ASC final rule with comment period, this amount would be \$1,466 (2 times the CY 2026 lower 48 AIR of \$733).

To determine the calculated per day cost for each drug HCPCS code, we propose to continue using an estimated payment rate based on the ASP methodology payment rate (generally ASP plus 0 percent) and then using the manufacturer-submitted ASP data from the fourth quarter of CY 2025 to determine the per day cost. For drugs that do not have either an ASP-based payment rate or a payment rate based on WAC, we propose to continue to use the arithmetic MUC of the items derived from the CY 2025 hospital claims data to determine their per day cost.

We propose that the amount of the add-on payment for each dose of a high-cost drug would continue to be the ASP for the drug with no additional payment (that is, ASP plus 0 percent). In the event ASP pricing information is not available for a particular drug, we propose to continue to pay the wholesale acquisition cost (WAC) plus 0 percent. If WAC pricing information is not available, we propose to continue to pay 89.6 percent of AWP. If AWP pricing information is not available, we propose to continue to pay the arithmetic MUC. Finally, we propose to continue the drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

c. Proposed List of Drugs Qualifying for the Add-on Payment for CY 2027

Using two times the lower 48 AIR amount of \$733 that is in effect for CY 2026 and applying the above described per-day cost methodology and pricing

⁸⁰ Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

hierarchy, we have included as proposed Addendum Q a preliminary list of the drugs that would qualify for the proposed add-on payment and their proposed add on payment rates for CY 2027.

We propose to create a final Addendum Q in the CY 2027 OPPS/ASC final rule with comment period using the claims data (units used per day) and ASPs, or pricing hierarchy, available at that time. We also propose that for HCPCS codes for drugs that are proposed for separate payment in CY 2027, but then have per day costs equal to or less than \$1,466 (2 times \$733) in the CY 2027 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2027 OPPS/ASC final rule with comment period, those drugs would still receive separate payment in CY 2027.

Finally, as we did in CY 2025 and CY 2026, we propose to modify the list on a quarterly basis (January, April, July, October) to add new-to-market drugs with per-day costs that exceed two times the lower 48 AIR and to update qualifying drugs' ASPs.

8. Medicare OPPS Drugs Acquisition Cost Survey

a. Background

(1) Publication of Notice of Intent To Conduct Medicare OPPS Drugs Acquisition Cost Survey

Section 1833(t)(14)(A)(iii) of the Act requires the Secretary to set payment rates for specified covered outpatient drugs (SCODs)⁸¹ beginning in 2006 at the amount the Secretary determines to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available. To collect the cost survey data for the Secretary to use for 2006 payment rates, section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the U.S. to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD. To inform payment rates in later years, section 1833(t)(14)(D)(ii) of the Act requires the Secretary periodically to conduct surveys of hospital acquisition costs for each SCOD. In developing that survey, section 1833(t)(14)(D)(i)(II) of the Act requires the Secretary to take into account certain recommendations from the Comptroller General regarding frequency and methodology of subsequent surveys.

The GAO conducted the required surveys in 2004 and 2005, and, in

reporting the results in 2006, recommended that the Secretary thereafter validate, “on an occasional basis—possibly every 5 or 10 years—ASP data that manufacturers report to CMS for developing SCOD payment rates”.⁸² As noted in the CY 2026 OPPS/ASC proposed rule (90 FR 33653), in the years following the GAO’s recommendation, CMS had not yet conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, “Lowering Drug Prices by Once Again Putting Americans First.”⁸³ Section 5 of the E.O., “Appropriately Accounting for Acquisition Costs of Drugs in Medicare,” directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the acquisition costs for SCODs at hospital outpatient departments.

Accordingly, in the CY 2026 OPPS/ASC proposed rule (90 FR 33653), we announced that under section 1833(t)(14)(D)(ii) of the Act we would be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs. We indicated that we intended for the survey to open starting at the end of CY 2025 to early CY 2026. We also stated that we had reviewed and taken into account the Comptroller General’s recommendations regarding the frequency and methodology of these surveys in developing our proposed survey, and that we intended for the survey to be completed in time for the survey results to be used to inform policy making beginning with the CY 2027 OPPS/ASC proposed rule. We indicated that we intended to propose and seek comment on any payment rates for SCODs based on the survey results in CY 2027 rulemaking.

In the CY 2026 OPPS/ASC final rule (90 FR 53754 through 53766 and 54049 through 54052), after responding to public comments, including those received through the proposed survey Paperwork Reduction Act (PRA) submission process, we finalized our proposal outlining our intent to conduct a required outpatient drug acquisition cost survey to all hospitals paid under the OPPS, pending final approval from OMB. OMB approval was granted on December 29, 2025 (OMB control

number 0938–1487, expires August 31, 2028).⁸⁴

(2) OPPS Drug Acquisition Cost Survey Design and Implementation

(a) Study Population

We identified approximately 4,500 entities for inclusion in the survey study population due to their submission of at least one qualifying Fee-For-Service claim under the OPPS during the survey study period (July 1, 2024 through June 30, 2025). Qualifying claims met all defined criteria: (1) claim date of service (July 1, 2024 and June 30, 2025), (2) claim type (Part B outpatient), (3) facility type code (12 [hospital inpatient/home health], 13 [hospital outpatient], 14 [hospital other], and 76 [community mental health center]), (4) payment amount (greater than zero), and (5) status indicator denoting separately payable drugs or other relevant Part B outpatient services with status indicators (G, H, J1, J2, K, Q1, Q2, Q3, Q4, R, S, T, U, OR V). We removed all claims billed by hospital types that are not paid under the OPPS.⁸⁵ Finally, we ensured that each entity had valid Medicare enrollment during the survey study period using the Provider Enrollment, Chain, and Ownership System (PECOS). There was no sampling as all OPPS hospitals were invited to participate in the survey and provide the required data.

As described in the PRA approved by OMB, we expect to survey these hospitals every four (4) years. We believe that this frequency will appropriately balance the burden imposed on hospitals of completing the survey with ensuring that we capture the required data to inform payment rates as required under section 1833(t)(14)(D)(i)(ii) of the Act. However, this frequency is an intention and could be revised.

(b) Survey Scope and Design

The guiding principle in the design of the survey was to collect the data necessary to inform payment policy as required by statute in a manner that imposed the least amount of burden to the extent practicable on the hospitals providing the data. The survey collected acquisition cost data for separately

⁸⁴ https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202511-0938-014 and https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202512-0938-024.

⁸⁵ As stated in 42 CFR 419.20(b), the following hospital types are not paid under the OPPS: critical access hospitals; Maryland waiver hospitals; hospitals located outside the 50 states, the District of Columbia, and Puerto Rico; Indian Health Service hospitals; and rural emergency hospitals. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20>.

⁸¹ For the definition of a SCOD, see section 1833(t)(14)(B) of the Act at <https://www.ssa.gov/OP-Home/ssact/title18/1833.htm>.

⁸² <https://www.gao.gov/assets/gao-06-372.pdf>.

⁸³ <https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf>.

payable outpatient drugs at the 11-digit National Drug Code (NDC) level for 1,843 NDCs, which correspond to 519 drug HCPCS.⁸⁶ We note that more than one NDC may be associated with a given HCPCS code and vice versa. These NDCs were identified by analyzing the drugs and biologicals that were separately payable under the OPSS during the survey period of July 1, 2024 through June 30, 2025 and for which there was a payment made under the OPSS during that period. We excluded NDCs with either an expiration date or a marketing end date prior to July 1, 2024, using FDA national drug code and structured product labeling data elements (NSDE) data⁸⁷ because these drugs would no longer be available for purchase during the study survey period.⁸⁸

(c) Acquisition Date Reporting and Data Elements

The survey captured acquisition data for drugs purchased between July 1, 2024 and June 30, 2025. This 12-month time period aligns with GAO's 12-month survey period for their original study of July 1, 2003 through June 30, 2004. This time period also provided a 6-month window between the end of the survey period and the start of the survey submission window to ensure adequate time for all rebates, discounts, and price concessions to be finalized, so they could be incorporated into the NDC acquisition cost submitted by hospitals.

The survey instructed hospitals to report 4 pieces of data for each NDC purchased during the 1-year survey period:

- Total Units Purchased—Non-340B
- Total Net Acquisition Cost—Non-340B
- Total Units Purchased—340B
- Total Net Acquisition Cost—340B

Net acquisition cost was defined as the total amount paid by the hospital inclusive of all discounts, rebates, and price concessions applicable at the NDC level.

This design reflected our recognition that certain discounts may apply depending on which provider furnished the drug and whether an eligible patient received the drug (for example, for drugs acquired through the 340B

Program). Consequently, the survey asked hospitals to separately list their acquisition costs for drug NDCs acquired through the 340B Program and drug NDCs acquired outside of the 340B Program to ensure that all discounts were accurately captured and represented the hospital's acquisition costs.

(d) Treatment of Discounts and Price Concessions

The survey asked hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC. This included both discounts able to be directly applied to each individual NDC and those discounts that were not necessarily linked to a single NDC (e.g., invoice-level discounts, wholesaler rebates, prompt pay discounts, and other financial concessions, or other discounts). Respondents were also asked to separately provide information about any non-NDC-specific discounts or rebates received as a result of membership in a Group Purchasing Organization (GPO) or other buying group.

(e) Data Collection Process

Data were collected through the CMS Fee-for-Service Data Collection System (FFSDCS) via the Medicare OPSS Drug Acquisition Cost Survey (hereinafter referred to as "ODACS") module. Hospitals first designated a Hospital Point of Contact (POC) and a Submitter responsible for data submission. Submitters then submitted data through (1) uploading of a standardized Excel (.xlsx) file; or (2) manual data entry through the FFSDCS via the ODACS module. Once the Submitter uploaded or entered the required data, they then officially submitted that data to CMS and attested to the validity, integrity, and completeness of the data being submitted.

(f) Data Validation and Quality Assurance

The FFSDCS ODACS module included automated validation checks to promote completeness, formatting accuracy, and logical consistency. For uploaded data, errors and missing information were flagged on the module upload page, accompanied by error explanations. For manually entered data, the module provided hover-over tips for data entry fields and was programmed to accept data only in specific formats. The system alerted users if data was formatted incorrectly. Submitters were able to correct and reupload data during the collection window prior to final attestation.

(g) Survey Window

The ODACS module opened on January 1, 2026 and closed on April 7, 2026. The original survey window was January 1, 2026 through March 31, 2026; however, after the survey window opened we extended the window for an additional week, through April 7, 2026, based on hospitals' request for additional time to respond. We believe that approximately 14 weeks was sufficient for hospitals to respond to the survey, particularly given the outreach and education that CMS engaged in prior to and during the survey window.

(h) Outreach and Education

We engaged in extensive outreach and education to hospitals in advance of the survey start date to ensure that respondents were aware of the survey and how to complete it. CMS began reaching out to hospitals using provider enrollment and other publicly available contact information in September 2025. Specifically, CMS identified a hospital POC from each hospital paid under the OPSS and reached out to them to make them aware of the survey and provide them with instructions on selecting a hospital representative (Submitter) to register with the CMS Identity Management System (IDM) to access the survey module and report the survey data. To walk respondents through this process, a step-by-step registration guide was issued by CMS in November 2025 and a data submission guide was provided on January 1, 2026.⁸⁹ These guides were posted to a new ODACS-specific web page⁹⁰ that was created by CMS to serve as a central hub for information and resources for hospitals. CMS also conducted two educational webinars⁹¹ with hospitals in December 2025, which were recorded and posted to the ODACS web page. To ensure that respondents had the support they needed during the survey, CMS established a dedicated email address and helpline to provide technical assistance. To address frequently asked questions, CMS posted a FAQ document⁹² to the ODACS web page and updated it during the survey to reflect additional questions asked by respondents via email and the helpline as the survey progressed. Finally, prior to and throughout the survey period,

⁸⁶ ODACS Acquisition Data Template: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-ops-drug-acquisition-cost-survey>.

⁸⁷ <https://www.fda.gov/industry/structured-product-labeling-resources/nsde>.

⁸⁸ The expiration date is the expiration date of the last lot distributed. The marketing end date signifies that the drug is no longer actively manufactured or promoted, or the company has officially decided to stop commercializing it.

⁸⁹ www.cms.gov/files/document/submitter-user-guide.pdf.

⁹⁰ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-ops-drug-acquisition-cost-survey>.

⁹¹ <https://www.cms.gov/files/document/odacs-training-webinar.pdf>.

⁹² <https://www.cms.gov/files/document/odacs-faq.pdf>.

CMS sent periodic communications to POCs to remind them of upcoming deadlines and resources available for assistance.

b. Data Analysis and Methodology

(1) Selection of a Methodology To Calculate Acquisition Cost Margins

In accordance with section 1833(t)(14)(D)(ii) of the Act, we took into account GAO's recommendations and analyzed the survey data to validate whether the manufacturers' reported drug ASP data appropriately and accurately reflects hospitals' drug acquisition costs. To do so, we compared hospitals' survey-reported acquisition costs for all survey-eligible drugs to the equivalent ASP-based Medicare payment amount for those drugs under the OPPTS, less any drug-specific payment rate add-ons. This comparison was constructed as a percent difference between these two values, termed the acquisition cost margin.

We calculated this acquisition cost margin by first finding the difference between (1) the total acquisition costs reported for all NDCs in the survey and (2) the volume-weighted sum of their corresponding ASP payment rates, the latter of which was calculated by multiplying the survey reported units purchased for each NDC by its applicable ASP plus 0 rate.⁹³ We then divided that difference by the total ASP-based payment to find the percent margin between acquisition costs and ASP. Negative values indicate that hospitals reported acquisition costs below ASP and positive values indicate that hospitals reported acquisition costs above ASP.

We used the volume-weighted sum of all survey-eligible NDCs' ASP payment rates in order to produce a representative estimate of aggregate Medicare payments that would be comparable to hospitals' aggregate acquisition costs reported for those NDCs. This approach is consistent with longstanding OPPTS principles of basing payment policy on observed utilization and resource use. We believe it is appropriate to compare hospitals' total acquisition costs to this weighted sum of ASPs rather than compare average acquisition costs to ASP because total acquisition costs encompass both the reported per-unit cost and the reported purchase volume for each NDC. In the absence of weighting by reported per-

unit cost, drugs that encompass a very low percentage of hospitals' total acquisition costs could exert a disproportionate influence on the aggregate margin between acquisition costs and ASPs. And in the absence of weighting by reported purchase volume, the ASPs for drugs with relatively low reported volume but atypical acquisition costs could exert a disproportionate influence on the aggregate margin. By contrast, the volume-weighted approach ensures that the ASPs for the drugs representing a larger share of total purchasing activity contribute more significantly to the estimated margin. We will illustrate using the following fictitious example:

- Ten units of NDC 1 were purchased for \$8 (average acquisition cost of \$0.80 per unit) and NDC 1 has an adjusted ASP⁹⁴ of \$1. The volume-weighted ASP is \$10. NDC 1 was reported as purchased with a margin of minus 20 percent, or 20 percent below ASP.

- One unit of NDC 2 was purchased for \$14 (average acquisition cost of \$14 per unit) and NDC 2 has an adjusted ASP of \$10. The volume-weighted ASP is \$10. NDC 2 was reported as purchased at a margin of plus 40 percent, or 40 percent above ASP.

Aggregating the two above NDCs, the total acquisition cost is \$22 (\$8 + \$14) and the volume-weighted sum of ASPs is \$20 (\$10 + \$10). Calculating the percent difference yields a plus 10 percent margin, calculated as $100 * ((\$22 - \$20) / \$20)$. However, if no volume weighting methodology was applied, the sum of ASPs would be \$11, and calculating the percent difference would yield a plus 100 percent margin, calculated as $100 * ((\$22 - \$11) / \$11)$.

We also considered weighting ASP payment rates for survey-eligible drugs by outpatient claims volume for survey-relevant HCPCS codes. We recognize the value of using OPPTS claims data as it directly reflects real-world utilization. However, we did not adopt this approach because we believe it is appropriate to rely on a consistent survey-based framework for both acquisition costs and volume measures. We believe that weighting by survey-reported purchase volume avoids potential inconsistencies between external claims data and survey responses, ensures that the resulting margins are fully grounded in the reported acquisition cost data, better reflects the distribution of hospital drug purchasing activity as captured via the

survey instrument, and is consistent with the statutory objective of approximating average acquisition cost in a manner that is both representative and methodologically sound. However, we seek comment on this approach to volume weight the average acquisition cost based on survey utilization data rather than OPPTS claims data utilization.

We performed this acquisition cost margin calculation separately for non-340B and 340B drug purchases to analyze the data in the same manner in which it was collected. We then calculated acquisition cost margins using different ASP benchmarks, at different levels of data aggregation, and across a variety of scenarios to detect specific trends and variations in the submitted data. First, given that a drug's ASP can vary by quarter, we calculated each margin using both the mean ASP and median ASP across the four quarters of the specified time period (Q3 of 2024 to Q2 of 2025). Determining acquisition costs relative to both the median and mean ASP ensured that we properly accounted for any fluctuations in payment rate over time while mitigating the influence of any quarters with abnormal payment rates and allowed us to assess any differences in the margins that resulted from the two ASP benchmarks. Second, we calculated margins at the NDC level as well as aggregated to the HCPCS level; in the latter, acquisition costs were adjusted to the HCPCS level using the billing units per NDC package. Third, we calculated margins stratified by drug therapeutic class and hospital characteristics (340B participation status, ODACS drug purchase volume, outpatient drug claims billing volume, hospital size, rurality, geographic location, GPO membership, GPO discount amount, and teaching status). These various analytic scenarios were all undertaken to determine the differential between reported acquisition costs and ASP along relevant stratifications and characteristics as well as validate the robustness of the findings used in this proposal.

(2) Selection of a Methodology To Identify and Trim Outliers

In analyzing the survey data, it is appropriate to mitigate the influence of extreme and potentially anomalous observations that may reflect atypical purchasing arrangements, data anomalies, or reporting inconsistencies and could distort estimates of hospital drug acquisition costs. Consistent with standard statistical practice and our general approach under the OPPTS to ensure that payment methodologies are

⁹³ ASP plus 0 is the ASP without any drug-specific payment rate add-ons (ASP plus 6 percent for most drugs and biologicals, ASP plus 8 percent for qualifying biosimilar products, or AMP plus 3 percent for select other drugs and biologicals).

⁹⁴ Since ASPs are reported by HCPCS billing unit, ASPs were adjusted to the NDC package units where necessary using an NDC-HCPCS adjustment factor.

based on representative data, we considered two different methods for identifying and excluding anomalous survey responses from the dataset. In both methods, the outlier identification and trimming process was performed separately for 340B and non-340B drug acquisitions, producing tailored outlier thresholds based on the unique data distribution for each drug through each purchasing channel.

First, we considered a trimming approach that excludes all observations with a per-unit acquisition cost more than three standard deviations from the geometric mean per-unit cost for each NDC. This approach is consistent with our standard methodology for processing extreme outliers to develop policy under the OPPS.⁹⁵ Application of the geometric mean trimming methodology necessitated removal of NDCs for which fewer than 10 survey respondents reported their purchase because outlier values cannot be detected with nine or fewer observations using this method.

We also considered the Tukey interquartile range (IQR) method⁹⁶ as an alternate outlier trimming approach and tested the impact of excluding outliers using the geometric mean approach compared to the IQR-based approach. Using the geometric mean approach to trim outliers removed 2,051 survey records (defined as the unique combination of hospital, NDC, and 340B or non-340B purchase from each survey response), or 1.3 percent of the total 160,430 original records while using the IQR approach to trim outliers removed 15,563 records, or 9.7 percent of the total 160,430 records. Upon manual review of the survey responses that were trimmed using each outlier approach and the data distribution for each NDC, we believe that the IQR approach erroneously identified some records as outliers despite their per-unit acquisition cost being generally in-line with the overall data distribution for that NDC. This is likely due to the

distributional characteristics of the survey data, including evidence of skew in the distribution of reported acquisition costs for some NDCs. It has been established that the effectiveness of Tukey's IQR lessens when data are skewed and may lead to overidentification of observations as outliers.^{97 98 99} In addition, we are concerned about the large number of survey records removed by the IQR trimming methodology, as one of our goals in conducting this survey is to analyze survey-reported drug acquisition costs using the largest amount of reasonable data received from hospitals as possible. Consequently, we do not propose to adopt the IQR-based outlier trimming methodology.

Rather, we propose to use the geometric mean approach to exclude identified outlier observations from the analyses used to estimate acquisition cost relationships. Specifically, we propose to trim records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC. We propose this approach to maintain consistency with the standard OPPS outlier trimming methodology. It also ensures that we retain the maximum number of responses with nonextreme values to estimate acquisition cost relationships from the survey data. By ensuring that the resulting estimates are based on data that are representative of typical hospital acquisition costs and are not unduly influenced by a small number of extreme observations, this approach is consistent with our longstanding objective of analyzing reliable and representative data to determine payment policy changes. We seek comment on our proposal to trim records with per-unit acquisition costs more than three standard deviations from either the 340B or non-340B geometric mean per-unit acquisition cost for that NDC.

(3) Application of Data Refinements To Remove Anomalous Data

Consistent with our general approach to ensuring that payment methodologies

are based on reliable and internally consistent data, we reviewed the survey responses for values that are not plausible given statutory requirements that covered entities cannot be required to pay more than the 340B ceiling price for drugs acquired under the 340B Program or that exhibit clear inconsistencies in reporting. We identified five scenarios in which reported data displayed anomalous values, which appear to be the result of data entry error, miscalculation, or other respondent confusion. Below we detail each identified scenario and the number of survey records that fall into each. We propose to exclude these survey responses from the analyses used to assess acquisition cost relationships to ensure that these calculations are not unduly influenced by implausible values.

First, we identified instances in which respondents that were not participating in the 340B Program during the relevant study time period (as verified using the 340B Office of Pharmacy Affairs Information System (340B OPAIS)) reported acquisition cost data in the 340B fields of the survey. These observations likely reflected reporting errors, given that these hospitals could not have accessed 340B discounts. Therefore, we propose to exclude 340B acquisition cost data submitted by non-340B hospitals from analyses of 340B acquisition cost to maintain consistency with the survey design and statutory framework. This proposed refinement removes 850 records out of the 160,430 records received through the survey.

Second, we identified instances in which respondents reported purchasing drugs through the 340B Program for 58 NDCs that did not have a 340B ceiling price during the survey time period. These observations may reflect reporting errors, such as reporting acquisition data for the incorrect NDC within a drug that was intended, given that no 340B agreement, or associated discount, was available for these NDCs. In some cases, where these NDCs had 340B ceiling prices during other quarters outside the survey time period, these observations may be the result of respondent confusion over survey reporting period or the time period when these NDCs had a 340B ceiling price in place. Alternatively, hospitals may have acquired non-340B NDCs through the 340B Prime Vendor Platform (PVP) without receiving a 340B discount price;¹⁰⁰ while hospitals may have

⁹⁵ <https://www.cms.gov/files/document/2026-nfrm-ops-claims-accounting.pdf>.

⁹⁶ Under this approach, for each NDC, we would calculate the first quartile (Q1) and third quartile (Q3) of per-unit acquisition cost based on the empirical distribution of hospitals' reported average acquisition cost values, and define the IQR as Q3 minus Q1. We would then establish outlier thresholds as follows: (1) an upper threshold equal to Q3 plus 1.5 times the IQR; and (2) a lower threshold equal to Q1 minus 1.5 times the IQR. Observations with per-unit acquisition costs that fall outside these thresholds are identified as outliers. Application of the IQR-based trimming methodology would necessitate removal of NDCs for which fewer than four survey respondents reported their purchase because outlier values cannot be detected with three or fewer observations using the Tukey IQR method.

⁹⁷ M. Hubert and E. Vandervieren, "An adjusted boxplot for skewed distributions," *Computational Statistics & Data Analysis* 52, no. 12 (August 15, 2008): 5186–5201, <https://doi.org/10.1016/j.csda.2007.11.008>.

⁹⁸ Neil C. Schwertman, Margaret Ann Owens, and Robiah Adnan, "A simple more general boxplot method for identifying outliers," *Computational Statistics & Data Analysis* 47, no. 1 (August 1, 2004): 165–174, <https://doi.org/10.1016/j.csda.2003.10.012>.

⁹⁹ Arefeh Mazarei et al., "Online boxplot derived outlier detection," *International Journal of Data Science and Analytics* 19 (2025): 83–97, <https://doi.org/10.1007/s41060-024-00559-0>.

¹⁰⁰ The 340B PVP website states that "The [PVP] . . . works with 155 manufacturers to obtain lower

considered these purchases to be 340B acquisitions for the purposes of their survey reporting, evaluating these responses as part of 340B margin calculations would provide an inaccurate picture of the acquisition costs for NDCs with 340B discounts. We also did not elect to evaluate these responses as part of non-340B margin calculations as it was impossible to separate instances of reporting errors from non-340B purchases made through the 340B PVP. Therefore, we propose to exclude 340B survey responses for these NDCs without 340B ceiling prices from analyses of both 340B and non-340B acquisition cost to maintain consistency with the survey design and statutory framework. This proposed refinement removes 839 records out of the 160,430 records received through the survey.

Third, we identified a small number of responses from hospital subunits that submitted identical data to their parent unit. Hospital subunits were identified as entities where the third digit of its CMS Certification Number (CCN) is T (representing inpatient rehabilitation units) or S (representing psychiatric units). Parent units were identified as entities where all six digits of its CCN are numeric.¹⁰¹ To identify a parent unit for each subunit, the T or S in the third digit was replaced with the numeric digit associated with the provider type of that subunit (either 0, 2, 3, or 4). If this replacement yielded more than one possible parent unit, the subunit was further matched with a parent unit based on CCN name and ZIP code. Identical parent-subunit data were identified as survey responses with the exact same number of total units and total net acquisition costs reported for the exact same NDCs. These observations likely reflect duplicative data reported by one submitter who was responsible for multiple entities. Accordingly, we propose to exclude these duplicative responses from subunits in favor of only retaining the equivalent responses from the parent unit. We identified 27 subunits with duplicative data to their parent unit,

and this proposed refinement removes 4,799 records out of the 160,430 records received through the survey.

Fourth, we identified instances in which reported acquisition costs for drugs purchased under the 340B Program exceeded the maximum applicable 340B ceiling price during the survey time period. By statute, covered entities cannot be required to pay more than the 340B ceiling price for drugs acquired under the 340B Program. Such observations are not representative of actual acquisition costs and are likely attributable to reporting or data entry errors (for example, miscalculations or incorrect decimal placement). Accordingly, we propose to exclude 340B drug purchases with average acquisition costs above the maximum ceiling price from our analysis. This proposed refinement removes 4,667 records out of the 160,430 records received through the survey.

Fifth, we observed that certain respondents reported units for specific drugs, including clotting factors and certain respiratory therapies, in international units (IU) or milligrams (MG) rather than the required NDC-based units. IU is the HCPCS billing unit for the clotting factors and MG is the HCPCS billing unit for the respiratory therapies;¹⁰² however, because the survey requires reporting at the NDC level, the use of IU- or MG-based units would result in substantial distortions in calculated per-unit acquisition costs, typically producing extremely high reported unit volumes and correspondingly low per-unit costs. These observations are not comparable to properly reported NDC-level data. To avoid possible selection bias that may result from specifically excluding responses with units reported in IU or MG, we therefore propose to exclude all survey responses for affected NDCs with units reported in IU or MG from the analysis. This proposed refinement removes 4,398 records out of the 160,430 records received through the survey. We note, if CMS would have included this data, the acquisition cost margins would have been significantly lower than Medicare payment rates.

The exclusion of these anomalous observations, in conjunction with the application of the outlier trimming methodology and other data standardization approaches described above, improves the reliability and validity of the resulting estimates of acquisition costs. In particular, it

ensures that the resulting estimates reflect plausible and internally consistent acquisition costs while minimizing the influence of erroneous or noncomparable data. Moreover, applying these five proposed data refinement exclusions did not have a substantial impact on the overall number of survey records included in analyses of acquisition cost. Collectively, these five refinements removed 14,313 records out of the 160,430 records received through the survey. In other words, after applying these five exclusions, there remained 146,117 survey records in the dataset, 91.1 percent of the total 160,430 original records we received from respondents. We note that there are some overlaps in each individual exclusion of survey records, where the same survey record was excluded for meeting more than one exclusion criterion.

For each of the five scenarios discussed above, we propose to exclude survey responses for values that are not plausible given statutory requirements or that exhibit clear inconsistencies in reporting. Specifically, we propose to exclude survey responses that were identified as meeting at least one of the five scenarios listed above based on our manual review of the data, ASP pricing files, Health Resources and Services Administration (HRSA) 340B ceiling pricing files, and relevant policy and billing guidance. We believe that this approach represents the most appropriate and methodologically sound means of estimating the typical margin in the survey data between hospitals' survey-reported acquisition costs and ASP. We solicit comment on our approach to identifying and excluding anomalous data, as well as on the overall methodology used to evaluate the survey data for purposes of this proposal.

c. OPDS Drug Acquisition Cost Survey Results

(1) Survey Response Rate and Respondent Characteristics

We first determined the response rate and hospital characteristics of survey respondents to understand which entities had submitted a survey response, then compared them to the characteristics of nonrespondents and the survey-eligible population to assess their representativeness relative to the overall population. We also applied a methodology to refine the population of survey-eligible hospitals to more precisely reflect those entities with meaningful outpatient acquisition volume for drugs included in the survey.

drug pricing for [340B covered entities] on non-340B items, such as vaccines"

¹⁰¹ Hospital type for each parent unit was identified based on the final four digits of its CCN. Short-term (general and specialty) hospitals were identified as those in the range 0001–0899; long-term care hospitals were identified as those in the range 2000–2299; rehabilitation hospitals were identified as those in the range 3025–3099; children's hospitals were identified as those in the range 3300–3399; psychiatric hospitals were identified as those in the range 4000–4499; and IPPS-exempt freestanding cancer hospitals were identified as CCNs listed on the CMS website <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/pps-exempt-cancer-hospitals-pchs>.

¹⁰² <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/ASP-Report-in-units-other-than-NDC.pdf>.

Approximately 43.6 percent of the 4,494 entities eligible for OPPS payment (hereinafter referred to as “survey-eligible hospitals”) submitted a survey response and approximately 29.8 percent of eligible hospitals reported that they had acquisition costs during

the survey time period. We received a number of responses, many of which appeared to be coordinated form letters, from eligible hospitals indicating that they would not be providing their acquisition data and explaining their reasons for not doing so. Before refining

the population, approximately 34.9 percent of non-340B hospitals and approximately 23.1 percent of 340B hospitals responded to the survey and reported that they had acquisition costs for survey-eligible drugs during the surveyed time period (Table 49).

TABLE 49: DESCRIPTIVE SURVEY RESPONDENT STATISTICS

Category			Total Hospitals
	Non-340B Hospitals	340B Hospitals	
Number of Survey-Eligible Hospitals	2537	1957	4494
Number of Overall Respondents	1421	537	1958
Percent of Overall Respondents	56.0%	27.4%	43.6%
Number of Respondents Reported Data	885	453	1338
Percent of Respondents Reported Data	34.9%	23.1%	29.8%

However, claims analysis of the eligible hospital population determined that a subset of entities that were included in the survey had zero outpatient claims for survey-relevant HCPCS codes during the survey study period. Many of these entities did not submit a survey response, likely because they did not acquire any survey-relevant drugs during the time period. Other entities were hospital subunits that did not submit a survey response or submitted a response reporting zero acquisition costs, but their parent unit submitted a survey response reporting acquisition data.

Consequently, we applied population refinements to consolidate subunits with their parent units and to remove entities from the survey that neither reported acquisition costs nor had outpatient billing volume for HCPCS codes corresponding to NDCs included in the survey during the specified time

period. These refinements resulted in a slightly smaller population that may more appropriately reflect the universe of eligible hospitals with meaningful and relevant outpatient drug acquisition volume. This population is almost exclusively composed of short-term acute care hospitals: 2,977 out of 3,147 total CCNs (94.6 percent) in the refined population are short-term acute care hospitals as compared to 3,018 out of 4,494 total CCNs (67.2 percent) in the original population. This change occurred for two reasons. First, by consolidating subunits with their parent unit, all subunits (that is, psychiatric units and inpatient rehabilitation units), which had accounted for 742 (16.5 percent) in the original population no longer appear in the population as distinct hospitals. Second, this refinement also markedly reduced the number of psychiatric hospitals, long-term care hospitals, and rehabilitation

hospitals in the refined population because the majority of these hospitals neither reported acquisition costs nor billed any relevant outpatient claims.

Of this refined study population, approximately 41.4 percent of hospitals responded to the survey and reported that they had acquisition costs during the surveyed study period. Additionally, approximately 53.3 percent of non-340B hospitals and approximately 28.6 percent of 340B hospitals in the refined population responded to the survey and reported that they had acquisition costs during the surveyed study period (Table 50). For discussion of analyses that we undertook to confirm that this response rate is sufficiently large to yield a statistically valid sample, we refer readers to the calculation of confidence intervals in section (3) Population Weight Adjustment and Statistical Validity.

TABLE 50: DESCRIPTIVE SURVEY RESPONDENT STATISTICS (REFINED POPULATION)

Category	Non-340B Hospitals	340B Hospitals	Total Hospitals
Refined Number of Survey-Eligible Hospitals Number	1639	1508	3147
Refined Number of Respondents Reported Data	873	431	1304
Refined Percent of Respondents Reported Data	53.3%	28.6%	41.4%

Using the refined population, we then compared observable hospital characteristics of survey respondents that reported acquisition costs to the characteristics of the survey-eligible population (Table 51). Compared to the overall survey-eligible population, hospitals that responded to the survey and reported acquisition cost data were

slightly more likely to have lower claims billing volume, be smaller, be located in a rural area, and not be major teaching hospitals.

Given these slight differences in hospital characteristics between respondents and the overall population, we performed inverse probability weighting (IPW) to confirm that

respondents' data yielded statistically representative estimates of hospital outpatient drug acquisition costs. We refer readers to the discussion of IPW-adjusted margins in section (3) Population Weight Adjustment and Statistical Validity.

BILLING CODE 4169-69-P

**TABLE 51: COMPARISON OF HOSPITAL RESPONDENTS VS NONRESPONDENTS
(REFINED POPULATION)**

Hospital Characteristic	All Survey-Eligible Hospitals		Respondents Reporting Acquisition Cost Data		Nonrespondents	
	Number	Percentage	Number	Percentage	Number	Percentage
<i>All Hospitals</i>	3,147	100.0%	1,304	100.0%	1,804	100.0%
<i>Outpatient Drug Claims Volume</i>						
Bottom Quintile	591	18.8%	287	22.0%	287	15.9%
Second Quintile	622	19.8%	327	25.1%	284	15.7%
Third Quintile	626	19.9%	256	19.6%	364	20.2%
Fourth Quintile	627	19.9%	221	16.9%	403	22.3%
Top Quintile	628	20.0%	160	12.3%	466	25.8%
No Billing	53	1.7%	53	4.1%	0	0.0%
<i>Hospital Size (Number of Beds)</i>						
Bottom Quintile	502	16.0%	263	20.2%	230	12.7%
Second Quintile	542	17.2%	236	18.1%	293	16.2%
Third Quintile	647	20.6%	267	20.5%	373	20.7%
Fourth Quintile	715	22.7%	284	21.8%	424	23.5%
Top Quintile	741	23.5%	254	19.5%	484	26.8%
<i>Geographic Rurality</i>						
Metropolitan	2,320	73.7%	937	71.9%	1,356	75.2%
Micropolitan	544	17.3%	224	17.2%	315	17.5%
Rural	283	9.0%	143	11.0%	133	7.4%
<i>Census Region</i>						
New England	136	4.3%	33	2.5%	101	5.6%
Middle Atlantic	346	11.0%	129	9.9%	212	11.8%
South Atlantic	518	16.5%	219	16.8%	295	16.4%
East North Central	484	15.4%	166	12.7%	314	17.4%
East South Central	266	8.5%	129	9.9%	128	7.1%
West North Central	237	7.5%	87	6.7%	148	8.2%
West South Central	504	16.0%	295	22.6%	199	11.0%
Mountain	226	7.2%	100	7.7%	124	6.9%
Pacific	388	12.3%	125	9.6%	263	14.6%
Puerto Rico	42	1.3%	21	1.6%	20	1.1%
<i>Teaching Status</i>						
Major Teaching	400	12.7%	134	10.3%	265	14.7%
Not Major Teaching	2,657	84.4%	1,128	86.5%	1,495	82.9%
Unknown	90	2.9%	42	3.2%	44	2.4%

Note: The number of hospitals shown in the "Respondents Reporting Acquisition Cost Data" and "Nonrespondents" columns does not sum to the total number of hospitals in the "All Survey-Eligible Hospitals" column because 39 survey respondents that reported no drug acquisitions during the survey period are excluded from this table. Of these hospitals, 28 (71.8 percent) were non-340B hospitals and 11 (28.2 percent) were 340B hospitals. The 39 survey respondents that reported no drug acquisitions during the survey period are excluded from Table 51. These hospitals generally had low outpatient drug billing volume, tended to be smaller facilities, and were predominantly located in metropolitan areas. The hospitals were geographically distributed across Census regions, and only one hospital was classified as a major teaching hospital.

BILLING CODE 4169–69–C

(2) Margins Between Survey-Reported Hospital Acquisition Costs and Volume-Weighted ASP

Using the methodology, refinements, and processes discussed throughout Section (2)(b) Data Analysis and Methodology, we evaluated the received survey data to determine the difference between hospitals' survey-reported acquisition costs and ASP-based Medicare payment amounts. We first identified the percent margin between aggregate acquisition costs and volume-weighted ASP for both non-340B and 340B drug acquisitions, then performed an analogous calculation to identify the margin between 340B ceiling prices and ASP as additional context for the 340B acquisition cost margins. Next, we tested alternate methodological specifications to evaluate whether these margins varied depending on the methods used. Finally, we stratified margins by individual therapeutic classes to identify possible variation in acquisition costs relative to ASP along drug type.

The survey provides valuable information regarding hospitals' drug acquisition costs. Following the GAO recommendation to validate Medicare payment rates using hospital acquisition costs, we assessed the survey data for trends where acquisition cost did not align with Medicare payment. The most immediately evident difference was between Medicare payment rates and acquisition cost data for 340B-acquired drugs by 340B-participating hospitals. Based on the survey response data and applying the methodologies discussed

above, we found that for drugs acquired through the 340B Program, hospitals' reported acquisition costs during the specified time period were approximately 33.4 percent below both the mean and the median ASP. For drugs acquired outside of the 340B Program, hospitals' survey-reported acquisition costs during the specified time period were approximately 2.7 percent above the mean ASP and 2.8 percent above the median ASP.

To help validate these findings, we compared aggregate 340B ceiling prices from HRSA for drugs included in the survey during the corresponding survey period to ASP amounts.¹⁰³ Based on this analysis, during the survey study period 340B ceiling prices were, in aggregate, 28.0 percent below the mean ASP and 29.2 percent below the median ASP, respectively. These findings help validate the survey response data for 340B acquired drugs, as the ceiling price average discount is generally representative of the maximum acquisition cost and minimum discount, though hospitals can negotiate additional discounts resulting in a sub-ceiling acquisition cost. This is reflected in the survey results where the aggregate 340B acquisition cost margin is approximately 33.4 percent below the mean ASP—several percentage points lower than the aggregate ceiling price margin of 28.0 percent below the mean ASP.

We sought to ensure that the resulting margins precisely reflected the relationship between hospitals' acquisition costs and ASP, and did not manifest substantial changes under

different methodological specifications. To do so, we tested the impact of weighting acquisition cost margins by OPPS claims volume and retaining 340B survey responses above the maximum ceiling price (Table 52). Although we are not proposing to adopt these alternative methodologies at this time for the reasons outlined in the methodology section, calculating acquisition cost margins with these specifications emphasizes two key points about 340B-acquired drugs. First, regardless of how one analyzes the data, there are considerable differences between hospitals' acquisition costs for 340B-acquired drugs and ASP-based payment amounts for 340B drugs. Second, these alternate methodologies had minimal impact on the acquisition cost margins for 340B-acquired drugs; regardless of calculation methodology, hospitals' survey-reported acquisition costs remained relatively consistent between approximately 29.9 percent and 33.4 percent below the average ASP and between 29.8 percent and 33.4 percent below the median ASP.

Application of different methodological specifications resulted in slightly more variation in the estimated margin between hospitals' survey-reported acquisition costs and mean or median ASP-based payments for drugs acquired outside the 340B Program. This greater variability could be attributed to wider distributional spread in the reported acquisition costs for non-340B drugs; this, in turn, could cause the non-340B margins to be more sensitive to application of different weighting methodologies.

TABLE 52: ODACS STATISTICAL DATA METHODOLOGIES AND RESULTS

Aggregate Margin Calculations: Methodology Specifications			Acquisition Cost to ASP Margin			
			Non-340B		340B	
			Mean ASP Margin	Median ASP Margin	Mean ASP Margin	Median ASP Margin
Geometric Mean Outliers Removed	Weighted by Survey Purchase Volume	Responses > Ceiling Price Included	2.7%	2.8%	–31.9%	–31.8%
		Responses > Ceiling Price Excluded			–33.4%	–33.4%
	Weighted by Outpatient Claims Volume	Responses > Ceiling Price Included	6.7%	6.7%	–29.9%	–29.8%
		Responses > Ceiling Price Excluded			–31.2%	–31.1%

¹⁰³ The 340B ceiling prices are the maximum statutory amounts drug manufacturers can charge covered entities for outpatient prescription drugs.

They are calculated by subtracting the unit rebate amount (URA) which is the Medicaid rebate manufacturers must pay to the government from the

average manufacture price (AMP) which is the average price paid to the manufacturer by wholesalers for a given drug.

To assess whether the magnitude of margins remained the same across different drug categories, we also examined acquisition cost margins by therapeutic class¹⁰⁴ for both 340B acquired and non-340B-acquired drugs . Hospitals’ survey-reported 340B acquisition costs were at least 28.9 percent below the mean ASP—and for most therapeutic classes lower than that—for drugs in all high-spending therapeutic classes (that is, those with more than \$100 million in reported acquisition costs) (Table 53). Again, this reinforces the significant, and

consistent, differences between hospitals’ acquisition cost for 340B acquired drugs and ASP for these drugs regardless of therapeutic class. The margins for non-340B drugs displayed in greater variation relative to the 340B drugs, which is likely attributable to greater heterogeneity in drug mix, provider type, and purchasing arrangements present outside the 340B Program. For instance, only certain drugs and biologicals are able to be acquired through the 340B Program and only certain types of hospitals can enroll as 340B participants. These restrictions necessarily limit which

drugs and hospitals can be included in the 340B calculations, leading to a somewhat more homogenous population. These restrictions do not play a role in the non-340B calculations. Additionally, and perhaps most significantly, certain types of 340B-participating hospitals have historically been prohibited from purchasing covered outpatient drugs through GPO arrangements,¹⁰⁵ which limits the purchasing arrangements applicable to 340B drugs, while non-340B drugs can be purchased under a variety of GPO or other buying group arrangements.

TABLE 53: ACQUISITION COST MARGINS BY THERAPEUTIC CLASS FOR 340B DRUGS

Therapeutic Class	340B	
	Mean ASP Margin	Median ASP Margin
Antineoplastics and Adjunctive Therapies	−28.9%	−28.8%
Hematopoietic Agents	−38.3%	−37.8%
Endocrine and Metabolic Agents	−52.6%	−52.8%
Passive Immunizing and Treatment Agents	−30.8%	−30.4%
Gastrointestinal Agents	−29.3%	−29.1%
Psychotherapeutic and Neurological Agents	−31.2%	−31.3%
Miscellaneous	−29.6%	−29.6%
Analgesics	−71.4%	−71.4%
Neuromuscular Agents	−31.8%	−31.9%

(3) Application of Population Weight Adjustment and Calculation of Confidence Intervals To Assess Statistical Validity

In accordance with section 1833(t)(14)(D)(iii) of the Act, after completing initial analysis of survey respondents’ acquisition costs, we

evaluated whether survey respondents comprised a large sample that is sufficient to generate statistically significant and representative estimates of hospitals’ acquisition costs. To do so, we conducted sensitivity analyses using inverse probability weighting (IPW) and confidence intervals, which we believe

support the statutory objective of obtaining acquisition cost estimates from survey responses that are accurate and representative of the outpatient drug acquisition costs incurred by all hospitals paid under the OPPS.

(i) IPW Methodology

¹⁰⁴Therapeutic class assignments were based on the Medi-Span Generic Product Identifier (GPI) classification system.

¹⁰⁵<https://www.hrsa.gov/sites/default/files/hrsa/opa/prohibition-gpo-participation-02-07-13.pdf>.

IPW is a widely used statistical technique in survey research^{106 107 108 109 110} to ensure that sample data produce estimates that accurately represent the population of interest. We applied IPW to account for the potential underrepresentation or overrepresentation of hospitals with particular characteristics among survey respondents and to evaluate whether acquisition cost margins derived from survey responses sufficiently reflected outpatient drug acquisition costs for all OPPS hospitals.

For purposes of the IPW analysis, we constructed respondent and nonrespondent populations that align with the refined hospital population discussed in above in (1) Survey Response Rate and Respondent Characteristics. We defined the respondent population as hospitals that submitted a survey response reporting the purchase of at least one surveyed NDC during the survey study period. We defined the nonrespondent population as survey-eligible hospitals that did not submit a survey response but billed at least one Fee-For-Service outpatient claim associated with a survey-relevant HCPCS code during the same period. Because acquisition cost margins were calculated separately for drugs purchased through the 340B Program and drugs purchased outside the 340B Program, we further stratified hospitals based on evidence of 340B drug use. Hospitals were identified as 340B participants using HRSA's 340B OPAIS enrollment information and

claims submitted with 340B modifiers. Hospitals that neither submitted an ODACS response nor billed relevant outpatient claims during the survey period were excluded from the IPW-adjusted population. Subunits were collapsed with their corresponding parent unit prior to constructing the respondent and nonrespondent populations.

After identifying the respondent and nonrespondent groups, we calculated response propensity scores using logistic regression models based on observed hospital characteristics, including number of beds, teaching hospital status, geographic rurality, and Census division. Propensity scores were estimated separately for hospitals purchasing drugs outside the 340B Program and hospitals purchasing drugs through the 340B Program. A higher propensity score means that the hospital was more likely to submit a survey response; a lower propensity score means that the hospital was less likely to submit a survey response.

We then calculated inverse probability weights equal to the inverse of each hospital's estimated probability of responding to the survey. Hospitals with a higher likelihood of responding received smaller weights, while hospitals with a lower likelihood of responding received larger weights. The weights were used to adjust for differential representation of hospital characteristics between the respondent sample and the broader population of survey-eligible hospitals. Down-weighting hospitals with a high probability of response (which are overrepresented in the received sample) while upweighting CCNs with a low probability of response (which are underrepresented in the received sample) accounted for the differential representation of hospital characteristics in the sample as compared to the full population.

Finally, we calculated the IPW-adjusted acquisition cost margins by first applying the calculated weights to hospitals' average acquisition costs and corresponding ASP-based payment amounts, then recalculating aggregate acquisition cost margins by finding the difference between the IPW-adjusted acquisition costs and IPW-adjusted

ASP-based payment and then dividing that difference by the IPW-adjusted ASP-based payment. We also applied the same methodology when calculating IPW-adjusted margins between acquisition costs and 340B ceiling prices.

(ii) Confidence Intervals Methodology

To evaluate whether the number of survey responses was sufficient to produce statistically valid estimates of hospitals' acquisition costs, we calculated confidence intervals for both unadjusted and IPW-adjusted acquisition cost margins. The confidence intervals provide measures of whether the survey response rate adequately captures true population-level results. When response rate is insufficiently low, confidence intervals are very wide due to the high degree of uncertainty regarding where the true result lies. Conversely, when response rate is sufficient, confidence intervals become narrower as uncertainty lessens.

We calculated confidence intervals using a bootstrap methodology. Specifically, we repeatedly sampled with replacement from the original survey dataset and recalculated acquisition cost margins for each repeated sample. We repeated this process 10,000 times to generate distributions of unadjusted and IPW-adjusted acquisition cost margin estimates. We then identified the 95 percent confidence intervals for each acquisition cost margin estimate using the 2.5th percentile as the lower bound and the 97.5th percentile as the upper bound.

(iii) Results of Population Weight Adjustments and Confidence Intervals From ODACS Data

Application of inverse probability weighting improved the alignment between the distribution of respondent hospital characteristics and the broader population of survey-eligible hospitals. We found that IPW-adjusted respondent characteristics more closely resembled the full population across measures such as rural/urban, teaching status, Census division, and 340B participation (Table 54).

BILLING CODE 4169-69-P

¹⁰⁶ "Behavioral Risk Factor Surveillance System: Weighting the Data (2011 Weighting Formula)," U.S. Centers for Disease Control and Prevention, last modified July 19, 2013, https://www.cdc.gov/brfss/annual_data/2011/2011_weighting.htm.

¹⁰⁷ "National Health and Nutrition Examination Survey—Weighting," U.S. Centers for Disease Control and Prevention, n.d., <https://www.cdc.gov/nchs/nhanes/tutorials/weighting.aspx>.

¹⁰⁸ "Weighting," U.S. Census Bureau, last modified January 12, 2022, <https://www.census.gov/programs-surveys/cps/technical-documentation/methodology/weighting.html>.

¹⁰⁹ "Weighting," U.S. Census Bureau, last modified August 19, 2022, <https://www.census.gov/programs-surveys/sipp/methodology/weighting.html>.

¹¹⁰ "Consumer Expenditures and Income: Calculation," U.S. Bureau of Labor Statistics, last modified September 12, 2022, <https://www.bls.gov/pub/hom/cex/calculation.htm>.

TABLE 54: POPULATION WEIGHT ADJUSTMENT BY HOSPITAL CHARACTERISTIC

Hospital Characteristic	Non-340B Drugs			340B Drugs		
	ODACS-Eligible Population	Unadjusted ODACS Respondents	IPW-Adjusted ODACS Respondents	ODACS-Eligible Population	Unadjusted ODACS Respondents	IPW-Adjusted ODACS Respondents
<i>340B Enrollment</i>						
340B Hospital	48.1%	32.8%	50.0%	100.0%	100.0%	100.0%
Non-340B Hospital	51.9%	67.2%	50.0%	N/A	N/A	N/A
<i>Number of Beds</i>						
Bottom Quintile	15.8%	20.0%	16.2%	7.4%	9.6%	6.9%
Second Quintile	17.1%	18.3%	16.9%	13.8%	16.7%	13.7%
Third Quintile	20.6%	20.6%	20.8%	17.5%	17.0%	17.7%
Fourth Quintile	22.7%	21.6%	23.4%	26.4%	27.0%	26.6%
Top Quintile	23.8%	19.6%	22.7%	35.0%	29.7%	35.2%
<i>Rurality</i>						
Metropolitan	73.8%	71.8%	74.6%	71.8%	69.5%	71.9%
Micropolitan	17.3%	17.2%	16.7%	20.0%	19.2%	20.3%
Rural	8.9%	11.0%	8.7%	8.3%	11.3%	7.8%
<i>Census Region</i>						
New England	4.3%	2.6%	4.6%	4.8%	3.4%	4.5%
Middle Atlantic	10.9%	9.7%	10.7%	12.1%	9.8%	13.1%
South Atlantic	16.6%	16.8%	16.0%	14.1%	11.8%	15.0%
East North Central	15.5%	12.9%	16.3%	17.0%	18.4%	16.6%
East South Central	8.3%	9.9%	8.3%	8.6%	9.8%	8.6%
West North Central	7.5%	6.6%	7.0%	8.3%	8.1%	8.1%
West South Central	15.8%	22.7%	15.9%	12.9%	18.2%	12.6%
Mountain	7.2%	7.7%	6.4%	6.3%	3.9%	6.4%
Pacific	12.6%	9.7%	13.0%	15.4%	15.0%	14.6%
Puerto Rico	1.2%	1.4%	1.9%	0.5%	1.5%	0.5%
<i>Teaching Status</i>						
Major Teaching	12.8%	10.2%	11.8%	19.5%	16.7%	19.5%
Not Major Teaching	84.4%	86.6%	85.6%	77.3%	79.1%	77.4%
Unknown	2.8%	3.3%	2.6%	3.2%	4.2%	3.1%

BILLING CODE 4169-69-C**(iv) Weighted Adjusted Acquisition Cost Margins**

We found that application of IPW had minimal impact on estimated acquisition cost margins for either non-340B drugs or 340B-acquired drugs. For drugs acquired outside the 340B

Program, the analysis conducted estimated that acquisition costs were approximately 2.7 percent above the mean ASP prior to IPW adjustment and approximately 2.8 percent above the mean ASP after IPW adjustment. For drugs acquired through the 340B Program, the analysis estimated that

acquisition costs were approximately 33.4 percent below the mean ASP prior to IPW adjustment and approximately 33.1 percent below the mean ASP after IPW adjustment. The consistency between unadjusted and IPW-adjusted results supports the robustness and representativeness of the acquisition

cost margins derived from survey responses (Table 55).

TABLE 55: EFFECT OF INVERSE PROBABILITY WEIGHT ADJUSTMENT ON ACQUISITION COST MARGINS AND 95 PERCENT CONFIDENCE INTERVALS (CI)

Aggregate Margin Calculations: Methodology Specifications		Acquisition Cost to Mean ASP Margin					
		Non-340B Drugs			340B Drugs		
		Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit	Mean ASP Margin	95% CI Lower Limit	95% CI Upper Limit
Responses > Ceiling Price Included	Unadjusted	+2.7%	−3.8%	+6.9%	−31.9%	−33.9%	−29.4%
	IPW-Adjusted	+2.8%	−1.6%	+6.5%	−31.6%	−33.4%	−29.3%
Responses > Ceiling Price Excluded	Unadjusted				−33.4%	−34.7%	−32.3%
	IPW-Adjusted				−33.1%	−34.3%	−32.1%

The 95 percent confidence intervals for both unadjusted and IPW-adjusted acquisition cost margins were not substantially different from each other, indicating the weighting adjustment had minimal impact on the resulting estimates. For non-340B drugs, the confidence intervals ranged from approximately 3.8 percent below the mean ASP to 6.9 percent above the mean ASP for unadjusted margin and between 1.6 percent below the mean ASP to 6.5 percent above the mean ASP for the IPW-adjusted margin. For 340B-acquired drugs, the confidence intervals were much narrower and ranged from approximately 34.7 percent to 32.3 percent below the mean ASP for the unadjusted margin and from 34.3 percent to 32.1 percent below the mean ASP for the IPW-adjusted margin (Table 55).

We believe the relatively narrow confidence intervals for 340B-acquired drugs support the statistical validity of the survey results on 340B drugs and indicate that the received sample is sufficiently large to produce reliable estimates of hospital outpatient drug acquisition costs for 340B drugs. We note that the confidence intervals for the non-340B drugs span a wider range of potential acquisition cost margins. This is expected given the greater distributional spread in the survey data for non-340B drugs, as discussed in this section V.B.2.8. of this proposed rule.

For an additional summary of our analysis of the survey results we refer readers to the 2026 Outpatient Prospective Payment System Drug Acquisition Cost Survey Technical

Report which will be posted on the Medicare Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey website.¹¹¹ We solicit comment on our process for how we evaluated ODACS data to determine the magnitude of the margins between hospitals' survey-reported acquisition costs and ASP-based Medicare payment amounts.

C. CY 2027 OPPS Payment Methodology for 340B Purchased Drugs Based on Survey Results

As described previously, section 1833(t)(14)(D)(ii) of the Act requires the Secretary to conduct periodic surveys to determine the hospital acquisition cost for each SCOD for use in setting the payment rates for SCODs under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(I) of the Act provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug (which at the option of the Secretary, may vary by hospital group) as determined by the Secretary, taking into account the survey data collected under subparagraph (D) of section 1833(t)(14) of the Act. Based on our analysis of the survey data, the most immediately evident and significant difference found between Medicare payment and acquisition cost was for 340B drugs acquired by 340B-participating hospitals, where the selected methodology shows that aggregate acquisition costs are

approximately ASP minus 33.4 percent. This indicates average acquisition costs that are 37.2 percent lower than the general OPPS payment rate (ASP plus six percent). These results clearly demonstrate that ASP plus 6 percent is not an appropriate payment proxy for hospitals that acquire drugs through the 340B Program. Consequently, we propose to adjust the OPPS payment policy for 340B drugs to better align payment with the acquisition costs demonstrated by the survey. Specifically, for CY 2027, as discussed further in this section V.C. of this proposed rule, we propose to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent.

Conversely, for non-340B drugs, after taking into account the survey data, we are proposing to maintain the current payment rate, which is generally ASP plus 6 percent, under the authority at 1833(t)(14)(A)(iii)(I) of the Act. As displayed in Table 52, the heterogeneity in acquisition costs for non-340B drugs is slightly greater than for 340B drugs; this variation has led us to believe this area warrants additional analysis by CMS and input from interested parties. The results of the survey for non-340B drugs generally indicate lower acquisition costs than current payment; however, the discrepancy is not as clear and significant as with 340B drugs. Therefore, we are continuing to analyze the data from this survey, aligning those reported costs with hospital claims billing patterns, to see if any additional significant trends exist that merit further adjustments to OPPS payment policy in future years. We are also assessing

¹¹¹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey>.

billing patterns among those hospitals that did not respond. Finally, we collected and analyzed information on non-NDC-specific GPO discounts that hospitals receive and are still considering how these discounts could be factored into future analysis and policymaking. We will consider these issues for future rulemaking.

1. Statistically Significant Estimate

Under section 1833(t)(14)(D)(iii) of the Act, the periodic surveys conducted by the Secretary under 1833(t)(14)(D)(i) and (ii) of the Act must “have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug.” Our survey results meet this standard, particularly because hospital acquisition cost is a price measure.¹¹² Reliable price measures require far less sampling than quantity or revenue measures because markets tend to compress this distribution of prices across transactions but do not compress the distribution of quantities or expenditures.¹¹³ Hospitals can differ in their acquisition cost on a 340B drug by a factor of 1000. While hospital acquisition cost for a branded drug would not be exactly equal across hospitals in the 340B Program, it would not differ by a factor of 1000 and rarely even a factor of 2. Because the standard errors of the 340B-hospital sample mean and the non-340B-hospital sample mean are each proportional to the standard deviation of the underlying population, a compressed price distribution translates directly into small standard errors and high statistical significance.¹¹⁴

As discussed previously and shown in Table 54, the 95 percent confidence intervals for 340B drugs were relatively narrow, ranging from approximately 34.7 percent to 32.3 percent below ASP for the unadjusted margin and from approximately 34.3 percent to 32.1 percent below ASP for the IPW-adjusted

margin. These results support the statistical validity of the estimated acquisition cost margins and indicate that the survey data provide reliable estimates of the acquisition cost discounts realized by 340B hospitals relative to ASP. These sampling requirements for price measurement are well known in national accounting. For example, the Department of Labor’s Bureau of Labor Statistics measures prices for the Consumer Price Index (CPI) using about 100,000 commodity- and-service price observations per month, while the Producer Price Index (PPI) uses approximately 64,000 monthly price quotations from about 16,000 establishments.¹¹⁵ These samples are tiny relative to the transactions they are designed to represent: the CPI commodity- and-service sample alone is less than 0.01 percent of such payments.¹¹⁶

In our efforts to obtain data from a statistically significant sample of hospitals paid under the OPPIs, we initially included for survey participation 100 percent of OPPIs hospitals. From this, we received replies from 53.3 percent of non-340B hospitals and 28.6 percent of 340B hospitals. These response rates are similar to past surveys of health care providers as determined by a separate meta-analysis¹¹⁷ and have resulted in sample sizes that show significant differences in acquisition costs between the two hospital categories.¹¹⁸ While we applied data cleaning to exclude specific survey records with anomalous or implausible data, very few hospitals were excluded from our population, only 27 subunits

that reported identical and duplicative data to their parent unit. Additionally, while we applied refinements to narrow the population of hospitals to only those who either responded to the survey or had OPPIs claims for survey-relevant HCPCS codes, these refinements did not remove any hospital with relevant data from analysis. These efforts were undertaken to maintain the largest possible pool of hospitals and data to evaluate. It is our view based on efforts to sensitivity test the responses and reweight the findings that the conclusion of statistical difference in the average acquisition costs for 340B and non-340B hospitals would likely not change.

2. Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) of the Act authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D).

In accordance with this authority, we propose to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program as 340B covered entity hospitals because their drug acquisition costs vary significantly from those not enrolled in that program. The significant drug acquisition cost discounts that 340B covered entity hospitals receive for 340B-acquired drugs enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we propose to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act. Therefore, for 340B drugs acquired by 340B covered entity hospitals, we propose changes to better align Medicare payment with average acquisition cost for the drug as specified in statute.

As discussed in more detail below, for drugs not acquired through the 340B Program, we propose that 340B and non-340B hospitals will continue to receive payment at a payment rate that is generally ASP plus 6 percent.

We acknowledge we could set a single payment rate for a drug for a hospital group (such as 340B hospitals) regardless of whether the drug was

¹¹⁵ Bureau of Labor Statistics, “Handbook of Methods: Consumer Price Index—Data Sources” (last modified Jan. 30, 2025), <https://www.bls.gov/opub/hom/cpi/data.htm> and Bureau of Labor Statistics, “Producer Price Index (PPI): Overview” (last modified Mar. 16, 2023), <https://www.bls.gov/ppi/overview.htm>.

¹¹⁶ As a back-of-the-envelope denominator for 100,000 CPI observations, the Federal Reserve Bank of Atlanta’s 2024 Survey and Diary of Consumer Payment Choice reports that U.S. consumers made 48 payments per consumer per month on average. Multiplying 267 million adults by 48 payments per month gives approximately 12.8 billion consumer payments per month. This is a conservative comparison for item-level CPI observations because a single consumer payment, such as a grocery receipt, may cover multiple items.

¹¹⁷ Vincent Maurice Meyer *et al.*, “Global Overview of Response Rates in Patient and Health Care Professional Surveys in Surgery: A Systematic Review,” *Annals of Surgery* 275, no. 1 (January 2022): e75–e81, <https://pubmed.ncbi.nlm.nih.gov/32649458/>; The Meyer *et al.* meta-analysis found an average response rate of 53.3% (±24.5%) over 1,746 surveys of health care professionals.

¹¹⁸ Vincent Maurice Meyer *et al.*, “Global Overview of Response Rates in Patient and Health Care Professional Surveys in Surgery: A Systematic Review,” *Annals of Surgery* 275, no. 1 (January 2022): e75–e81, <https://pubmed.ncbi.nlm.nih.gov/32649458/>.

¹¹² Hospital acquisition cost is the price paid in a business-to-business market, particularly in transactions between hospitals and wholesalers or distributors. Unlike revenue, hospital acquisition cost is measured per unit quantity.

¹¹³ With some exaggeration, this is known in economics as the “law of one price.” The Chicago Price Theory textbook explains with more nuance that “Price is sometimes easier to measure than quantity because price can be seen from a sample; just go to one of the sellers in the market—say, a grocery store—and look at their price for eggs. Quantity measurement can be more difficult—you have to ask every seller what they sold; you’d need some kind of census of sellers” (Sonia Jaffe, Robert Minton, Casey B. Mulligan and Kevin M. Murphy, *Chicago Price Theory*, 2019, p. 48).

¹¹⁴ Weighting observations by volume shares, as the CMS sample does, further reduces standard errors and further increases statistical significance.

acquired through the 340B Program, but that does not align with our intent to more appropriately align payment with acquisition costs. As such, we are only applying the reduced payment rate to drugs acquired through the 340B Program by the hospital group defined as 340B hospitals as this most appropriately aligns payment with acquisition cost of drugs of this hospital group. For non-340B drugs acquired by 340B hospitals, we propose that payment will not be adjusted. We seek comment on these proposals. Specifically, we seek comment on our proposal to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I) of the Act and our proposal to vary the amount of payment for 340B-acquired drugs by the group of hospitals that are enrolled in the 340B Program to more appropriately align payment with the average acquisition cost for the drug.

3. Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) of the Act provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug “as determined by the Secretary taking into account” the survey data collected under subparagraph (D). In accordance with this authority, we propose to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. Applying a single discount factor to ASP creates a standardized payment reduction. Conversely, calculating individual acquisition costs links reimbursement directly to the exact, variable purchase prices hospitals pay for specific 340B drugs.

We considered calculating payment rates derived from individual acquisition cost amounts for 340B drugs; however, given the dynamic nature of drug pricing we concluded that it would be more appropriate to apply a single discount factor to ASP. We believe this is more appropriate as ASP is also dynamic in nature. ASP changes over time (quarter to quarter), so tying the payment amount to an average discount of ASP results in a more accurate payment amount, by quarter, than if hospitals had to wait until the next survey cycle.

Each drug HCPCS code has its own specific payment rate calculated that is unique to the drug described by the applicable HCPCS code. We would apply an average discount, calculated as described previously under V.B.9.b. and

V.B.9.c.(2). of this proposed rule, to the drug specific ASP amount. This makes our proposed payment rate specific to the average acquisition cost for the drug. Applying the payment rate in this manner also allows for this average discount to apply to newly calculated ASPs as they are updated on a quarterly basis. It would not be practical to calculate a drug specific payment rate for each NDC, and each HCPCS code, based on the survey data, as the survey collected data is based on a snapshot in time and would not reflect future changes in average acquisition costs. Therefore, as drug prices change, we believe it is appropriate and reasonable to continue to update the calculated ASPs and then to reduce payments by an appropriate percentage of ASP to better align payment with the average cost of the drug.

As an alternative to establishing one aggregate discount amount based on survey data, we are considering establishing one aggregate discount amount based on 340B ceiling prices from HRSA.¹¹⁹ Under this alternative, we would use HRSA’s 340B ceiling price data, rather than survey data, to calculate an average discount. As described previously, when assessing the 340B ceiling price, we calculated an analogous acquisition cost margin of ASP minus 28 percent for 340B drugs, which was calculated as the difference between the 340B ceiling price for each NDC in the survey and ASPs that were volume-weighted by 340B OPPS claims data utilization during the duration of the survey. We believe this could be a reasonable alternative to our proposal, as it is based on objective data from HRSA, can be updated regularly (such as quarterly or annually) with the release of new ceiling prices and new claims utilization data, and significantly diminishes the discrepancy between Medicare payment and hospital acquisition costs for these drugs. We seek comment on this alternative to set OPPS payment for 340B acquired drugs at ASP minus 28.0 percent, per the methodology described to calculate this OPPS claims volume weighted mean margin of the 340B ceiling price from ASP. We note this figure is volume weighted using OPPS claims data for the

duration of the survey, but we also solicit comment on volume weighting this average based on the claims data available for the applicable calendar year in which the policy would be effective. For example, for the CY 2027 rule, this would be volume weighting based on claims data available for that year’s rule, which would be claims data from CY 2025. At the end of this section, we also provide estimated impacts of this alternative policy proposal of ASP minus 28 percent based on the 340B ceiling price data, so interested parties are aware of these impacts if CMS ultimately adopts this policy for CY 2027.

We seek comment on our proposal to apply a single discount factor to the ASP for 340B-acquired drugs in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs.

4. Add-on Payment for 340B Drugs

Under the OPPS, Medicare pays separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs may also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) of the Act authorizes, but does not require, the Secretary to make an adjustment to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Because we took a prudent approach in estimating the average acquisition costs for 340B-acquired drugs, we do not believe that it is necessary to establish an add-on for overhead and handling as we believe that a conservative estimate may already account for the costs of overhead. We also believe that hospitals will likely negotiate additional discounts that will render an additional add-on payment unnecessary. This approach also aligns with the requirement under section 1833(t)(14)(A)(iii) of the Act to pay at the average acquisition cost. Therefore, for CY 2027 and subsequent years, we propose to pay for 340B drugs acquired under the 340B Program by 340B hospitals at ASP minus 33.4 percent with no add-on payment. We solicit comment on our proposal to not include an add-on payment.

5. 340B Payment Policy for Drugs for Which ASP Is Unavailable

Section 1847A of the Act establishes the average sales price (ASP) methodology, which provides the amount payable for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Based on this, our historic policy has been to pay for most drugs at ASP plus 6 percent. There are

¹¹⁹ HRSA calculates the ceiling price for each covered outpatient drug. The 340B ceiling price is the drug’s average manufacturer price (AMP) minus the unit rebate amount (URA), which is a statutory formula that varies depending on whether the drug is an innovator single source drug (no generic available), an innovator multiple source drug (a brand drug with available generic(s)), or a non-innovator multiple source (generic) drug. The 340B ceiling price represents the maximum price a participating drug manufacturer can charge a covered entity for the drug.

some situations, however, where it is not possible to pay ASP because, for example, a drug is sufficiently new so there is no sales data available upon which to derive an average. In these situations, our historic policy has been to pay for the drug according to the following hierarchy: In general, if ASP information is not available, payment is based on the WAC with WAC plus 6 percent. If WAC information also is not available, then payment is based on AWP with 95 percent of AWP being paid. If AWP is not available, then payment is based on Mean Unit Cost (MUC) and if MUC is not available then payment is based on the invoice price.

Consistent with this policy, starting in CY 2027, we propose that payment for 340B drugs when ASP is unavailable mirrors CMS's historic payment policies for drugs paid under OPSS. If ASP information is not available, payment is based on the WAC, with WAC minus 33.4 percent. If WAC information also is not available, we propose a payment rate of 59.69¹²⁰ percent of AWP. This percent was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup. Then we applied the 33.4 percent reduction WAC-similar AWP value to obtain the 59.69 percent of AWP, which is similar to either ASP minus 33.4 percent or WAC minus 33.4 percent. For 340B drugs paid based on MUC, we propose to continue to pay them at 100 percent of MUC. These MUC based payments are calculated based on hospital claims data, which already accounts for hospital acquisition costs and does not need to be discounted further. Similarly, we propose to continue to pay for invoice priced 340B drugs at the invoice amount as the invoice price amount should already reflect the 340B discount. We seek comment on this proposal.

6. Applicability

We propose to apply our proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program. This approach would establish a uniform payment policy consistent with our historic OPSS payment policy of paying the same payment rate for SCODs and non-SCODs. We note our proposal to apply this policy to separately payable drugs

and biologicals that are not SCODs is a policy proposal rather than a statutory requirement. We note that the survey included both SCODs and drugs and biologicals that we have historically treated as SCODs for payment purposes. We have treated non-SCOD drugs as SCODs for payment purposes since CY 2006. We seek comment on this proposal.

The proposed payment policy would not apply to vaccines, as they are excluded from the 340B Program; drugs with transitional pass-through payment status, which are paid under 1833(t)(6)(D) of the Act; and non-opioid pain management drugs as defined under section 1833(t)(16)(G) of the Act, as we believe reducing payment for those drugs would be inconsistent with statutory instructions on payment amount for those qualifying products.

As previously described in the OMB approved PRA, CMS may continue to validate the results of this survey on a periodic basis; for example, perhaps as often as every 4 years. We seek comment on this proposal. Specifically, we seek comment on the proposal that the proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent would apply to all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired under the 340B Program, and would not apply to vaccines, drugs with transitional pass-through payment status and non-opioid pain management drug.

Additionally, as we propose to apply a single discount factor to the ASP for 340B-acquired drugs in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs, we believe it is appropriate to apply this payment adjustment using the single discount factor to existing and new drugs that are paid under the OPSS.

7. Beneficiary Copayments

An important consequence of our proposed policy is that it will reduce Medicare beneficiaries' copayments for Medicare Part B drugs. Medicare beneficiaries are liable for a copayment that is typically equal to 20 percent of the OPSS payment rate, which is currently generally ASP plus 6 percent (regardless of the 340B purchase price for the drug). As the survey demonstrates, in some cases, beneficiary coinsurance alone exceeds the amount the hospital paid to acquire the drug under the 340B Program. For example, Lupron Depot (NDC 00074-3663-03) had a mean adjusted ASP of \$4,690.08 compared to an average 340B acquisition cost of \$667.94, excluding outliers and responses above the 340B

ceiling price, yielding an absolute margin of –\$4,022.14 and a percent margin of –85.8 percent. As the drug is paid at ASP plus 6 percent, the payment rate for one package of the NDC averaged \$4,971.49, of which a beneficiary would pay 20 percent, or \$994.30. Therefore, a beneficiary's copay would be over \$300 above the average hospital's 340B acquisition cost. During the ODACS study period, 3,544 beneficiaries had an OPSS claim for Lupron Depot, meaning that a sizeable beneficiary population is affected by these high coinsurance amounts. This is also not a small sample size aberration: 137 hospitals reported purchasing this drug through 340B (after excluding outliers and responses above the 340B ceiling price).

Additionally, sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A (i) of the Act which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs for each calendar quarter beginning on or after January 1, 2023, if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. Pursuant to section 1847A(i)(5) of the Act, the IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount.

Section 11101(b) of the IRA amended section 1833(t)(8) of the Act by adding a new subparagraph (F) to modify OPSS copayments for Part B rebatable drugs. In the CY 2024 OPSS/ASC final rule with comment period, we codified the OPSS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41, which states in the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of

¹²⁰ Except for new drugs and biologicals that have not been assigned a HCPCS code. Under section 1833(t)(15) of the Act, these drugs and biologicals are required to be paid at 95 percent of AWP.

the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the outpatient prospective payment system is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under § 419.41(d) (other than application of the limitation described in paragraph § 419.41(c)(4)(i)), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply. In the CY 2025 PFS final rule, we codified policies regarding the computation of the inflation-adjusted beneficiary coinsurance, including § 427.201, which specifies that the methodology set forth in § 427.201(b) will be used to calculate the inflation-adjusted beneficiary coinsurance and associated Medicare payment percentage for Part B rebatable drugs as set forth in §§ 410.152(m), 419.41(e), and 489.30(b)(6). The methodology at § 427.201(b) ensures that coinsurance adjustments are not applied in a manner that would increase beneficiary coinsurance. For additional details on this coinsurance policy, we refer readers to the full discussion at 89 FR 98237 and 98238.

Under 1833(t)(8)(F) of the Act and current OPPS regulations at § 419.41(e), beneficiary coinsurance is adjusted for Part B rebatable drugs paid under the OPPS only where a Part B rebatable drug is paid the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act—that is, for single source drugs and biologicals, paid 106 percent of the lesser of ASP or WAC, and for biosimilar biological products, paid the amount determined under 1847A(b)(8) of the Act. Because, as proposed, separately payable, non-pass-through, 340B-acquired drugs would be paid an amount other than the amount under section 1847A(i)(3)(A)(ii)(I) of the Act, the coinsurance adjustment provisions of the Medicare Part B Inflation Rebate Program would not apply to separately payable, non-pass-through, 340B-acquired drugs under the proposed payment policy. We believe this is appropriate and consistent with the statutory intent of the Medicare Part B Inflation Rebate Program, as the coinsurance adjustment at 1847A(i)(5) of the Act is intended to reduce the coinsurance amount to equal that of 20 percent of the inflation-adjusted

payment amount described at 1847A(i)(3)(C) of the Act, and we expect that the applicable coinsurance under the payment proposal for 340B-acquired drugs would likely be lower than 20 percent of such inflation-adjusted payment amount. We seek comment on the interaction between coinsurance adjustments under 1847A(i)(5) and the proposed policy to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent.

We anticipate that our proposed policy to pay for separately paid drugs acquired under the 340B Program at ASP minus 33.4 percent will collectively reduce beneficiary copayments by an estimated \$1.15 billion for CY 2027.

8. 340B Payment Policy Exemptions

We propose to exempt children's hospitals and PPS-exempt cancer hospitals from our proposed policy to adjust OPPS payments for drugs acquired under the 340B Program. In accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their "pre-BBA amount," and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. Consequently, we believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our

analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2027 and subsequent years, we propose that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be exempted from the 340B payment adjustment and that these hospitals would continue to generally be paid ASP plus 6 percent for drugs. We may revisit our policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction, in future rulemaking.

We note that hospitals listed under 42 CFR 419.20(b),¹²¹ such as Critical Access Hospitals (CAHs) and Rural Emergency Hospitals (REHs), would not be subject to our proposed payment adjustment for 340B-acquired drugs.

We seek comment on our proposal to exempt children's hospitals, PPS-exempt cancer hospitals and rural SCHs from the 340B drug payment adjustment.

9. 340B Payment Policy for Drugs Furnished by Nonexcepted Off-Campus Departments of a Hospital

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699), we discussed implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act. Specifically, this provision amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and will instead be paid “under the applicable payment system” under Medicare Part B if the requirements for such payment are

¹²¹ <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20>.

otherwise met. We indicated that, in order to be considered part of a hospital, an off-campus department of a hospital must meet the provider-based criteria established under 42 CFR 413.65.

Accordingly, we refer to an “off-campus outpatient department of a provider,” which is the term used in section 603 of the Bipartisan Budget Act of 2015, as an “off-campus outpatient provider-based department” or an “off-campus PBD.” For a detailed discussion of the legislative history and statutory authority related to payments under section 603 of the Bipartisan Budget Act of 2015, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729).

To implement the amendments made by section 603 of Public Law 114–74, we issued an interim final rule with comment period (81 FR 79720) which accompanied the CY 2017 OPPS/ASC final rule with comment period to establish the PFS as the “applicable payment system” that applies in most cases, and we established payment rates under the PFS for those nonexcepted items and services furnished by nonexcepted off-campus PBDs. Specifically, we established a PFS relativity adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (90 FR 53770). These PFS rates incorporate the same packaging rules that are unique to the hospital outpatient setting under the OPPS, including the packaging of drugs that are unconditionally packaged under the OPPS. This includes packaging certain drugs and biologicals that would ordinarily be separately payable under the PFS when furnished in the physician office setting. For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with

comment period (79720 through 79729). For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

We note that, ordinarily, Medicare pays for drugs and biologicals furnished in the physician’s office setting at ASP plus 6 percent. This is because section 1842(o)(1)(A) of the Act provides that if a physician’s, supplier’s, or any other person’s bill or request for payment for services includes a charge for a drug or biological for which payment may be made under Medicare Part B and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount for the drug or biological is equal to the following: The amount provided under section 1847, section 1847A, section 1847B, or section 1881(b)(13) of the Act, as the case may be for the drug or biological.

Generally, in the hospital outpatient department setting, low-cost drugs and biologicals are packaged into the payment for other services billed under the OPPS. Separately payable drugs (1) have pass-through payment status, (2) have a cost per day exceeding a threshold, or (3) are not policy-packaged or packaged in a C–APC. As described in sections V.A. and V.B. of this proposed rule, section 1847A of the Act establishes the ASP methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the WAC, and the AWP (90 FR 53682). As noted in section V.B. of this proposed rule, since CY 2013, our policy has been to pay for separately payable drugs and biologicals at ASP plus 6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default) (90 FR 53702). Consequently, in the case of services furnished in a hospital outpatient department, Medicare has historically paid ASP plus 6 percent for separately payable Part B drugs and biologicals. For a detailed discussion of our current OPPS drug payment policies, we refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 53697 through 53766).

As a general matter, in the nonexcepted off-campus PBD setting, we pay hospitals under the PFS for all drugs and biologicals that are packaged

under the OPPS based on a percentage of the OPPS payment rate, which is determined using the PFS relativity adjuster. Because OPPS packaging rules apply to the PFS payments to nonexcepted off-campus PBDs, the PFS payment for some nonexcepted items and services that are packaged includes payment for some drugs and biologicals that would be separately billable under the PFS if a similar service had been furnished in the office-based setting. As we noted in the CY 2017 final rule with comment period, in analyzing the term “applicable payment system,” we considered whether and how the requirements for payment could be met under alternative payment systems in order to pay for nonexcepted items and services, and considered several payment systems under which payment is made for similar items and services (81 FR 79712). Because the PFS relativity adjuster that is applied to calculate payment to hospitals for nonexcepted items and services furnished in nonexcepted off-campus PBDs is based on a percentage (40 percent) of the amount determined under the OPPS for a particular item or service, and the OPPS is a prospective payment system, we believe that items and services furnished by nonexcepted off-campus PBDs paid under the PFS are payable on a prospective payment basis. Therefore, we believe we have flexibility to pay for separately-payable drugs and biologicals furnished in nonexcepted off-campus PBDs at an amount other than the amount dictated by sections 1842(o)(1)(C) and 1847A of the Act.

As discussed previously, our proposal to adjust the payment rate for separately payable drugs and biologicals (other than vaccines, drugs on pass-through payment status and non-opioid pain management drugs) acquired under the 340B Program from ASP plus 6 percent to ASP minus 33.4 percent would apply to separately payable drugs and biologicals paid under the OPPS. Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, nonexcepted items and services furnished by nonexcepted off-campus PBDs are not covered outpatient department services and, therefore, are not payable under the OPPS. This means that, absent our inclusion of them in our proposed policy, nonexcepted off-campus PBDs would not be subject to the payment changes we propose. Because hospitals can, in some cases, acquire drugs and biologicals under the 340B Program for use in nonexcepted off-campus PBDs, we believe that not adjusting payment for these departments would present a

significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished. This incongruity would distort the relative accuracy of the resource-based payment amounts under the site-specific PFS rates and could result in significant perverse incentives for hospitals to acquire drugs, biologicals, biosimilars, and radiopharmaceuticals under the 340B Program and avoid Medicare payment adjustments that account for the discount by providing these drugs to patients predominantly in nonexcepted off-campus PBDs. It would also undermine our goals of reducing beneficiary cost-sharing for these drugs and biologicals and moving towards site neutrality through the section 603 amendments to section 1833(t) of the Act. To avoid such perverse incentives and the resulting distortions, we propose for CY 2027 and subsequent years, to pay an amount equal to ASP minus 33.4 percent, or equivalent, for drugs, biologicals, biosimilars, and radiopharmaceuticals acquired under the 340B Program that are furnished by nonexcepted off-campus PBDs.

Consistent with the approach to budget neutrality we adopted when we previously implemented a reduction for 340B acquired drugs furnished by nonexcepted off-campus PBDs (83 FR 59021) and our approach to budget neutrality for items and services provided by nonexcepted off-campus PBDs generally (83 FR 58832), these adjusted payments would not be budget neutralized. We expect that for CY 2027 this would result in savings of approximately \$735 million to the Medicare Part B Trust Fund and would collectively reduce beneficiary copayments by an estimated \$185 million. These beneficiary savings are included in the \$1.15 billion figure in section 7. Beneficiary Copayments.

10. Billing Modifiers

To effectuate the payment adjustment for 340B-acquired drugs, we propose that, beginning January 1, 2027, providers who are not exempted from

the 340B payment adjustment would report modifier “JG” (Drug or biological acquired with 340B Drug Pricing Program Discount) to identify if a drug was acquired under the 340B Program. The phrase “acquired under the 340B Program” would include all drugs acquired under the 340B Program or Prime Vendor Program, regardless of the level of discount applied to the drug. Drugs that were not acquired under the 340B Program would not be reported with the modifier “JG”. For separately payable drugs (status indicator “K”), application of modifier “JG” would trigger a payment adjustment such that the 340B-acquired drug is paid at ASP minus 33.4 percent.

We additionally propose that, beginning January 1, 2027, for drugs or providers that are exempted from the 340B drug payment policy for CY 2027, which include pass-through drugs (SI “G”), non-opioid treatment for pain relief drugs authorized under section 4135 of the CAA, 2023 (SI “K1”), rural SCHs, children’s hospitals, and PPS-exempt cancer hospitals, should not report modifier “JG”. Instead, these exempted providers should report the informational modifier “TB” (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) to identify OPPS separately payable drugs purchased with a 340B discount. The informational modifier “TB” will facilitate the collection and tracking of 340B claims data for OPPS providers that are exempted from the payment adjustment in CY 2027. However, use of modifier “TB” will not trigger a payment adjustment and these providers will generally receive ASP plus 6 percent for separately payable drugs furnished in CY 2027, even if such drugs were acquired under the 340B Program.

We also propose that, beginning January 1, 2027, all providers report a distinct modifier to identify drugs and biologicals that were not acquired under the 340B Program. Specifically, we are establishing a new modifier, “XX” (Drug or biological not acquired under the 340B Drug Pricing Program), which we

propose will be required to be reported for all separately payable drugs that were purchased outside of the 340B Program. Note, “XX” is a placeholder modifier code that will be updated in the CY 2027 OPPS/ASC final rule with comment period, if this policy is finalized.

The requirement to use modifier “XX” would apply to all providers paid under the OPPS, including excepted and non-excepted off campus provider-based departments. Reporting the modifiers “XX”, “JG”, or “TB” for applicable drugs would ensure that all drug claims are consistently categorized as either 340B-acquired or non-340B-acquired. We believe that requiring the use of modifier “XX” for non-340B drugs will improve the completeness and consistency of claims data, facilitate program integrity and oversight, and enhance our ability to monitor acquisition patterns across providers. The use of modifier “XX” would not trigger a payment adjustment and such drugs would continue to be paid at the applicable OPPS rate (generally ASP plus 6 percent for separately payable drugs) consistent with existing policy. In summary, we propose all separately paid drug claims reported under the OPPS would be reported with a modifier of either “JG,” “TB,” or “XX” (Table 56). We solicit comment on our proposal to require all separately paid drug claims to be reported with a modifier of either “JG,” “TB,” or “XX”.

We believe the addition of this new modifier is consistent with the decisions that hospitals are already making (is the drug a 340B-acquired drug or a non-340B-acquired drug) when billing for these drugs. As previously mentioned, we believe requiring the use of modifier “XX” for non-340B drugs will improve the completeness and consistency of claims data—this requirement could even decrease burden on hospitals as it may improve the accuracy of billing, thus decreasing the need for hospitals to reprocess claims that were billed incorrectly. We request comment as to whether the addition of modifier “XX” would create additional burden for hospitals.

TABLE 56: DRUG CLAIM MODIFIERS FOR ENTITIES PAID UNDER THE OPPTS

Hospital Type	Pass-through Drug (SI “G”)	Separately Payable Drug (SI “K”)	Non-Opioid Treatment for Pain Relief Drug (SI “K1”)	Packaged Drug (SI “N”)
340B Drugs				
340B Hospitals	TB	JG	TB	TB
Children’s Hospitals	TB	TB	TB	TB
PPS-Exempt Cancer Hospitals	TB	TB	TB	TB
Rural Sole Community Hospitals	TB	TB	TB	TB
Non-340B Drugs				
All OPPTS Hospitals	XX			XX Optional

Additionally, we acknowledge this billing modifier proposal would have implications for how we identify billing units of drugs acquired through the 340B Program under the Medicare Part B Drug Inflation Rebate Program. In the CY 2025 Physician Fee Schedule (PFS) final rule (89 FR 98583), we codified at § 427.303(b)(1)(iv) that we will exclude from Part B rebate calculations separately payable billing units in claim lines for institutional claims that are billed with the “TB” modifier for claims with dates of service on or after January 1, 2025. If we finalize our proposal to establish the requirement to use the “JG” modifier, in addition to the requirement to use the “TB” modifier, then such 340B modifier changes would necessitate changes to how we identify 340B units to exclude from Part B rebate calculations.

Consequently, we propose a conforming change at § 427.303(b)(1)(iv) to reflect proposed changes to the requirements to use billing modifiers for 340B-acquired drugs as described in section V.B.10. of this proposed rule. Specifically, to account for these billing modifier proposals, at

§ 427.303(b)(1)(iv), we propose to add “or successor billing modifiers to identify 340B units”. This means, for the purposes of Part B inflation rebate calculations, we would exclude billing units acquired under the 340B Program as identified through separately payable units in claim lines billed with the “TB” modifier, or successor billing modifiers to identify 340B units for 340B-acquired drugs, for claims with dates of service on or after January 1, 2025. Therefore, as a matter of operations, effective January 1, 2027, CMS would identify separately payable billing units in claim lines billed with the “TB” modifier and proposed “JG” modifier. We recognize that policy amendments for the Medicare Prescription Drug Inflation Rebate Program are typically proposed in the PFS; however, we believe it is appropriate to propose an amendment to § 427.303(b)(1)(iv) in this OPPTS/ASC proposed rule due to timing differences in the publication of the CY 2027 PFS proposed rule relative to the OPPTS/ASC proposed rule and to ensure we are able to appropriately exclude 340B units from Part B rebate calculations starting January 1, 2027.

D. CY 2027 OPPTS Payment Methodology for Non-340B Acquired Drugs Based on ODACS

CMS analyzed acquisition cost data collected through the ODACS for drugs acquired outside the 340B Program and evaluated several methodologies for estimating the relationship between hospitals’ acquisition costs and ASP-based payment amounts as previously discussed in this section.

Using our preferred proposed methodology, which calculates acquisition cost margins using the geometric mean of survey-reported acquisition costs, we estimate that hospitals’ acquisition costs for non-340B drugs were approximately 2.7 percent above ASP during the survey period. However, we recognize that acquisition costs reported through the survey may not fully reflect all manufacturer rebates, chargebacks, administrative fees, or other post-purchase price concessions received by hospitals, as we have not incorporated GPO discounts into the ASP plus 2.7 percent figure. Therefore, even ASP plus 2.7 percent, the reported acquisition costs, may overstate hospitals’ net acquisition

costs. As a result, the estimated margin of ASP plus 2.7 percent may, in part, reflect differences in how manufacturer rebates and other retrospective discounts were reported rather than solely the underlying acquisition costs of the drugs.

The survey results for non-340B drugs exhibit greater variation than the survey results for 340B-acquired drugs. As a result, the confidence intervals for the estimated non-340B acquisition cost margins span a slightly wider range of potential values. We believe this finding is expected given the diversity of purchasing arrangements, contracting structures, and acquisition channels available to hospitals when acquiring drugs outside the 340B Program. The broader distribution of survey-reported acquisition costs suggests greater uncertainty regarding the precise average acquisition cost margin for non-340B drugs relative to the margin observed for 340B-acquired drugs.

Although the survey data suggest that hospitals' acquisition costs for non-340B drugs may be lower on average from the current payment rate of ASP plus 6 percent, the survey results are subject to slightly greater variability and may be affected by differences in the reporting of manufacturer rebates and other price concessions. Consequently, we believe the survey data should be interpreted further as we assess the need for a payment rate change for non-340B drugs.

Given the need to further consider the non-340B survey results for the reasons mentioned, including the range of reasonable acquisition cost estimates supported by the data, we are not proposing at this time to establish a survey-based payment rate for non-340B drugs. Rather, for CY 2027, after taking into account the survey results, we propose to continue paying separately payable non-340B drugs, biologics, biosimilars, and radiopharmaceuticals as we do in CY 2026, which is generally at a rate of ASP plus 6 percent. We believe this approach appropriately considers the survey findings, including the uncertainty associated with manufacturer rebate reporting and the broader distribution of acquisition cost estimates, while maintaining stability in payment rates and allowing CMS to continue evaluating acquisition cost information obtained through its survey authority under section 1833(t)(14)(B)(iii) of the Act.

Under the same survey-based methodology proposed for determining payment for 340B-acquired drugs, such an approach for non-340B drugs would be based on the geometric mean acquisition cost estimate derived from

the survey data, resulting in a payment rate of approximately ASP plus 2.7 percent. In the case of the 340B acquired drugs, the discrepancy between acquisition cost and Medicare payment is substantial and obviously apparent; however, the discrepancy between acquisition cost and Medicare payment for non-340B acquired drugs is much less significant. Therefore, we are proposing to continue paying for non-340B acquired drugs at a rate of ASP plus 6 percent. We also intend to continue evaluating the acquisition cost survey data for non-340B acquired drugs and may consider the results of this analysis in future rulemaking.

E. Summary

In summary, using the authority under section 1833(t)(14)(A)(iii)(I) of the Act, we propose for CY 2027 and subsequent years to pay for drugs acquired under the 340B Program at ASP minus 33.4 percent and for drugs acquired outside of the 340B Program at ASP plus 6 percent. This proposal includes our previously discussed methodology used to arrive at the proposed payment rate of ASP minus 33.4 percent that we propose to apply to all drugs acquired under the 340B Program. This methodology includes using the survey volume-weighted estimate of the margin between total acquisition costs and ASP-based payments, the longstanding OPPS geometric mean trimming methodology to identify and exclude outliers and the five data refinement exclusions to remove anomalous data. Our intent is that, if finalized, this payment methodology would apply beginning January 1, 2027. We also propose that rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B Payment Policy for CY 2027 and subsequent years. To effectuate the payment adjustment for 340B-acquired drugs, we propose that, effective January 1, 2027, hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as CAHs or REHs) or exempted from the 340B drug payment policy for CY 2027, would be required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug; the modifier "TB" for all pass-through drugs, non-opioid treatment for pain relief drugs, and 340B-acquired drugs reported by rural SCHs, children's hospitals and PPS-exempt cancer hospitals for informational purpose; and the modifier "XX" for all drugs that were not acquired through the 340B Program. We note these payment proposals apply to both excepted and

non-excepted provider-based departments of a hospital. Finally, we propose a conforming change to § 427.303(b)(1)(iv) to ensure our process to identify 340B units for purposes of Part B inflation rebate calculations aligns with our proposed 340B modifier billing requirements.

F. Budget Neutrality

As we propose the previously defined payment adjustments through our authority under section 1833(t)(14)(A)(iii)(I) of the Act, we also propose making this adjustment in a budget neutral manner. To maintain budget neutrality within the OPPS, we have estimated that OPPS payment for 340B acquired drugs will be reduced by approximately \$4.85 billion in CY 2027; however, these payments will be redistributed in an equal offsetting amount to all hospitals paid under the OPPS through increased payment rates for non-drug items and services furnished by all hospitals paid under the OPPS. Specifically, the redistributed dollars will increase the conversion factor for OPPS non-drug items and services by 8.44 percent for CY 2027.

We also estimated the alternative methodology previously described to pay 340B acquired drugs at ASP minus 28 percent, which is the average acquisition cost calculated from the 340B ceiling prices and volume weighted by OPPS utilization data. Through this method, we estimate that OPPS payment for 340B acquired drugs would be reduced by approximately \$4.68 billion in CY 2027. Specifically, the redistributed dollars will increase the conversion factor for OPPS non-drug items and services by 8.14 percent for CY 2027.

For additional details on our proposed budget neutral implementation of this policy, please see section II.B. of this proposed rule.

F. Proposed Payment Rates for Skin Substitute APCs

In the CY 2026 OPPS/ASC final rule with comment period, we finalized a policy to separately pay for skin substitute products as incident-to supplies in the physician office, hospital outpatient, and ambulatory surgical center settings effective January 1, 2026 (90 FR 53729 through 53748). As part of this final policy, we assigned sheet-form skin substitute products to one of three clinical APCs we created based on FDA regulatory categories: APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products). For CY 2026, we set an initial payment

rate of \$127.14/cm² for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products). We stated we would update the payment rates for skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. In the event ASP data was not available for a particular product, we stated we would use the outpatient hospital MUC data. If MUC was not available, we stated we would use the product's WAC or 89.6 percent of AWP if WAC was also unavailable. We finalized a policy to include all skin substitute products used across both settings as well as the combined product utilization patterns and, as soon as data was available that reflects the results of this policy, to determine a weighted average per-unit cost by group to set the payment rates for each of the three categories.

At this time, we do not believe we have sufficient data upon which to propose a revised payment rate for all three skin substitute product APCs. We also believe that updating the payment rates for CY 2027, before the impacts of the payment policy are reflected in the CY 2026 claims that will be used for CY 2028 OPPS/ASC and PFS rulemaking, could result in payment disruptions or introduce unnecessary volatility. Because updated use patterns reflecting the CY 2026 policy changes are not yet available, we propose for CY 2027 to continue the policy finalized for CY 2026 in its entirety, which includes maintaining the payment rate of \$127.14/cm² for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products).

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act

requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2027 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2027. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2026 or beginning in CY 2027. The sum of the proposed CY 2027 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2027 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2026 OPPS/ASC final rule with comment period (90 FR 53766 through 53769). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment

for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (79 FR 66885 through 66888). In CY 2026, we finalized a policy to consider skin substitutes with an approved Biologics License Application (BLA) under transitional drug pass-through payment status and skin substitutes with the Food and Drug Administration (FDA) Premarket approval (PMA) or FDA 510(k) clearance continue to be evaluated under transitional device pass-through payment status. (90 FR 53636). Therefore, for CY 2027, we also propose to include an estimate of any skin substitutes and similar products with FDA PMA or FDA 510(k) clearance in our estimate of pass-through spending for devices and skin substitutes with an approved BLA under transitional drug pass-through spending for drugs and biologicals.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Consistent with current policy, we propose to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2027, and therefore our estimate of drug and biological pass-through payment for CY 2027 for this group of items is \$12.2 million.

Payment for certain drugs,¹²² specifically contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package non-pass-through drugs and biologicals that function as supplies when used in a diagnostic test or procedure unless a high-cost diagnostic radiopharmaceutical with a per-day cost greater than the proposed per-day

¹²² In the CY 2025 OPPS/ASC final rule with comment period, we finalized the high-cost diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this proposed rule for more information regarding this policy.

threshold referenced in section II.A.3.c. of this proposed rule is used for the test or procedure. We policy-package all drugs and biologicals that function as supplies when used in a surgical procedure or for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c. of this proposed rule. Consistent with current policy, for CY 2027, we propose that policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP plus 6 percent, like other pass-through drugs and biologicals less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2027 is not \$0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81774 through 81776), we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the

specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. Consistent with current policy described in section V.A.5. of this proposed rule, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2027. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in CY 2027. The sum of the CY 2027 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2027 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2027

For CY 2027, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPTS payments for CY 2027, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPTS policy from CY 2004 through CY 2026 (90 FR 53767). The pass-through payment percentage limit is calculated

using pass-through- spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2027, there are 15 active categories for CY 2027. The active categories are described by HCPCS codes C1605, C1606, C8000, C1735, C1736, C1737, C1738, C1739, C9610, C1740, C1741, C1742, C1607, C1608, and C1743. Based on CY 2025 Medicare hospital outpatient claims data available by the time of this proposed rule and information from the device manufacturers provided in their respective pass-through applications regarding the device cost and the projected CY 2027 OPPTS utilization, we estimated the CY 2027 pass-through expenditures for each of the 15 device categories in Table 56A.¹²³ Therefore, we propose an estimate for the first group of devices of \$177.6 million.

¹²³ Estimated costs are updated to reflect the Medicare hospital outpatient claims data for each HCPCS code as such data becomes available. Prior to the availability of Medicare hospital outpatient claims data, estimated costs are based on the device cost and projected CY OPPTS utilization provided by the device manufacturer in the device pass-through application. As such, the estimated pass-through costs for HCPCS codes C1605, C1606, C8000, C1735, C1736, C1737, C1738, C1739, and C9610 are based on CY 2025 Medicare hospital outpatient claims data available for this proposed rule. The estimated pass-through costs for HCPCS codes C1740, C1741, C1742, C1607, C1608, and C1743 are based on information provided by the device manufacturers in the respective device pass-through applications regarding the device cost and the projected CY 2027 OPPTS utilization.

TABLE 56A: ESTIMATED PASS-THROUGH EXPENDITURES FOR DEVICE CATEGORIES THAT ARE CURRENTLY ELIGIBLE AND WILL CONTINUE TO BE ELIGIBLE FOR PASS-THROUGH PAYMENT IN CY 2027

HCPCS Code	Effective Date	Pass-through Expiration Date	Estimated Pass-through Expenditures in CY 2027
C1605	07/01/2024	06/30/2027	\$8.4 million
C1606	07/01/2024	06/30/2027	\$0.4 thousand
C8000	10/01/2024	09/30/2027	\$0.9 million
C1735	01/01/2025	12/31/2027	\$6.8 million
C1736	01/01/2025	12/31/2027	\$3.6 million
C1737	01/01/2025	12/31/2027	\$1.4 million
C1738	01/01/2025	12/31/2027	\$0.1 million
C1739	01/01/2025	12/31/2027	\$0.6 million
C9610	01/01/2025	12/31/2027	\$36.1 million
C1740	10/01/2025	09/30/2028	\$31.7 million
C1741	10/01/2025	09/30/2028	\$7.5 million
C1742	10/01/2025	09/30/2028	\$0.7 million
C1607	01/01/2026	12/31/2028	\$12.5 million
C1608	01/01/2026	12/31/2028	\$22.4 million
C1743	04/01/2026	03/31/2029	\$44.9 million

In estimating our proposed CY 2027 pass-through- spending for device categories in the second group, we included the following: (1) device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2027; (2) additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2027; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2027. For CY 2027, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, we propose to deny six CY 2027 device pass-through applications. We propose to continue device pass-through payment status for seven device pass-through applications that were granted conditional approval in CY 2027.¹²⁴ The proposed estimate of

CY 2027 pass-through spending for this second group of device categories is \$5.6 million.

To estimate proposed CY 2027 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2027, we propose to use the CY 2025 Medicare hospital outpatient claims data regarding their utilization, information provided in their respective pass-through applications, other historical hospital

under the alternative pathway effective October 1, 2025; the pass-through applications for SetPoint System and TOUCH® CMC 1 Prosthesis were preliminarily approved for transitional pass-through payment under the alternative pathway effective January 1, 2026; the pass-through application for Esprit™ BTK Everolimus Eluting was preliminarily approved for transitional pass-through payment under the alternative pathway effective April 1, 2026; and the pass-through application for TOPS™ System was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2026. Due to the timing of the preliminary approvals, the CY 2027 spending estimate for MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, WiSE®, SetPoint System, TOUCH® CMC 1 Prosthesis, and Esprit™ BTK Everolimus Eluting is included in the CY 2027 spending estimate for the first group of devices, and the CY 2027 spending estimate for the TOPS™ System is included in the CY 2027 spending estimate for the second group of devices.

claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2027 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged contrast agents, drugs, biologicals, radiopharmaceuticals with per-day costs at or below the packaging threshold that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2027, we estimated the pass-through payment amount as the difference between the general payment rate of ASP plus 6 percent and the payment rate for non-pass-through drugs and biologicals that would be separately paid. Because we propose to utilize a payment rate of ASP plus 6 percent for most separately payable drugs and biologicals in this proposed rule, the proposed payment rate difference between the pass-through payment amount and the non-pass-through payment amount is \$0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2027 pass-

¹²⁴ As discussed in section IV.A.2. of this proposed rule: the pass-through applications for MY01 Continuous Compartmental Pressure Monitor, RemeOs™ Screw LAG Solid, and WiSE® (Wireless Stimulation of the Endocardium Technology) CRT System were preliminarily approved for transitional pass-through payment

through estimate the difference between payment for the policy-packaged drug or biological at ASP plus 6 percent (or wholesale acquisition cost (WAC) plus 3 or 6 percent according to the policy in section V.B.2.a. of this proposed rule, or 95 percent of average wholesale price (AWP), if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment. Diagnostic radiopharmaceuticals that currently have pass-through status, but would likely be paid separately because of the policy initially established in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93953) to separately pay for high-cost diagnostic radiopharmaceuticals with per-day costs greater than the proposed per-day threshold and which we propose to continue as discussed in section II.A.3.c. of this proposed rule, are not considered to be policy-packaged and therefore are not included in this group. For this first group of policy-packaged drugs and biologicals, we estimated a pass-through spending for CY 2027 of \$2.2 million.

To estimate proposed CY 2027 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2026, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2027, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2027), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2027 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2027 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group

of drugs and biologicals of approximately \$10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2027 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2027 would be approximately \$195.3 million (approximately \$183.1 million for device categories and approximately \$12.2 million for drugs and biologicals), which represents only 0.18 percent of total projected OPPS payments for CY 2027 (approximately \$111 billion). Therefore, we estimate that pass-through spending in CY 2027 will not exceed the 2.0 percent of total projected OPPS CY 2027 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2027, we propose to continue our current clinic and emergency department (ED) hospital outpatient visit payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448 and 70449). We also propose to continue our payment policy for critical care services for CY 2027. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449 through 70453), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by excepted off-campus provider-based departments (PBDs) applies for CY 2022 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2022 and subsequent years (86 FR 63664). As stated in the CY 2018 PFS final rule (82 FR 53020 through 53024), the PFS-equivalent rate for CY 2018 and subsequent years is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid 40 percent of the OPPS rate for the clinic visit service in CY 2027.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047

through 72051), we finalized a policy for CY 2023 and subsequent years that excepted off-campus PBDs (departments that bill the modifier “PO” on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051).

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare began paying for intensive outpatient services furnished by hospital outpatient departments, community mental health centers (CMHCs), Federally qualified health centers, and rural health clinics in addition to opioid treatment programs. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Background

1. Partial Hospitalization

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders (SUD). Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician’s diagnosis, the type, amount, frequency, and duration

of the items and services provided under the plan, and the goals for treatment under the plan.

Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a CMHC, as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding PHP.

PHP policies and payment have been addressed under OPPS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes, by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP Ambulatory Payment Classification (APC) per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176). We also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with

comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 and 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70453 through 70467), we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule with comment period data with respect to hospital-based PHP providers, and renumbered the PHP APCs. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an 8-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381 and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID-19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, as long as the location met all conditions of participation to the extent not waived. A hospital or CMHC could furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary was registered as an outpatient. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72247), we confirmed that these provisions applied only for the duration of the COVID-19 PHE. On May 11, 2023, the COVID-19 PHE ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 and 63666), as a result of the COVID-19 PHE, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OP/PS/ASC final rule with comment period (87 FR 71995), we finalized our proposal to use the latest available CY 2021 claims but use the cost information from prior to the COVID-19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs. The application of the OP/PS standard methodology, including the effect of budget neutralizing all other OP/PS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, \$142.70. In addition, we clarified the payment under the OP/PS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital that would not be recognized as PHP services; however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

In the CY 2024 OP/PS/ASC final rule with comment period (88 FR 81811), we revised the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act, as amended by section 4124(a) of Division FF of the CAA, 2023. In addition, we modified the regulations for PHP at § 410.43 to include references to SUD. In the same CY 2024 OP/PS/ASC final rule with comment period, we also established separate payment rates for PHP days with 3 services and days with 4 or more services. Accordingly, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). We also finalized a policy to utilize the separate CMHC rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted off-campus hospital outpatient department

furnishes three or four PHP services in a day. Lastly, we finalized several changes beginning in CY 2024 to align coding, billing, and payment between PHPs and intensive outpatient programs.

In the 2026 OP/PS/ASC final rule with comment period (90 FR 53770 through 53780), we modified the payment rate methodology for calculation of CMHC costs for PHP. We applied the 40 percent MPFS Relativity Adjuster to the hospital-based PHP costs to determine the CMHC costs for PHP.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023, amended section 1861(ff) of the Act, establishing Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. An intensive outpatient program (IOP) is a distinct and organized program of psychiatric services for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and SUD. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. Section 1861(ff)(4) of the Act defines intensive outpatient services as the items and services described in section 1861(ff)(2) of the Act prescribed by a physician for an individual determined (not less frequently than every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in intensive outpatient services. Section 1861(ff)(4)(C) of the Act specifies that an IOP is a program furnished by a hospital to its outpatients, by a CMHC, by a Federally qualified health center (FQHC), or by a rural health clinic (RHC) as distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i),

1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding IOP.

In the CY 2024 OP/PS/ASC final rule with comment period (88 FR 81812 through 81857), we established payment and program requirements for the IOP benefit furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC. In addition, we established Medicare Part B coverage for IOP services provided by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD).

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(4) of the Act, we finalized regulations at 42 CFR 410.44 to set forth the conditions and exclusions applicable for intensive outpatient services, and at § 424.24 to set forth the content of the certification and plan of treatment requirements for intensive outpatient services. We also revised certain existing regulations at §§ 410.2, 410.3, 410.10, 410.27, 410.150, and 419.21 to add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OP/PS. Additionally, we created regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we revised § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023.

In addition, as discussed in greater detail in the following sections, we established coding, billing, and payment policies for IOP that align with the policies established for PHP provided in the same settings. Specifically, we established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively). Similar to the policy finalized for PHP, we finalized a policy to utilize the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes three or four IOP services in a day.

For IOP services provided by an RHC or FQHC, we established a three-service per day payment rate based on the same rate as APC 5861, which is the three-service hospital-based IOP rate (§ 405.2462(j)). In the CY 2025 PFS final rule, we established a four or more services per day payment rate for an IOP provided by an RHC or FQHC based on the same rate as APC 5862, which is the four or more services hospital-based IOP rate (89 FR 98017 and 98018). Information regarding payment policies for IOP services furnished by FQHCs and RHCs, including information regarding proposed CY 2027 policies for those settings, can be found in the CY 2027 PFS proposed rule, which is published elsewhere in the **Federal Register**.

Furthermore, in the CY 2024 OPPTS/ASC final rule with comment period, we established a payment adjustment for IOPs provided by an OTP based on three times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)). We finalized regulations at § 410.67(d)(4)(ii) to add that the payment amount for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor (GAF) described in § 414.26. Lastly, we amended § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services is updated annually using the Medicare Economic Index described in § 405.504(d). Payment rates for IOP provided in the OTP setting are updated as part of the OTP fee schedule and are not addressed in this proposed rule.

In the 2026 OPPTS/ASC final rule with comment period (90 FR 53770 through 53780), we modified the payment rate methodology for calculation of CMHC costs for IOP. We applied the 40 percent MPFS Relativity Adjuster to the hospital-based IOP costs to determine the CMHC costs for IOP.

B. Coding and Billing for PHP and IOP Services Under the OPPTS

In the CY 2024 OPPTS/ASC final rule with comment period, we finalized a billing requirement that all providers use condition code 41 to indicate that a claim is for partial hospitalization services and use condition code 92 to identify intensive outpatient claims, effective January 1, 2024. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we stated in the CY 2024 OPPTS/ASC final rule with comment period that we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial

hospitalization services and intensive outpatient services. The use of condition codes 41 for PHP claims and 92 for IOP claims allows us to differentiate between these services for billing purposes.

We recognize that the level of intensity of mental health services that a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits supports a smooth transition for patients when a change in the intensity of their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as individual mental health services. The full list of HCPCS codes recognized under the PHP and IOP benefits can be found in the Medicare Claims Processing internet Only Manual, Chapter 4, sections 260.1 and 261.1, respectively, and their subsections, available at <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf>.

To qualify for payment for the IOP APC (5851, 5852, 5861, or 5862) or the PHP APC (5853, 5854, 5863, or 5864), one service provided that day must be from the Partial Hospitalization and Intensive Outpatient Primary list. We refer readers to the CY 2024 OPPTS/ASC final rule with comment period for further discussion regarding our expectation that at least one of the services on the PHP and IOP Primary list will be indicated per day for patients who need the level of care offered by a PHP or IOP program. The PHP and IOP Primary List can be found in the CY 2024 OPPTS/ASC final rule with comment period at 88 FR 81821.

Beginning in CY 2024, we recognized caregiver training services and Principal Illness Navigation (PIN) services as PHP and IOP services. We explained that the reported costs associated with providing such services are included when we calculate the PHP and IOP payment rates; however, these services do not count toward the determination of whether a PHP or IOP day is paid at the 3-service or 4-service rate. We refer readers to the CY 2024 OPPTS/ASC final rule with comment period for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81821 and 81822), if new codes are

established that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively, such codes are added to the list of codes recognized for payment for PHP or IOP through sub-regulatory guidance. We note that coding updates frequently occur outside of the standard rulemaking timeline. We adopted this sub-regulatory process to pay expeditiously when new codes are created that describe any of the services enumerated at §§ 410.43(a)(4) and 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We explained that this policy applies to new codes that are cross walked to a previously included code, or whose code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. We stated that any additional services not described at § 410.43(a)(4) or § 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking.

In the CY 2025 OPPTS/ASC final rule with comment period (89 FR 94266 through 94268) and CY 2026 OPPTS/ASC final rule with comment period (90 FR 53770 through 53780), we did not add any new services not described at § 410.43(a)(4) or § 410.44(a)(4) to the list of PHP and IOP services.

C. Proposed CY 2027 Payment Rates for PHP and IOP

For CY 2027, we propose to maintain the current payment rate methodology that we use for calculating PHP and IOP payment rates for hospital-based providers. It has been our longstanding policy since CY 2011 to pay separate PHP APC per diem payment rates for CMHCs and hospital-based PHPs (75 FR 71992). As we explained in the CY 2026 OPPTS/ASC final rule with comment period, beginning in CY 2024, we applied this payment structure to IOP because we expected (and subsequently have observed) differences in resource use between CMHCs and hospital OPDs for the provision of both PHP and IOP services (90 FR 53777).

As finalized in the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53775 and 53776), we would apply the 40 percent MPFS Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs. Specifically, we would multiply the CY 2027 rates for the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs.

1. Background

Beginning in CY 2024, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-

service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we finalized a policy to calculate payment rates using the broader OPPS data set, instead of using hospital-based PHP data only. We explained that using the broader OPPS data set allows CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we established consistent coding and payment between the PHP and IOP benefits, we considered all OPPS data for PHP days and non-PHP days that include three or more of the same service codes. We established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81829 and 81830), we noted that the standard PHP day is typically four services or more per day. We explained that we have historically provided payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient is at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment.

In the same CY 2024 OPPS/ASC final rule with comment period, we also explained that prior to CY 2024, we historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We

direct the reader to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPPS/ASC proposed rule or final rule with comment period. We stated that these PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as noted earlier, we finalized a methodology for CY 2024 to calculate hospital-based PHP payment rates for three services per day and four services per day based on cost per day using the broader OPPS data set. Accordingly, we did not apply PHP-specific trims and data exclusions, but rather we applied the same trims and data exclusions consistent with the OPPS.

We stated in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81830) that while no IOP benefit existed prior to the CAA, 2023, the types of items and services included in IOP had been, and were, paid for by Medicare either as part of the PHP benefit or under the OPPS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

In addition, in the same CY 2024 OPPS/ASC final rule with comment period, we explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration the information we received from the comment solicitation to construct an appropriate data set to develop proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we stated that we believe it was appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. We explained that although PHP claims can be specifically

identified, there was no specific identifier or billing code to indicate IOP services that may have been provided before CY 2024. However, we noted that hospitals have been permitted to furnish and bill for many of these services as outpatient services under the OPPS. Thus, we analyzed a broader set of data that included both PHP and non-PHP days with three or more services in order to calculate proposed payment for PHP services. To establish consistent payment between PHP and IOP, we set IOP payment rates at the same rates as PHP. We stated that the primary goal in developing the payment rate methodology for IOP and PHP services was to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years. We stated that setting the IOP payment rates equal to the PHP payment rates was appropriate because IOP was a newly established benefit, and we did not have definitive data on utilization. However, we explained that both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week, depending on the program. Therefore, we stated that we expect it would be appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81833) we established a policy of applying the 4-service day payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with four or more services. For days with three or fewer services, we apply the 3-service day payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals). As we noted in the CY 2024 OPPS/ASC final rule with comment period, we expect days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269), for beneficiaries in a PHP or IOP, we maintained the payment rate methodology finalized in the CY 2024 OPPS/ASC final rule with comment period.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 and 53775), we explained that the calculated CY 2026 geometric mean per diem cost for CMHC PHP and IOP providers would result in an inversion (that is, the

CMHC three-service geometric mean per diem costs were greater than the CMHC four-service geometric mean per diem costs). We stated that we believed the inverted geometric mean per diem costs were influenced by the small number of CMHCs that bill Medicare for PHP and IOP services, as well as CMHCs with low costs that first began billing Medicare for services in CY 2024. We remedied this cost inversion and preserved our longstanding payment policy of appropriately reflecting the observed cost differences between the CMHC and hospital settings by applying the 40 percent MPFS Relativity Adjuster to the hospital-based PHP and IOP costs to calculate the PHP and IOP payment rates for CMHCs.

2. CY 2027 Payment Rate Methodology for PHP and IOP

For CY 2027, we propose to maintain our current methodology of calculating separate rates for hospitals and CMHCs. For the four hospital-based PHP and IOP APCs (that is, APCs 5861, 5862, 5863, and 5864), we propose using the latest available cost information, from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking, and CY 2025 OPPS claims to update the payment rates. This proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section II.A.1.a. of this proposed rule.

In accordance with the methodology finalized in the CY 2024 OPPS/ASC final rule with comment period, we propose to base the payment rate for each hospital-based PHP APC on the geometric mean per diem cost for days with three services and four or more services. We propose to use the broader set of OPPS data to calculate the geometric mean costs for hospital outpatient departments, and we propose to apply the same trims and exclusions consistent with the OPPS. We also propose to set the payment rates for the hospital-based IOP APCs based on the geometric mean per diem cost for PHP days with three services and four or more services.

For the four CMHC PHP and IOP APCs (that is, APCs 5851, 5852, 5853, and 5854), we propose to calculate the CY 2027 geometric mean per diem costs based on 40 percent of the corresponding hospital-based PHP and IOP APCs (APCs 5861, 5862, 5863, and 5864, respectively), in keeping with the methodology established in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53775 and 53776). We implemented this change in methodology for calculating the four CMHC PHP and IOP APCs to avoid possible future cost inversions (that is, the cost for 3-service days being greater than the cost for 4-service days). We believe this methodology would continue to be generally appropriate for estimating CMHC costs and aligns with

the methodology that is used for other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital outpatient department. For additional information on our analyses of the data used for setting the PHP and IOP payments rates for CY 2026 and application of the 40 percent MPFS Relativity Adjuster, we refer readers to sections VIII.C.2. and VIII.C.3. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53774 through 53779).

Lastly, we propose that if more recent hospital cost data subsequently become available after the publication of this proposed rule, we would consider using such updated data as appropriate to determine the CY 2027 payment rates for the four hospital-based PHP and IOP APCs.

Table 57 shows the proposed calculated geometric mean per diem costs for hospital-based PHP and IOP APCs, and the proposed geometric mean per diem costs for CMHC PHP and IOP APCs with application of the 40 percent MPFS Relativity Adjuster for this CY 2027 OPPS/ASC proposed rule. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this proposed rule can be found online at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>.²

TABLE 57: PROPOSED CY 2027 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2027 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	\$130.63
5852	Intensive Outpatient (4 or more services per day) for CMHCs	\$173.78
5853	Partial Hospitalization (3 services per day) for CMHCs	\$130.63
5854	Partial Hospitalization (4 or more services per day) for CMHCs	\$173.78
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	\$326.57
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	\$434.46
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	\$326.57
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	\$434.46

D. Proposed Outlier Policy for CMHCs

For CY 2027, we propose to maintain the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation,

outlier payment cap, and fixed dollar threshold according to previously established policies to include PHP and IOP services. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81834 through

81836) for more details on CMHC outlier policies, and to section II.G. of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS/ASC final rule with comment period (68 FR 63469 and 63470), we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C. of that same final rule with comment period (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082). We are not proposing any changes to the CMHC outlier percentage policy for CY 2027.

3. Cutoff Point and Percentage Payment Amount

Also described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. This

same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 and 58997), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 and 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR 81835). In the CY 2024 OPPS/ASC final rule with comment period, we extended this policy to intensive outpatient services. We are not proposing any changes to the cutoff point and payment amount policy for CY 2027.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 and 58875 and 81 FR 79678 through 79680, respectively). We are not proposing any changes to the outlier reconciliation policy for CY 2027.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). Our analysis of CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated costs from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem

payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. This cap was established after detailed analysis of claims data, which showed that a cap set at 8 percent would effectively address excessive outlier payments while minimally impacting CMHCs with legitimate high-cost cases. The cap applies to each CMHC's total per diem payments, which include both the Medicare payment portion and the beneficiary cost-sharing amount. The 8 percent cap continues to be calculated and applied on a calendar year basis, with outlier payments monitored throughout the year to ensure compliance with the cap.

This outlier payment cap only affects CMHCs; it does not affect other provider types (that is, hospital-based PHPs) and is in addition to and separate from the current outlier policy and reconciliation policy in effect. We are not proposing any changes to the outlier payment cap for CY 2027.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2026, CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852) are the only APCs for which CMHCs may receive payment under the OPPS, and these APCs are for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852), it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR

63508), the CY 2023 OPPTS/ASC final rule with comment period (87 FR 72004), the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81836), the CY 2025 OPPTS/ASC final rule with comment period (89 FR 94271), and the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53780). We are not proposing any changes to the fixed-dollar threshold policy for CY 2027.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

The Inpatient Only (IPO) list was established in rulemaking as part of the initial implementation of the Outpatient Prospective Payment System (OPPS) in 2000, pursuant to the Secretary's authority under section 1833(t)(1)(B)(i) of the Act (65 FR 18455) to determine the services covered and paid for under the OPPS. The IPO list was created to identify services excluded from payment under the OPPS by designating certain procedures as "inpatient only" and therefore payable only when furnished in the inpatient hospital setting under Medicare Part A (65 FR 18442). Services included on the IPO list were those determined to require inpatient care because of the invasive nature of the procedures, the underlying physical condition of the Medicare patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The creation of the IPO list was based on the premise (rooted in the practice of medicine at that time) that Medicare should not pay for procedures furnished as outpatient services when those procedures were being performed on an inpatient basis virtually all of the time for the Medicare population because performing these procedures on an outpatient basis was not safe or appropriate, and therefore not reasonable and necessary under Medicare rules (86 FR 63671; 63 FR 47571). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696). Rather, from the beginning, we have emphasized our expectation that, in every case, the physician or surgeon

and hospital will exercise their professional judgment and assess the risk of the procedure or service to the individual patient, taking into account the site of service and act in that patient's best interest (65 FR 18456). We have also previously stated that for procedures that are not included on the inpatient list, we rely on the practitioner's judgment to determine on a patient-by-patient basis whether or not a particular procedure would be most appropriately performed in the inpatient setting (70 FR 68698).

In the CY 2021 OPPTS/ASC final rule with comment period (85 FR 86084 through 86088), we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at 42 CFR 419.22(n) to state that, effective January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the 2022 OPPTS/ASC final rule with comment period, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we returned most services removed from the IPO list in 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition (86 FR 63676). We also finalized our proposal to codify the following five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation at § 419.23 (86 FR 63672):

- Most outpatient departments are equipped to provide the service or procedure to the Medicare population.
- The simplest service or procedure described by the code may be performed in most outpatient departments.
- The service or procedure is related to codes that CMS has already removed from the Inpatient Only list.
- CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.
- CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure,

or CMS has proposed to specify it as a covered ambulatory surgical procedure.

For CY 2023 through CY 2025, we maintained the IPO list and continued to evaluate services brought forth by interested parties for removal using the five longstanding criteria (87 FR 72004 through 72012; 88 FR 81858 through 81863; and 89 FR 94271 through 94275).

In the CY 2026 OPPTS/ASC final rule with comment period, we again finalized a policy to eliminate the IPO list over the course of three years, beginning by removing 285 mostly musculoskeletal procedures for CY 2026 (90 FR 53780 through 53802). As we stated in that rule, since the creation of the IPO list, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes such as improvements in pain management, that have reduced the inpatient length of stay and the need for postoperative care following a surgical service. We also recognize that since we previously considered elimination of the IPO list in the CY 2021 OPPTS/ASC final rule with comment period, there have also been other innovations in the practice of medicine; for example, innovations in infection control spurred by the COVID-19 PHE. Additionally, we believe that there are a number of safety mechanisms that will continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives (90 FR 53857). Given the significant number of services on the list and that we would establish new reimbursement rates for those services under the OPPS, we recognized that interested parties may need time to adjust to the removal of procedures from the list. Providers may need time to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS. Therefore, we finalized our proposal to transition services off the IPO list over a 3-year period (90 FR 53783). We also refer readers to the CY 2026 OPPTS/ASC final rule with comment period for further discussion on operational and beneficiary considerations, including the continuation of 2-midnight exemptions for services removed from

the IPO list, effects on beneficiary cost-sharing, and implications on the 3-day stay requirement for skilled nursing facilities (90 FR 53786 through 53788). After consideration of the comments received and the issues discussed, in the CY 2026 OPPS/ASC final rule with comment period, we finalized our proposal eliminating the criteria for removing procedures from the IPO list as it was then codified at § 419.23 and amended § 419.22(n) to state that, effective on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition period, with the list eliminated in its entirety by January 1, 2029 (90 FR 53788 to 53789 and 53086; 91 FR 8384). For further discussion on the elimination of the IPO list, please refer to section IX. of the CY 2026 OPPS/ASC final rule with comment period (90 FR 53780 through 53802).

B. Proposed CY 2027 Changes to IPO List

Currently, there are 1,438 services remaining on the IPO list. For CY 2027, we propose to remove approximately half of the remaining IPO services as the second phase of the elimination of the IPO list. Therefore, we propose to remove 637 services from the following clinical families: auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary. If we finalize our proposal to remove these services for CY 2027, the majority of remaining services are more complicated in nature, and we believe the services in these clinical families may require a lengthier review process and potential changes to our current APCs in order to determine an appropriate APC assignment. For example, some of the remaining procedures for removal in CY 2028 would be from the neurological family, cardiovascular family, solid organ, intestinal, and islet cell transplants and related services. We believe these services require additional considerations due to their complex clinical nature and resources required. We expect that these remaining clinical families and services would be removed from the IPO list for CY 2028, during the third and final phase of the elimination.

The clinical families proposed for the second phase of the elimination of the IPO list were selected based on stakeholder feedback and concerns regarding proper APC placement. In the CY 2026 OPPS/ASC proposed rule, we solicited comment on the order of removal of additional clinical families

of services, and/or specific services, for each of the CY 2027 and CY 2028 rulemaking cycles (90 FR 33669). We received comments requesting that we wait to remove certain invasive procedures involving craniectomy, craniotomy, and/or burr holes and cardiovascular procedures until the last phase, and we stated we would take the suggestions into consideration in future rulemaking (90 FR 53788). After further consideration, we agree with the commenters that we should wait to remove these more clinically complex and unique procedures, including the neurological and cardiovascular procedures, until the final phase. We believe that the complicated nature of the services in these clinical families may require a lengthier review process and potential changes to our current APCs in order to determine an appropriate APC assignment. Additionally, the clinical families listed above and proposed for removal in CY 2027 include multiple procedures that have been previously recommended by interested parties for removal from the IPO list. Based on our review, we also believe that the procedures in these clinical families require less adjustment to existing APCs compared to those clinical families we propose to remove in CY 2028, including the neurological and cardiovascular clinical families, meaning, they have clinical similarities and resource needs similar to that of existing procedures payable under the OPPS. As these groups of services are the next most clinically similar families, they are the natural next step in the phase out of the IPO. Therefore, we propose to remove selected less-complex services in the auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory, and urinary clinical families from the IPO list for CY 2027 and are maintaining the remaining clinical families for CY 2027. If we finalize our policy as proposed, we expect to address all of the remaining clinical families and their removal during CY 2028 rulemaking.

As we have previously stated, when removing a service from the IPO list, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). As stated in previous rulemaking, services that are no longer included on the IPO list are payable in either the inpatient or hospital outpatient setting subject to the general coverage rules requiring that any procedure be reasonable and necessary, and payment should be made pursuant

to the otherwise applicable payment policies (86 FR 63675). We determined the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and reviewing the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS. It should be noted, however, that we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting (67 FR 66740). Additionally, we are continuing to seek comments on whether we should restructure or create any new APCs or C-APCs to allow for efficient OPPS payment for services that are removed from the IPO list to account for this significant increase in services that will now be eligible for OPPS payment.

In summary, we propose to remove 637 services from the IPO list for CY 2027 as the second phase of the elimination of the IPO list. These services and their proposed status indicators and APC assignments (if applicable) are listed in the public use file titled “Proposed Procedures for Removal from the IPO List for CY 2027”, which is available on the CMS website. The services proposed for removal from the IPO list for CY 2027 and their proposed status indicators and APC assignments (if applicable) are also included in Addendum B of this proposed rule. The complete list of codes that describe services that are proposed to be paid by Medicare in CY 2027 as Inpatient Only services is included as Addendum E to this proposed rule.

X. Nonrecurring Policy Changes

A. Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

1. Background

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of clinic visit services furnished in excepted off-campus provider-based departments (PBDs). We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and payment policies we developed to address unnecessary increases in the volume of covered outpatient department (OPD) services. Below we discuss the policy we

finalized in the CY 2019 OPPS/ASC final rule with comment period and its expanded application under the OPPS in subsequent years.

In the CY 2019 OPPS/ASC final rule with comment period, we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services. We applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier “PO” on claim lines). However, we phased in the application of the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted provider-based department setting over 2 years. For CY 2019, the payment reduction was phased-in by applying 50 percent of the total reduction in payment that would have applied if these departments were paid the site-specific PFS rate for the clinic visit service. The PFS-equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). We provided for a 2-year phase-in of this policy under which one-half of the total 60 percent payment reduction (a 30 percent reduction) was applied in CY 2019. These departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30 percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second year of the 2-year phase-in, we stated that we would apply the total reduction in payment that is applied if these departments (departments that bill the modifier “PO” on claim lines) are paid the site-specific PFS rate for the clinic visit service described by HCPCS code G0463. For CY 2020 and subsequent years, the PFS-equivalent rate was 40 percent of the proposed OPPS payment (that is, 60 percent less than the OPPS rate).

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we implemented this policy in a non-budget neutral manner. We did so to ensure that our method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs did not simply increase other unnecessary expenditures

within the OPPS, thus driving different utilization-distorting decisions.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy which provided that off-campus PBDs (departments that bill the modifier “PO” on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2024 and subsequent years, we continued to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy.

In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53448), we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services for additional services. We finalized a policy for CY 2026 and subsequent years to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a non-excepted off-campus PBD (the PFS payment rate) for any HCPCS codes assigned to the drug administration services APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier “PO” on claim lines) (90 FR 53821). In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53824), we also finalized a policy which provided that off-campus PBDs (departments that bill the modifier “PO” on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the volume control method policy for drug administration services that applies a PFS-equivalent payment rate for the drug administration services APCs (5691–5694), when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of both policies, we refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 53802 through 53824).

We noted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53810 through 53812) that section 1833(t)(2)(F) of the Act provides authority to implement this policy. The U.S. Court of Appeals for the District of

Columbia Circuit held in *American Hospital Ass’n v. Azar* that a service-specific, non-budget-neutral reduction of the reimbursement rate for OPD services “qualifies as a ‘method for controlling unnecessary increases in the volume of covered [outpatient] services’ under that provision. 964 F.3d 1230, 1245 (D.C. Cir. 2020) (quoting section 1833(t)(2)(F) of the Act, 42 U.S.C. 1395l(t)(2)(F)). The D.C. Circuit reasoned in part that “[t]he lower the reimbursement rate for a service, the less the incentive to provide it, all else being equal[.]” and “[r]educing the reimbursement rate . . . is naturally suited to addressing unnecessary increases in the overall volume of a service provided by hospitals.” *Id.* at 1241. It ultimately concluded that the policy “falls comfortably within the plain text” of section 1833(t)(2)(F) of the Act, *id.* at 1241, “and ‘fits the design of the statute as a whole . . . and its object and policy,’” *id.* at 1245 (quoting *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 418 (1993)). We noted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53810) that we continue to believe that our interpretation of the Act is the best one, and that this policy falls well within the Act’s delegation to the Secretary to “develop a method for controlling unnecessary increases in the volume of covered OPD services”.

2. Expanding the Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments

As described in the CY 2019 OPPS/ASC final rule with comment period, we found that earlier rulemaking efforts were insufficient to control the unnecessary growth of certain covered OPD services and as a result we implemented a method to control for unnecessary growth in covered OPD services by adjusting the payment rate for clinic visits in excepted off-campus PBDs to the PFS-equivalent rate rather than the higher OPPS rate. While this regulatory change has had a positive impact, we noted in CY 2026 OPPS/ASC proposed rule that there is evidence of continued unnecessary growth in the volume of OPD services driven by site-of-service payment differentials rather than clinical need for other service families.

We continue to be concerned that beneficiaries are being driven into higher cost settings of care because of financial incentives when they could safely receive care in a lower cost setting. This creates greater financial burden both for Medicare and for

beneficiaries in the form of increased coinsurance. Volume increases that seek to take advantage of financial incentives created by payment policy rather than clinical need are unnecessary and therefore warrant policy changes to address these increases. As the D.C. Circuit explained, “[i]t is reasonable to think that Congress . . . would have wanted the agency to avoid causing unnecessary volume growth with its own reimbursement practices.” *Am. Hosp. Ass’n v. Azar*, 964 F.3d at 1245. Accordingly, for CY 2026, we finalized a policy to remove this differential for drug administration services delivered in excepted PBDs. We are continuing to study and identify services that we believe have experienced unnecessary growth in volume driven by site-of-service payment differentials rather than clinical need.

In the CY 2026 OPPS/ASC proposed and final rules, we indicated we are particularly concerned about the services within the imaging without contrast APCs (APCs 5521–5524).

Imaging without contrast services are often high-volume, low-intensity services that can be provided in OPDs or freestanding offices. In the CY 2026 OPPS/ASC proposed rule, we stated that we are concerned that these services have experienced unnecessary growth and that a volume control method may be appropriate to apply in the future (90 FR 33690). Additionally, we solicited comments on whether it might be appropriate to apply a volume control method to the imaging without contrast APCs in the future.

Many healthcare services can be performed in multiple settings. Even when there is little variation in the service provided across settings, the Federal Supplementary Medical Insurance Trust Fund and Medicare beneficiaries typically pay more when that service is performed in an OPD than when the same service is performed in a physician office. That payment differential creates an incentive for providers to shift the care of beneficiaries to an OPD rather than a physician office or ASC, even if the services can be safely performed in the physician office or an ASC. Generally, 20 percent of any increased payment is the responsibility of the beneficiary in the form of coinsurance. Taking into account that any payment differential occurs across millions of claims for a variety of services each year, this threatens to create a significant source of unnecessary spending both by Medicare beneficiaries in the form of unnecessarily high copayments and by Medicare in the form of unnecessarily high Medicare payments for services

that are being performed in an OPD because of the site-of-care payment difference.

In the CY 2019 OPPS/ASC final rule with comment period, we discussed vertical consolidation and the practice of hospitals purchasing freestanding physician practices and converting the billing from the PFS to higher paying OPD visits. These conversions shift market share from freestanding physician offices to OPDs. We stated that we believed there was a correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. More favorable reimbursement for hospital-owned sites compared to physician-owned sites has been shown to encourage hospitals’ acquisition of physician practices.^{125 126} Once a practice is acquired and designated as an OPD, physician services can be billed at higher hospital-based rates. This type of consolidation has been associated with higher Medicare spending and more intense treatment patterns.^{127 128 129}

The impact of vertical integration and the increases in volume of outpatient services extends to multiple clinic families. Studies have shown that, after vertical integration, the number of imaging tests performed in hospital sites of care increased while the number of procedures performed in nonhospital sites of care decreased.¹³⁰

Our policy in the CY 2019 OPPS/ASC final rule with comment period to pay for clinic visits in excepted off-campus PBDs at the PFS-equivalent rate addressed the financial incentive for only one type of service in one outpatient setting. However, the share of other ambulatory services billed under the OPPS has continued to increase. We built upon this policy in the CY 2026 OPPS/ASC proposed rule to address the unnecessary growth in drug administration services. Like with clinic visit and drug administration services, we believe the difference in payment between OPDs and freestanding offices creates a strong incentive for providers to shift imaging without contrast services to the higher-cost setting.

For CY 2027, we have examined the growth in imaging without contrast

services provided in excepted PBDs. Imaging without contrast services are diagnostic imaging procedures that do not require the administration of contrast agents and instead rely on standard imaging modalities such as X-ray, ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and dual-energy X-ray absorptiometry scans (DXA) to produce clinically meaningful images. These services are generally low- to moderate-complexity and are routinely used to evaluate a wide range of conditions, including musculoskeletal injuries, organ structure, and disease screening. Imaging without contrast services can be safely and effectively furnished in multiple settings, including freestanding physician offices and hospital OPDs, without compromising diagnostic quality or patient safety.

For example, in 2023, for transthoracic echocardiograms (HCPCS 93306), a high-volume imaging without contrast service frequently provided in OPDs and freestanding physician offices, Medicare paid 294 percent more in an OPD than in a freestanding office.¹³¹ HCPCS code 77080, which describes a DXA scan measuring bone density at the axial skeleton (hips, pelvis, spine), is the most frequently billed imaging without contrast code in excepted PBDs. In 2025, this service had a physician office payment rate of around \$30 and an OPPS payment rate of approximately \$106, making the same scan more than three times as expensive in the OPD than in the physician office. Based on our claims data analysis, the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. Conversely, from 2016 through 2024, the volume of HCPCS code 77080 has only grown by 2 percent in the freestanding physician office setting. This service can be and routinely is safely performed in either setting, but there is a clear financial incentive to perform this service in excepted PBDs due to substantially higher payment in the outpatient setting compared to the physician office setting.

We estimate that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. These codes comprise the overwhelming majority of imaging without contrast services provided in excepted PBDs. From 2016 to 2025, the provision of these services grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a

¹²⁵ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830>.

¹²⁶ <https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13613>.

¹²⁷ <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591>.

¹²⁸ <https://www.healthaffairs.org/doi/10.3777/hlthaff.2020.01183>.

¹²⁹ <https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14172>.

¹³⁰ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9924392/>.

¹³¹ https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.

33 percent increase in spending, corresponding to approximately \$126 million in additional spending in CY 2025. This growth in the volume of imaging without contrast services in excepted PBDs can largely be attributed to the financial incentive to furnish low-complexity imaging services in OPDs rather than physician offices.

We considered whether other factors, such as coding changes, updates to clinical practice guidelines, or shifts in beneficiary case mix, might explain this growth. However, we believe these alternative explanations are unlikely to account for the observed patterns. Our analysis focuses on a stable set of high-volume HCPCS codes that consistently represent the vast majority of imaging without contrast services over time, limiting the likelihood that coding changes are driving the increase. In addition, we are not aware of any broad changes in clinical guidelines during this period that would warrant substantial increases in the use of routine, low- to moderate-complexity imaging services across these modalities. Finally, although there may be some variation in beneficiary characteristics over time, the magnitude of the growth in utilization, particularly when considered alongside declining fee-for-service enrollment and relatively stable or modest volume growth in physician offices, suggests that changes in case mix are not the primary driver of growth in excepted PBDs. Taken together, these considerations support the conclusion that site-of-service payment differentials, rather than clinical or coding factors, are a principal contributor to the observed increases in volume.

We stated in the CY 2026 OPPTS/ASC proposed rule that we believe that financial incentives have driven volume from the office setting to the higher paying OPD setting, creating unnecessary increases in the volume of OPD services. We also stated that we believe that this problem is pervasive and exists across a number of service families. Section 1833(t)(2)(F) of the Act directs the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services, and CMS has previously interpreted this provision to permit payment adjustments that address financial incentives contributing to such increases. Consistent with this authority, CMS may implement a volume control method for imaging without contrast services furnished in excepted off-campus PBDs, where evidence demonstrates increases in utilization and that increase is disproportionately concentrated in

higher-paid hospital outpatient settings. Because these services are commonly furnished in physician offices and do not generally require hospital-level resources, higher OPPTS payment rates may incentivize shifts in site of care and increased utilization that are not clinically driven. As CMS established in the CY 2019 OPPTS/ASC final rule with comment period and reaffirmed in subsequent rulemaking, including the CY 2026 OPPTS/ASC final rule with comment period, and as the D.C. Circuit held in *American Hospital Ass'n v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020), aligning payment rates across settings for clinically comparable services is an appropriate “method” to mitigate these incentives. Accordingly, applying a PFS-equivalent payment rate to imaging without contrast services in excepted PBDs represents a reasonable approach to controlling unnecessary increases in OPD service volume.

Any time a service is provided in the higher cost OPD when it could be provided safely in the physician office but is not because of financial incentives, it potentially represents unnecessary utilization of the OPD setting. In CY 2019, we started by addressing a pervasive problem with the clinic visit provided in excepted PBDs. In that case, it was practical to address only a single code, G0463, the clinic visit. For CY 2026, we finalized a policy to address drug administration services provided at excepted PBDs. We chose to address payment for these services across the APC family, meaning all codes assigned to these APCs, as we believe this volume control method should apply to all drug administration services at excepted PBDs. For CY 2027, we again propose addressing services across an APC family.

Our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered OPD services authorizes us to address real world effects of these payment inequalities. Given these continued disparities, we believe it is necessary to further examine and refine our volume control method by identifying additional covered OPD services that we believe are being shifted to the hospital setting based on financial incentives rather than medical necessity. We conducted an analysis of imaging without contrast services paid under the OPPTS and present our findings on the utilization and payment of these services in the sections below.

3. Utilization of Imaging Without Contrast Services

The high volume of imaging without contrast services and the magnitude of rate differences between the physician office and OPD settings make it a family of services likely to migrate to a higher paying setting of care. Imaging without contrast services can be performed in either physician offices or OPDs. In the OPPTS, imaging without contrast services are categorized into four levels of complexity. Payments are set at a category level, called an Ambulatory Payment Classification (APC). The APCs for imaging without contrast service are 5521 (Level 1 Imaging Without Contrast), 5522 (Level 2 Imaging Without Contrast), 5523 (Level 3 Imaging Without Contrast), and (Level 4 Imaging Without Contrast) 5524. For 2026, 337 Healthcare Common Procedure Coding System (HCPCS) codes make up the four levels of the imaging without contrast APCs. Although there are 337 HCPCS codes in the four imaging without contrast APCs, we estimate that 70 HCPCS codes account for over 95 percent of the volume of imaging without contrast services provided in excepted PBDs. This trend extends to non-excepted PBDs, where 70 HCPCS codes also make up over 95 percent of claims volume. There is an approximate 90 percent overlap of the top 70 most frequently billed imaging without contrast codes in excepted and non-excepted PBDs. HCPCS codes that are similar in terms of cost and clinical attributes are placed in the same APC. All HCPCS codes in the same APC have the same OPPTS payment rate. The individual HCPCS and APC assignments are available in Addendum B to this proposed rule.

We evaluated the growth in volume and spending for multiple families of APCs in OPDs across multiple years of claims data. Should commenters wish to replicate any of our analyses, the CMS website includes information about obtaining the “Limited Data Set,” <https://www.cms.gov/data-research/files-for-order/data-disclosures-and-data-use-agreements-duas/limited-data-set-lds> through which OPPTS claims data are available for purchase. Additionally, we will make publicly available a file containing the 70 HCPCS codes that we estimate account for more than 95 percent of the volume of imaging without contrast services provided in excepted PBDs.

The PO modifier was established to identify services furnished in off-campus PBDs and became mandatory following implementation of section 603 of the Bipartisan Budget Act of 2015.

CMS finalized this requirement in the CY 2016 OPPI/ASC final rule with comment period, requiring hospitals to report the PO modifier for services provided in excepted off-campus PBDs beginning January 1, 2016. We subsequently established the PN modifier to identify services furnished in nonexcepted off-campus PBDs, which are paid under the PFS-equivalent rate rather than the full OPPI rate. Hospitals were required to begin reporting the PN modifier starting January 1, 2017. The mandatory use of the PO and PN modifiers has enabled CMS, MedPAC, and the hospital industry to track utilization patterns.

We found that there has been an increase in the volume of services paid through the imaging without contrast APCs (5521–5524) over time, which indicates that there has been migration of these services to the OPD setting. From 2016 to 2025, the volume of the 70 HCPCS codes which account for over 95 percent of imaging without contrast services provided in excepted PBDs grew over 38 percent. From 2016 to 2025, these increases in volume have resulted in a 33 percent increase in spending, corresponding to approximately \$126 million in additional spending in CY 2025. This growth persisted even with the introduction of the PFS-equivalent rate for PBDs subject to section 603 of the Bipartisan Budget Act of 2015 starting in 2017. The COVID–19 Public Health Emergency (PHE) did impact utilization across the OPPI, but we have seen the volume of imaging without contrast services rebound and return to this pattern of unnecessary volume growth. Between 2016 and 2025 we have seen increases in the volume of imaging without contrast services provided in OPDs utilized per beneficiary.¹³² Between 2016 and 2025, for the top 70 most frequently billed imaging without contrast HCPCS codes provided in excepted PBDs, there has been an over 67 percent increase in utilization per beneficiary. This upward trend persists despite a declining Part B FFS population. During this same time, for example, FFS enrollment decreased by approximately 17 percent, indicating that imaging services are being used more frequently on a per-beneficiary basis rather than growth being driven by enrollment.

In addition to looking at the growth in volume and spending at the APC level for imaging without contrast services provided at excepted PBDs, we also examined the growth in volume at the

HCPCS code level. Analysis of HCPCS-level utilization trends from 2016 through 2025 indicates that several imaging without contrast services experienced particularly pronounced growth in volume, with increases far exceeding overall Medicare enrollment growth. Several codes experienced growth in the excepted PBDs that outpaced growth in the physician office setting.

HCPCS code 77080, which describes a DXA scan measuring bone density at the axial skeleton (hips, pelvis, spine), is the most frequently billed imaging without contrast code in excepted PBDs. In 2025, this service had a physician office payment rate of around \$30 and an OPPI payment rate of approximately \$106, making the same scan more than three times as expensive in the OPD compared to the physician office. Based on our claims data analysis, the volume of this service has grown by over 55 percent in excepted PBDs between 2016 and 2025. In contrast, from 2016 to 2025, utilization of this code in the physician office setting decreased modestly, by less than half a percent. HCPCS code 71045, which describes a simple chest x-ray, was created in 2018 as part of the 2018 CPT/HCPCS code restructuring for chest radiography. In 2025, this service had a physician office payment rate of around \$17 and an OPPI payment rate of approximately \$88, making the same scan 417 percent more expensive in the OPD than in the physician office. Based on our claims data analysis, the volume of this service has grown by over 92 percent in excepted PBDs between 2018 and 2025. From 2018 to 2025, this code decreased in volume by 33 percent in the physician office setting.

The volume for HCPCS 71250, which describes a CT scan of the chest performed without contrast dye, increased roughly 72 percent in the excepted PBD setting between 2016 and 2025. In contrast, the physician office setting experienced a comparatively modest increase of 33 percent over the same time period. In 2025, this service has a physician office payment rate of around \$83 and an OPPI payment rate of approximately \$106, making the same CT scan 27 percent more expensive in the OPD than in the physician office.

Similarly, HCPCS 70551, which describes an MRI scan of the brain, including the brainstem, performed without contrast material grew by 41 percent between 2016 and 2025 at excepted PBDs. From 2016 to 2025, this code only grew by 14 percent in the physician office setting. In 2025, this service had a physician office payment rate of around \$127 and an OPPI

payment rate of approximately \$243, making the same scan 91 percent more expensive in the OPD than in the physician office.

HCPCS 76536, which describes an ultrasound of the head and neck, had excepted PBD volume increase 48 percent from 2016 to 2025. The same code only experienced a 4 percent increase in volume in the physician office setting during the same time period. In 2025, this service had a physician office payment rate of around \$82 and an OPPI payment rate of approximately \$106, making the same scan 29 percent more expensive in the OPD than in the physician office.

Breast imaging services also demonstrated substantial increases, with the volume of ultrasound breast complete (HCPCS 76641) increasing 52 percent in the excepted PBD setting from 2016 to 2025. From 2016 to 2025, this code decreased in volume by 25 percent in the physician office setting. In 2025, this service had a physician office payment rate of around \$66 and an OPPI payment rate of approximately \$106, making the same scan 60 percent more expensive in the OPD than in the physician office.

These services are generally low- to moderate-complexity imaging procedures that can be safely performed in multiple settings, and their growth in volume in excepted PBDs suggests increased utilization intensity beyond what would be expected based solely on growth in the Medicare population. We believe that the financial incentives created by payment policy rather than clinical need are a significant factor in shifting these services to OPDs. If there was not a material difference in payment rates, we believe fewer of these services would have shifted to OPDs and the corresponding increase in Medicare payments and beneficiary cost-sharing would not have occurred.

We also examined trends across excepted and non-excepted PBDs, alongside the physician office setting. There are approximately four times as many providers billing with the PN modifier (nonexcepted PBDs) as compared to the PO modifier (excepted PBDs). This substantial difference suggests that non-excepted PBD services are distributed across a much broader provider base, while volume in excepted PBDs remains concentrated among a smaller group of providers.

Excepted PBDs continue to account for the overwhelming share of imaging without contrast volume, even as non-excepted PBDs have grown steadily in recent years. Across the highest-volume services, the gap remains substantial: in 2025, excepted PBDs furnished roughly

¹³² Based on our analysis of claims data and Medicare FFS enrollment.

4 to 5 times the volume of non-excepted PBDs for key services, accounting for about 75–82 percent of total combined PBD volume. For example, excepted PBDs represent approximately 81 percent of volume for HCPCS 77080 (DXA bone density scan), 79 percent for HCPCS 71046 (chest x-ray, 2 views), 79 percent for HCPCS 93306 (complete transthoracic echocardiography), and 83 percent for HCPCS 71250 (CT thorax without contrast). In the physician office setting, by contrast, these same services show relatively stable or modest growth over time rather than rapid expansion. Importantly, these are routine imaging services that rely on widely available equipment and standardized protocols and they are clinically comparable regardless of setting, meaning they can be safely and effectively performed in physician offices, non-excepted PBDs, or excepted PBDs without meaningful differences in patient acuity or quality.

For example, in its 2023 report, MedPAC examined APCs where such potentially unnecessary payment differentials exist.¹³³ To identify appropriate APCs, MedPAC compared the volume of services in each APC that was provided in OPDs, ASCs, and freestanding offices over the period of 2016 through 2021, but omitted 2020 because the coronavirus pandemic affected the volume of care in ambulatory settings. If freestanding offices had the highest volume for an APC, MedPAC concluded that the services in that APC could be provided safely in freestanding offices for most beneficiaries and that beneficiaries would be able to access the services in that APC. Therefore, for those services, it would be reasonable to align the OPPS payment rates with the PFS payment rates. MedPAC found that all four of the imaging without contrast APCs had higher volume in freestanding facilities than in OPDs, indicating that these services can be safely provided to beneficiaries in a lower cost setting of care.

We believe MedPAC's analysis aligns well with the rationale CMS adopted in the CY 2019 OPPS/ASC final rule with comment period: we consider OPPS utilization potentially unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in the hospital outpatient setting because of site-of-service payment differentials.

In our review of the utilization of imaging without contrast services in

excepted PBDs, we found increases in the volume of services over time, increases in the volume of services provided per beneficiary, and significant volume growth for some individual HCPCS codes within the imaging without contrast APC family. We believe that these changes represent unnecessary increases in the volume of covered OPD imaging without contrast services and, therefore, we propose to apply our volume control method to these services under section 1833(t)(2)(F) of the Act.

4. Payment for Imaging Without Contrast Services at PBDs

As discussed in the CY 2017 OPPS/ASC interim final rule with comment period (81 FR 79726), we established a Medicare PFS relativity adjuster that is applied to the OPPS rate for the billed non-excepted items and services furnished in a non-excepted off-campus PBD to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the non-excepted items and services furnished in non-excepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The PFS relativity adjuster, as discussed in the CY 2018 PFS final rule, is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). Non-excepted PBDs are required to use the modifier “PN” so that the PFS relativity adjuster is applied to the payment of their claim. Excepted PBDs use the modifier “PO” on their claims to indicate that the service was provided at an excepted off-campus PBD and that payment should generally be made at the OPPS rate.

In the CY 2019 OPPS/ASC final rule with comment period, we stated that we consider the shift of services from the physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting (83 FR 59006). To better understand the migration of services to off-campus OPDs, we analyzed claims data for imaging without contrast services to assess whether increases in volume and spending could be driven by payment incentives. We examined the top 70 most frequently billed HCPCS codes in the imaging without contrast APC family at both excepted and non-excepted off-campus PBDs. These 70

HCPCS codes account for over 95 percent of the volume of imaging without contrast services in off-campus PBDs. We found that over 90 percent of these codes in the imaging without contrast APCs were in the top 70 most frequently billed codes at both excepted and non-excepted off-campus PBDs with slight variations in the order based on volume. We therefore concluded that the majority of HCPCS codes in the imaging without contrast APCs were being billed with both the “PO” and “PN” modifiers, indicating that these imaging without contrast services were safely being provided in both excepted and non-excepted PBDs.

We also compared OPPS and PFS payment rates by using PFS payment rates for the most frequently billed imaging without contrast HCPCS codes by excepted PBDs (departments that bill the modifier “PO” on claim lines) and volume-weighting them to create a PFS proxy average APC payment rate for all imaging without contrast services. Using this approach, we found that, on average, OPPS payment rates for excepted off-campus PBDs are approximately 2.5 times higher than PFS rates, while non-excepted PBD rates are closely aligned with the PFS. At the APC level, PFS payments range from about 31 percent to 54 percent of OPPS payments, confirming a substantial and consistent payment differential. A similar pattern is observed for beneficiary cost-sharing, where average cost-sharing in excepted PBDs is more than double that in freestanding physician offices, while cost-sharing for services provided in non-excepted PBDs is closely aligned with cost-sharing in physician offices.

We presently believe that the differential in our payment rates has created a payment incentive that has led to unnecessary growth for the services in the imaging without contrast APCs. We consider the shift of services from the physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives. We presently believe the OPPS payment rate for the imaging without contrast APCs being several times greater than the PFS rate creates such a payment incentive and that the growth in imaging without contrast services at excepted PBDs is therefore unnecessary.

We do not believe that the imaging payment limitation established under section 5102 of the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171), codified at section 1848 of the Act), constrains our ability to implement a

¹³³ www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.

volume control method for imaging without contrast services furnished in excepted off-campus PBDs. The DRA provision applies specifically to services paid under the PFS and limits payment to the lesser of the PFS or OPPS amount, but it does not directly affect payment for services furnished in PBDs. The DRA functions as a ceiling on PFS payments, ensuring they do not exceed OPPS rates, while the PFS relativity adjuster is used to scale payments appropriately when applied in the PBD setting. As a result, using PFS-equivalent rates for imaging without contrast services in excepted PBDs aligns excepted PBD payment rates under the OPPS with payment rates for these services under the PFS and therefore would not conflict with the DRA.

5. Patient Severity and Cost of Care

In comments to the CY 2019 OPPS/ASC proposed rule and subsequent rulemaking, we heard from commenters that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. We recognize that OPDs serve unique patient populations and provide services to medically complex beneficiaries; however, we presently believe that there is no evidence to demonstrate the need for higher payment for services provided in OPDs that could also be provided in lower-cost settings. This is particularly relevant for imaging without contrast services, which are generally low- to moderate-complexity diagnostic procedures, such as standard CT, MRI, ultrasound, radiography, and bone density testing, that do not require the administration of contrast agents or the associated monitoring and infrastructure. These services can be safely and effectively furnished in multiple settings, including physician offices, without compromising quality or patient safety.

In general, despite marked differences in payment rates for a range of services, identical services are being delivered to very similar patients across physicians' offices, hospital OPDs, and ASCs.¹³⁴ ¹³⁵

Moreover, a 2023 literature review found no peer-reviewed evidence that shows differences in the quality of services delivered across hospital OPDs and physicians' offices.¹³⁶ In their 2023 report, MedPAC evaluated risk scores from the CMS hierarchical condition category (CMS-HCC) risk-adjustment model to compare the medical complexity of OPD patients with patients in freestanding offices. They found that, on average, OPD patients have higher risk scores, which suggests that OPD patients are potentially more medically complex than those in physician offices. However, they also found substantial overlap in the CMS-HCC risk scores of patients in these two settings, which suggests that the difference in patient severity between settings is small. Their analysis showed that the effects of patient severity on cost of care for the aligned services is not statistically significant as the services, like imaging without contrast services, are generally of low complexity. In addition, if there is a need to bill for more complex cases, under the OPPS providers can often bill separately for additional services that a patient might need such as prolonged observation, emergency medications, or additional diagnostic testing furnished in response to a complication or change in the patient's condition during the outpatient encounter. Accordingly, we continue to believe that higher OPPS payment rates for imaging without contrast services are not justified by differences in patient complexity or resource needs and may instead contribute to unnecessary increases in utilization in higher-cost settings.

6. Impact of Unnecessary Increases in Volume on the OPPS

Our concern with unnecessary increases in the volume of imaging without contrast services is tied to the health and sustainability of the OPPS. As described in table 51 in the CY 2019 OPPS/ASC final rule with comment period, we found that the mean and median annual increases in the volume and intensity of hospital outpatient

services were about 5.5 percent and 5.4 percent, respectively, from 2011 to 2019. Over that period, the estimated increase in aggregate annual hospital incurred payments through Medicare FFS Part B was \$28.2 billion.¹³⁷

More recent data indicates that this trend has persisted and accelerated. As shown in Table 58, from 2019 through 2027, hospital outpatient costs per FFS enrollee are projected to grow at a mean annual rate of approximately 7.7 percent and a median annual rate of 9.2 percent.¹³⁸ After a temporary decline in 2020, annual growth rebounded sharply to 19.7 percent in 2021. From 2022 through 2027, the projected year-over-year annual growth rates are expected to range from 4.7 percent to 9.5 percent annually. As seen in Table 59, over this period outpatient hospital spending per FFS enrollee is projected to increase from \$1,738 in 2019 to \$3,238 in 2027, an increase of about 86 percent.¹³⁹ This translates to an increase of approximately \$35 billion in aggregate annual incurred reimbursements for hospital outpatient services between 2019 and 2027. This level of growth exceeds that observed in other categories of Part B services in dollar terms and occurs despite relatively stable or declining FFS enrollment over much of the period.

When looking at this time period it is important to note that the COVID-19 Public Health Emergency (PHE) likely contributed significantly to the increase in claims volume in 2021. During the acute phase of the pandemic in 2020, many outpatient services were delayed or deferred as beneficiaries postponed routine care and providers limited non-urgent services. As these restrictions eased in 2021, utilization rebounded sharply as providers worked through substantial backlogs of postponed services and beneficiaries returned for deferred evaluations and treatment. This pent-up demand for outpatient care likely contributed to the pronounced increase in year-over-year outpatient hospital cost growth observed in 2021.

¹³⁵ https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.

¹³⁶ <https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf>.

¹³⁷ Available in Table IV.B6. at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf>.

¹³⁸ <https://www.cms.gov/oact/tr/2025>.

¹³⁹ <https://www.cms.gov/oact/tr/2025>.

¹³⁴ <https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf>.

TABLE 58: GROWTH IN HOSPITAL OUTPATIENT COSTS PER FEE-FOR-SERVICE ENROLLEE¹³⁸

Calendar Year	Percent Increase
2019	5.2
2020	-5.8
2021	19.7
2022	4.7
2023	8.4
2024	9.4
2025	9.4
2026 (Estimated)	9.2
2027 (Estimated)	9.5

Calendar Year	Outpatient Hospital Spending Per Fee-For-Service Enrollee
2019	\$1,738.46
2020	\$1,663.57
2021	\$2,021.31
2022	\$2,072.33
2023	\$2,230.61
2024	\$2,450.22

Taken ¹⁴¹ together, the sustained acceleration in per-enrollee spending and aggregate expenditures suggests that factors beyond underlying beneficiary need, such as increases in service volume and intensity, are contributing to spending growth in the hospital outpatient setting. Continued increases in the volume of imaging without contrast services raise concerns about potentially unnecessary utilization. Such trends have implications for beneficiary exposure to low-value care as well as for the financial sustainability of the OPSS.

As we stated in the CY 2019 OPSS/ASC final rule with comment period (83 FR 59018), there is evidence that increased volume and intensity of certain covered OPD services is likely driven by financial incentives to furnish services in hospitals in order to receive higher reimbursement, rather than making site-of-service decisions based on medical necessity. We continue to be concerned with the rate of increase in program expenditures under the OPSS for several reasons. The OPSS was originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this Congressional purpose, the OPSS has continued to be one of the fastest growing sectors of Medicare payments out of all payment systems under

Medicare Parts A and B.¹⁴²

Furthermore, we are concerned that the persisting rate of growth relative to other payment systems suggests that payment incentives, rather than patient acuity or medical necessity, continue to affect site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Our authority to implement volume control methods is an important tool in combating unnecessary OPSS utilization. We have seen success in stemming unnecessary growth in the volume of clinic visits at excepted PBDs. Since 2019, when we began phasing in our volume control method, there has been a 25 percent decrease in the volume of clinic visit services performed in excepted PBDs. Since 2023, the volume of clinic visit services at excepted PBDs has stayed relatively steady. We believe that imaging without contrast services provided at excepted PBDs are in need of similar treatment.

7. Multiple Procedure Discounts

In the CY 2009 OPSS/ASC final rule with comment period (73 FR 68559 through 86569), we finalized a policy that, effective January 1, 2009, we make a single payment each time a hospital

submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session. We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3 of this proposed rule.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPSS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);

¹⁴² <https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf>.

- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (non-composite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. As discussed in section XX of this proposed rule, for CY 2027 we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology.

The multiple imaging composite APC policy reflects the efficiencies that hospitals can achieve when furnishing multiple imaging procedures within the same imaging family during a single session. A similar principle underlies the multiple procedure payment reduction (MPPR) policy for diagnostic imaging services under the PFS. Under the MPPR policy, when multiple diagnostic imaging procedures are furnished to the same patient in the same session, payment for the technical component of the subsequent procedures is reduced to reflect efficiencies associated with the preparation of the patient, positioning, and other clinical and administrative activities that do not need to be repeated for each additional imaging procedure. Both the OPPI multiple imaging composite APC policy and the PFS MPPR policy recognize that furnishing multiple imaging services during the same encounter generally requires fewer resources than furnishing those services separately. Consistent with other services furnished in non-excepted PBDs, when multiple imaging procedures are performed at a non-excepted PBD and paid through one of the multiple imaging composite APCs, providers are required to report modifier “PN,” and the PFS relativity adjuster is applied to the composite APC payment.

As discussed later in this section, we propose to apply our volume control methodology to the imaging without

contrast APCs (5521–5524). We believe it is also appropriate to apply the volume control methodology to APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite). APCs 8004, 8005, and 8007 are comprised of HCPCS codes assigned to the imaging without contrast APCs that would be subject to the volume control methodology when paid separately. In other words, the underlying imaging without contrast services that qualify a claim for payment under APCs 8004, 8005, and 8007 are the same imaging procedures for which we propose to apply the volume control methodology under the standard APC payment structure.

Accordingly, excluding APCs 8004, 8005, and 8007 from the volume control methodology would result in different payment treatment for the same underlying imaging procedures based solely on whether those procedures were paid separately or through a multiple imaging composite APC. We do not believe such differential treatment would be appropriate. Moreover, because APCs 8004, 8005, and 8007 are comprised of HCPCS codes assigned to the imaging without contrast APCs that would be subject to the volume control methodology when paid separately, excluding these composite APCs would allow a portion of the same imaging services that contribute to the volume concerns identified above to be paid outside the volume control methodology when furnished in excepted PBDs. Further, because these composite APCs are already subject to the PFS relativity adjuster when furnished at non-excepted PBDs, excluding them from the volume control methodology in excepted PBDs could create inconsistent payment incentives across settings and undermine the effectiveness of the volume control methodology. Therefore, we propose to apply the volume control methodology to APCs 8004, 8005, and 8007.

8. Payment for Imaging Without Contrast Services for CY 2027 and Subsequent Years

As we stated in the CY 2019 OPPI/ASC final rule with comment period, we consider the shift of services from the

physician office to the hospital OPD unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives (83 FR 59006). We believe the increase in the volume of imaging without contrast services is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could generally be safely provided in a lower cost setting, we believe that the growth in imaging without contrast services paid under the OPPI is unnecessary. Further, we believe that paying for imaging without contrast services provided at excepted off-campus PBDs at the PFS-equivalent rate could be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. We believe this method will control unnecessary volume increases both in terms of the number of covered OPD services furnished and costs associated with those services.

Therefore, given the unnecessary increases in the volume of imaging without contrast services in hospital OPDs, we propose to apply the PFS-equivalent payment rate to HCPCS codes assigned to the imaging without contrast APCs and to services paid through APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite) when furnished at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill modifier “PO” on claim lines). Under our authority in section 1833(t)(2)(F) of the Act, we would implement this proposal by applying an amount equal to the site-specific PFS payment rate for non-excepted items and services furnished by a non-excepted off-campus PBD (the PFS-equivalent payment rate). Table 60 shows the specific APCs that we would identify for this proposal, which are APCs 5521 through 5524, 8004, 8005, and 8007. Off-campus PBDs that are not excepted from section 603 (departments that bill the modifier “PN”) already receive a PFS-equivalent payment rate for any HCPCS codes assigned to the imaging without contrast APCs.

TABLE 60: PROPOSED NEW APCS PAID THE PFS-EQUIVALENT RATE FOR SERVICES PROVIDED AT EXCEPTED OFF-CAMPUS PBDS FOR CY 2027

APC	APC Description
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
8004	Ultrasound Composite
8005	CT and CTA without Contrast Composite
8007	MRI and MRA without Contrast Composite

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), we finalized our method to address the unnecessary increases in utilization of clinic visits in the OPD setting in a non-budget neutral manner. In the CY 2026 OPPS/ASC final rule with comment period (90 FR 53448), we likewise finalized an expansion of our method to address the unnecessary increases in utilization of drug administration services in the OPD setting in a non-budget neutral manner. For CY 2027, we propose to implement this proposed method to address the unnecessary increases in utilization of imaging without contrast services in the OPD setting in a non-budget neutral manner. We continue to believe that, while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled “Periodic review,” provides, in part, that the Secretary must annually review and revise the groups, “the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors” (emphasis added). Section 1833(t)(9)(B) of the Act, titled “Budget neutrality adjustment” provides that if “the Secretary makes *adjustments* under subparagraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made” (emphasis added). However, a volume-control method under section 1833(t)(2)(F) of the Act is not an “adjustment” under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the

outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a “method” for controlling unnecessary increases in the volume of covered OPD services, not an “adjustment.” Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those subparagraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in subparagraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent* year. We therefore continue to interpret this provision to mean that the Secretary can implement a volume control method under section 1833(t)(2)(F) of the Act in a non-budget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method (see 83 FR 59009).

We stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59010) that we believe implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the

volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613). We believe that concern applies to imaging without contrast services just the same. The estimated payment impact for various provider classifications is displayed in Table 88: Estimated Impact of the Proposed CY 2027 Update to the ASC Payment System on Aggregate CY 2026 Medicare Program Payments by Surgical Specialty or Ancillary Items and Services Group of this proposed rule. For CY 2027, the estimated savings are \$260 million, with \$190 million of the savings accruing to Medicare, and \$70 million saved by Medicare beneficiaries in the form of reduced beneficiary coinsurance. And beginning in 2028, the savings from this proposed policy begin to flow into the baseline for Medicare Advantage rates, thus resulting in a significant increase in savings in subsequent years. For 2027, the Medicare Advantage rates have already been calculated at the time of this proposed rule and thus the 2027 Medicare Advantage rates are not impacted by this proposed policy. From 2027–2036 we estimate that this policy will lower net Part B spending by \$7.2 billion. To effectively establish a method for controlling the unnecessary growth in the volume of imaging without contrast services furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a non-budget neutral manner. The impact associated with this proposal is further described in section XXVI. of this proposed rule.

While we are refining our method to control for unnecessary increases in the volume of hospital OPD services, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. We solicit public comments on other ways or other services for which we should exercise the Secretary’s statutory

authority under section 1833(t)(2)(F) of the Act.

9. Exemption for Rural Sole Community Hospitals

As stated above, we propose to expand our method to control unnecessary increases in the volume of covered OPD services by paying a PFS-equivalent payment rate for imaging without contrast services furnished in excepted off-campus PBDs. We believe that this policy is an appropriate method for controlling unnecessary volume of imaging without contrast services in excepted off-campus PBDs because beneficiaries can generally safely receive these same services in a lower cost setting but instead may receive care in a higher cost setting due to payment incentives. In these cases, we maintain that, similar to the clinic visit volume control policy established in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the drug administration volume control policy established in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53806 through 53821), to the extent similar services can be safely provided in more than one setting, we do not believe it is appropriate for the Medicare program to pay more for these services in one setting than another. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the physician's office setting to the hospital OPD.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051) and the CY 2026 OPPS/ASC final rule with comment period (90 FR 53821 through 53824), we finalized exemptions to our clinic visit and drug administration volume control policies for PBDs of rural SCHs. Under these exemptions, we pay the full OPPS payment rate, rather than the PFS-equivalent rate, when the clinic visit or drug administration service is furnished in excepted PBDs of rural SCHs. In those rules, we explained that rural SCHs have historically received special payment treatment to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. Because we propose a volume control payment policy for imaging without contrast services, we have additionally considered whether a similar policy for rural SCHs or other provider types would be appropriate.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established several special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers five statutory hospital payment designations in which rural or isolated hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital (CAH),¹⁴³ Sole Community Hospital (SCH),¹⁴⁴ Rural Emergency Hospital (REH),¹⁴⁵ or Medicare Dependent Hospital¹⁴⁶—each of which has different eligibility criteria and payment methodologies. With the exception of CAHs, rural hospitals may also qualify as Low Volume Hospitals¹⁴⁷ and Rural Referral Centers (RRCs),¹⁴⁸ which qualify these hospitals for additional payments or exemptions. Not all rural or isolated hospitals receive special payment treatment under the OPPS. For instance, CAHs are not paid under the OPPS and are reimbursed at 101 percent of reasonable costs for outpatient services.

Rural SCHs are a hospital type that has received special payment treatment under the OPPS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary, by January 1, 2006, to provide for an appropriate adjustment under subparagraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A) of the Act, that the costs to rural hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have

continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in section II.E. of this proposed rule, for CY 2027 we propose to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

As noted above, in the CY 2023 OPPS/ASC final rule with comment period, we finalized an exemption for clinic visits to our policy to pay the PFS-equivalent rate for the clinic visit service at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were generally supportive of this proposal and noted that rural SCHs are typically the chief, if not sole, source of community outpatient care for rural residents and stated that this exemption would be vital to ensuring continued access to the care they need. Some commenters stated that the exemption should be extended to other types of hospitals, including urban SCHs. In that rule, we explained that our analysis did not find that urban SCHs had the additional resource costs for covered OPD services that rural SCHs have and only finalized applying the clinic visit policy exemption to rural SCHs (87 FR 72049).

Similarly, in the CY 2026 OPPS/ASC final rule with comment period, we finalized an exemption for rural SCHs to our policy to pay the PFS-equivalent rate for drug administration services at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were again generally supportive of the proposal and emphasized that rural SCHs have higher costs and are important for access in rural areas. Some commenters suggested extending the exemption to other types of hospitals such as urban SCHs, Medicare Dependent Hospitals (MDHs), urban and rural safety-net hospitals, REHs, FQHCs, and all rural hospitals. However, because our historical analysis did not demonstrate that these hospitals had the additional resource costs that rural SCHs do, we did not finalize any exemptions beyond our exception for rural SCHs (90 FR 53823).

b. Exemption to Volume Control Payment Policy for Imaging Without Contrast Services Furnished in Off-Campus Provider-Based Departments of Rural SCHs

Earlier in this section, where we propose the volume control method policy for imaging without contrast services, we state that to the extent there are lower-cost sites of service available beneficiaries and the physicians treating them should be able to choose the

¹⁴³ 42 CFR 485.601 through 485.647.

¹⁴⁴ 42 CFR 412.92.

¹⁴⁵ 42 CFR 419.91.

¹⁴⁶ 42 CFR 412.108.

¹⁴⁷ 42 CFR 412.101.

¹⁴⁸ 42 CFR 412.96.

appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons. However, as we have previously noted, many rural providers, and rural SCHs in particular, are often the only source of care in their communities,¹⁴⁹ which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas likely further drives utilization to off-campus PBDs in areas where rural SCHs are located.

As with clinic visits and drug administration services, we do not believe that rural SCH site-of-service decisions for imaging without contrast services are being driven by differences in payment rates. As we have previously observed, rural areas often experience lower availability of health care professionals and hospitals than urban areas.¹⁵⁰ Hospital closures in rural communities are associated with lower access to health care and worse health outcomes.¹⁵¹ Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries from being admitted as an inpatient because beneficiaries in rural settings face unique challenges that impact their health. In the CY 2023 OPPS/ASC final rule with comment period, we explained that we believe that exempting rural SCHs from the clinic visit policy would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments (87 FR 72049). We extended this exemption to drug administration in the CY 2026 OPPS/ASC final rule with comment period on the same basis (90 FR 53822), and we propose to extend it to our proposed imaging without contrast policy for similar reasons. Specifically, we propose to exempt rural SCHs from payment of the site-specific PFS-equivalent payment for imaging without contrast services, as described by APCs 5521 through 5524, 8004, 8005, and 8007, when furnished at an off-campus PBD exempted from section 1833(t)(21)

of the Act (departments that bill the modifier "PO" on claim lines). Under this proposed policy, a rural SCH would continue to bill services in APCs 5521 through 5524, 8004, 8005, and 8007 with the "PO" modifier for CY 2027 and the payment rate for such services would continue to be the full OPPS payment without the PFS relativity adjuster.

This exemption, should it be finalized, would result in higher payments to excepted off-campus PBDs of rural SCHs compared to if it were not finalized and rural SCHs were subject to the proposed volume control method. By exempting rural SCHs, the Medicare payments for these services would remain at the OPPS level. We note, however, that these figures do not represent increases in costs to Medicare or the beneficiaries above the current policy, as our proposed exemption would maintain current payment rates at excepted off-campus PBDs of rural SCHs of 107.1 percent of the OPPS payment rate for these services. These figures are solely for the purpose of comparing potential savings should we implement a method to control unnecessary volume in imaging without contrast services without such an exemption. We invite comments on all aspects of the proposed exemption for rural SCHs from the method to control unnecessary volume of imaging without contrast services. Specifically, we request comments on whether such an exemption is appropriate for rural SCHs; what the impact on SCHs would be, should we finalize the method without an exemption for rural SCHs; and whether we should consider any other hospital types for an exemption to any of the three policies to control unnecessary volume of outpatient services at off-campus PBDs. Additionally, we request comments on whether the current exemptions for rural SCHs from the method to control unnecessary volume of clinic visit and drug administration services remain appropriate.

B. OPPS Payments for SaMS Diagnostic Services

1. Payment for Software as a Medical Service (SaMS)

In recent years, there have been rapid developments in the use of software-based technologies with novel functionalities, including artificial intelligence, to support clinical decision-making in the outpatient and physician office settings. New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection

(CAD), is becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients, relying on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment planning of a patient's condition. In previous rulemaking, we have referred to these algorithm-driven services that assist practitioners in making clinical assessments or diagnoses as Software as a Service (SaaS). Some of the software functions that are used in these services are FDA-regulated medical devices. Unlike prescription digital therapeutics (PDTs), for example PDTs that provide cognitive behavioral therapy to treat substance disorders or chronic insomnia, SaaS technologies do not currently treat illnesses or patient injuries. SaaS is also separate from remote patient monitoring (RPM) and remote therapeutic monitoring (RTM), which are digital healthcare tools for tracking patient data outside traditional office settings (90 FR 49394). For CY 2027, we propose a change in terminology. We now understand that in other industries, the existing SaaS terminology is used for general cloud-based computing service models outside of a health care context, which may cause confusion as we are using it to describe specific services that provide a medical function for purposes of OPPS/ASC Medicare payment policy. To dispel any ambiguity and clarify that distinction, we propose to change our terminology from SaaS to Software as a Medical Service (SaMS) to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. We welcome public comments on the proposed change in terminology.

CMS has been evaluating how to develop a comprehensive and consistent approach to SaMS payment for several years with the novel and evolving nature of these technologies. We have sought public input through two comment solicitations (87 FR 72035 through 87 FR 72036, 89 FR 94129 through 89 FR 94131) and expressed our objective to seek a payment strategy that aligns with our agency's mission to increase quality, improve health, reduce costs, and strengthen the healthcare system. However, questions remain regarding how best to structure payment for these services. One challenge is that current Medicare Part B payment systems for SaMS, including in the OPPS, are primarily designed to pay for services that rely on material resources,

¹⁴⁹ https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf.

¹⁵⁰ <https://www.gao.gov/assets/gao-21-93.pdf>.

¹⁵¹ Mills CA, Yeager VA, Unroe KT, Holmes A, Blackburn J. The impact of rural general hospital closures on communities—A systematic review of the literature. *J Rural Health*. 2024; 40:238–248. <https://doi.org/10.1111/jrh.12810>.

rather than technologies whose value is driven by proprietary algorithms and scalable, non-material costs. This creates difficulties in establishing appropriate valuation methodologies, as the current cost-based system often offers only limited transparency into underlying costs and may not effectively constrain pricing. Another challenge is determining how to account for the various ways in which these technologies are acquired and billed by hospital OPDs, particularly in cases with subscription- or license-based arrangements, as well as per-use or “per-click” fees, which raises concerns regarding program integrity.

As coding for SaMS continues to rapidly increase and technologies evolve, establishing a consistent and timely payment methodology for these services is a priority. New SaMS technologies are continuing to be introduced to the market, each often accompanied by unique CPT codes reflecting their proprietary algorithms or specific characteristics. Interested parties are frequently seeking Medicare payment and coding for SaMS technologies through the new technology APC process or requesting clinical APC assignments. As a result, CMS is continuously assessing and evaluating payment for SaMS through different pathways. As we consider this policy, we want to ensure that we are moving toward a more standardized approach that reduces payment rate variation across similar technologies.

Given the growing need for a comprehensive and tailored payment methodology, as we work to gather additional data to better understand and more fully address the inherent payment challenges in this area, we propose an interim payment policy for SaMS for CY 2027 while we examine a range of approaches to payment for these kinds of technologies.

Specifically, we propose to assign SaMS technologies to new technology APCs for CY 2027. We propose to designate 36 HCPCS codes as SaMS services and reassign the proposed designated SaMS services that are currently paid separately (assigned to status indicator “S”) under clinical APCs, to new technology APCs that closely align with their current CY 2026 payment rates. We propose to assign the separately paid SaMS technologies to new technology APCs because we believe that the existing clinical APC structure does not adequately accommodate SaMS. We believe that the new technology APCs are more appropriate to accommodate SaMS on a temporary basis, as there have historically been placements under the OPSS that allow

us to provide consistent payment for new procedures that are not yet reflected in our claims data or for which we lack sufficient clinical information and cost data until we can identify an appropriate clinical APC. In certain circumstances, we have also assigned some services to new technology APCs through rulemaking, even when they have not met the specific regulatory criteria (66 FR 59897 through 59903) or have not applied for new technology APC assignment through the subregulatory process. For example, we have assigned certain services to new technology APCs in special cases where an appropriate clinical APC to which to assign the service does not exist. In the CY 2026 OPSS/ASC final rule with comment period, we maintained the new technology APC assignment for HCPCS codes G2082 and G2083 because we did not believe there was an appropriate clinical APC to which to assign the service (90 FR 53551). This proposed approach of assigning SaMS services to the same APC series would allow CMS to take the first step towards standardization and applying a consistent payment methodology across these services as we consider more comprehensive long-term approaches, including those that may better align payment with clinical outcomes.

We also believe it is important to distinguish SaMS technologies from other services that are assigned to new technology APCs because not all new services assigned to new technology APCs are SaMS technologies. Therefore, we propose to create a new status indicator under OPSS specifically for SaMS technologies. For CY 2027, we propose to create status indicator “O1” (Software as a Medical Service, Paid under OPSS; separate APC payment) and assign all services that we propose to designate as SaMS to status indicator “O1.” Functionally, we propose for status indicator “O1” to have the same payment specifications as status indicator “S,” to allow for separate payment. We request public comment on this proposal. We also request public comment regarding whether a new status indicator with the same specification as status indicator “T” (Procedure or service subject to multiple procedure discounting) would provide more appropriate payment for these services while addressing any potential program integrity concerns.

For CY 2027, we propose to designate the HCPCS codes listed in Table 61 as SaMS technologies. Of these, we propose to assign 21 HCPCS codes to new technology APCs from clinical APCs, maintaining approximate payment rate continuity with CY 2026

payment, and status indicator “O1.” Table 61 provides the list of HCPCS codes and proposed new technology APC and status indicator assignments for CY 2027. For SaMS that are already assigned to new technology APCs for CY 2026, we propose to continue to assign these services to new technology APCs for CY 2027 while proposing to update the status indicator assignment to “O1” to designate these technologies as SaMS. We refer readers to section III.C. of this proposed rule for a discussion on our proposals for SaMS technologies that are currently assigned to new technology APCs for CY 2026.

We note that there are a small number of technologies we consider to be SaMS that are currently paid under the OPSS and assigned to an OPSS status indicator of “Q1” (STV-Packaged Codes; Paid under OPSS), indicating that the service is conditionally packaged. Services assigned to an OPSS status indicator of “Q1” will receive packaged payment when furnished with a significant procedure but will be separately paid when the service appears on the claim without a significant procedure. Because services assigned to new technology APCs are exempt from C-APC packaging policies, we do not believe it would be appropriate to propose to assign SaMS HCPCS codes that are currently conditionally packaged for CY 2026 to new technology APCs with status indicator “S” (Procedure or Service, Not Discounted When Multiple) to indicate separate payment. As an alternative, we considered unconditionally packaging SaMS services that are currently assigned to status indicator “Q1” by proposing to assign the services a status indicator of “N” (Items and Services Packaged into APC Rates). However, we believe proposing to unconditionally package payment for CY 2027 for SaMS technologies that are currently conditionally packaged under the OPSS may result in interruptions to patient access. Given that we intend for this policy to be a first step towards more comprehensive payment policy changes and seek to minimize disruption, we believe it is more appropriate to propose to maintain the clinical APC and status indicator assignments for these codes. Therefore, for CY 2027, we propose to maintain the clinical APC and status indicator assignments for SaMS that are currently conditionally packaged under the OPSS.

Similarly, there are other HCPCS codes that describe SaMS that are assigned to status indicator “E1” (Items, codes, and services not covered by any Medicare outpatient benefit category; statutorily excluded; not reasonable and

necessary), status indicator “N” (Items or services packaged into APC rates), or status indicator “M” (Items and services not billable to the FI or MAC). Since these are not separately paid services under the OPPS for CY 2026, for CY 2027, we propose to maintain the OPPS status indicators to which they are currently assigned.

The various SaMS HCPCS codes that are impacted by our proposals in this section are listed in Table 61. Table 61

provides the current APC assignments, and the proposed CY 2027 APC and status indicator assignments for codes we propose to designate as SaMS services and that are currently assigned to clinical APCs or are not separately paid under the OPPS for CY 2026. We refer readers to section III.C. of this proposed rule for a discussion on the proposed CY 2027 payment rates for SaMS codes that are currently assigned to new technology APCs for CY 2026. In

addition, we refer readers to Addendum B for proposed CY 2027 OPPS payment rates and status indicators for HCPCS codes that we propose to designate as SaMS. We request comment on our proposals, including the list of HCPCS codes we propose to designate as SaMS and that we propose to reassign to new technology APCs for CY 2027, including whether there are any additional HCPCS codes we should consider.

BILLING CODE 4169–69–P

TABLE 61: PROPOSED NEW TECHNOLOGY APC AND SI ASSIGNMENTS FOR PROPOSED SAMS HCPCS CODES FOR CY 2027

HCPCS Code	Long Descriptor	CY 2026 OPFS FR APC, SI	CY 2027 OPFS NPRM New Technology APC, SI
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	APC 5732 (Level 2 Minor Procedures), S	APC 1502 (New Technology - Level 2 (\$51 - \$100)), O1
0932T	Noninvasive detection of heart failure derived from augmentative analysis of an echocardiogram that demonstrated preserved ejection fraction, with interpretation and report by a physician or other qualified health care professional	APC 5743 (Level 3 Electronic Analysis of Devices), S	APC 1505 (New Technology - Level 5 (\$301 - \$400)), O1
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 (\$801 - \$900)), O1
0555T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; retrieval and transmission of the scan data	APC 5731 (Level 1 Minor Procedures), S	APC 1493 (New Technology - Level 1C (\$21-\$30)), O1
0556T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone-mineral density	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
0615T	Automated analysis of binocular eye movements without spatial calibration, including disconjugacy, saccades, and pupillary dynamics for the assessment of concussion, with interpretation and report	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 (\$101 - \$200)), O1
0712T	Noninvasive arterial plaque analysis using software processing of data from noncoronary computerized tomography angiography; quantification of the structure and composition of the vessel wall and assessment for lipid-rich necrotic core plaque to assess atherosclerotic plaque stability	APC 5722 (Level 2 Diagnostic Tests and Related Services), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
0731T	Augmentative AI-based facial phenotype analysis with report	APC 5733 (Level 3 Minor Procedures), S	APC 1502 (New Technology - Level 2 (\$51 - \$100)), O1

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 (\$101 - \$200)), O1
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram	APC 5734 (Level 4 Minor Procedures), S	APC 1503 (New Technology - Level 3 (\$101 - \$200)), O1
0865T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the brain during the same session	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
0866T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion detection, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the brain (List separately in addition to code for primary procedure)	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 (\$801 - \$900)), O1

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 (\$801 - \$900)), O1
0992T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat without concurrent computed tomography (CT) scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
0993T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat with concurrent computed tomography scan of the heart, and including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	APC 5523 (Level 3 Imaging without Contrast), S	APC 1504 (New Technology - Level 4 (\$201 - \$300)), O1
C8001	3D anatomical segmentation imaging for preoperative planning, data preparation and transmission, obtained from previous diagnostic computed tomographic or magnetic resonance examination of the same anatomy	APC 5721 (Level 1 Diagnostic Tests and Related Services), S	APC 1503 (New Technology - Level 3 (\$101 - \$200)), O1
C9793	3d predictive model generation for pre-planning of a cardiac procedure, using data from cardiac computed tomographic angiography and/or magnetic resonance imaging with report	APC 5724 (Level 4 Diagnostic Tests and Related Services), S	APC 1510 (New Technology - Level 10 (\$801 - \$900)), O1
G0183	Quantitative software measurements of cardiac volume, cardiac chambers volumes and left ventricular wall mass derived from CT scan(s) data of the chest/heart (with or without contrast)	APC 5521 (Level 1 Imaging without Contrast), S	APC 1502 (New Technology - Level 2 (\$51 - \$100)), O1
G0566	3D radiodensity-value bone imaging, algorithm derived, from previous magnetic resonance examination of the same anatomy	APC 5721 (Level 1 Diagnostic Tests and Related Services), S	APC 1503 (New Technology - Level 3 (\$101 - \$200)), O1
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	APC 5733 (Level 3 Minor Procedures), Q1	APC 5733 (Level 3 Minor Procedures), Q1
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	APC 5732 (Level 2 Minor Procedures), Q1	APC 5732 (Level 2 Minor Procedures), Q1

HCPCS Code	Long Descriptor	CY 2026 OPPS FR APC, SI	CY 2027 OPPS NPRM New Technology APC, SI
0902T	QTc interval derived by augmentative algorithmic analysis of input from an external, patient-activated mobile ECG device	APC 5734 (Level 4 Minor Procedures), Q1	APC 5734 (Level 4 Minor Procedures), Q1
0904T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; tracing only	APC 5733 (Level 3 Minor Procedures), Q1	APC 5733 (Level 3 Minor Procedures), Q1
0944T	3D contour stimulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation.	APC 5523 (Level 3 Imaging without Contrast), Q1	APC 5523 (Level 3 Imaging without Contrast), Q1
0557T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density utilizing data from a computed tomography scan; interpretation and report	N/A, M	N/A, M
0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission	N/A, N	N/A, N
0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report	N/A, M	N/A, M
0899T	Noninvasive determination of absolute quantitation of myocardial blood flow (AQMBF), derived from augmentative algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	N/A, E1	N/A, E1
0900T	Noninvasive estimate of absolute quantitation of myocardial blood flow (AQMBF), derived from assistive algorithmic analysis of the dataset acquired via contrast cardiac magnetic resonance (CMR), pharmacologic stress, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	N/A, E1	N/A, E1
0903T	Electrocardiogram, algorithmically generated 12-lead ECG from a reduced-lead ECG; with interpretation and report	N/A, M	N/A, M

HCPCS Code	Long Descriptor	CY 2026 OPPTS FR APC, SI	CY 2027 OPPTS NPRM New Technology APC, SI
0905T	Electrocardiogram, algorithmically generated 12-lead ecg from a reduced-lead ecg; interpretation and report only	N/A, M	N/A, M
C8937	Computer-aided detection, including computer algorithm analysis of breast mri image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	N/A, N	N/A, N
0174T	Computer-aided detection (cad) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (list separately in addition to code for primary procedure)	N/A, N	N/A, N
0175T	Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation	N/A, N	N/A, N

BILLING CODE 4169-69-C**2. SaMS Analyses Performed on Laboratory Tests**

In recent years, we have seen an increase in laboratory tests that combine laboratory analyses, such as genomic sequencing or immunoassays, with computer algorithms to produce a clinical test result. The AMA CPT Editorial Panel created a category called Multi-Analyte Assays with Algorithmic Analysis, to categorize test codes that combined laboratory analyses with computer algorithms to generate clinical information. More recently, however, we are seeing the development of distinct algorithmic analyses alone.

For example, when the genomic sequencing of an individual is performed, this sequencing will likely only need to be performed once. However, once the genomic sequence has been generated, the subsequent algorithmic analyses of that sequence data can be performed an infinite number of times to produce a wide range of results and/or diagnostic or risk-related information. These

secondary analyses of original genomic sequences can be proprietary and unique to a single laboratory, but could also be conducted at a range of settings. For purposes of this proposal, we are referring to subsequent stand-alone algorithmic analyses that are separate from a CLIA certified laboratory's examination of human material, as defined by 42 CFR 493.21, as "SaMS laboratory analyses performed on laboratory tests".

Currently, certain SaMS analyses performed on laboratory tests are treated as clinical diagnostic laboratory tests (CDLTs) and paid under the Clinical Laboratory Fee Schedule (CLFS). Section 1861(s) of the Act specifies items and services included as "medical and other health services" under Part B, including diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests as described in section 1861(s)(3) of the Act. Section 1861(s)(17) of the Act states that no diagnostic tests performed in any laboratory shall be included within paragraph (3) unless such laboratory meets CLIA certification requirements

under section 353 of the Public Health Service Act, among other requirements. Sections 1833(h) and 1834A of the Act and the implementing regulations at 42 CFR part 414, subpart G, set forth the CLFS ratesetting methodologies for CDLTs. We do not believe it is appropriate to consider these secondary algorithmic analyses to be CDLTs or establish CLFS payment rates for these analyses because these secondary algorithmic analyses do not require laboratory services or entities, regulated by CLIA, to perform them. Referring to the example above, while an individual's genomic sequence must be performed by a CLIA certified laboratory entity to allow for Medicare payment under the CLFS, the subsequent algorithmic analyses of the sequence data as part of the SaMS analyses performed on laboratory tests can be performed by any non-regulated entity with the computer software needed to perform the analyses. Our position is that the secondary analyses are "other diagnostic tests" under section 1861(s)(3) of the Act as opposed to "diagnostic laboratory tests." As noted

previously, Medicare will not pay for CDLTs on the CLFS unless they are furnished by laboratories that meet applicable CLIA certification requirements. Tests that examine materials derived from the human body are assigned to and paid under the CLFS only when furnished by such certified laboratories in accordance with 42 CFR 410.32(d). Because SaMS analyses performed on laboratory tests are downstream evaluations of the data generated by a prior laboratory test, an entity that performs only algorithmic analyses of previously sequenced data may not qualify as a CLFS laboratory under 42 CFR 493.2 or require CLIA certification. We believe SaMS that evaluate data generated by a prior laboratory test should not be treated as CDLTs for Medicare payment purposes.

We are also concerned that paying for these analyses based on existing CLFS payment methodologies may create significant vulnerabilities for the Medicare program, due to the lack of data transparency and CDLTs not being subject to beneficiary cost-sharing or budget neutrality. 42 CFR 414.508 outlines the ratesetting methodologies CMS uses to set payment rates for new tests on the CLFS. Under § 414.508(b), CMS determines the payment amount based on either crosswalking or gapfilling methodologies until applicable information is available to establish a payment amount under the methodology described in § 414.507(b). Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Gapfilling is used when no comparable existing CDLT is available. Public consultation for payment for a new clinical diagnostic laboratory tests is required in determining payment amounts, receiving public comments and recommendations (and data on which the recommendations are based) as well as recommendations from the Advisory Panel on CDLTs per 414.506. A significant challenge to the ratesetting process for CMS is the lack of transparent data received from laboratories outlining resource costs of a test, particularly for the algorithmic portions of tests that are combined with other analytes. In the past, laboratories

have explained to CMS that the algorithmic components of laboratory tests are highly proprietary and details cannot be shared. Thus, CMS has worked with the limited information available on the details of methods or resources for the algorithmic portions of tests or analyses, and has thus far relied on other laboratory methods provided in the CPT descriptor (*i.e.* NGS sequencing, RT-PCR, or DNA methylation analysis). As CMS has gathered more information on SaMS analyses performed on laboratory tests, we now believe that since these analyses are entirely computer-based, comparison based on laboratory methodologies is not appropriate. Additionally, in contrast to the OPSS, the CLFS generally does not include beneficiary cost-sharing or budget neutrality adjustments, which limits transparency regarding pricing and creates challenges for ensuring appropriate valuation of these services.

Finally, CMS has an interest in ensuring that services that are fundamentally similar are paid for and treated in the same way, regardless of the setting of care in which the service is furnished. Since SaMS analyses performed on laboratory tests do not require performance by a CLIA-certified laboratory, and like many other SaMS analyses discussed in this section, perform algorithmic analyses on previously generated data, we believe SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the OPSS. Accordingly, we believe that whether the SaMS performs algorithmic analyses of an imaging test (*e.g.* CT scan) or whether it performs an algorithmic analysis on data generated from a laboratory test, all algorithmic analyses should be treated consistently. We believe that this uniform approach for SaMS technologies would promote stability and predictability in payment for similar services.

Therefore, for CY 2027, we propose to assign 10 HCPCS codes describing various SaMS analysis performed on laboratory tests to new technology APCs under the OPSS, using the latest available CLFS data to crosswalk to new technology APCs with payment rates that closely approximate the current CY

2026 CLFS payment rates for these codes. The proposed payment rates for SaMS performed on prior laboratory tests cannot be expected to align exactly with current CLFS payment rates because assignment to new technology APCs is based on established cost bands rather than individual test-specific payment amounts. For example, if a HCPCS code is currently paid \$430.17 under the CLFS, the appropriate new technology APC assignment under this proposal would be APC 1506 (New Technology—Level 6 (\$401–\$500)), which has a standardized payment rate of \$450.50, rather than receiving a payment rate that exactly matches the current CLFS amount. We note that, under this proposal, SaMS analyses performed on laboratory tests would be paid separately by being assigned to new technology APCs with the newly proposed status indicator “O1” (Software as a Medical Service, Paid under OPSS; separate APC payment) for CY 2027. Table 62 shows the list of currently payable SaMS analyses performed on laboratory tests under the CLFS with proposed new technology APC assignments under the OPSS for CY 2027. These 10 HCPCS codes were identified based on the CPT descriptor for the code. If there were no laboratory methods included in the code descriptor, and only an algorithmic analysis was described, we identified the code as a SaMS laboratory analysis. We would appreciate public comment on this proposed list and any other similar analyses that should be removed from the CLFS and paid under the OPSS.

In addition, for CY 2027 and subsequent years, we propose to assign any new SaMS analyses performed on laboratory test codes to new technology APCs for payment under the OPSS. We request public comment on these proposals, including the list of 10 HCPCS codes that we identified as SaMS analyses performed on laboratory tests and any additional HCPCS codes that we should designate as SaMS and pay under the OPSS rather than the CLFS. CMS may finalize a policy that includes such payment for additional HCPCS codes in the final rule based on public comment.

BILLING CODE 4169–69–P

TABLE 62: PROPOSED NEW TECHNOLOGY APC AND SI ASSIGNMENTS FOR SAMS ANALYSES PERFORMED ON LABORATORY TESTS FOR CY 2027

HCPCS Code	Long Descriptor	CY 2027 Proposed New Technology APC, SI
0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype	APC 1506 (New Technology - Level 6 (\$401 - \$500)), O1
0511U	Oncology (solid tumor), tumor cell culture in 3d microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug	APC 1524 (New Technology - Level 24 (\$3001-\$3500)), O1
0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)	APC 1509 (New Technology - Level 9 (\$701 - \$800)), O1
0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker	APC 1509 (New Technology - Level 9 (\$701 - \$800)), O1
0208U	Oncology (medullary thyroid carcinoma), mrna, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma	APC 1506 (New Technology - Level 6 (\$401 - \$500)), O1
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1-3, ret, ros1), and kras g12c and pd-l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker	APC 1509 (New Technology - Level 9 (\$701 - \$800)), O1
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	APC 1509 (New Technology - Level 9 (\$701 - \$800)), O1
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	APC 1509 (New Technology - Level 9 (\$701 - \$800)), O1
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate	APC 1509 (New Technology - Level 9 (\$701 - \$800)), O1
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (list separately in addition to code for primary procedure)	APC 1575 (New Technology - Level 38 (\$10,001-\$15,000)), O1

BILLING CODE 4169-69-C*C. Adjustment for Cost-of-Living in Alaska and Hawaii*

We have heard from a variety of interested parties about the particularly difficult cost environment facing hospitals located in Alaska and Hawaii.

These challenges stem from the unique circumstances of those geographies, including dependency on outside goods and components, remote locations and transportation challenges, and other factors inherent to providing healthcare in these non-contiguous States.

A review of the available cost report data used in OPPS ratesetting highlights these issues. We observe a number of hospitals in Alaska and Hawaii with payment-to-cost ratios (PCRs) that range from 0.6 to 0.7, significantly below the average PCR for OPPS hospitals of 0.89 used as an initial target for the cancer

hospital adjustment discussed in section II.F. of this proposed rule. In addition, the overall ancillary cost-to-charge ratios for several hospitals located in these States are higher than average, indicating that there are higher costs relative to what those hospitals are able to charge for the outpatient services they provide compared to other OPSS hospitals.

Under the IPPS, section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. To account for higher non-labor-related costs for these two States in the IPPS, we apply an adjustment factor to the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at <https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates> to update this nonlabor portion.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. OPM every 4 years (coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii.

In general, under the existing IPPS methodology, we update the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison

of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index, and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547).

As discussed in the FY 2027 IPPS/LTCH PPS proposed rule, effective for FY 2027, we propose to adjust non-labor related costs for hospitals located in Alaska and Hawaii, using the Overseas Cost-of-Living Allowance (OCOLA) data published by the Department of Defense (DOD). Starting with the FY 2027 payment year, we also propose to no longer cap the IPPS COLA factors at 25 percent. We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule for further discussion of the proposed changes to the methodology for calculating the IPPS COLA factors for FY 2027 (91 FR 19813 through 19814).

While higher labor-related costs for these two States are taken into account under the OPSS through the adoption of the IPPS hospital wage index and associated wage index policies, the nonlabor portion of OPSS payment is not currently adjusted to address higher nonlabor costs in these States as is addressed in the IPPS through the COLA policy. We have historically adopted the IPPS wage index and wage index policies under the OPSS, most recently in the CY 2026 OPSS/ASC final rule with comment period (90 FR 53494 through 53498). As discussed in section II.C of this proposed rule, we propose to continue to adopt the IPPS wage index and wage index policies under the CY 2027 OPSS and also continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPSS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. We think this same logic would apply to adopting the IPPS COLA policy for hospital outpatient services in Alaska and Hawaii, as additional nonlabor costs that apply to hospital inpatient services provided in these States likely

also apply to hospital outpatient services in these States. Further, not addressing the discrepancy between the IPPS and OPSS adjustment to account for nonlabor related costs would potentially continue a disincentive to provide services in the hospital outpatient setting due to the adjustment only applying to inpatient services.

Based on our review of the costs of providing outpatient services in these States and our general practice of applying consistent policies across the inpatient and outpatient hospital settings where possible, we propose to use the equitable adjustment authority provided by section 1833(t)(2)(E) of the Act to propose to apply the IPPS COLA factors to the nonlabor share of OPSS payment amounts for hospitals located in Alaska and Hawaii for CY 2027 and future years. We note that for OPSS payments for which there is no wage adjustable portion, we propose to apply the COLA to the full OPSS payment, as would be the case for status indicator assignments of "G," "H," "K," "R," and "U".

As noted earlier in this section, in the FY 2027 IPPS/LTCH PPS proposed rule we proposed several changes to the current COLA methodology including using the OCOLA data published by the DOD for the FY 2027 factors as well as to remove the cap of 25 percent (91 FR 19813 through 19814). Consistent with our historical practice of aligning OPSS payment methodologies with those of the IPPS where appropriate, we propose to adopt the IPPS COLA factors as finalized in the FY 2027 IPPS/LTCH PPS final rule as the CY 2027 OPSS COLA factors for hospitals located in Alaska and Hawaii.

Under the OPSS, section 1833(t)(2)(E) of the Act grants the Secretary the authority to establish equitable adjustments as necessary, and we propose to use that authority to establish a COLA for outpatient hospital services provided in Alaska and Hawaii that mirrors the COLA provided for inpatient hospital services provided in these States. Associated with this proposed policy, we also propose to add conforming regulation text changes by adding subsection (l) to § 419.43. This new subsection describes the cost-of-living adjustment to the nonlabor portion of the OPSS payment amounts for hospitals located in Alaska and Hawaii. Finally, we note that under our authority at section 1833(t)(2)(E) of the Act this adjustment would be budget neutral, and the associated budget neutrality adjustment is discussed in section II.B. of this proposed rule.

D. Provision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR) and Pulmonary Rehabilitation (PR) Services to Hospital Outpatients in Their Homes Via Audio and Video Real-Time Communications Technology

Section 6211(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026), amended section 1861(eee)(2)(A)(ii) of the Act to allow for the provision of cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR) and pulmonary rehabilitation (PR) services to hospital outpatients in their homes via audio and video real-time communications technology (excluding audio-only), through December 31, 2027.

Section 6211(b) of CAA, 2026, authorizes the Secretary to implement

the amendment made by section 6211(a) via program instruction or otherwise. Consistent with that authority, we have issued sub-regulatory guidance relating to the provision of CR, ICR and PR services to hospital outpatients in their homes via audio and video real-time communications technology. This guidance is available at <https://www.cms.gov/medicare/coverage/telehealth>.

XI. Proposed CY 2027 OPPS Payment Status and Comment Indicators

A. Proposed CY 2027 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS.

They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code.

For CY 2027 and subsequent years, we propose to create a new status indicator for software as a medical service that is paid separately under the OPPS. Under the OPPS, software as a medical service that is paid separately would be assigned a status indicator of “O1”—(Software as a Medical Service, paid under OPPS; separate APC payment). Further discussion of the proposed payment policy for SaMS can be found in section X.B of the CY 2027 OPPS/ASC proposed rule. The proposed definition and payment status of proposed status indicator “O1” can be found in Table 63.

TABLE 63: PROPOSED DEFINITIONS AND PAYMENT STATUSES OF PROPOSED STATUS INDICATORS O1 AND E2

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
O1	Software as a Medical Service, paid under OPPS; separate APC payment.	Paid under OPPS; separate APC payment.
E2	Items and Services: For which pricing information and claims data are not available.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). Exception: claims under drug invoice pricing policy are contractor priced.

For CY 2027 and subsequent years, we also propose to revise the current definition of status indicator “E2” to comply with the drug invoice policy. Further discussion of the proposed drug invoice payment policy can be found in section V.2.c of this proposed rule. The proposed revised definition of status indicator “E2” can be found in Table 63.

We do not propose to make any other changes to the existing definitions of status indicators that are listed in Addendum D1 to this proposed rule which is available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

The complete list of proposed CY 2027 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>. The proposed CY 2027 payment status

indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

We solicit public comments on the proposed definitions of the OPPS payment status indicators for CY 2027.

B. Proposed CY 2027 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2027 OPPS. These comment indicators, “CH”, “NC”, “NI”, and “NP”, are in effect for CY 2026; and we propose to continue their use in CY 2027. The proposed CY 2027 OPPS comment indicators are as follows:

- “CH”—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will

be discontinued at the end of the current calendar year.

- “NC”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the CY 2026 OPPS/ASC proposed rule; final APC assignment; comments will not be accepted on the final APC assignment for the new code.

- “NI”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.

- “NP”—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments

will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPTS comment indicators for CY 2027 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>.

We solicit public comments on our proposed definitions of the OPPTS comment indicators for CY 2027.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make interested parties aware of certain MedPAC recommendations for the OPPTS and ASC payment systems as discussed in its March 2026 report.

A. OPPTS Payment Rates Update

The March 2026 MedPAC “Report to the Congress: Medicare Payment Policy”, recommended that the Congress update Medicare OPPTS payment rates by the amount specified in current law. We refer readers to the March 2026 report for a complete discussion of this recommendation.¹⁵² We appreciate MedPAC’s recommendation and, as discussed further in section II.B. of this proposed rule, we propose to increase the OPPTS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

In the March 2026 MedPAC “Report to the Congress: Medicare Payment Policy”, MedPAC stated that their recommended update to IPPS and OPPTS payment rates under current law may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommended we redistribute the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-

developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommended adding \$1 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to the Congress transitional approaches for an MSNI policy. The FY 2027 IPPS/LTCH proposed rule (91 FR 19312) provides additional information regarding statutory requirements for disproportionate share hospital and uncompensated care payments. We look forward to working with the Congress on these matters.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2026 OPPTS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; 87 FR 72054 through 72096; 88 FR 81900 through 81961; 89 FR 94309 through 94367; and 90 FR 53834 through 53916).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPTS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPTS payment policies, and we use quarterly change requests (CRs) to update services paid for under the OPPTS. We also provide quarterly update CRs for ASC covered surgical

procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPTS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPTS rulemaking cycle, is particularly important because the OPPTS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes

¹⁵² Medicare Payment Advisory Committee. March 2026 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.61–96. Available at <https://www.medpac.gov>.

Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 ASC final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPI/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have

substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in the proposed rule (and respond to those comments in the CY 2027 OPPI/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2027 OPPI/ASC final rule with comment period (and responding to those comments in the CY 2028 OPPI/ASC final rule with comment period).

2. April 2026 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2026 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2026 ASC quarterly update (Transmittal 13704, dated April 7, 2026, CR 14445), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 64 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2026) of this proposed rule, lists the new Level II HCPCS codes that were implemented April 1, 2026. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2026, are assigned to comment indicator “NP” in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC

assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that the following ASC addenda and OPPI Addendum O are available via the internet on the CMS website.

- ASC Addendum AA: Proposed ASC Covered Surgical Procedures for CY 2027 (Including Surgical Procedures for Which Payment is Packaged),
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2027 (Including Ancillary Services for Which Payment is Packaged),
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2027,
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2027,
- ASC Addendum EE: Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2027, and
- ASC Addendum FF: Proposed ASC Device Offset Percentages for CY 2027, and
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2027.

We invite public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2026 through the quarterly update CRs, as listed in Table 64 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2026) of this proposed rule. We propose to finalize their payment indicators in the CY 2027 OPPI/ASC final rule with comment period.

BILLING CODE 4169-69-P

TABLE 64: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE APRIL 1, 2026

HCPCS Code	Long Descriptor
A2040	Microlyte painguard, per square centimeter
A2041	Foundation drs+ duo, per square centimeter
A2042	Foundation drs+ solo, per square centimeter
A2043	Biobrane, per square centimeter
A2044	Biobrane glove, each
A2045	Novashield or novogen wound matrix, per square centimeter
C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
C8007	Open implantation of hypoglossal nerve neurostimulator array and pulse generator, not requiring an insertion of a separate distal respiratory sensor electrode or electrode array
C8008	Revision or replacement of hypoglossal nerve neurostimulator array including connection to existing pulse generator
C8009	Removal of hypoglossal nerve neurostimulator array and pulse generator
C8010	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
C8011	Open implantation of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver, including external power source and all system components
C8012	Revision or replacement of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C8013	Removal of hypoglossal nerve(s) neurostimulator electrode array(s) and receiver
C9818	suzetrigine, oral, 1 mg
G0681	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area
G0682	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute for a wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
G0683	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
G0684	Application of a premarket approval (pma), 510(k), 361 human cells, tissues or cellular and tissue-based products (hct/p) non-sheet form skin substitute graft for a wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area or part

HCPCS Code	Long Descriptor
	thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
J0463	Injection, atropine sulfate (fresenius and therapeutically equivalent), 0.01 mg
J1098	Articaine ophthalmic, 8% solution, 0.4 mL
J1164	Injection, diltiazem hydrochloride in 0.72% sodium chloride, 0.5 mg
J1553	Injection, immune globulin (yimmugo), 100 mg
J8502	Injection, aprepitant (aponvie), 1 mg
J9183	Gemcitabine intravesical system, 225 mg
J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
J9278	Injection, carboplatin (avyxa), 1 mg
J9601	Injection, linvoseltamab-gcpt, 1 mg
Q4418	Biolab membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4419	Biolab membrane wrap lite flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4421	Biolab membrane wrap solo, per square centimeter (add-on, list separately in addition to primary procedure)
Q4422	A/c wrap, per square centimeter (add-on, list separately in addition to primary procedure)
Q4423	Biolab tri-membrane wrap flow, per square centimeter (add-on, list separately in addition to primary procedure)
Q4424	Revive ft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4425	Revive tl, per square centimeter (add-on, list separately in addition to primary procedure)
Q4426	Dermabind tl + or dermabind tl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4427	Dermabind dl n or dermabind dl + or dermabind dl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4428	Dermabind sl n or dermabind sl + or dermabind sl x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4429	Dermabind ch n or dermabind ch x, per square centimeter (add-on, list separately in addition to primary procedure)
Q4435	Renati membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4436	Renati ac membrane, per square centimeter (add-on, list separately in addition to primary procedure)
Q4437	Revival ac, per square centimeter (add-on, list separately in addition to primary procedure)
Q4438	Protect, per square centimeter (add-on, list separately in addition to primary procedure)
Q4439	Instagraft, per square centimeter (add-on, list separately in addition to primary procedure)
Q4440	Curamatrix, per square centimeter (add-on, list separately in addition to primary procedure)
Q5162	Injection, denosumab-nxxp (biltyos/bilprevda), biosimilar, 1 mg

BILLING CODE 4169-69-C**3. July 2026 HCPCS Codes Proposed Rule Comment Solicitation**

In the July 2026 ASC quarterly update (Transmittal R13836, Change Request 14522, June 24, 2026), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered

ancillary services. Table 65 (New HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective July 1, 2026) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2026. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed

rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2026, are assigned to comment indicator “NP” in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their

interim APC assignments. The list of comment indicators and definitions used under the ASC payment system

can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are

available via the internet on the CMS website.

BILLING CODE 4169-69-P

TABLE 65: NEW HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2026

HCPCS Code	Long Descriptor
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
A9574	Injection, ferumoxitol, 1 mg
C1609	Vertebral device, motion-preserving, with screw fixation
C8014	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, including use of a suction enabled ureteral access sheath, with irrigation (if performed)
C9310	Injection, leucovorin calcium (avyxa), 1 mg
J0528	Injection, fosfomycin disodium, 20 mg
J1289	Injection, narsoplimab-wuug, 1 mg
J1577	Injection, immune globulin (qivigy), 100 mg
J2361	Injection, depemokimab-ulaa, 1 mg
J2789	Riboflavin 5'-phosphate, ophthalmic solution (epioxahd/epioxa), up to 2 mL
J7176	Injection, human fibrinogen - chmt (fesilty), 1 mg
J9062	Injection, amivantamab 5 mg and hyaluronidase-lpuj
J9232	Injection, docetaxel (hospira), not therapeutically equivalent to j9171, 1 mg
Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5165	Injection, denosumab-mobz (oziltus), biosimilar, 1 mg
Q5166	Injection, denosumab-desu (osvyrti/jubereq), biosimilar, 1 mg
Q5167	Injection, denosumab-qbde (enoby/xtrenbo), biosimilar, 1 mg
Q5168	Injection, ranibizumab-leyk (nufymco), biosimilar, 0.1 mg
Q5169	Injection, pegfilgrastim-unne (armlupeg), biosimilar, 0.5 mg
Q5170	Injection, aflibercept-boav (eydenzelt), biosimilar, 1 mg
Q5171	Injection, denosumab-mobz (boncresa), biosimilar, 1 mg

BILLING CODE 4169-69-C

We invite public comments on the proposed payment indicators for the new HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services effective April 1, 2026 and July 1, 2026, through the quarterly update CRs, as listed in Tables 64 and 65. We propose to finalize the payment indicators in the CY 2027 OPPS/ASC final rule with comment period.

4. October 2026 HCPCS Codes Final Rule Comment Solicitation

For CY 2027, consistent with our established policy, we propose that the Level II HCPCS codes that will be

effective October 1, 2026, would be “NI” in Addendum BB to the CY 2027 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2026. We will invite public comments in the CY 2027 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

5. January 2027 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we incorporate those new Level II

HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2027 OPPS/ASC

final rule with comment period, January 2027 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2027, we propose to continue our established policy of assigning comment indicator “NI” in Addendum AA and Addendum BB to the CY 2027 OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2027, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2027 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2028 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2027 ASC update, we received the CPT codes that will be effective January 1, 2027, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator “NP” in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the

code is new for the next calendar year, or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2027 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appeared in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new CY 2027 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled “CY 2027 OPPS/ASC Proposed Rule 5-Digit Placeholder Code”. We intend to include the final CPT code numbers in the CY 2027 OPPS/ASC final rule with comment period.

In summary, we solicit public comments on the proposed CY 2027 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2027. Because these codes are

listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2027 OPPS/ASC final rule with comment period. The proposed payment indicators and comment indicators for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new CPT codes that will be effective January 1, 2027, are assigned to comment indicator “NP” in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim payment ASC payment assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 66, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

TABLE 66: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED ASC-RELATED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2026	HCPCS (CPT and Level II codes)	April 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
July 2026	HCPCS (CPT and Level II codes)	July 1, 2026	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
October 2026	HCPCS (CPT and Level II codes)	October 1, 2026	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period
January 2027	CPT Codes	January 1, 2027	CY 2027 OPPS/ASC proposed rule	CY 2027 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2027	CY 2027 OPPS/ASC final rule with comment period	CY 2028 OPPS/ASC final rule with comment period

6. Proposed ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, NTIOLs, or qualifying nonopioid devices. We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the

timeframe when comments will be accepted. The comment indicator “NI” is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator “NI” also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622). The comment indicator “NP” is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator “NP” also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497). The “CH” comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The “CH”

comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment. In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator “K5”—Items, Codes, and Services for which pricing information and claims data are not available. No payment made—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available. In CY 2024 OPPS/ASC final rule with comment period, we finalized the addition of two ASC payment indicators, “D1”—“Ancillary dental service/item; no separate payment made” and “D2”—“Non office-based dental procedure added in CY 2024 or later”, for new dental codes for CY 2024 and subsequent calendar years to indicate potentially payable dental services and procedures in the ASC setting (88 FR 81907). We added these two codes to Addendum DD1 (which is available via the internet on the CMS website). In CY 2025 OPPS/ASC final rule with comment period, we finalized the modification of the descriptor of ASC payment indicator “L6” to “Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices”, to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023 (89 FR 94317).

We added this code to Addendum DD1 (which is available via the internet on the CMS website). In CY 2026 OPPS/ASC final rule with comment period, we finalized the addition of one payment indicator, “S2”—“Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate” to describe skin substitute products paid separately in an ASC (90 FR 53843). We added this code to Addendum DD1 (which is available via the internet on the CMS website).

b. Proposed ASC Payment and Comment Indicators for CY 2027

For CY 2027, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2027 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2027, compared to the CY 2026 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with comment indicator “NP” to indicate that these CPT and Level II HCPCS codes are open for comment as part of this proposed rule.

We will respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2027 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of this proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2027 update. Addenda DD1 and DD2 to this proposed rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2027.

C. Proposed Payment Policies Under the ASC Payment System

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with

payment indicators “G2” and “A2.” Payment indicator “A2” was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator “A2” is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator “A2” because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators “P2,” “P3,” and “R2”) are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b. of this proposed rule, we update the payment amounts for office-based procedures (payment indicators “P2,” “P3,” and “R2”) using the most recent available PFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which is lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator “J8”) is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4. of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators “Q1” and “Q2”) describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the

OPPS are generally packaged (payment indicator “N1”) under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator “Q2”)—we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2027

We propose to update ASC payment rates for CY 2027 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4. of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators “A2” and “G2”.

We propose to calculate payment rates for office-based procedures (payment indicators “P2,” “P3,” and “R2”) and device-intensive procedures (payment indicator “J8”) according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4. of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2027 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2027 PFS nonfacility PE RVU-based amount or the proposed CY 2027 ASC payment amount calculated

according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2026, for CY 2027, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators “Q1” and “Q2”) will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed Payment for ASC Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain “J1” service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b. of this proposed rule, we apply a complexity adjustment by promoting qualifying paired “J1” service code combinations or paired code combinations of “J1” services and add-on codes from the originating Comprehensive APC (C–APC) (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. A “J1” status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b. of this proposed rule, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource

requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator “J1” or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of “J1” services, or combinations of a “J1” service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described previously, we promote the claim to the next higher cost C–APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new C–APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the “J1” primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the proposed complexity adjustments for “J1” and add-on code combinations for CY 2027, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice>).

(2) CY 2027 ASC Special Payment Policy Proposal for OPPS Complexity-Adjusted C–APCs

For CY 2027, we propose to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080). We also propose to make a minor change to the long descriptor of

ASC complexity adjustment code C7570.

For those ASC complexity adjustment codes for which we have claims data, we propose to use the claims data to calculate the code combination utilization and estimated payments for the ASC payment system budget neutrality calculations for CY 2027. Any ASC complexity adjustment budget neutrality calculations are discussed further in section XIII.H.2.a. of this proposed rule. The full list of the proposed ASC complexity adjustment codes, inactive ASC complexity adjustment codes, their short descriptors, long descriptors, and proposed ASC payment indicators for CY 2027 can be found in the CY 2027 proposed ASC CPX supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions. ASC Addendum AA also includes our proposed active ASC complexity adjustment codes and their ASC payment rates. Both files are published on the CMS website at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notice>. Since the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for the proposed payment policy changed slightly from the previous year. Additionally, since complexity adjustment assignments may change between the proposed rule and final rule under the OPPS, the final list of ASC complexity adjustment codes eligible for this payment policy may be slightly different than the proposed list of ASC complexity adjustment codes.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100

claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for the CY 2027 OPPS/ASC proposed rule, we propose to designate five brachytherapy APCs and four clinical APCs as Low Volume APCs under the ASC payment

system. The four clinical APCs and five brachytherapy APCs met our criteria of having fewer than 100 single claims in the relevant claims year (CY 2025 for the CY 2027 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Eight of the nine APCs were designated as Low Volume APCs in CY 2026. Based on data for the CY 2027 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) had 87 single claims and now meets our criteria to be designated as a Low Volume APC.

Table 67 includes the CY 2025 claims available for ratesetting for each of the APCs we propose to be designated as a Low Volume APCs for CY 2027. The cost statistics for our Low Volume APCs, such as the median, arithmetic mean, and geometric mean costs, are available for download with this proposed rule on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices>; click on the relevant regulation to download the Low Volume APC cost statistics under the standard (ASC) ratesetting methodology in the “Downloads” section of the web page.

TABLE 67: PROPOSED LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2027

APC	APC Description	CY 2025 Claims Available for Ratesetting
2635	Brachytx, non-str, HA, P-103	28
2642	Brachytx, stranded, C-131	41
2643	Brachytx, non-stranded, c-131	78
2645	Brachytx, non-str, gold-198	87
2647	Brachytx, NS, Non-HDR Ir-192	13
5244	Level 4 Blood Product Exchanges and Related Services	2
5494	Level 4 Intraocular Procedures	11
5495	Level 5 Intraocular Procedures	34
5496	Level 6 Intraocular Procedures	12

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators “N,” “Q1,” and “Q2”) under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS

(status indicators “Q1” and “Q2”). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indicator “N1”) under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear

medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to “Z2” so that payment is made based on the ASC standard ratesetting methodology rather than the PFS nonfacility PE RVU amount (“Z3”), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to “Z2” for radiology services that use contrast agents so that payment for these procedures will be based on the OPSS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPSS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPSS or, if OPSS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPSS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPSS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoice costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPSS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure’s OPSS relative payment

weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a “device offset” to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPSS pass-through payment status.

In the CY 2015 OPSS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPSS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPSS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator “Z2” and revised the definition of payment indicator “Z2” to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator “Z3”, and revised the definition of payment indicator “Z3” to include a reference to diagnostic services.

In the CY 2026 OPSS/ASC final rule with comment period (90 FR 53887 through 53888), we finalized our policy to unpackage and pay separately for certain skin substitute supplies when provided integral to a covered surgical procedure under the ASC payment system in conjunction with our policy to unpackage and pay separately for the same such items under the OPSS. We finalized the addition of a new ASC payment indicator “S2”—“Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPSS rate” to indicate a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical

procedure. We finalized that payment for separately payable skin substitute supplies under the ASC payment system would be made at the same rate as is provided under the OPSS.

b. Proposed Payment for Covered Ancillary Items and Services for CY 2027

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPSS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2027 OPSS and ASC payment rates and subsequent years’ payment rates. We propose to continue to set the proposed CY 2027 ASC payment rates and subsequent years’ payment rates for brachytherapy sources and separately payable drugs, biologicals, and skin substitute supplies equal to the OPSS payment rates for CY 2027 and subsequent years’ payment rates.

Covered ancillary services and their proposed payment indicators for CY 2027 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2027. For a discussion of the PFS rates, we refer readers to the CY 2027 PFS proposed rule with comment period which is available on the CMS website at <https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notice>.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as “office-based” those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians’ offices based on consideration of the most recently available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that final rule, we also finalized our policy to exempt all

procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that final rule with payment indicator “P2” (Office-based surgical procedure added to ASC list in CY 2008 or later with PFS nonfacility PE RVUs; payment based on OPPS relative payment weight); “P3” (Office-based surgical procedures added to ASC list in CY 2008 or later with PFS nonfacility PE RVUs; payment based on PFS nonfacility PE RVUs); or “R2” (Office-based surgical procedure added to ASC list in CY 2008 or later without PFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the PFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either

temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2027 Proposed Office-Based Procedures

In developing the CY 2027 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. Historically, we also review the most recent claims volume and utilization data (CY 2025 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2026 of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically “P2,” “P3,” or “R2” in the CY 2026 OPPS/

ASC final rule with comment period (89 FR 94322 through 94326).

Our review of the CY 2025 volume and utilization data of covered surgical procedures currently assigned a payment indicator of “G2” (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of two surgical procedures—CPT code 0102T (Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle) and 60660 (Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency)—that we believe meet the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians’ offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians’ offices. We have included CPT codes 0102T and 60660 in our list of surgical procedures we propose to permanently designate as office-based for CY 2027 in Table 68.

TABLE 68: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICEBASED FOR CY 2027

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Proposed CY 2027 ASC Payment Indicator*
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle	G2	P2*
60660	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency	G2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS proposed rates.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence

of claims data, we use other available information, including our clinical advisors’ judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

In Table 130 of the CY 2026 OPPS/ASC final rule with comment period, we

finalized assigning temporary office-based designations to four surgical procedures for CY 2026 (90 FR 53850). We reviewed CY 2025 volume and utilization data for the four surgical procedures designated as temporarily office-based in the CY 2026 OPPS/ASC final rule with comment period. As shown in Table 69 of this proposed rule, for one of the four surgical procedures—CPT code 53866 (Catheterization with

removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate)—there are greater than 50 claims available and the volume and utilization indicated this procedure was

not performed predominantly in the office setting based on CY 2025 claims data. Therefore, we propose to no longer designate this procedure as temporarily office-based and to designate this procedure a payment indicator of

“G2”—“Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.” for CY 2027.

TABLE 69: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2027

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Proposed CY 2027 ASC Payment Indicator*
53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	R2	G2

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS proposed rates.

For the remaining three procedures that were designated as temporarily office-based in the CY 2026 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically “P2”, “P3”, or “R2,” there were fewer than 50 claims; therefore, there was an insufficient number of claims to determine if the office setting was the predominant setting of care for these

procedures. Therefore, as shown in Table 70, we propose to continue to designate such procedures as temporarily office-based for CY 2027 and assign one of the office-based payment indicators. Additionally, for CY 2027, we did not propose to designate any new CY 2027 CPT codes for ASC covered surgical procedures as temporarily office-based.

The procedures for which the proposed office-based designation for CY 2027 is temporary are also indicated by an asterisk in Addendum AA to this proposed rule (which is available via the internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASCRegulations-and-Notices>).

TABLE 70: CY 2027 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE DESIGNATED AS TEMPORARILY OFFICE-BASED

CPT/HCPCS Code	Long Descriptor	Final CY 2026 ASC Payment Indicator	Proposed CY 2027 ASC Payment Indicator*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2027 PFS proposed rates.

4. Proposed Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and

subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:
 - ++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or
 - ++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = “N1”) procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code’s APC assignment is based on its corresponding OPPS complexity adjustment code’s APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the “device offset amount”) and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code’s APC payment rate. Further, we apply our standard ASC payment system ratesetting

methodology to the non-device portion of the ASC complexity adjustment code’s APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a modification to our policy regarding default device offset percentages for new codes that meet our criteria for device-intensive status. Under both the OPPS and ASC payment system, for new device-intensive procedures that lack claims data, or lack claims data from a predecessor code or a clinically-similar code that uses the same device, we apply the greater of the APC-wide device offset percentage or 31 percent (the previous default device offset percentage). We believe that an APC-wide average device offset percentage is, in most cases, a better reflection of device costs when the typical device costs of procedures assigned to such APC are significantly greater than 31 percent. This policy does not apply to new device-intensive procedures assigned to New Technology APCs.

In the CY 2026 OPPS/ASC final rule with comment period, we discussed the implementation of the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 rule and the impact of the OPPS conversion factor on the ASC payment system. Since most ASC payment rates for surgical procedures are constructed from OPPS relative weights or the PFS unadjusted nonfacility PE RVU-based amount, the remedy’s proposed prospective offset to the OPPS conversion has a very limited impact on the ASC payment system. The only impact of the proposed reduction to the OPPS conversion factor is the payment rate for device-intensive procedures under the ASC payment system. Since the ASC payment system holds device portions constant between the two settings, the device portion is the device offset percentage multiplied by the OPPS payment rate. As we stated in that rule, we believed it would be inaccurate and inappropriate to use OPPS payment rates that have been reduced by the remedy’s prospective offset since this could accumulate to have a potentially noticeable impact on ASC payment rates for certain device-intensive procedures over time. Therefore, we finalized our policy that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not incorporate the prospective offset to the OPPS conversion factor as a result of the 340B

remedy offset that we proposed to implement in the CY 2026 OPPS/ASC proposed rule.

As discussed in section XIII.G.2.a. of this proposed rule, historically, the device portions of device-intensive procedures have not been scaled so that payment for device portions would remain constant between the OPPS and ASC payment system. However, due to increased utilization of orthopedic procedures in the ASC setting, ASC expenditures on device portions of device-intensive procedures represent a substantially larger share of total ASC expenditures than in prior years. For this proposed rule, we estimate a proposed large increase in the device portions for device-intensive procedures as a result of the proposed 340B drug payment policy which results in a large decrease in the ASC weight scaler. We solicit comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scaler. If we were to include device portions as subject to scaling, ASC payment rates for device-intensive procedures would decrease and ASC payment rates for non-device intensive procedures would increase. We estimate that treating device expenditures for device-intensive procedures as scalable prospective expenditures would increase the proposed ASC weight scaler from 0.809 to 0.865 in CY 2027 but would decrease the ASC payment for the device portion of device intensive procedures by approximately 14 percent.

We are not proposing any changes to our device-intensive procedure policies under the ASC payment system for CY 2027, but we are soliciting comment on whether our device-intensive calculation methodology should continue to exclude device portions from the ASC weight scaler or whether device portions should represent scalable prospective expenditures. For the proposed CY 2027 device offset percentages, which include device offset percentages based on CY 2025 claims processed through March 31, 2026, we refer readers to Addendum FF of the CY 2027 OPPS/ASC proposed rule. Final CY 2027 device offset percentages may differ from the proposed percentages as we rely on the most recently available claims data for the CY 2027 OPPS/ASC final rule with comment period (CY 2025 claims data processed through June 30, 2026).

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS “FB” modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we

estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS “FC” modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure’s performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our “FB”/“FC” modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to

the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure’s performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We are not proposing any changes to our policies related to no cost/full credit or partial credit devices for CY 2027.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Proposed Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the

list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by interested parties.

Under our current regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2026, are surgical procedures that meet the criteria specified in § 416.166(b)(2). In the CY 2026 OPPTS/ASC final rule with comment period, we finalized a policy to expand the ASC CPL by revising our criteria for adding surgical procedures to the ASC CPL (90 FR 53855 through 53886). Under the revised criteria, procedures added to the ASC CPL must be separately paid under the OPPTS and are not (1) currently designated as requiring inpatient care under § 419.22(n), (2) only able to be reported using a CPT unlisted surgical procedure code, or (3) otherwise excluded under § 411.15. Additionally, we moved certain general standards and exclusions used to evaluate services for addition to the ASC CPL prior to January 1, 2026, to a new section of the following non-binding physician considerations: (1) Is not expected to pose a significant safety risk when performed in an ASC; (2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure; (3) Generally results in extensive blood loss; (4) Requires major or prolonged invasion of body cavities; (5) Directly involves major blood vessels; (6) Is generally emergent or life-threatening in nature; and (7) commonly requires systemic thrombolytic therapy. We believe that these revised criteria are sufficient to ensure, along with appropriate patient selection and complex medical judgement of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve the five previous exclusion criteria. We believe that this expansion of the ASC CPL could advance the goals of increasing physician and patient choice and expanding site neutral options in conjunction with patient safety considerations. For further discussion on our policy to revise the ASC CPL criteria and expand the procedures added to the list, please refer to section XIII.D. of the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53855 through 53886).

In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59029 through 59030), we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as “surgery” (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the criteria established in previous years for addition to the ASC CPL.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 through CY 2026 OPPTS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; 88 FR 81923 through 81945; 89 FR 94331 through 94334; and (90 FR 53855 through 53886).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2027

Historically, we have reviewed the clinical characteristics of procedures and consulted with appropriate medical organizations, other interested parties, and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 42 CFR 416.166.

As part of our evaluation process to add procedures to the CPL, we assess potential procedures against the revised ASC CPL criteria at § 416.166(b)(2). For CY 2027, we reviewed interested parties' nominations received in the pre-proposed rule nominations process. Additionally, we reviewed procedures that are proposed to be removed from the IPO list for CY 2027, as part of the continuation of the elimination of the IPO list, as described in section IX. discussed earlier in this proposed rule. Based upon this review, we propose to update the ASC CPL by adding 618 procedures that we propose to remove from the IPO list for CY 2027. This includes four procedures that were recommended by interested parties for addition to the ASC CPL: CPT code 49596 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated), 49616 (Repair of anterior

abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated), 40617 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible), and 40618 (Repair of anterior abdominal hernia(s) (*i.e.*, epigastric, incisional, ventral, umbilical, spigelian), any approach (*i.e.*, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated). We believe these procedures would meet the revised ASC CPL criteria under 42 CFR 416.166, if we finalize our proposal to remove these services from the IPO list for CY 2027. These procedures are listed in the public use file titled “Proposed Additions to the List of ASC Covered Procedures for CY 2027,” which is available on the CMS website.

3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPTS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPTS; (5) certain radiology services for which separate payment is allowed under the OPPTS; and (6) non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174; and (7) groups of skin substitute supply products. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy

to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2026, but will be packaged under the CY 2027 OPPS, we would also package the ancillary service under the ASC payment system for CY 2027 to maintain consistency with the OPPS. Comment indicator “CH” is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2025.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise § 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490). In the CY 2025 OPPS/ASC final rule with comment period, we revised § 416.164(b)(6) to read “Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174,” as we finalized a policy to place qualifying medical devices on the ASC covered ancillary services list (89 FR 94361).

In the CY 2026 OPPS/ASC final rule with comment period, we finalized our proposal to pay separately for the provision of certain groups of skin substitute products when used during a covered surgical procedure, by revising § 416.164(b) to include groups of skin substitute products as covered ancillary items and services that are integral to a covered surgical procedure.

E. Proposed CY 2027 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provide for temporary additional payments for non-

opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, paragraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Paragraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act.

Additional payments under this policy began on January 1, 2025. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94344), the statute directs CMS to provide “additional payment”, and for purposes of this policy, we interpret this language to be equivalent to “separate payment,” since CMS provides an additional payment by unpackaging the product and then making a separate payment. “Separate payment” is the more commonly used terminology in the OPPS rule and likely more familiar to readers. To avoid confusion, we will continue to use “separate payment” throughout the rest of this section, which we believe to be synonymous with “additional payment.” Under section 1833(t)(2)(E) of the Act, the temporary separate

payments must be made in a budget neutral manner.

For background information on the ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs and Biologicals prior to CY 2025, please see the summary provided in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94343).

2. Finalized CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2025, CMS finalized our implementation methodology for section 4135 of CAA, 2023 (89 FR 94343 through 94361) to provide for temporary separate payments for certain non-opioid treatment for pain relief in the hospital outpatient department and ambulatory surgical center settings on a temporary basis from January 1, 2025 through December 31, 2027. CMS also finalized regulation text at 42 CFR 416.174 and 42 CFR 419.43(k), which outline the payment for non-opioid pain management drugs, biologicals, and medical devices under both the ASC payment system and OPPS, respectively.

a. Drugs and Biologicals Subject to the ASC Non-Opioid Policy (42 CFR 416.174)

Section 1833(i)(10)(B), titled “Transition”, provides that a drug or biological that meets the requirements of the regulation at 42 CFR 416.174, the current ASC non-opioid policy, and also meets the definition of a non-opioid treatment for pain relief at section 1833(t)(16)(G)(iv) of the Act shall receive separate payments under section 4135 of the CAA, 2023, subject to the payment limitation. In light of this requirement, we finalized in the CY 2025 OPPS/ASC final rule with comment period that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 of the CAA, 2023 that were subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act in CY 2024, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135 of the CAA, 2023 (89 FR 94344).

b. Definition of Non-Opioid Treatment for Pain Relief

Section 1833(t)(16)(G)(iv) of the Act defines a non-opioid treatment for pain relief for a drug, biological product, or medical device and requires, in part, that such treatment does not receive transitional pass-through payment and

has payment that is packaged into a payment for a covered OPD service (or group of services). In addition, in order for a drug or biological product to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(I), the product must have “a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body’s opioid receptors”. In order for a medical device to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(II) of the Act, it must, in part, be “used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia”. A medical device must also, pursuant to section 1833(t)(16)(G)(iv)(II)(aa) and (bb) of the Act have both “an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act” and “demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal”.

c. Evidence Requirement for Medical Devices

To determine whether a medical device fulfills the statutory requirement that it has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, we finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345) a policy to review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids. In CY 2025, we encouraged interested parties submitting non-opioid device recommendations to submit any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision with their public comments. We review any literature submitted and determine whether it meets this evidence criterion. There is no requirement that commenters submit any data or literature with their device recommendations. If there is no data or literature submitted for a medical

device, or if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, the medical device would not meet this evidence criterion and would not qualify for separate payment under section 4135 of the CAA, 2023.

d. Non-Opioid Product Indications

(1) FDA-Approved Indications for Drugs and Biologicals

Section 1833(t)(16)(G)(iv)(I) of the Act specifies that to meet the definition of a non-opioid treatment for pain relief and to be eligible for separate payment, a drug or biological product must have a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body’s opioid receptors.

Given these statutory requirements, we finalized a policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346) only to approve separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce postoperative pain or produce post-surgical or regional analgesia. We noted that products without an indication that meets this statutory requirement would not qualify. We specifically stated that products with only a general pain indication will not qualify.

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346), we note that the Congress specifically included language at section 1833(t)(16)(G)(iv)(I) of the Act requiring that drugs or biologicals have “a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body’s opioid receptors”. Therefore, products without an indication that meets the statutory requirement will not qualify.

(2) Intended Use for Medical Devices

Regarding medical devices, section 1833(t)(16)(G)(iv)(II) of the Act specifies that such a device must be used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia to qualify for separate payment under section 4135 of the CAA, 2023. It also must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), have been cleared for market under

section 510(k) of the FD&C Act, or be exempt from the requirements of section 510(k) of the FD&C Act pursuant to section 510(l) or (m) or 520(g) of the FD&C Act. For CY 2025, for medical devices, we finalized without modification our proposal that a device must be used to deliver a therapy to reduce postoperative pain or produce postsurgical or regional analgesia to qualify for separate payment under section 4135 of the CAA, 2023 (89 FR 94346 through 94347). We also finalized that the medical device must have an application approved under section 515 of the FD&C Act, which has been cleared for market under section 510(k) of the FD&C Act, or be exempt from the requirements of section 510(k) of the FD&C Act pursuant to sections 510(l) or (m) or 520(g) of the FD&C Act. (89 FR 94346 through 94347). This is consistent with the regulation text at 42 CFR 419.43(k)(2)(i) through (iv).

e. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act provides that, for a non-opioid treatment for pain relief that is a drug or biological product, the amount of separate payment is the amount of payment for such product determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to a limitation, as described in the next section. Section 1833(t)(16)(G)(ii)(II) of the Act provides that, for a non-opioid treatment for pain relief that is a medical device, the amount of separate payment is the amount of the hospital’s charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device, subject to a limitation, as described in the next section.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025 (89 FR 94347 through 94348). A zero dollar offset means that we would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates. We finalized a zero dollar offset for the initial year of the policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected yet in the cost of procedures in which they may be used. Therefore, we stated that the separate payment for a drug or biological would be determined

by subtracting from the amount calculated using the methodology outlined in section 1847A of the Act the portion of the otherwise applicable Medicare OPD fee schedule associated with the drug or biological, which as previously discussed, we finalized to be zero dollars for CY 2025. For the amount of payment for a medical device, since we are unable to reduce charges to costs for ASCs, we stated that the separate payment amount would be contractor-priced by the ASC's Medicare Administrative Contractor reduced by the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we finalized to be zero dollars for CY 2025. These separate payment amounts are all subject to the payment limitation, described in the subsequent section.

Section 1833(i)(10) of the Act establishes the same separate payment for the ASC setting as for hospital outpatient departments, as described in section 1833(t)(16)(G)(ii) of the Act. Both separate payments are subject to the limitation in section 1833(t)(16)(G)(iii) of the Act, which specifies that the separate payment amount shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished. Given this statutory requirement, we finalized paying the same separate payment amount for qualifying non-opioid products in both the HOPD and ASC settings starting on January 1, 2025 through December 31, 2027.

As the statute requires separate payment for these non-opioid treatments for pain relief, these products cannot be packaged into the procedure payment. Under our current threshold packaging policy, if the estimated per day cost for a drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure. Similarly, under our comprehensive APC (C-APC) policy, we package all payments for services integral, ancillary, supportive, dependent, and adjunctive to the primary service into a single payment for the primary comprehensive service. For CY 2025, we finalized that non-opioid treatments for pain relief would not be subject to the threshold packaging policy and would also be separately paid when used during a comprehensive APC (C-APC) procedure in the HOPD setting (89 FR 94347 through 94348). See section V.B.1.a. of

this proposed rule for more information regarding the drug packaging threshold. Section II.A.2.b. of this proposed rule contains further information on C-APC packaging.

f. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the separate payment amount specified in clause (ii), (which is described in the previous section) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary.

In the CY 2025 OPPTS/ASC final rule with comment period, we finalized a policy to base the 18 percent payment limitation on the volume weighted average of the payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy. We also finalized applying the 18 percent payment limitation per date of service billed (89 FR 94349).

g. Payment Limitation With No Claims Data

For drugs, biologicals, and devices with no claims data, such as for newly FDA-approved and marketed products or products that did not previously have their own product-specific HCPCS code by which to track payment and utilization data, we finalized in the CY 2025 OPPTS/ASC final rule with comment period (89 FR 94350) a policy where CMS will utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, to calculate the payment limitation based on expected clinical use patterns. The finalized policy stated that CMS will determine the service, or group of services, to use to calculate the payment limitation through engagement with interested parties and a review by CMS Medical Officers and clinical staff during annual rulemaking. In the absence of engagement from interested parties, we will determine clinically appropriate procedures with which we would expect the drug or device to be frequently used in order to determine the payment limitation, including review of FDA approval materials, procedures identified in literature available to CMS, and other relevant materials. We noted that we may update the payment limitation amount in future rulemaking as we gather additional claims data on the utilization of and payment for this product.

3. Final CY 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2026, we finalized to continue the policies implemented in the CY 2025 OPPTS ASC final rule (90 FR 53888 through 53909), with minor modifications to permit timely consideration of qualifying products. In that final rule we finalized to maintain a zero-dollar offset for all qualifying products regulated under the non-opioid policy, consistent with our belief that costs for some of these products may not be fully reflected yet in the cost of procedures in which they may be used. Additionally, the data used for CY 2026 ratesetting was derived from CY 2024 claims, which was prior to the effective date of this policy in CY 2025. We also finalized conforming regulatory text changes at 42 CFR 416.174(c)(1) to remove language specific to CY 2025, allowing us to consider or revise the offset amount through annual rulemaking.

We finalized a list of qualifying drugs, biologicals, and devices that meet the statutory criteria for separate payment under section 4135. Similarly, we finalized payment limitation calculations for the qualifying non-opioid products, and finalized our approach to determining those payment limitations based on the proposed procedure payment rates and utilization data available in the CY 2026 OPPTS/ASC proposed rule, which we stated was the best data available at the time of writing the CY 2026 OPPTS/ASC proposed rule.

In response to public comments, we finalized a modification to allow for more timely consideration of qualifying products by establishing a process to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis, rather than limiting consideration to annual rulemaking. We also made conforming regulatory text revisions at 42 CFR 419.43(k) and 416.174 to remove references tying qualification only to annual rulemaking.

4. Proposed CY 2027 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

For CY 2027, we propose to continue the policies finalized in the CY 2026 OPPTS/ASC final rule without modification (90 FR 53448), aside from a technical modification to the payment limitation calculations as described further in this section.

We continue to believe a zero-dollar offset is appropriate for all qualifying products regulated under the non-opioid policy as some of these products

are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected in the cost of procedures in which they may be used. Additionally, given the clinical nature of non-opioid treatments for pain relief, they can be used in a variety of procedures, making an APC offset impractical. A continued zero-dollar offset aligns with comment support for a zero-dollar offset as discussed in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53892).

We note that the payment limitation calculations will now be displayed in a public use file for the proposed rule. The non-opioid payment limitation public use file is available on the CMS website under downloads for the CY 2027 OPPS proposed rule. By including the payment limitations in the public use file, we are able to use the most

recently available data to calculate the payment limitations. Therefore, the payment limitations calculated for this proposed rule will be based on the payment rates and utilization data available for this proposed rule. Accordingly, the final payment limitation calculation in the CY 2027 OPPS/ASC final rule with comment period will be based on the final rule procedure payment rates and utilization data available for the final rule. Therefore, there could be slight changes between the proposed rule payment calculations and the final rule payment calculations as the payment rates and utilization data is updated between the proposed and final rules.

Table 71 includes the drugs and biologicals we propose to have met the statutory requirements and qualify for separate payment for this CY 2027

OPPS/ASC proposed rule. Given our updated policy to evaluate and approve additional non-opioid treatments for pain relief on a quarterly basis finalized in the CY 2026 OPPS/ASC final rule with comment period, we anticipate that we will incorporate additional qualifying non-opioid products into Table 71 in the final rule with comment period. For parties interested in submitting additional products for consideration under this policy, we refer readers to the guidance posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/non-opioid-treatments-pain-relief>. We will review eligible products as provided in the guidance.

We welcome comments on our proposals.

BILLING CODE 4169-69-P

TABLE 71: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN CY 2027 UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor
Exparel	J0666*	Injection, bupivacaine liposome, 1mg
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Zynrelef	J0668 (previously C9088**)	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
Journavx	C9818	suzetrigine, oral, 1 mg
Caldolor	J1741	Injection, ibuprofen, 100 mg
ON-Q Pump	C9804	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
SPRINT Peripheral Nerve Stimulator System	C9807	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Cryo Nerve Block Therapy	C9808	Nerve cryoablation probe (e.g., cryoICE, cryoSPIHERE, cryoSPIHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump	C9806	Rotary peristaltic infusion pump (e.g., ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Iovera System	C9809	Cryoneurolysis needle (e.g., iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
IceMan	C9810	Water circulating motorized cold therapy device (e.g., IceMan) including all system components (e.g. pads, console, disposable parts), non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the cCAA 2023)
Sapphire Infusion Pump	C9811	Electronic ambulatory infusion pump (e.g. Sapphire pump), including all pump components, including disposable components , non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)

Brand Name	HCPCS Code	Long Descriptor
Ultrasound-visible nerve block needles (SonoPlex, SonoBlock, SonoTap)	C9812	Echogenic nerve block needles (e.g. SonoPlex, SonoBlock, SonoTap), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Perforated continuous infusion catheter set (InfiltraLong)	C9813	Perforated continuous infusion catheter set (e.g. InfiltraLong), including all components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Continuous anesthesia conduction catheter sets (SonoLong, E-Cath)	C9814	Continuous anesthesia echogenic conduction catheter set (e.g. SonoLong, E-Cath), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
CADD-Solis infusion pump	C9815	Linear peristaltic pain management infusion pump (e.g. CADD-Solis ambulatory infusion pump), and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump (Reusable)	C9816	Rotary peristaltic infusion pump (e.g., reusable ambIT Pump) including all disposable system components, reusable non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)
Game Ready System	C9817	Electronic cryo-pneumatic compression, pain management system (e.g. Game Ready® GRPro 2.1 System), including control unit, anatomically correct wrap(s), and other system component(s), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)

*Previously described by HCPCS code C9290.

**HCPCS Code C9088 was replaced by HCPCS code J0668 (Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg) effective October 1, 2025.

BILLING CODE 4169-69-C

F. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline which is announced in the annual OPPS/ASC final rule with comment period. For a request to be considered complete, we require submission of the information requested in the guidance document titled "Application Process and Information

Requirements for Requests for a New Class of NTIOLs or Inclusion of an IOL in an Existing NTIOL Class" posted on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols>.

- We announce annually, in the CY OPPS/ASC proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103-432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests to establish a new NTIOL class as published in the proposed rule.

- In the final rule with comment period updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2027

We did not receive any requests for review to establish a new NTIOL class for CY 2027 by March 1, 2026, the due date published in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53910).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is \$50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2027.

G. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule with comment period (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of \$41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2. of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the PFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive-procedures).

As discussed in the August 2, 2007 ASC final rule with comment period (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to acute care hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes result in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the pre-floor, pre-reclassified hospital wage indexes, which are updated yearly and are used by several other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs (89 FR 23424). Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index for the fiscal year under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On July 21, 2023, OMB issued OMB Bulletin No. 23–01, which provided the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the U.S. and Puerto Rico based on the standards published on July 16, 2021, in the **Federal Register** (86 FR 37770) and 2020 Census Bureau data. (A copy of this bulletin may be obtained at <https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf>.) As discussed in the FY 2025 IPPS/LTCH PPS final rule with comment period (89 FR 69253 through 69266), we finalized our proposal to use the new CBSAs delineations issued by OMB in OMB Bulletin 23–01 for the IPPS hospital wage index beginning in CY 2025. Therefore, because the ASC wage indexes for the calendar year are the pre-floor and pre-reclassified IPPS hospital wage indexes for the fiscal year, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94362 through 94363) we finalized our proposal to incorporate the new OMB delineations into CY 2025 ASC wage indexes. We believe that using the revised delineations based on OMB Bulletin No. 23–01 will increase the integrity of the ASC wage index system by creating a more accurate representation of current geographic variations in wage levels. In addition to adopting the revised delineations based on OMB Bulletin No. 23–01, we also finalized our proposal to limit year-to-year ASC wage index value changes to no more than a 5-percent decrease, similar to the policy of other Medicare payment systems under Parts A and B. This 5-percent cap, implemented in a budget neutral manner through the wage index scalar, mitigates any large negative impacts of adopting the new

delineations and prevents large year-to-year declines in wage index values as a means to reduce volatility in Medicare payments.

The proposed CY 2027 ASC wage indexes reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin No. 23–01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. When all of the areas contiguous to the CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, our policy has been to determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). For CY 2026, we applied this methodology to ASCs located in CBSA 35 (Rural North Dakota) (90 FR 53911). For CY 2027, we propose to continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 35 (Rural North Dakota). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index. For CY 2027, we propose that we continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA). Further, the proposed CY 2027 ASC wage index includes our policy finalized in the CY 2025 OPPS/ASC final rule with comment period that limits wage index changes to decrease by no more than 5 percent from the final CY 2026 ASC wage index value. As we discussed in the April 2025 Update to the Ambulatory Surgical Center Payment System (Change Request 14017), to limit wage index changes by no more than 5 percent from the final CY 2026 ASC wage index, some counties may require a transition CBSA before being fully reflected in the OMB labor market delineations as set forth in OMB Bulletin No. 23–01.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2027 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts,

as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

As discussed in section II.A.1.a. of this proposed rule, we are using the CY 2025 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2027 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2025, we propose to compare the estimated total payment using the CY 2026 ASC relative payment weights with the estimated total payment using the CY 2027 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2026 and CY 2027.

In consideration of our policy to provide a higher ASC payment rate with ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporated estimated total spending and estimated utilization for these codes in our budget neutrality calculation for CYs 2023 and 2024. For this proposed rule, our proposed ASC complexity adjustment codes for CY 2027 did not impact the ASC weight scalar.

Additionally, as discussed in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94361), section 4135(a) and (b) of the CAA, 2023, titled "Access to Non-Opioid Treatments for Pain Relief", amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary separate payments for non-opioid treatments for pain relief. As discussed in further

detail in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period, for qualifying non-opioid products, we finalized applying an 18 percent payment limitation on the volume weighted payment average of the top 5 services associated with the use of the qualifying non-opioid product. In CY 2024, four of these qualifying nonopioid products were separately payable without the 18 percent payment limitation—HCPCS Codes C9089 (Bupivacaine implant, 1 mg), J0666 (Inj, bupivacaine liposome), J1096 (Dexametha oph insert 0.1 mg), and J1097 (Phenylep ketorolac oph soln). Therefore, to maintain budget neutrality, we estimated the total anticipated reduction in ASC spending for these qualifying non-opioid products for CY 2025 as a result of the 18 percent payment limitation required by section 4135 of the CAA, 2023. Based on the updated 18 percent payment limitations and CY 2025 utilization, we estimate that the proposed CY 2027 payment limitations will not impact the ASC weight scalar.

We propose to use the ratio of estimated CY 2026 to estimated CY 2027 total payments (the weight scalar) to scale the proposed ASC relative payment weights for CY 2027. The proposed CY 2027 ASC weight scalar is 0.809. Consistent with historical practice, we propose to scale, using this method (with an ASC weight scalar rounded to the nearest thousandth), the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We propose that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount, would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services or the portion of those services. The ASC payment weights for those services without predetermined national payment amounts would be scaled to eliminate any difference in the total payment between the current year and the update year.

Historically, the device portions of device-intensive procedures were not scaled so that payment for device portions would remain constant between the OPPS and ASC payment system. However, due to increased utilization of orthopedic procedures in the ASC setting, ASC expenditures on device portions of device-intensive procedures represent a substantially larger share of total ASC expenditures than in prior years. We estimate that spending attributable to device portions increased from approximately 5.4 percent of total ASC expenditures in CY 2016 to roughly 32.4 percent of total ASC expenditures in 2026. As device expenditures account for an increasingly significant share of total ASC spending, large year-to-year increases in the estimated device portions of surgical procedures require correspondingly larger reductions to the non-device portions of surgical procedures and certain ancillary services to maintain budget neutrality.

The change in the proposed ASC weight scaler for CY 2027 illustrates this effect. Specifically, the ASC weight scaler would decrease from 0.872 in CY 2026 to a proposed 0.809 in CY 2027. This reduction is largely attributable to the substantial increase in expenditures for device portions of device-intensive procedures under the ASC payment system. In turn, this increase in device portions results from the proposed budget-neutral increase in OPPS payment rates for surgical procedures that would offset the drug payment reductions associated with our proposed payment policy for 340B acquired drugs as a result of the OPPS Drug Acquisition Cost Survey.

As the ASC payment system uses the OPPS conversion factor to determine payment for the device portions of device-intensive procedures, this alters the payment relativity between services under the OPPS because the entire portion of ASC payment rates for non-device-intensive procedures is based on the lower ASC conversion factor. Because of the proposed large increase in the device portions for device-intensive procedures in CY 2027 as a result of the proposed 340B drug payment policy, we solicit comment on whether the device portions of device-intensive procedures calculated using the OPPS conversion factor should continue to be excluded from the ASC weight scaler, or alternatively, whether these device portions should be included in the expenditures subject to scaling through the ASC weight scaler. We estimate that treating device expenditures for device-intensive procedures as scalable prospective

expenditures would increase the proposed ASC weight scaler from 0.809 to 0.865 in CY 2027 and would reduce the device portions of device intensive procedures by approximately 14 percent.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We propose to use the CY 2025 claims data to model our budget neutrality adjustment for CY 2027.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor.

For CY 2027, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2025 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2027 ASC wage indexes. Specifically, holding CY 2025 ASC utilization, service-mix, and the proposed CY 2027 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2026 ASC wage indexes and the total adjusted payment using the proposed CY 2027 ASC wage indexes which included the 5-percent cap on wage index declines. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2026 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2027 ASC wage indexes and applied the resulting ratio of 1.0016 (the proposed CY 2027 ASC wage index budget neutrality adjustment) to the CY 2026 ASC conversion factor to calculate the proposed CY 2027 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act defines

the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2027 was projected to be 0.8 percentage point, as published in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19496) based on IGI's 2025 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the hospital market basket update (which is the inpatient hospital market basket percentage increase reduced by the productivity adjustment) to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there was a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there were any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. At that time, the most recently available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period was within the period from CY 2019 through CY 2022. However, the impact of the COVID-19 PHE on health care

utilization, CY 2020 in particular, was tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings, when possible, to avoid possible infection from the SARS-CoV-2 virus. As a result, it was nearly impossible to disentangle the effects from the COVID-19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we needed to use claims data from a period during which the COVID-19 PHE had less of an impact on health care utilization. Therefore, for CY 2024, we finalized our proposal to extend the 5-year interim period an additional 2 years through CY 2024 and CY 2025 which we subsequently extended through CY 2026 in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53914 through 53915). We believed hospital outpatient and ASC utilization data from CYs 2023 through 2025 would enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We revised our regulations at § 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii) which establish the annual update to the ASC conversion factor, to reflect these extensions.

For this proposed rule, we propose to extend our utilization of the hospital market basket update factor in the ASC payment system for one additional year, through CY 2027, as we continue to review and evaluate hospital outpatient and ASC utilization data, as well as the migration of surgical procedures between settings. In conjunction with our proposal, we are revising our regulations at § 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii), which establish the annual update to the ASC conversion factor, the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and the productivity adjustment, to reflect this one year extension.

2. CY 2027 Proposed ASC Conversion Factor

For CY 2027, we propose to utilize the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.8 percentage point, resulting in a final hospital market basket update of 2.4 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to

apply a 2.4 percent hospital market basket update factor to the CY 2026 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2027 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the hospital market basket update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements.

For CY 2027, we are adjusting the CY 2026 ASC conversion factor (\$56.322) by a wage index budget neutrality factor of 1.0016 in addition to the productivity-adjusted hospital market basket update of 2.4 percent, discussed previously, which results in a proposed CY 2027 ASC conversion factor of \$57.766 for ASCs meeting quality reporting requirements. For ASCs not meeting quality reporting requirements, we are adjusting the CY 2026 ASC conversion factor (\$56.322) by the wage index budget neutrality factor of 1.0016 in addition to the reduced productivity-adjusted hospital market basket update of 0.4 percent, discussed above, which results in a proposed CY 2027 ASC conversion factor of \$56.638 for ASCs not meeting the quality reporting requirements.

3. Display of the Proposed CY 2027 ASC Payment Rates and Alternative CY 2027 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2027 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the proposed CY 2027 payment rates. Specifically, in Addendum AA, a “Y” in the column titled “To be Subject to Multiple Procedure Discounting” indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with

comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

The values displayed in the column titled “Proposed CY 2027 Payment Weight” are the proposed relative payment weights for each of the listed services for CY 2027. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the PFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2027 payment rate displayed in the “Proposed CY 2027 Payment Rate” column, each ASC payment weight in the “Proposed CY 2027 Payment Weight” column was multiplied by the proposed CY 2027 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update as reduced by the productivity adjustment. The proposed CY 2027 ASC conversion factor uses the proposed CY 2027 productivity adjusted hospital market basket update factor of 2.4 percent (which is equal to the inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.8 percentage point). We also propose that if more recent data subsequently become available (for example, a more recent estimate of the inpatient hospital market basket percentage increase and the productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 ASC conversion factor in the final rule.

In Addendum BB, there are no relative payment weights displayed in the “Proposed CY 2027 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “Proposed CY 2027 Payment” column displays the proposed CY 2027 national unadjusted

ASC payment rates for all items and services. The proposed CY 2027 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are generally based on the most recently available data used for payment in physicians' offices. For CY 2021, we finalized adding a new column to ASC Addendum BB titled "Drug Pass-Through Expiration during Calendar Year" where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

Addendum EE to this proposed rule provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2027.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the APC device offset percentage, the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2027 for covered surgical procedures.

XIV. Proposed Measure Removal for the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs

A. Background

We refer readers to sections XV. and XVII. of this proposed rule for program-specific background information, including statutory authority and program measure sets, regarding the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center (ASC) Quality Reporting Programs, respectively.

B. Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure in the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs

We refer readers to the CY 2014 OPPS/ASC final rule with comment period where we adopted the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure into the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs (78 FR 75101 through 75102 and 78 FR 75127 through 75128), and the CY 2024 OPPS/ASC final rule with comment period where we modified the measure to align with updated clinical guidelines (88 FR 81972 through 81973 and 88 FR 82020 through 82021). The Colonoscopy

Follow-Up Interval measure assesses the percentage of patients aged 45 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.¹⁵³

When we adopted the Colonoscopy Follow-up Interval measure, we sought to address what was, at the time, the critical issue of colonoscopies potentially performed too frequently and potentially increasing patients' exposure to procedural harm.^{154 155} The measure was designed to promote adherence to recommended screening intervals through documentation of follow-up recommendations in the colonoscopy report, thereby increasing provider and patient awareness of appropriate screening intervals. Importantly, this measure assesses whether the recommended 10-year interval for a follow-up colonoscopy is documented in the colonoscopy report, rather than whether appropriate clinical care is delivered. In other words, the measure does not assess whether the follow-up colonoscopy was performed according to this recommended interval.

We continue to believe that it is important to encourage high-quality colonoscopy care in hospital outpatient departments and ASCs. We note that the Hospital Outpatient Quality Reporting Program and ASC Quality Reporting Program measure sets both currently include another measure that is tied more closely to outcomes of continued interest and importance—the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure (79 FR 66948 through 66955 and 79 FR 66970 through 66979, respectively), which assesses the incidence of hospital returns within 7 days of a colonoscopy, including emergency department visits, observation stays, and unplanned readmissions. The Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure is therefore a more patient-outcome focused measure of procedure-related

adverse events across both programs in contrast to the Colonoscopy Follow-Up Interval measure, which assesses documentation of recommended follow-up intervals rather than patient outcomes.¹⁵⁶ For these reasons, we propose to remove the Colonoscopy Follow-Up Interval measure from the Hospital Outpatient Quality Reporting and the ASC Quality Reporting Programs, beginning with the CY 2027 reporting period/CY 2029 payment determination. For both programs, removal is appropriate under removal factor 6 (42 CFR 419.46(i)(3)(i)(F) and 416.320(c)(2)(vi)), the availability of a measure that is more strongly associated with a desired patient outcome for the particular topic. The Hospital Outpatient Quality Reporting Program and ASC Quality Reporting Program measure sets would continue to retain the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure.

Additionally, we continue to prioritize appropriate colonoscopy care in our other quality reporting or value-based programs. For example, we have a Colorectal Cancer Screening measure within the gastroenterology Merit-based Incentive Payment System (MIPS) Value Pathway¹⁵⁷ and the Medicare Shared Savings Program,¹⁵⁸ which assess the percentage of adults 45–75 years of age who had appropriate screening for colorectal cancer.

We invite public comment on this proposal.

XV. Hospital Outpatient Quality Reporting Program

A. Background

The Hospital Outpatient Quality Reporting Program promotes transparency and quality of care furnished at hospital outpatient departments (HOPDs). Section 1833(t)(17)(A) of the Act sets forth that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0-percentage point reduction to their annual Outpatient Department fee

¹⁵³ Partnership for Quality Measurement. Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. Available at <https://p4qm.org/measures/0658>.

¹⁵⁴ Lieberman, D. A., Faigel, D. O., Logan, J. R., Mattek, N., Holub, J., Eisen, G., Morris, C., Smith, R., & Nadel, M. (2009). Assessment of the quality of colonoscopy reports: results from a multicenter consortium. *Gastrointestinal endoscopy*, 69(3 Pt 2), 645–653. <https://doi.org/10.1016/j.gie.2008.08.034>.

¹⁵⁵ Goodwin, J. S., Singh, A., Reddy, N., Riall, T. S., & Kuo, Y. F. (2011). Overuse of screening colonoscopy in the Medicare population. *Archives of internal medicine*, 171(15), 1335–1343. <https://doi.org/10.1001/archinternmed.2011.212>.

¹⁵⁶ Partnership for Quality Measurement. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at <https://p4qm.org/measures/2539>.

¹⁵⁷ CMS Quality Payment Program Reporting Requirements. Available at <https://qpp.cms.gov/reporting-requirements/measures-activities/explore-mvps/2025/M1422>.

¹⁵⁸ CMS Measures Inventory Tool. Colorectal Cancer Screening, Medicare Shared Savings Program. Available at <https://cmit.cms.gov/cmit/#/MeasureView?variantId=11552&sectionNumber=1>.

schedule increase factor. We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital Outpatient Quality Reporting Program. We have codified certain program requirements at 42 CFR 419.46. We also refer readers to the CMS website at <https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-outpatient-quality-reporting-program> for general background on the Hospital Outpatient Quality Reporting

Program, as well as the CMS QualityNet website at <https://qualitynet.cms.gov/outpatient> for current program requirements and measure specifications.

B. Hospital Outpatient Quality Reporting Program Measure Set

We refer readers to section XIV. of this proposed rule for a cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure from the Hospital Outpatient

Quality Reporting and Ambulatory Surgical Center (ASC) Quality Reporting Programs beginning with the CY 2027 reporting period/CY 2029 payment determination. We are not proposing any other changes to the Hospital Outpatient Quality Reporting Program measure set. Table 72 summarizes the previously finalized Hospital Outpatient Quality Reporting Program measure set for the CY 2028 to CY 2032 payment determinations.

BILLING CODE 4169–69–P

TABLE 72: PREVIOUSLY FINALIZED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

Consensus -Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
Chart-Abstracted Measures						
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*	ü	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
0661	Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival	ü	ü	ü	ü	ü
None	Left Without Being Seen	ü	ü			
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients	ü	ü			
Claims-Based Measures						
None	Abdomen CT - Use of Contrast Material	ü	ü	ü	ü	ü
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	ü	ü	ü	ü	ü
None	Breast Cancer Screening Recall Rates	ü	ü	ü	ü	ü
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	ü	ü	ü	ü	ü
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery	ü	ü	ü	ü	ü
Patient-Reported Outcomes-Based Performance Measures (PRO-PMs)						
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)	Voluntary	ü	ü	ü	ü
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty	Voluntary	Voluntary	Voluntary	ü	ü

Consensus -Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
	(TKA) in the HOPD Setting (THA/TKA PRO-PM)					
Survey-Based Measures						
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	ü	ü	ü	ü	ü
Electronic Clinical Quality Measures (eCQMs)						
4625e	Emergency Care Access & Timeliness		Voluntary	ü	ü	ü
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM (Excessive Radiation)	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
None	ST-Segment Elevation Myocardial Infarction (STEMI)	ü	ü	ü	ü	ü

üMeasure is mandatory for the specified payment determination year.

Voluntary: Submission of this measure is optional, and HOPDs that do not report the measure are not subject to a payment reduction.

*Proposed for removal beginning with the CY 2029 payment determination.

BILLING CODE 4169–69–C

C. Request for Information on the Advance Care Planning Electronic Clinical Quality Measure

1. Background

We are seeking feedback on potential inclusion of an Advance Care Planning electronic clinical quality measure (eCQM) and other quality measure concepts related to advance care planning for the Hospital Outpatient Quality Reporting Program. Advance care planning is a continuous process that supports patients in understanding and communicating their goals, values, and preferences regarding future medical care and decision-making. The 1990 Patient Self-Determination Act supports advance care planning by requiring health care facilities to inform patients of their rights regarding medical decision-making and to document in the medical record whether the patient has executed an advance directive; however, it does not require that a copy of the directive itself

must always be placed in the medical record.¹⁵⁹

HOPDs provide care for adults with serious and complex conditions, including those receiving cancer treatment, visiting the emergency department (ED), or undergoing surgical procedures. In the CY 2026 OPPI/ASC final rule with comment period (90 FR 53780 through 53786), we finalized the phase-out of the Inpatient-Only (IPO) list over a 3-year period, beginning January 1, 2026, and ending January 1, 2029. As part of the first step of the IPO phase-out, for 2026, we removed 285 HCPCS codes (mostly for musculoskeletal procedures) from the IPO list. As more procedures shift from the inpatient to the outpatient setting, complex procedures may increasingly be furnished in HOPDs. Outpatient encounters can provide repeated opportunities for clinicians to build relationships with patients over time, which may support the initiation or updating of advance care planning

¹⁵⁹ Patient Self-Determination Act of 1990. 42 U.S.C. 1395cc(f) and 1396a(w).

documentation, including when patients are relatively stable or before their illness progresses.¹⁶⁰ Many patients assume that their caregivers know their preferences regarding their care; however, research indicates that caregivers incorrectly predict patients' preferences approximately one-third of the time.¹⁶¹ Additionally, care preferences may change over time,¹⁶²

¹⁶⁰ Marshall, K. H., Riddiford-Harland, D. L., Meller, A. E., Caplan, G. A., Naganathan, V., Cullen, J., Gonski, P., Zwar, N. A., O'Keeffe, J. A., Krysinska, K., & Rhee, J. J. (2024). Feasibility and Acceptability of Facilitated Advance Care Planning in Outpatient Clinics: A Qualitative Study of Patient and Caregivers Experiences. *Journal of applied gerontology: the official journal of the Southern Gerontological Society*, 43(4), 339–348. <https://doi.org/10.1177/07334648231206742>.

¹⁶¹ National Institute on Aging. (2022). Advance Care Planning: Advance Directives for Health Care. Available at <https://www.nia.nih.gov/health/advance-care-planning/advance-care-planning-advance-directives-health-care>.

¹⁶² Mastropolo, R., Cernik, C., Uno, H., Fisher, L., Xu, L., Laurent, C. A., Cannizzaro, N., Munneke, J., Cooper, R. M., Lakin, J. R., Schwartz, C. M., Casperson, M., Altschuler, A., Kushi, L., Chao, C. R., Wiener, L., & Mack, J. W. (2024). Evolution in Documented Goals of Care at End of Life for Adolescents and Younger Adults With Cancer.

particularly in response to changes in an individual's health status or personal circumstances.¹⁶³ ¹⁶⁴ Regular reassessment and transparent communication are essential to maintaining person-centered care. Advance care planning facilitates shared decision-making by documenting patient preferences and ensuring that care remains aligned with patients' goals across care settings and transitions.¹⁶⁵

We are interested in receiving feedback on whether the Advance Care Planning eCQM is appropriate for use in the hospital outpatient setting, with or without modifications. We seek input on this and on other potential quality measures related to this topic that may be appropriate for the hospital outpatient setting.

2. Advance Care Planning Electronic Clinical Quality Measure Overview

The Advance Care Planning eCQM was proposed for adoption for the Hospital Inpatient Quality Reporting, PPS-Exempt Cancer Hospital Quality Reporting, and Medicare Promoting Interoperability Programs in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568). Potentially adopting the eCQM across our quality reporting programs promotes the use of standardized advance care planning documentation in the electronic health record (EHR). Such documentation helps ensure that care remains aligned with patients' stated preferences, leverages EHRs to facilitate health information exchange, and supports the advancement of person-centered care across the care continuum.

We refer readers to the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19564 through 19568) for a complete discussion of the proposals to adopt the Advance Care Planning eCQM in certain inpatient quality reporting programs. The eCQM currently calculates the proportion of adult patients with one or

more hospitalizations during the measurement period who, by the time of discharge for at least one encounter, have either an advance care planning document in the EHR or documentation of an advance care planning discussion that results in a documented decision in the patient's EHR. The numerator comprises any one of the following: (1) an advance care planning document as evidenced by the following types of documents: designated health care agent (health care proxy or medical power of attorney for health care), advance directive (or living will), or a portable medical order (medical order for life-sustaining treatment [MOLST], physician order for life-sustaining treatment [POLST], or do not resuscitate [DNR] orders);¹⁶⁶ or (2) documentation that an advance care planning discussion resulting in a documented decision occurred during the measurement period.¹⁶⁷ ¹⁶⁸

To be counted in the numerator, the advance care planning document must be available in the patient's EHR during any hospitalization in the measurement period. The measure does not require documentation of the date the advance care planning document was originally created or last updated. However, we encourage clinicians to discuss with the patient or their surrogate whether the document accurately reflects the patient's current preferences. To be considered an advance care planning discussion leading to a decision, the documentation of the discussion with a decision must have a date in the EHR that occurs during a hospital encounter in the measurement period. If a patient has multiple encounters during the measurement period, an advance care planning discussion with a decision occurring in any one of the hospital encounters during the measurement period is counted toward the numerator. The denominator includes all patients aged 18 years and older at the start of the measurement period who are discharged from a hospitalization during the 12-month measurement

period. The Advance Care Planning eCQM is calculated as a proportion by dividing the number of patients who meet the numerator criterion by the total number of eligible patients who meet the denominator criterion.¹⁶⁹

There are no exclusions for the Advance Care Planning eCQM as the measure is intended to encourage advance care planning among all adult patients, recognizing that serious illness or injury can occur at any time, regardless of age or baseline health. The measure is designed to account for situations where a patient does not have capacity to engage in, declines, or defers advance care planning by crediting pre-existing advance care planning documents in the EHR and including EHR data elements that include advance care planning discussions with a decision documented during a hospital encounter (including those conducted with a surrogate when the patient does not have capacity) and documentation that a patient declined or deferred advance care planning.

For more details on the Advance Care Planning eCQM, please refer to <https://www.p4qm.org/prmr-measures/muc2025-020>. We refer readers to the Electronic Clinical Quality Improvement (eCQI) Resource Center for more details on the measure specifications at (<https://ecqi.healthit.gov/ecqm/hosp-inpt/2028/cms1317v1>) and to the CMS QualityNet website for a list of the EHR data elements that comprise the numerator (<https://qualitynet.cms.gov/inpatient/iqr/proposedmeasures>).

3. Solicitation for Public Comment

We are seeking input on the importance, relevance, appropriateness, and applicability of including the Advance Care Planning eCQM in the Hospital Outpatient Quality Reporting Program, as well as on other measure concepts related to advance care planning for the hospital outpatient setting. We invite public comment on the following considerations:

- Tools and measures that capture advance care planning processes and outcomes in hospital outpatient settings, including the potential future use of and modifications to the Advance Care Planning eCQM to better tailor it for the Hospital Outpatient Quality Reporting Program.

- Other approaches or measure concepts that may more effectively capture advance care planning activities in the HOPD setting.

JAMA network open, 7(12), e2450489. Available at <https://doi.org/10.1001/jamanetworkopen.2024.50489>.

¹⁶³ Shah, M. P., Wenger, N. S., Glaspy, J., Hays, R. D., Sudore, R. L., Rahimi, M., Gibbs, L., Anand, S., Tseng, C. H., & Walling, A. M. (2025). Patient-reported discordance between care goals and treatment intent in advanced cancer. *Cancer*, 131(17), e35976. Available at <https://doi.org/10.1002/cncr.35976>.

¹⁶⁴ Young Y, Stone A, Perre T. (2022). Are Young Adults Ready to Complete Advance Directives? *American Journal of Hospice & Palliative Medicine*, 39(10), 1188–1193. Available at <https://doi.org/10.1177/10499091211066494>.

¹⁶⁵ McMahan, R. D., Tellez, I., Sudore, R. L. (2021). Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. *Journal of the American Geriatrics Society*, 69(1), 234–244. Available at <https://doi.org/10.1111/jgs.16801>.

¹⁶⁶ Some state organizations may refer to a MOLST or POLST form by other terms such as medical orders for scope of treatment (MOST), physician orders for scope of treatment (POST), clinical orders for life-sustaining treatment (COLST), or a transportable physician orders for patient preferences (TPOPP).

¹⁶⁷ Documentation that an advance care planning discussion resulting in a documented decision occurred during the measurement period includes a discussion with the patient or the surrogate. This allows discussion with a surrogate in instances where a patient is unable to participate (e.g., incapacitated) without requiring prior discussion with the patient.

¹⁶⁸ Partnership for Quality Management. Advance Care Planning. Available at <https://www.p4qm.org/prmr-measures/muc2025-020>.

¹⁶⁹ Partnership for Quality Management. Advance Care Planning. Available at <https://www.p4qm.org/prmr-measures/muc2025-020>.

- Relevant aspects of advance care planning for the HOPD setting, such as whether an advance care planning measure should focus on specific patient populations, higher-acuity procedures, or select departments (such as oncology, emergency department, and surgical areas).

- Timing and frequency of advance care planning, such as when and how often it should occur in the HOPD setting.

- Other measure development/re-specification ideas or opportunities for addressing advance care planning in the HOPD setting, including but not limited to changes to the current Advance Care Planning eCQM.

D. Proposed Updates to the Validation of Hospital Outpatient Quality Reporting Program Data

We refer readers to previous OPPIs/ASC rulemaking¹⁷⁰ and 42 CFR 419.46(f) for our existing policies regarding data validation in the Hospital Outpatient Quality Reporting Program. We also refer readers to our outpatient data validation resources at <https://qualitynet.cms.gov/outpatient/data-management/data-validation/resources>.

To ensure the accuracy of Hospital Outpatient Quality Reporting Program data and the ability of interested parties to rely on such data using the provider comparison tool on *Medicare.gov* (<https://www.medicare.gov/care-compare/>), we propose to incorporate the validation of eCQM data into the Hospital Outpatient Quality Reporting Program's existing validation process as well as to streamline certain validation processes. In addition, we propose to: (1) change the validation selection pool from 500 to up to 400 hospitals; (2) clarify application of the targeting criteria to eCQMs; (3) update the number of cases for chart-abstracted and eCQM validation; (4) include eCQM validation in the timing and submission of medical record requests; (5) align the submission quarters for chart-abstracted and eCQM validation; (6) establish an

eCQM validation scoring method based on data accuracy; and (7) update the educational review process for validation results. We anticipate the cumulative impact of these proposals would reduce burden for hospitals while increasing the accuracy of data reported under the program to better facilitate beneficiary decision-making and hospital quality improvement efforts.

1. Proposed Electronic Clinical Quality Measure Data Validation

To incorporate validation of eCQMs into the existing Hospital Outpatient Quality Reporting Program data validation process, we propose that validation begin with each eCQM when there is a full year of data available. For example, hospitals are required to submit all four quarters of data for the Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) eCQM beginning with data from the CY 2027 reporting period (86 FR 63837 through 63840); therefore, validation for the STEMI eCQM would begin with data from the CY 2027 reporting period. Likewise, validation for the Emergency Care Access & Timeliness (ECAT) eCQM would begin with data from the CY 2028 reporting period, which is the first year that submitting four quarters of data for this measure is mandatory (90 FR 53925 through 53934). Any future eCQMs adopted into the measure set would become eligible for validation after mandatory reporting of a full year of data is in effect, and information regarding the measures to be validated would be obtained from the CMS QualityNet website (or other CMS-designated website).

2. Proposed Changes to Selection Process for Hospital Outpatient Quality Reporting Program Validation

a. Validation Selection Pool

In the CY 2012 OPPIs/ASC final rule with comment period (76 FR 74484 through 74485), we finalized an annual process for the Hospital Outpatient Quality Reporting Program of selecting a random sample of 450 hospitals for validation purposes and an additional 50 hospitals based on specific targeting criteria. Since this process was finalized, we have found that hospitals randomly selected for validation generally have high accuracy rates for chart-abstracted measures and believe the number of hospitals randomly selected for validation could be reduced without impacting our ability to assess the accuracy of hospital data. At the

same time, we believe that increasing the number of hospitals selected for validation based on specific targeting criteria will help to ensure data accuracy by allowing a greater number of hospitals meeting specific targeting criteria to have their data submissions reviewed for accuracy.

Therefore, we propose that, beginning with hospital selections for validation affecting the CY 2030 payment determination, up to 200 hospitals would be selected at random and up to 200 hospitals would be selected using targeting criteria, for a total of up to 400 hospitals selected for validation. As we have found consistently high agreement rates and relatively low variation among randomly selected hospitals, this change would reduce the total number of hospitals selected for validation each year from 500 to up to 400 hospitals, while maintaining a sufficiently reliable sample size. Since the total number of hospitals required to participate in validation each year would be fewer, this proposed change would also reduce overall burden for hospitals. Re-balancing the number of randomly selected hospitals compared to the number of hospitals selected by targeting criteria would also more effectively and efficiently direct validation program resources to ensure data accuracy. Beginning with validation affecting the CY 2030 payment determination, we would require any hospital selected for validation, either randomly or after meeting targeting criteria, to submit both chart-abstracted measure and eCQM data for validation. Under the current policy, hospitals selected for validation affecting the CY 2029 payment determination would continue to participate only in chart-abstracted measure validation as no eCQMs would yet be eligible for validation. Hospital selections for validation affecting the CY 2029 payment determination would continue under the existing policy. Additionally, hospitals selected for validation affecting the CY 2030 payment determination would only be required to submit eCQM data for validation when the relevant eCQM is required and eligible for validation for the applicable reporting period. This aligns with the validation process finalized for the Hospital Inpatient Quality Reporting Program, which hospitals are familiar with (85 FR 58946 through 58949). We propose to update the codified policy at § 419.46(f)(3) to reflect this proposed change.

¹⁷⁰ Existing validation policies were adopted for the Hospital Outpatient Quality Reporting Program in the CY 2011 OPPIs/ASC final rule with comment period (75 FR 72103 through 72106), CY 2012 OPPIs/ASC final rule with comment period (76 FR 74484 through 74487), CY 2013 OPPIs/ASC final rule with comment period (77 FR 68484 through 68487), CY 2014 OPPIs/ASC final rule with comment period (78 FR 75117), CY 2015 OPPIs/ASC final rule with comment period (79 FR 66964 through 66966), CY 2016 OPPIs/ASC final rule with comment period (80 FR 70524), CY 2018 OPPIs/ASC final rule with comment period (82 FR 59441 through 59443), CY 2021 OPPIs/ASC final rule with comment period (85 FR 86185), CY 2022 OPPIs/ASC final rule with comment period (86 FR 63870 through 63873), and CY 2023 OPPIs/ASC final rule with comment period (87 FR 72115 through 72116).

b. Targeting Criteria for Validation Selection Pool

We have previously established several targeting criteria set forth at § 419.46(f)(3)(i) through (v):

- The hospital fails the validation requirement that applies to the previous year's payment determination; or
- The hospital has an outlier value for a measure based on the data it submits. An "outlier value" is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score; or
- Any hospital that has not been randomly selected for validation in any of the previous 3 years; or
- Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or
- Any hospital with a two-tailed confidence interval that is less than 75

percent, and that had less than four quarters of data due to receiving an extraordinary circumstance exception (ECE) for one or more quarters.

We propose to apply the targeting criteria at § 419.46(f)(3)(i) through (v) to all measures eligible for validation in the Hospital Outpatient Quality Reporting Program, including but not limited to chart-abstracted measures and eQCMs.

3. Case Selection for Validation

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485 through 74486) and CY 2013 OPPS/ASC final rule with comment period (77 FR 68486), where we finalized that for each hospital selected through either random sampling or targeting criteria, we will validate up to 48 randomly selected patient cases (12 cases per quarter) from the total number of cases that the

hospital successfully submitted to the CMS Clinical Data Warehouse via the Hospital Quality Reporting (HQR) system.

We propose to revise the number and distribution of cases selected for validation under the Hospital Outpatient Quality Reporting Program to ensure a balanced assessment across measure types. Specifically, we propose to validate up to 32 randomly selected patient cases for each measure, starting with validation of CY 2027 data affecting the CY 2030 payment determination. For each chart-abstracted clinical process of care measure, cases would be submitted quarterly, with up to 8 cases validated per quarter. For each eQCM, up to 32 cases would be submitted annually, allowing validation of up to 8 cases from each quarter. Table 73 illustrates these proposed changes.

TABLE 73: PROPOSED CASE SELECTION FOR VALIDATION IMPACTING CY 2029 TO CY 2031 PAYMENT DETERMINATIONS

Payment Determination Year	Reporting Period Data*	Measures Included in Validation	Number of Measures Validated	Number of Cases Validated
CY 2029	CY 2027	• Median Time from ED Arrival to ED Departure for Discharged ED Patients • Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival	2	48 cases under the current policy
CY 2030	CY 2027	• Median Time from ED Arrival to ED Departure for Discharged ED Patients • Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival • STEMI eCQM	3	Up to 96 cases under this proposal
CY 2031 (and subsequent years)	CY 2028 (and subsequent years)	• Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival • STEMI eCQM • ECAT eCQM	3	Up to 96 cases under this proposal

* We refer readers to section XV.D.5.c. of this proposed rule for our proposal to shift the payment impact of validation from 2 years after the reporting period to 3 years after the reporting period.

We believe this approach would support a more balanced and representative assessment of data accuracy across both chart-abstracted

measures and eQCMs. We further believe that broadening the selection of cases across measure types, rather than concentrating cases within a single

measure, would improve our ability to detect potential data inaccuracies and systemic reporting issues.

Under this proposed validation policy, all hospitals selected for validation purposes would receive a total of five medical record requests for complete supporting medical record documentation from CMS or its designated contractor: four quarterly requests containing randomly selected chart-abstracted cases and one annual request containing randomly selected eCQM cases. We refer readers to § 482.24(c) for a definition of what is expected in a medical record submitted for validation.

4. Timing and Electronic File Submission for Medical Records Requests

a. Chart-Abstracted Measures

We refer readers to the CY 2022 OP/PS/ASC final rule with comment period (86 FR 63870 through 63871) and § 419.46(f)(1) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests and the time period for data validation, including the deadlines for submitting medical records to CMS. We are not proposing any changes affecting the time period or deadlines for electronic file submission for chart-abstracted measures under our validation policy.

b. Electronic Clinical Quality Measures

Under this proposal, we would apply the same electronic file submissions policy to eCQM medical records requests in alignment with the chart-abstracted measures that hospitals are already familiar with. Upon written request by CMS or its contractor, a

hospital would be required to submit portable document format (PDF) copies of medical records using direct electronic file submission via a CMS-approved secure file transmission process (currently, Unified File Management [UFM]/Managed File Transfer [MFT]). A hospital must submit the supporting medical record documentation to CMS or its contractor within 30 days of the date on the written request. We would continue to reimburse hospitals at \$3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

5. Submission Quarters

a. Background

Currently, hospitals selected for chart-abstracted validation are required to submit data from 2 years prior to the applicable CY payment determination year, consisting of validation quarter 1 (January 1 through March 31), validation quarter 2 (April 1 through June 30), validation quarter 3 (July 1 through September 30), and validation quarter 4 (October 1 through December 31) (80 FR 70524).

Under our proposed validation policy, hospitals selected for eCQM validation for a given payment determination year would be required to submit data from the calendar year that is 3 years prior to the applicable payment determination year because eCQM data are reported annually rather than quarterly. A 3-year cycle allows sufficient time to complete sampling, medical record abstraction, confidence interval calculation, educational reviews, and quality

assurance prior to payment determination.

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, we would shift the payment impact of validation from 2 years after the reporting period to 3 years after the reporting period. During this transition, the validation results for CY 2027 chart-abstracted data would affect both the CY 2029 and the CY 2030 payment determination, as detailed below.

b. Validation Affecting the CY 2029 Payment Determination

To maintain the continuity of annual validation activities while we shift to a 3-year cycle, CY 2027 chart-abstracted data would continue to be used for the CY 2029 payment determination under the existing 2-year cycle in accordance with existing policy for chart-abstracted measure validation. In other words, there will be no change from our current policy for the CY 2029 payment determination.

c. Validation Affecting the CY 2030 Payment Determination

For the CY 2030 payment determination, CY 2027 chart-abstracted data would be used again in combination with CY 2027 eCQM data for validation. That is, validation results for CY 2027 chart-abstracted data would impact both the CY 2029 and CY 2030 payment determinations. Table 74 illustrates our proposed changes, including a transition year, to align the validation for chart-abstracted and eCQM data.

TABLE 74: PREVIOUSLY FINALIZED AND PROPOSED VALIDATION PROCESS FOR CY 2029 TO CY 2031 PAYMENT DETERMINATIONS

Payment Determination Year	Reporting Period Data	Data Type	Validation Cycle	Notes
CY 2029	CY 2027	Chart-abstracted	Current: 2-years between reporting period and payment determination	Continues current policy to maintain annual validation continuity.
CY 2030	CY 2027	Chart-abstracted and eCQM	Proposed: 3-years between reporting period and payment determination	Supports transition to combined validation process. CY 2027 chart-abstracted data are used again for CY 2030 payment. This overlap ensures no gap in annual validation activities during the transition.
CY 2031 (and subsequent years)	CY 2028 (and subsequent years)	Chart-abstracted and eCQM	Proposed: 3-years between reporting period and payment determination	Steady state begins after transition year.

For the transition year affecting the CY 2030 payment determination, we propose a one-time modification of the hospital selection and targeting methodology such that hospitals selected for validation based on CY 2027 data, affecting the CY 2029 payment determination, would not be selected again, either randomly or through targeted selection, for validation of the same data affecting the CY 2030 payment determination. For example, we would not automatically reselect a hospital that failed to meet the validation requirements for the CY 2029 payment determination under the targeting criterion at § 419.46(f)(3)(i) for validation affecting the CY 2030 payment determination. This approach is intended to eliminate the potential burden to hospitals that would have gone through the validation process for the CY 2029 payment determination while allowing validation activities to continue during the transition year.

d. Validation Affecting the CY 2031 Payment Determination and for Subsequent Years

As seen in Table 74, following the transition period, we would adopt a 3-year validation cycle, under which validation results for an annual reporting period would be applied to the applicable payment determination 3 years later. That is, beginning with CY 2028 chart-abstracted and eCQM data, validation results would impact the payment determination 3 years following the reporting period, which for CY 2028 reporting period data is the

CY 2031 payment determination. Following the transition year, we would proceed with validation policies under the 3-year validation cycle, including the use of aligned data submission periods and the application of established hospital selection and targeting methodologies. We believe aligning the quarters of submission data used for both chart-abstracted measures and eCQM validation would allow hospitals selected for validation to more easily track and meet validation requirements.

6. Scoring Method

a. Chart-Abstracted Measures

In the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72103 through 72106), we finalized the calculation of validation scores under the Hospital Outpatient Quality Reporting Program using the upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level. We are not proposing any changes to this threshold.

b. Electronic Clinical Quality Measures

We propose that eCQM validation scores would be determined using the same methodology currently used to score chart-abstracted measure validation, such that eCQM validation scoring would be based on the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted to CMS), beginning with CY 2027 eCQM data affecting the CY 2030 payment determination. Consistent with the data validation scoring

threshold currently applied to chart-abstracted measures and codified at § 419.46(f)(2), a minimum score of 75 percent accuracy would be required for the hospital to pass the eCQM validation requirement. Applying an upper bound of a 90 percent two-sided confidence interval with a 75 percent lower bound threshold level is appropriate because it accounts for sampling variability, reflects a reasonable standard of data accuracy, and aligns with existing validation thresholds for chart-abstracted measures while allowing for legitimate differences in hospital data implementation.

To incentivize the timely and complete submission of requested medical records, we propose that any missing medical records would be treated as mismatches, beginning with the validation of the CY 2027 eCQM data affecting the CY 2030 payment determination and for subsequent years. Because mismatches would count against the agreement rate, treating any missing medical records as mismatches would encourage submission of complete medical records and disincentivize selective medical record submissions. We note that this approach is consistent with our existing policy for chart-abstracted measure validation, under which missing records are treated as mismatches.

Using this approach, at the end of each calendar year, we would compute an eCQM confidence interval using the results of all four quarters to determine the final eCQM validation score. Hospitals' submitted eCQM data and the

submitted medical records would be used to compute an agreement rate and the associated confidence interval around the score. The upper bound of the 90 percent two-sided confidence interval would be used as the final eCQM validation score for the selected hospital. We would then compare this final validation score to the 75 percent accuracy threshold described below to determine whether the hospital meets the eCQM validation requirement. Data validation scoring is at the measure level, not the individual data element level. If CMS or its contractor does not reach the same outcome as the hospital's original submission, then the case may be considered a mismatch. We selected 75 percent as the threshold for the validation score because we believe this level is reasonable to reflect accurate performance, but still realistic for hospitals to achieve. It also allows for legitimate differences in how hospitals implement measures and map their data. We note we adopted the same eCQM scoring method for the Hospital Inpatient Quality Reporting Program (89 FR 69574 through 69577).

c. Annual Payment Update

Beginning with the validation of CY 2027 data affecting the CY 2030 payment determination, hospitals would receive two validation scores: one for chart-abstracted measure data and one for eCQM data. As we finalized in the CY 2008 OPPI/ASC final rule with comment period (72 FR 66873 through 66874), a hospital that does not meet validation requirements will not receive the full annual payment update under the OPPI. Therefore, if a hospital does not meet either chart-abstracted validation requirements or eCQM validation requirements, we propose the hospital would not receive the full OPPI annual payment update. In other words, to be eligible for a full annual payment update, provided all other Hospital Outpatient Quality Reporting Program requirements are met, a hospital selected for validation would need to attain at least a 75 percent validation score for chart-abstracted measure validation and at least a 75 percent validation score for eCQM data validation. We also propose to codify this policy by updating the regulatory text at § 419.46(f)(2).

7. Educational Review Process

a. Chart-Abstracted Measures

We refer readers to the CY 2018 OPPI/ASC final rule with comment period (82 FR 59441 through 59443) and the CY 2021 OPPI/ASC final rule with comment period (85 FR 86185) where

we finalized and codified a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. We also refer readers to § 419.46(f)(4) for our policies regarding the educational review process, including validation score review and correction, for chart-abstracted measures. As described in the CY 2018 OPPI/ASC final rule with comment period (82 FR 59441 through 59443), for CY 2020 and subsequent years, if a hospital requests an educational review for any of the first three quarters of validation and this review yields incorrect CMS validation results for chart-abstracted measures, the corrected quarterly score will be used to compute the final confidence interval.

We propose to revise our policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval, beginning with the CY 2030 payment determination. Under our current policy, due to time constraints, educational reviews for the final quarter of data are not completed in time to affect validation results, and hospitals must use the reconsideration process. Under the proposal to extend the validation timeline from a 2-year cycle to a 3-year cycle, sufficient time would become available to complete educational reviews for all four quarters. As a result, any corrected scores from educational reviews across all quarters would be used in calculating the final confidence interval.

b. Electronic Clinical Quality Measures

We propose extending the educational review process established for chart-abstracted measure validation to eCQM validation beginning with validation affecting the CY 2030 payment determination (that is, starting with validated data from CY 2027). We believe that expanding the educational review process to include eCQMs would allow hospitals to better understand the processes and data for eCQM validation.

Hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation of eCQMs. A hospital would have 30 calendar days following receipt of the validation results to contact CMS' Validation Support Contractor requesting a written explanation of its performance. Because hospitals receive eCQM validation results on an annual basis, they would have the opportunity to request an educational review once annually. Upon receipt of an

educational review request, we would review the requested data elements and written justifications provided by the hospital. We would also provide the results of the eCQM validation educational review to the requesting hospital, including our findings of whether the scores were correct or incorrect, through a CMS-approved secure file transmission process (currently, UFM/MFT). If the results of a validation educational review determine that the original validation score was incorrect, the corrected score would be used to compute the final validation score and confidence interval at the end of each calendar year.

We propose to codify this policy by revising § 419.46(f)(4) to include eCQMs. As proposed, § 419.46(f)(4) would indicate that hospitals selected for validation may request an educational review within 30 calendar days from the date validation results are made available. Under the proposed revisions to § 419.46(f)(4), if the results of an educational review indicate one or more measures were incorrectly scored, the corrected validation score will be used to compute the final validation score used for payment determination. Refer to section XXIV.A. of this proposed rule for more information on the burden estimates associated with these proposals.

We invite public comment on the proposed changes regarding data validation in the Hospital Outpatient Quality Reporting Program, including incorporating eCQM validation into the existing validation process for chart-abstracted measures, reducing the validation selection pool from 500 to up to 400 hospitals, updating the number of cases for chart-abstracted and eCQM validation, transitioning from a 2-year to a 3-year cycle between the reporting period and the payment determination year, establishing the eCQM validation scoring method, and expanding the educational review process to include eCQM validation.

E. Proposed Updates to the Hospital Outpatient Quality Reporting Program Validation Reconsiderations and Appeals Procedures

1. Reconsiderations and Appeals

We refer readers to § 419.46(g) for our reconsideration and appeals procedures. Under our existing requirements at § 419.46(g)(2)(vii), hospitals submitting reconsideration requests are required to submit a copy of all materials that the hospital submitted to comply with the requirements of the affected payment determination year. In the CY 2022 OPPI/ASC final rule with comment

period, we finalized a requirement for hospitals to submit only electronic files rather than paper copies of medical records for validation of chart-abstracted measures, beginning with validation affecting the CY 2024 payment determination and for subsequent years (86 FR 63871).

2. Proposed Removal of the Re-Submission of Supporting Medical Documentation for Validation Reconsideration Requests

With the transition to all electronic submission of copies of medical records for Hospital Outpatient Quality Reporting Program data validation, the current reconsideration requirement to resubmit records used for validation results in a validation-related reconsideration request is no longer necessary and creates duplicative files and administrative burden. We note the Hospital Inpatient Quality Reporting Program finalized a policy in the FY 2025 IPPS/LTCH PPS final rule with comment period to remove the requirement to resubmit medical records as part of their request for reconsideration of a validation determination beginning with CY 2023 discharges affecting the FY 2026 payment determination (89 FR 69577).

We propose to revise existing § 419.46(g)(2)(vii) and (viii) of our regulations to no longer require hospitals to resubmit materials previously submitted to CMS for validation reconsideration requests, unless specifically requested by CMS, and to require only that the hospital provide any evidence supporting its validation reconsideration request. Under this proposal, hospitals that need to submit a revised medical record may still do so, but those hospitals that would otherwise be submitting copies of previously submitted records would no longer be required to submit them. Removing resubmission of medical documentation as a requirement for validation reconsideration would reduce administrative burden for most hospitals that do not have revised records to submit, as well as for CMS to collect and track medical records that are already available. Please refer to section XXIV.A.5. of this proposed rule for more information on the burden estimates associated with this proposed removal.

We invite public comment on this proposal to remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination. We also

propose to codify this policy by updating the regulatory text at § 419.46(g).

F. Payment Reduction for Hospitals That Fail To Meet the Hospital Outpatient Quality Reporting (OQR) Program Requirements for the CY 2027 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0-percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this proposed rule, which is available via the internet on the CMS website): “J1”, “J2”, “P”, “Q1”, “Q2”, “Q3”, “R”, “S”, “T”, “V”, or “U”. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status

indicator “S” or “T”. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator “Q4” because services and procedures coded with status indicator “Q4” are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the “reporting ratio” to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS/ASC final rule with comment period, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update, and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD

update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor – 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor
Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor – 0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for

purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2027

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2027 annual payment update factor. For the CY 2027 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of \$102.004, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of \$100.015. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of “J1,” “J2,” “P,” “Q1,” “Q2,” “Q3,” “R,” “S,” “T,” “V,” and “U” (other than New Technology APCs to which we have proposed status indicator assignments of “S” and “T”).

We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we propose to continue to calculate the reporting ratio to four decimals.

XVI. Rural Emergency Hospital (REH) Quality Reporting Program

The Rural Emergency Hospital (REH) Quality Reporting Program, implemented under section 1861(kkk)(7) of the Act, ensures transparency and quality for rural emergency hospitals (REHs), defined at section 1861(kkk)(2) of the Act. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82046 through 82047) for a detailed discussion of the history of the REH Quality Reporting Program. The REH Quality Reporting Program requirements are codified at 42 CFR 419.95. We also refer readers to the CMS QualityNet REH Quality Reporting Program website at <https://qualitynet.cms.gov/reh/rehqr> for current program requirements and measure specifications. We are not proposing any changes to the REH Quality Reporting Program in this proposed rule.

XVII. Ambulatory Surgical Center Quality Reporting Program

A. Background

The Ambulatory Surgical Center (ASC) Quality Reporting Program promotes transparency regarding the quality of care provided at ASCs. Section 1833(i)(7)(A) of the Act authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0 percentage points for such year that an ASC fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory authority of the ASC Quality Reporting Program. We have codified certain ASC Quality Reporting Program requirements at 42 CFR part 416, subpart H (§§ 416.300 through 416.330). We also refer readers to the CMS website at <https://www.cms.gov/medicare/quality/initiatives/asc-quality-reporting> for general background on the ASC Quality Reporting Program and to the CMS QualityNet ASC Quality Reporting Program website at <https://qualitynet.cms.gov/asc> for current program requirements and measure specifications.

B. ASC Quality Reporting Program Measure Set

We refer readers to section XIV. of this proposed rule for a cross-program proposal to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

measure from the ASC Quality Reporting and Hospital Outpatient Quality Reporting Programs beginning with the CY 2027 reporting period/CY 2029 payment determination. We are

not proposing any other changes to the previously finalized ASC Quality Reporting Program policies in this proposed rule.

Table 75 summarizes the previously finalized ASC Quality Reporting Program measure set for the CY 2028 to CY 2032 payment determinations.

BILLING CODE 4169-69-P

**TABLE 75: PREVIOUSLY FINALIZED ASC QUALITY REPORTING PROGRAM
MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT
DETERMINATION (PD)**

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
Chart-Abstracted Measures						
None	All-Cause Hospital Transfer/Admission	ü	ü	ü	ü	ü
0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*	ü	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
None	Normothermia Outcome	ü	ü	ü	ü	ü
None	Patient Burn	ü	ü	ü	ü	ü
None	Patient Fall	ü	ü	ü	ü	ü
None	Unplanned Anterior Vitrectomy	ü	ü	ü	ü	ü
None	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	ü	ü	ü	ü	ü
Claims-Based Measures						
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	ü	ü	ü	ü	ü
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (ASCs)	ü	ü	ü	ü	ü
3366	Hospital Visits After Urology ASC Procedures	ü	ü	ü	ü	ü
3470	Hospital Visits After Orthopedic ASC Procedures	ü	ü	ü	ü	ü
Patient-Reported Outcomes-Based Performance Measures						
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)	Voluntary	Voluntary	Voluntary	ü	ü
Survey-Based Measures						
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary

Consensus-Based Entity #	Measure Name	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD	CY 2032 PD
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	ü	ü	ü	ü	ü

üMeasure is mandatory for the specified payment determination year.

Voluntary: Submission of this measure is optional, and ASCs that do not report on the measure are not subject to a payment reduction.

* Proposed for removal beginning with the CY 2029 payment determination.

BILLING CODE 4169–69–C

C. Request for Information on Stratification of the All-Cause Transfer/Admission Measure

We previously adopted the All-Cause Transfer/Admission measure in the ASC Quality Reporting Program in the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74499). The All-Cause Transfer/Admission measure is an outcome measure that assesses the rate of patients receiving care in an ASC who require transfer to a hospital or admission to a hospital upon discharge from the ASC. Currently, the measure does not distinguish the phase of care in which a transfer occurs (pre-procedure, intra-procedure, or post-procedure).¹⁷¹

As reported in MedPAC's 2025 Report to Congress, extracapsular cataract removal with intraocular lens insertion was the most common Medicare Fee-for-Service procedure performed by ASCs in 2023, accounting for 19 percent of all ASC Fee-For-Service volume. In addition, a substantial number of ASCs that bill Medicare specialize in a single clinical area, with gastroenterology and ophthalmology among the most common specialties providing services to Medicare beneficiaries.¹⁷² A recent retrospective study which examined the causes and timing of direct hospital transfers from an ophthalmology-specific surgery center over a 2-year period reported that about 77 percent of hospital transfers were associated with concerns identified prior to the induction of anesthesia, including transfers identified in the preoperative area or upon connection to monitoring equipment in the operating room.¹⁷³

¹⁷¹ Partnership for Quality Measurement. All-Cause Hospital Transfer/Admission. Available at <https://p4qm.org/measures/0265>.

¹⁷² MedPac. (2025). Report to the Congress: Medicare Payment Policy-Ambulatory Surgical Center Services: Status Report. Available at https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch10_MedPAC_Report_To_Congress_SEC.pdf.

¹⁷³ Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery:

Nearly 23 percent of these transfers were directly related to anesthesia or the surgical procedure, including events occurring during induction or intraoperatively. These findings suggest that the majority of hospital transfers from ophthalmology-specific ASCs could be occurring preoperatively rather than procedural complications. While many of these events occur prior to anesthesia induction, they are often identified during anesthesia-led pre-procedure evaluation, reflecting important safety checks in patient assessment.¹⁷⁴

Based on these findings and discussions with interested parties, we are considering whether adding a phase of care stratification relative to the surgical encounter (for example, pre-procedure, intra-procedure, and post-procedure) could improve the interpretability and usefulness of the All-Cause Transfer/Admission measure in the ASC Quality Reporting Program. The current measure reports an overall rate of transfers/admissions and does not specify when during the ASC encounter the need for transfer/admission is identified. Stratification by phase of care would improve attribution and interpretability across the diverse range of ASC services, including non-operative procedures such as those associated with pain management, for hospital transfers/admissions associated with ASC care.

It is important to measure and monitor transfers/admissions that occur pre-procedure, intra-procedure, and post-procedure, as each stratum could provide insight into care processes between facilities. Pre-procedure events

insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery*, 51(5), 376–381. <https://doi.org/10.1097/j.jcrs.0000000000001613>.

¹⁷⁴ Stange, N. R., & Rauen, M. P. (2025). Evaluating ASC–4 transfer rates in cataract surgery: insights into timing and causes of hospital transfers. *Journal of cataract and refractive surgery*, 51(5), 376–381. <https://doi.org/10.1097/j.jcrs.0000000000001613>.

may reflect the effectiveness of pre-operative evaluation, patient selection, and escalation or transfer processes, while intraoperative and post-procedure events may be more closely associated with anesthesia administration, the procedure itself, and immediate recovery, including complications that arise during or after the ASC encounter. A phase of care stratification may also provide more comprehensive information to support beneficiary decision-making and patient safety monitoring.

We seek public comment on clinically meaningful and operationally feasible approaches for incorporating a phase of care stratification for the All-Cause Transfer/Admission measure. Specifically, we seek input on potential stratification frameworks, including appropriate time anchors, their operational definitions, and the corresponding time windows that could be used to define each stratification category.

D. Form, Manner, and Timing of Data Submission

We refer readers to prior OPPTS/ASC final rules with comment period and § 416.310 for information regarding the data submission and reporting requirements for claims-based,¹⁷⁵ survey-based,¹⁷⁶ web-based¹⁷⁷ (that is, data submitted via a CMS-designated information system), and patient-reported outcome-based performance

¹⁷⁵ We refer readers to §§ 416.310(a) and (b) and the CY 2016 OPPTS/ASC final rule with comment period (80 FR 70534 through 70536) for information regarding the claims-based measure data submission and reporting requirements.

¹⁷⁶ We refer readers to § 416.310(e) and the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63905 through 63909) for information regarding the survey-based data submission and reporting requirements.

¹⁷⁷ We refer readers to § 416.310(c)(1) and the CY 2025 OPPTS/ASC final rule with comment period (89 FR 94435 and 94436) for details regarding submission of web-based data via a CMS-designated information system (currently the Hospital Quality Reporting (HQR) system).

measures¹⁷⁸ in the ASC Quality Reporting Program. We maintain measure technical specification manuals (referred to as Specifications Manuals) that can be found on the CMS website at <https://qualitynet.cms.gov/asc/specifications-manuals>.

We are not proposing any changes to these policies in this proposed rule.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPTS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2027, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update was the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional 2 years (through CY 2025) in the CY 2024 OPPTS/ASC final rule with comment period (88 FR 81960). In the CY 2026 OPPTS/ASC final rule with comment period (90 FR 53915), we extended the interim period an additional year (through CY 2026). As discussed in section XIII. of this proposed rule, we propose to continue using the productivity-adjusted hospital market basket update as the update factor for the ASC payment system for CY 2027. Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPTS/ASC final rule with comment

period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPTS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update conversion factor; (2) to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination; and (3) that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment. The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the internet on the CMS website): “A2”, “D2”, “G2”, “P2”, “R2”, and “Z2”, as well as the service portion of device-intensive procedures identified by “J8” (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators “A2”, “D2”, “G2”, “J8”, “P2”, “R2”, and “Z2.” These services include separately payable drugs, biologicals, and radiopharmaceuticals, skin substitute supplies, software-as-a-service codes, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPTS payment rates,

and certain office-based procedures, radiology services, and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians’ offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPTS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPTS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPTS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary’s national unadjusted coinsurance for a service to

¹⁷⁸ We refer readers to the CY 2024 OPPTS/ASC final rule with comment period (88 FR 82041 through 82045) for information regarding the patient-reported outcome-based performance measure data submission and reporting requirements.

which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2026 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We propose to continue applying these policies for the CY 2027 reporting period/CY 2029 payment determination and for subsequent years.

XVIII. Accrediting Organization (AO) Deeming Authority for the Emergency Medical Treatment and Labor Act (EMTALA)

A. Background

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted in 1986 and codified as section 1867 of the Act (42 U.S.C. 1395dd) to address concerns regarding the inappropriate transfer of, or refusal to treat individuals with emergency medical conditions who are seeking emergency department care, commonly referred to as “patient dumping.” EMTALA applies to hospitals that participate in Medicare and operate emergency departments, including critical access hospitals (CAHs) and rural emergency hospitals (REHs). For purposes of this discussion, the term “hospitals” includes CAHs and REHs. To enroll and participate in Medicare under section 1866(a)(1)(I) of the Act (42 U.S.C. 1395cc(a)(1)(I)), all such hospitals must agree to comply with EMTALA’s statutory and regulatory requirements.

Section 1867 of the Act establishes the three core obligations of EMTALA. First, when an individual comes to a hospital’s emergency department and requests examination or treatment, the hospital must provide an appropriate medical screening examination to

determine whether an emergency medical condition exists. Second, if the hospital determines that the individual has an emergency medical condition, the hospital must provide either necessary stabilizing treatment within its capability or arrange for an appropriate transfer to another medical facility. Third, hospitals with specialized capabilities or facilities shall not refuse to accept appropriate transfers of individuals requiring such capabilities or facilities if the receiving hospital has the capacity to treat the individual. The statute also authorizes the imposition by the Office of Inspector General (OIG) of civil monetary penalties and, for physicians, exclusion from participation in Federal health care programs for violations, and permits the Centers for Medicare & Medicaid Services (CMS) to impose termination of a hospital’s Medicare provider agreement for non-compliance in accordance with 42 CFR 489.53.

CMS has implemented EMTALA through regulations at 42 CFR 489.20 and § 489.24, which address two distinct categories of obligations. Section 489.20(l), (m), (q) and (r) sets forth administrative requirements, including to post EMTALA signage, maintain a central log of individuals who present to the emergency department, retain transfer records for 5 years, and maintain an on-call physician list. These administrative obligations support transparency, documentation, and accountability in emergency care operations. These requirements are provider agreement commitments, and obligations hospitals accept as a condition of Medicare participation under section 1866(a)(1)(I) of the Act. They are distinct from the substantive individual care protections at § 489.24.

Section 489.24 implements the statute’s substantive protection requirements for individuals who present to the emergency department and request examination or treatment, including detailed provisions governing the provision of medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities. These requirements reflect the core protections established by section 1867 of the Act and are directly enforceable by CMS and/or the Office of Inspector General (OIG).

Enforcement of EMTALA has historically occurred through complaint investigations conducted by State Survey Agencies (SAs) under CMS direction. However, hospitals may also participate in Medicare via accreditation from a CMS-approved accrediting organization (AO) under section

1865(a)(1)(A) of the Act and implementing regulations at 42 CFR part 488. Pursuant to § 488.6, CMS “deems” a hospital to meet Medicare requirements if it is accredited by an AO with a hospital accreditation program approved by CMS. CMS will approve such organizations if it finds that its standards and survey processes provide reasonable assurance that accredited entities meet or exceed applicable Medicare requirements. Hospitals accredited by such AOs are deemed to meet the Medicare CoPs but are subject to CMS validation surveys and complaint investigations in accordance with existing CMS policies and procedures. More than 90 percent of Medicare-participating hospitals (excluding CAHs and REHs) and more than 40 percent of CAHs, independent of hospitals, are accredited by AOs with CMS-approved accreditation programs. At this time, no REHs are deemed to meet requirements through a CMS-approved accreditation program.

We propose that if an AO identifies EMTALA deficiencies at § 489.24 during an accreditation or reaccreditation survey, the matter would have to be referred to the CMS location for further review and possible SA investigation. If an AO identifies EMTALA deficiencies at § 489.20(l), (m), (q) and (r), they would require the hospital or CAH to submit an acceptable Plan of Correction (PoC) addressing how it would come into compliance with the cited EMTALA requirements. If the PoC is accepted and the hospital has returned to compliance, then no further enforcement action would be taken. If the PoC is rejected, the AO would be required to contact the CMS location for further review. Under § 488.5(a)(4)(ix), accreditation organizations are already required to timely notify CMS if an AO survey identifies an “immediate jeopardy”; the proposed EMTALA requirement would augment the already-existing reporting requirement. If a complaint alleging an EMTALA violation is received by CMS (or the SA acting under an agreement pursuant to section 1864 of the Act), it would be triaged to determine its investigation priority level. The SA or CMS conducts an onsite investigation and if a violation is identified, a deficiency is cited and the survey findings documented. Currently the SA refers § 489.24 violations to the OIG, which has independent statutory authority to impose civil money penalties and potential exclusion of physicians from Federal health care programs. CMS retains the authority to terminate a hospital’s Medicare provider agreement

for EMTALA noncompliance at § 489.53.

In CY 2025, we issued 1,071 EMTALA citations for violations of the two applicable regulations, underscoring the need for Medicare-participating hospitals to comply with emergency care obligations. Of these, 521 citations were issued under § 489.20 requirements, 530 citations were issued under § 489.24, the more expansive regulation that governs the specific medical screening, stabilization, and transfer requirements hospitals must fulfill when an individual presents to a dedicated emergency department and requests examination or treatment, and 20 citations were issued under both § 489.20 and § 489.24. Administrative compliance under § 489.20 appears to be a leading indicator of overall EMTALA program integrity. A hospital that cannot maintain accurate on-call logs, post required notices, or retain transfer documentation is a hospital whose broader EMTALA compliance posture warrants closer scrutiny. Incorporating a structured, thorough review of § 489.20 requirements into every hospital survey is essential to fulfilling the protective intent of EMTALA. The incorporation of the requirements at § 489.20(l), (m), (q) and (r) into the accreditation and reaccreditation survey process mean that AOs would assess whether hospitals are maintaining the documentation, recordkeeping, and operational safeguards that support transparency and accountability in emergency care. Because these obligations are record-based and procedural, we propose to review AO survey processes as part of our hospital accreditation program approval to check that EMTALA requirements are included within the existing accreditation framework.

This proposal does not alter the existing framework governing CMS' disclosure of accreditation survey findings. Under section 1865(b) of the Act, the Secretary is prohibited from disclosing any accreditation survey released to the Secretary and conducted by a CMS-approved AO, unless the survey and information related to such a survey relates to an enforcement action or to a home health agency or hospice program survey. Accordingly, most accreditation survey reports submitted by CMS-approved AOs are not subject to the same government disclosure requirements as SA-conducted surveys. However, the statute does not prohibit the AO itself or a client hospital from disclosing its own survey findings.

It should be noted that findings related to potential § 489.24 violations must be referred to CMS for SA investigation and those findings would continue to follow existing public disclosure procedures applicable to complaint-based SA investigations, which are separate from AO accreditation survey reports. Section 1865(b) of the Act explicitly permits the Secretary to publicly disclose AO surveys and information related to them to the extent that such surveys and information relate to an enforcement action taken by the Secretary.

Our regulations at 42 CFR part 488 govern AO approval and oversight. The proposal described in this rule would operate within section 1865 of the Act and part 488 statutory and regulatory structures by integrating review of EMTALA's administrative requirements into existing accreditation organization processes for accrediting and re-accrediting hospitals, while preserving CMS and OIG enforcement authority over EMTALA's core statutory protections under section 1867 of the Act. We anticipate several benefits associated with this proposal. First, integrating EMTALA administrative review into accreditation and state certification surveys would minimize operational disruption for hospitals. Rather than undergoing separate review processes triggered by administrative deficiencies, hospitals would address these requirements within the structured accreditation survey framework.

Second, this policy may improve compliance consistency with the documentation and operational safeguards at § 489.20(l), (m), (q) and (r). Because these requirements are record-based and procedural in nature, they are well-suited to routine survey evaluation. Regular review during accreditation surveys may enhance sustained compliance.

Third, this proposal would free SAs from needing to carry out EMTALA-only initial investigations, and allow such SAs to concentrate more resources on complaint-based investigations involving potential violations of § 489.24, including issues related to appropriate medical screening examinations, stabilizing treatment, and appropriate transfers. These investigations often require case-specific fact-finding and clinical review, and preserving SA capacity for these activities supports effective enforcement of EMTALA's core protections.

B. CMS Approval of Accreditation Organizations

We propose to clarify at § 488.5(a) that an AO with CMS-approved accrediting programs for hospitals under section 1865 of the Act may assess compliance with the EMTALA-related administrative requirements set forth at § 489.20(l), (m), (q) and (r) as part of their initial accreditation and reaccreditation surveys for those provider types. This proposal is limited to AOs conducting initial accreditation or reaccreditation surveys within the scope of their existing CMS-approved accrediting programs. This amendment would formally require CMS-approved AOs to incorporate review of these specified EMTALA obligations into the existing accreditation framework, while preserving CMS' direct enforcement authority over EMTALA's core statutory protections.

Under this proposal, AOs would evaluate hospital compliance with the administrative commitments codified at § 489.20(l), (m), (q) and (r), including requirements to post appropriate EMTALA signage; maintain a central log of individuals who present to the emergency department; retain transfer records for a period of 5 years; and maintain an on-call physician list to ensure availability of specialty services. These obligations are documentary and administrative in nature, are well-established in regulation, and are conducive to structured review within the context of accreditation and reaccreditation surveys.

If an AO identifies noncompliance with any of the EMTALA administrative requirements at § 489.20(l), (m), (q) and (r), the AO would cite the deficiency and address it through its established procedures, consistent with the procedures it used to address other Medicare deficiencies identified during accreditation and reaccreditation surveys. This would include requiring corrective action plans, monitoring compliance, and reporting findings to CMS in accordance with existing oversight and validation protocols. CMS would retain ultimate oversight responsibility and could take additional action as appropriate under its survey and enforcement authorities.

Importantly, this proposal would not authorize AOs to assess or enforce compliance with the EMTALA requirements at § 489.24. CMS and OIG would retain enforcement authority over those provisions, including obligations related to medical screening examinations, stabilizing treatment, appropriate transfers, and receiving hospital responsibilities. If an AO

identified potential noncompliance with § 489.24 during an initial accreditation or reaccreditation survey, the AO would be required to refer the matter to CMS for further review and possible SA investigation, consistent with existing procedures outlined in the CMS State Operations Manual (SOM) Chapter 5, “Complaint Procedures.” In addition, the OIG would continue to exercise its statutory authority under section 1867(d) of the Act to impose civil monetary penalties or exclusion, as applicable. CMS would also retain authority to terminate a hospital’s Medicare provider agreement for EMTALA violations under section 1866(b)(2) of the Act and § 489.53.

We believe that the administrative requirements at § 489.20(l), (m), (q) and (r) are appropriate for evaluation during initial accreditation and reaccreditation surveys. Integrating review of these provisions into the AO survey process would promote more consistent monitoring of established documentation and recordkeeping obligations, reduce duplicative investigations triggered solely by administrative concerns, and minimize disruption to hospital operations. At the same time, this approach would allow SAs to concentrate their resources on complaint-based investigations involving potential violations of § 489.24.

To implement this proposal, we would revise § 488.5(a) by adding a new paragraph (21), laying out the AO’s responsibility to incorporate the EMTALA administrative requirements into its accreditation standards and survey processes and to identify and address noncompliance with those provisions within the deeming framework.

C. Evaluation of Accreditation Authority Request

In § 488.5, we propose to add a new paragraph (a)(21) to integrate review of the EMTALA administrative requirements at § 489.20(l), (m), (q) and (r) into the existing hospital accreditation deeming framework.

Under this proposal, AOs with a CMS-approved accrediting program for hospitals would be required to assess compliance with the § 489.20(l), (m), (q) and (r) administrative requirements including required signage display, maintenance of an emergency department log, retention of transfer records, and maintenance of an on-call physician list as part of their accreditation and reaccreditation surveys. AOs would have to document the procedures used to assess compliance with these requirements

and would be required to cite and address any identified deficiencies through their established accreditation procedures, consistent with the procedures used to address Medicare deficiencies identified during accreditation and reaccreditation surveys.

XIX. Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPTS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services (84 FR 61142, 61446 through 61456) using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop “a method for controlling unnecessary increases in the volume of covered OPD services”.¹⁷⁹ As part of the CY 2021 OPPTS/ASC final rule with comment period, we added two additional service categories to the prior authorization process for certain hospital OPD services (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPTS/ASC final rule with comment period, we added one more service category to the prior authorization process for certain hospital OPD services (87 FR 71748, 72224 through 72233). The regulations governing the prior authorization process for certain hospital OPD services are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89, with the specific service categories listed in § 419.83.

Section 419.83(a)(1) lists the specific service categories for which prior authorization must be obtained for service dates on or after July 1, 2020: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. Section 419.83(a)(2) lists two additional service categories for which prior authorization must be obtained for service dates on or after July 1, 2021: cervical fusion with disc removal, and implanted spinal neurostimulators. Section 419.83(a)(3) lists Facet Joint Interventions as an additional service category for which prior authorization must be obtained for service dates on or after July 1, 2023. Section 419.83(b) states that CMS will adopt the list of hospital outpatient department service categories requiring prior authorization, and any updates or geographic restrictions, through formal notice-and-comment rulemaking.

¹⁷⁹ See also correction notice issued January 3, 2020 (85 FR 224).

Section 419.83(c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and § 419.83(d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

In accordance with § 419.83(b), we propose to expand prior authorization requirements to include additional Botulinum Toxin Injection services. The eight additional Botulinum Toxin Injection codes would be incorporated into the existing list at proposed revised § 419.83(a)(2) and would require prior authorization for services provided on or after July 1, 2027. Additionally, to improve readability and brevity, we propose to remove effective date language from the regulatory text and revise the section numbering. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) would be renumbered as (a)(1) through (8).

1. Expansion of Service Category

We propose that additional Botulinum Toxin Injection codes that would require prior authorization beginning on July 1, 2027, are those identified by the HCPCS codes in Table 76. For ease of reference, in Table 77 we have included the 2020 Final List of Outpatient Services that Require Prior Authorization for the five initial service categories, the 2021 Final List of Outpatient Services that Require Prior Authorization for two additional service categories, and the 2023 Final List of Outpatient Services that Require Prior Authorization for one more service category. As we mentioned previously, we propose to incorporate additional codes into the existing Botulinum Toxin Injections service category that was established through the CY 2020 OPPTS/ASC final rule with comment period.

2. Basis for Expanding Service Category

As part of our responsibility to protect the Medicare Trust Funds, we routinely analyze data associated with all aspects of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued

appropriateness of payment for services furnished in the hospital OPD setting.

In proposing the addition of these new services, we reviewed over 100 million OPD claims from 2017 through 2024. We determined that, on average, the number of OPD claims submitted for payment to the Medicare program decreased yearly by 1.1 percent. This reflects a decrease from approximately 114 million OPD claims submitted for payment in 2017 to approximately 104 million claims submitted for payment in 2024, with claim counts rounded for reporting purposes. The 1.1 percent decrease in overall OPD claims annually represents a decrease compared to the 0.6 percent increase identified in the CY 2023 OPPS/ASC proposed rule when we looked at the period from 2012 through 2021. Our analysis also showed that the Medicare allowed amount (the amount Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) for overall OPD claims increased from approximately \$65.4 million in 2017 to approximately \$101.1 million in 2024, representing an average annualized growth rate of 3.5 percent. Again, this is a decrease when compared to the 4.2 percent rate of growth identified in the CY 2023 OPPS/ASC proposed rule from 2012 through 2021. This analysis provides a benchmark regarding overall Medicare spending trends for OPD services during the same period.

In contrast to overall OPD utilization trends, utilization of all Botulinum Toxin Injection codes listed in Table 76 (2027 Proposed List of Additional Outpatient Department Services That Require Prior Authorization) has grown at a notably higher rate. This difference suggests that these services are increasing faster than overall OPD utilization, which warrants further review to ensure appropriate utilization. Our analysis of Integrated Data Repository (IDR)¹⁸⁰ data showed that claim volume for Botulinum Toxin Injection codes listed in Table 76 increased by 42.8 percent overall between 2017 and 2024,¹⁸¹ based on a direct comparison of claims volume in

2017 and 2024, and there was a 4.6 percent average annualized growth rate increase during the same time period. Specifically, claims volume for the additional Botulinum Toxin Injection codes increased from approximately 43,500 claims submitted for payment in 2017 to approximately 62,103 claims submitted for payment in 2024. By comparison, the overall OPD claims volume decreased by 8.3 percent between 2017 and 2024,¹⁸² based on a direct comparison of total OPD claims in 2017 and 2024, and by the 1.1 percent average annualized rate decrease in OPD claims submitted for payment during the same time period. We also recognize that additional FDA-approved indications for botulinum toxin products during this period may have contributed to some increase in utilization. However, the newly approved indications represent a limited number of additional clinical uses and are not expected to account for the full magnitude of the observed increase in utilization, suggesting that other factors may also be contributing. Accordingly, we do not believe that expanded indications alone fully explain the magnitude of the observed growth, which suggests that other factors may also be contributing to increased utilization. Specifically, overall OPD claims decreased from approximately 114 million claims in 2017 to approximately 104 million claims in 2024. The codes included in this proposal represent approximately \$102 million in annual Medicare payments and constitute a subset of overall botulinum toxin utilization selected based on observed utilization volume, growth trends, and program integrity considerations.

When analyzing the data, we took the COVID-19 Public Health Emergency (PHE) into consideration. As a result of the PHE, health care use and spending dropped sharply due to cancellations of elective and non-emergency care to increase hospital capacity and social distancing measures to reduce the community spread of the coronavirus. Consequently, the claims data for CY 2020 showed a notable decrease in volume of services compared to the previous year. This decline in CY 2020 due to the PHE is reflected in the overall trend for the 2017 through 2024 period, including calculations of the 1.1 percent average annualized decrease in OPD claims submitted for payment over the

2017 through 2024 period discussed previously, which is based on year-over-year changes across all years in the period, including CY 2020. Although a decline in utilization was observed in CY 2020, claims volume for these services increased significantly in subsequent years and exceeded levels that would have been reasonably expected based on overall OPD utilization trends. Accordingly, we do not believe any claim decreases resulting from the PHE affect our conclusion that there were “unnecessary increases in the volume of covered” claims for these services. This determination is based on several considerations, including utilization growth for Botulinum Toxin Injection services substantially exceeding overall OPD utilization trends during the same period, despite overall OPD claims volume declining. In addition, the increased utilization persisted over multiple years rather than reflecting a temporary fluctuation. CMS also reviewed potential explanations for the increase in utilization, including changes in clinical need, coding changes, and other factors that could reasonably explain sustained growth in service volume, but did not identify sufficient evidence to account for the magnitude of the increase observed. CMS further considered broader program integrity concerns, including billing patterns and utilization trends that may indicate a risk of unnecessary utilization.

Our conclusion that increases in volume for Botulinum Toxin Injections are unnecessary is based not only on data specific to these services but also on a comparison of the rate of increase for these procedures to the overall trends for all OPD services. We believe that comparing the utilization rate for specific services to the overall Medicare OPD utilization trends is generally an appropriate method for identifying unnecessary increases in volume, particularly when there are no legitimate clinical or coding reasons for the changes. The Medicare allowed amount analysis discussed above provides additional information regarding broader Medicare spending trends during the same period. As we have stated in the previous OPPS/ASC final rules with comment period, we believe that prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in the volume of covered OPD Services without adding onerous new documentation requirements. Therefore,

¹⁸⁰ The IDR is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and durable medical equipment claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html>.

¹⁸¹ Using the formula $(2024 \text{ claims} - 2017 \text{ claims}) \div 2017 \text{ claims}$, this results in a 42.8 percent increase. This calculation is separate from the 4.6 percent compound annual growth rate, which reflects the annualized rate of growth during the same period.

¹⁸² Using the formula $(2024 \text{ claims} - 2017 \text{ claims}) \div 2017 \text{ claims}$, this results in an 8.3 percent decrease. This calculation is separate from the 1.1 percent average annualized decrease, which reflects the average year-over-year change during the same period.

we believe prior authorization for these additional codes will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for

services that are determined not to be medically necessary. This will also serve as a tool within CMS' broad program integrity strategy to address potential fraud, waste, and abuse. We request comments on the addition of

these new services, specifically on the potential for unintended clinical consequences that may result from this addition.^{183 184 185 186}

BILLING CODE 4169-69-P

TABLE 76: 2027 PROPOSED LIST OF ADDITIONAL OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning service dates on or after July 1, 2027	
Code	(2) Botulinum Toxin Injections
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed.
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64644	Chemodenervation of one extremity; 5 or more muscles
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

¹⁸³ CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

¹⁸⁴ CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

¹⁸⁵ CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule with comment period.

¹⁸⁶ CPT codes 64492 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)) and 64495 (Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)) will be removed on August 16, 2024.

TABLE 77: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(1) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair ¹⁸¹
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(2) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(3) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(4) Rhinoplasty, and related services ¹⁸²
20912	Cartilage graft; nasal septum

Beginning for service dates on or after July 1, 2020	
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(5) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(6) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace

Beginning for service dates on or after July 1, 2020	
Code	(7) Implanted Spinal Neurostimulators ¹⁸³
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Beginning for service dates on or after July 1, 2023	
Code	(8) Facet Joint Interventions ¹⁸⁴
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

BILLING CODE 4169-69-c

XX. Codification of Section 6225 of the Consolidated Appropriations Act, 2026 for the Requirements for Provider-Based Status (§§ 413.65 and 419.23)

A. Background

Section 1861(u) of the Act lists the types of facilities that are regarded as providers of services but does not use or define the term “provider-based”. Since the beginning of the Medicare program, however, some providers, referred to as *main providers*, have functioned as a single entity while owning and operating multiple subordinate facilities that were treated as part of the main provider for Medicare purposes (as related to, for instance, payment; certification; coverage; and/or billing). With this treatment, compared to being treated as a freestanding facility, provider-based facilities might experience a number of advantages, including most notably, increased payments from Medicare. Therefore, we have maintained that having clear criteria for treating a facility as provider-based, as opposed to operating as a freestanding facility, is important

because failure to properly distinguish between the two risks inaccurate program payments, which can result in provider overpayments and increased beneficiary coinsurance liability, with no commensurate benefit to the Medicare program or its beneficiaries. Section 413.65 specifies the criteria for treating a facility as provider-based and the requirements for a CMS determination of provider-based status, including an attestation by the provider that the facility meets the provider-based criteria. Provider compliance with provider-based rules is mandatory, but since the passage of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554, App’x F), a provider has needed to submit an attestation only if it wishes to obtain a CMS determination of provider-based status.

B. Requirements at Section 6225 of the Consolidated Appropriations Act, 2026

Section 6225 of the Consolidated Appropriations Act, 2026 (CAA, 2026), Public Law 119–75, enacted on February 3, 2026, amends section

1833(t) of the Act by adding new paragraph (23). In brief, section 6225 of the CAA, 2026 will prohibit Medicare payments under the OPPS beginning January 1, 2028, unless off-campus outpatient departments of a provider bill using a separate National Provider Identifier (NPI) and the main provider has submitted an attestation that the departments meet the provisions at § 413.65. As noted previously, although provider compliance with provider-based rules is mandatory, payment had not been conditioned on verification of such compliance.

Section 1833(t)(23)(A) of the Act, as added by section 6225 of the CAA, 2026, specifies that no payment may be made under that subsection (or under an applicable payment system pursuant to paragraph (21) of section 1833(t) of the Act) for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider unless that department has obtained, and the items and services are billed under, an NPI that is separate from the NPI of the main provider; the main provider has submitted to the Secretary, during the 2-year period

ending on the date such items and services are furnished, an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65 (or a successor regulation); and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. The initial attestation may include an attestation submitted in accordance with existing § 413.65(b)(3) until the Secretary establishes the new attestation submission process, which is discussed further below.

New section 1833(t)(23)(B)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish a process for each provider with an off-campus outpatient department to submit an initial and subsequent attestation, for the review of each such attestation and for the determination, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether each off-campus outpatient department is compliant with the requirements described in subparagraph (A). In addition, new section 1833(t)(23)(C) of the Act defines an “off-campus outpatient department of a provider” for purposes of paragraph (23) as a department of a provider (as defined in § 413.65) that is not located on the campus (also defined in § 413.65) of the main provider or is not within the distance described in such definition of campus from a remote location of a hospital (also defined in § 413.65).

C. Proposed Modifications To Implement the Provisions of Section 6225 of the CAA, 2026

1. Proposed Modification to the Hospital OPps Regulations

As discussed previously, section 1833(t)(23)(A) of the Act, as added by section 6225, specifies that no payment may be made under the OPps for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider unless that department has obtained, and the items and services are billed under, an NPI that is separate from the NPI of the main provider; the main provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are furnished, an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65; and the main provider has submitted a subsequent attestation within the timeframe specified by the

Secretary. We are proposing to add new section § 419.23 to codify this requirement. (We note the proposed changes to the provider-based regulations at § 413.65 to implement the attestation requirements are discussed in the next section. We also note, as discussed in greater detail in the next section, we propose that prior to submitting an attestation, providers must obtain an NPI for each provider-based department.)

2. Proposed Modifications to the Provider-Based Regulations at § 413.65

In this proposed rule, we propose changes to the provider-based regulations at § 413.65 to implement the new requirements in section 6225 of the CAA, 2026. First, we propose the addition of a new entry in the list of definitions in § 413.65(a)(2) for an “Off-campus outpatient department of a provider”. CMS currently defines a “department of a provider” as a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider. The definition of a department of a provider does not include rural health clinics (RHCs) or, except as specified in § 413.65(n), Federally Qualified Health Centers (FQHCs). In accordance with the statutory definition provided in section 1833(t)(23)(C) of the Act, we propose to add a new definition to paragraph (a)(2) describing an off-campus outpatient department of a provider as a department of a provider that is not located on the campus of the main provider or within 250 yards of a remote location of a hospital. Under this proposed definition, facilities or organizations that are not located on the campus of the main provider would be considered off-campus for provider-based purposes. This would include remote locations of a hospital, which are defined in § 413.65 as facilities that provide inpatient services in a location off the campus of a main provider. Remote locations are often referred to as secondary or subordinate “multi-campus” locations of a hospital, and in most cases operate in a substantially similar manner as the main provider. Section 6225 of the CAA, 2026, adding section 1833(t)(23)(C) to the Act, defines an “off-campus outpatient department of a provider” as neither being on the campus of the main provider, nor within the distance specified in the definition of campus of a remote location of a hospital.

Section 413.65(e) includes additional requirements applicable to off-campus facilities or organizations. These requirements apply to all off-campus outpatient facilities, including those that are in close proximity to (and often within the same building as) inpatient remote locations. The implementation of section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74) in the CY 2017 OPps/ASC final rule with comment period (81 FR 79699 through 79719) and interim final rule with comment period (81 FR 79720 through 79729), however, excepted outpatient departments located within 250 yards of a remote location from payment policy implications for off-campus departments. Given the definition of an “off-campus outpatient department of a provider” in section 603 of the Bipartisan Budget Act of 2015 and section 6225 of the CAA, 2026 separates outpatient departments located outside the regulatorily-specified distance of a remote location of a hospital and provider off-campus outpatient departments, we believe that it would be appropriate to distinguish off-campus requirements from those for hospital outpatient departments that are within 250 yards of a remote location of the main provider. Therefore, we propose to revise § 413.65(e) to specifically exclude outpatient departments located within 250 yards of a remote location of a hospital, and to revise § 413.65(b)(3)(ii), (g)(1)(i), and (h) to append “or within 250 yards of a remote location of a hospital” to the references of being on the campus of the main provider. We believe these proposed conforming changes will better clarify which facilities are affected by the new legislation and will better align the current provider-based rules with statutory provisions regarding the distinction between on- and off-campus locations and services. In addition, we propose to make a technical change to § 413.65(g)(1)(i) and (ii) to revise “treated by Medicare” to “treated by CMS” consistent with the other proposals discussed in this section.

We propose to add a reference to the new mandatory attestation requirements required by section 6225 of the CAA, 2026 and propose a maximum 5-year timeframe for any subsequent attestation(s). Specifically, we propose to add § 413.65(b)(6) to state that, as of January 1, 2028, a main provider must submit an initial attestation of provider-based status for each of its off-campus outpatient departments within the 2-year period prior to furnishing services, and subsequent attestation(s) within a period not to exceed 5 years thereafter.

We anticipate addressing the subsequent attestation requirement in the 2028 rulemaking cycle; nonetheless, we welcome comments on the subsequent attestation at this time. For all off-campus outpatient departments providing services on or before January 1, 2028, we propose initial attestations must be submitted between January 1, 2026 and December 31, 2027, and off-campus outpatient departments that begin providing services after January 1, 2028, must submit an attestation within the 2 years prior to when the billed services are delivered. Subsequent attestation(s) would be submitted at an interval to be specified by CMS and not to exceed 5 years thereafter. In addition, providers who submit initial attestations within the 2-year period prior to January 1, 2028, would meet the attestation requirements of section 6225 of the CAA, 2026, even if they have not received a provider-based status determination from CMS by January 1, 2028. We also seek comments on an initial mandatory attestation for provider departments that received a determination of provider-based status prior to January 1, 2026, and remain in compliance with all applicable provisions of § 413.65. For these departments, we are considering having the authorized official attest with a letter to CMS with evidence of CMS determination attached affirming its continued compliance with § 413.65. Indian Health Service and Tribal facilities described in § 413.65(m) and certain FQHCs and “look alike” described in § 413.65(n) are considered to be in compliance with provider-based requirements, and would not be subject to review of provider-based status. We, therefore, propose to exclude these facilities from the proposed attestation requirements. Other parts of § 413.65 not specifically addressed are outside the scope of this rulemaking.

To implement section 6225 of the CAA, 2026, we propose to establish a standardized attestation form for provider-based determinations, which would replace the current Medicare Administrative Contractor (MAC)-specific templates and ensure consistency across MACs. Through this standardization, CMS proposes that main providers would submit the attestation through a centralized electronic system, which we believe would result in a reduction in administrative burden for providers and a more efficient review process for MACs and CMS. Further, we anticipate that standardization and centralized submission processes may reduce unnecessary duplicative documentation

burden while continuing to support appropriate compliance review and program integrity oversight. Until the standardized form and centralized electronic system are finalized, providers may continue to submit attestations in accordance with existing § 413.65(b)(3)(ii) in satisfaction of section 6225 of the CAA, 2026 to their servicing MAC.

To ensure providers have clarity on how to satisfy the mandatory attestation requirement under section 6225 of the CAA, 2026, we propose to require that providers submit attestations using the referenced CMS-standardized attestation form. The attestation would be a list of identifying information of the main provider and provider-based department such as name, address, and NPI that includes a list of the requirements at § 413.65(d)(e), (g), and (h) with a certifying statement affirming compliance to be signed by an authorized official of the main provider. A draft is located at the following link for comment: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notice/cms-1850-p>. Under the current attestation process, providers submit their attestations and supporting documentation to their MAC, which performs a preliminary review and forwards its recommendation to CMS for the initial determination. We propose to modify this process so that CMS’ contractors, including MACs, conduct standardized review and validation activities in support of initial determination regarding compliance with § 413.65, rather than requiring separate CMS review of each attestation recommendation. To reflect this proposal, we propose to revise § 413.65(b)(3)(iii) to specify that CMS “or its agents” will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness and consistency with information in the possession of CMS “or its agents” at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based. We also propose that the determinations issued through this process would constitute CMS initial determinations for purposes of § 498.3(b)(2). In conducting review and validation activities, CMS and its contractors, including MACs, would employ standardized review, validation, and risk-based screening processes to assess attestations for completeness, consistency with the provider’s enrollment records, and compliance with the applicable requirements of

§ 413.65. These processes may include automated validation activities, data analysis, targeted documentation review, and contractor review procedures designed to support consistent national implementation and program integrity oversight. We propose to establish, through operational guidance, specific review criteria, validation protocols, and documentation standards that CMS and its contractors, including MACs, must apply in conducting review and validation activities and supporting initial determinations, in order to promote consistent assessment of provider-based requirements across all CMS contractors including MAC jurisdictions. CMS will conduct ongoing quality review and oversight of attestation determinations and related review activities. (For additional discussion of our proposed documentation requirements for provider-based attestations and proposed verification and oversight activities, refer to sections XX.D, and XX.E, respectively, of this preamble.)

We also propose an additional modification to § 413.65(b)(3)(ii) to revise the timing and modernize the manner in which supporting documentation is submitted for off-campus provider-based facilities and organizations. CMS and its contractors, including MACs, proposed to employ standardized review and validation processes, including automated validation activities, data analysis, risk-based screening methodologies, targeted documented review, and other program integrity activities, to evaluate attestations and identify submissions requiring additional review of compliance verification. Providers would continue to be required to maintain documentation demonstrating compliance with applicable provider-based requirements and to furnish such information to CMS or its contractors, including MACs, upon request as part of review, validation, audit, or oversight activities. We believe these proposals will afford providers greater flexibility in meeting the statutory deadlines imposed by section 6225 of the CAA, 2026, while continuing to allow CMS oversight and access to information necessary to evaluate compliance and make a determination. We also propose a modification to § 413.65(k) to remove references to what constitutes a ‘complete’ attestation, with supporting documentation and additional information to be requested from the provider, as necessary, after the standardized attestation form has been submitted.

We propose that main providers, prior to submitting an attestation, must obtain an NPI for each provider-based department and update Provider Enrollment, Chain, and Ownership System (PECOS). As discussed previously, to implement section 6225 of the CAA, 2026, CMS proposes to establish a standardized attestation form for provider-based determinations that would replace the current MAC-specific templates; the attestation would then be submitted through a centralized electronic system. We believe this standardized approach would ensure consistency across MACs and would result in a reduction in administrative burden for providers and a more efficient review process for MACs and CMS. For providers that submit attestations for more than one off-campus outpatient department, CMS is considering streamlined supporting documentation requirements and seeks input on how best to minimize burden while ensuring robust oversight. Further, we anticipate a reduction in the documentation supporting the attestation. For instance, we anticipate leveraging system capabilities to reduce duplicative documentation submissions by allowing supporting documentation applicable to multiple locations to be submitted a single time, where appropriate.

The future standard attestation format would request identifying information for both the main provider and the provider-based entity, including applicable NPIs. Once all attestations are submitted, providers would indicate their submission is complete. CMS and its contractors, including MACs, may employ automated validation, screening, targeted review and risk-based methodologies to identify attestations requiring additional review, supporting documentation, or follow-up activities. We anticipate giving providers a reasonable period, generally not to exceed 60 days, to furnish requested supporting documentation.

If CMS or its contractor, including MACs, determine that an attestation demonstrates compliance with the provider-based requirements at § 413.65, we propose that an approval notice would be issued. CMS and its contractor, including MACs, propose to request supporting documentation at any stage of the review, validation, audit or oversight process to evaluate compliance with applicable provider-based requirements. If CMS or its contractor determines that an attestation fails to demonstrate compliance with the provider-based requirements, or if the provider fails to furnish all requested information or attest to all

applicable requirements, we propose that a denial would be issued, including applicable appeal rights. Until the standardized form and centralized electronic system are finalized, we propose providers may continue to submit attestations in accordance with § 413.65(b)(3), in satisfaction of Section 6225. As noted previously, an off-campus outpatient department of a provider will also need to obtain an NPI before January 1, 2028, consistent with section 1833(t)(23)(A)(i) of the Act as added by Section 6225.

In addition, we propose to use program integrity mechanisms currently available to CMS, or that may become available in the future, whether through improved technology, contracting, data analysis or other means, to evaluate compliance with provider-based requirements and identify attestations requiring additional review or oversight activities. In § 413.65(k), we propose to specify that these activities may include site visits, remote audits, investigations, or require submission of additional documentation as may be necessary to make a determination of compliance with the provider-based requirement, and the use of current or future Medicare program integrity contractors. We believe this proposal would continue to address CMS' longstanding concerns, regarding potential increased costs to the Medicare program and its beneficiaries by ensuring compliance with provider-based regulations. For additional discussion of our proposed documentation requirements for provider-based attestations, refer to section XX.D of this preamble. For additional discussion of the proposed CMS verification and oversight activities, refer to section XX.E of this preamble.

D. Documentation Requirements for Provider-Based Attestations

To support meaningful CMS oversight of provider compliance with the provider-based requirements of § 413.65, and consistent with the mandatory attestation requirement established by section 6225 of the CAA, 2026, we propose that attestations submitted through the proposed standardized attestation process include, or be supported by, documentation sufficient to demonstrate compliance with the applicable provisions of § 413.65(d), (e), (g), and (h). We describe in this section the categories of documentation that providers may be required to submit or retain in connection with their attestations. As discussed further, CMS anticipates that not all documentation described herein would be required at

the time of initial attestation submission; rather, CMS and its contractors, including MACs, will employ risk-based screening and targeted documentation review processes to identify those attestations for which additional documentation is warranted. The rationale behind using targeted documentation review is that any main provider typically manages its departments in a consistent manner. By drawing a sample from each main provider's universe of provider-based departments, we would be able to gain a reliable understanding of their universe. This approach would not only ensure adequate representation across all providers, regardless of their volume—it would also provide meaningful insight into whether compliance standards are being upheld across all departments. We invite public comment on the appropriate scope of documentation requirements, including whether any of the categories described should be modified, consolidated, or eliminated in order to reduce provider burden while preserving CMS' ability to evaluate compliance and protect the Medicare program. Specifically, we propose the following documentation framework:

- *Attestation Form Completeness and Authorization:*

++ We propose that providers must submit a completed attestation using the CMS-standardized attestation form, signed and dated by an authorized official of the main provider as identified in PECOS. The attestation would be required to identify both the main provider and each off-campus outpatient department of the provider for which provider-based status is sought, including the applicable NPIs, provider numbers, addresses, and the date on which provider-based conditions were met or the date the department was acquired, as applicable. Where a provider designates a consultant or outside representative as the primary contact for the attestation, we propose the provider must authorize the representative in writing.

- *Location:*

++ We anticipate the attestation system would have the ability to measure the distance requirement. However, if the distance is not systematically verified or exceeds 35-miles, we propose providers would be required to submit supporting documentation in support of § 413.65(e)(3).

- *Licensure:*

++ We propose providers must be prepared to demonstrate that the off-campus outpatient department is operated under the same licensure as

the main provider, consistent with § 413.65(d)(1), or to provide documentation that the applicable State does not require a separate license for the department.

- *Clinical Services Integration:*

++ We propose providers must be prepared to demonstrate that the off-campus outpatient department meets the clinical integration requirements of § 413.65(d)(2), including that professional staff at the department hold privileges at the main provider; that appropriate monitoring and oversight of the department by the main provider is in place; that inpatient and outpatient services of the department and the main provider are integrated; and that patients treated at the department who require further care have full access to all services of the main provider.

- *Financial Integration:*

++ We propose providers must be prepared to demonstrate that the revenues and expenses of the off-campus outpatient department are integrated with those of the main provider, consistent with § 413.65(d)(3), such that the department does not maintain a separate general ledger or trial balance independent of the main provider.

- *Public Awareness:*

++ We propose that providers must be prepared to demonstrate that the off-campus outpatient department is clearly identified to the public as part of the main provider, consistent with § 413.65(d)(4), and that patients entering the department are aware they are receiving services from the main provider.

- *Obligations of Hospital Outpatient Departments:*

++ For off-campus outpatient departments that are departments of hospitals, we propose that providers must be prepared to demonstrate compliance with the applicable obligations of hospital outpatient departments under § 413.65(g), including compliance with Emergency Medical Treatment and Labor Act (EMTALA) requirements, antidumping rules, site-of-service billing requirements, and the requirement to provide written notice to Medicare beneficiaries of their potential financial liability prior to the delivery of services at an off-campus location.

- *Ownership, Control, Administration, and Supervision (Off-Campus Departments):*

++ We propose providers must be prepared to demonstrate that the department operates under the ownership and control of the main provider consistent with § 413.65(e)(1), including that the department is 100

percent owned by the main provider and that the main provider retains final approval over administrative decisions, personnel policies, and medical staff appointments. We also propose providers must also be prepared to demonstrate that the administrative functions of the department are integrated with those of the main provider consistent with § 413.65(e)(2), including through submission of an organizational chart reflecting the reporting relationship between the department and the main provider.

E. CMS Verification and Oversight Activities

Section 1833(t)(23)(B)(i) of the Act directs the Secretary to establish a process for determining, through site visits, remote audits, or other means as determined appropriate by the Secretary, whether each off-campus outpatient department of a provider is compliant with the applicable requirements. Consistent with this statutory direction, we propose that CMS and its contractors, including MACs, employ a layered, risk-based approach to verification and oversight that is designed to promote efficient processing of the significantly increased volume of attestations expected under the mandatory attestation requirement while preserving meaningful CMS oversight of provider compliance with § 413.65.

At the initial review stage, CMS and its contractors, including MACs, would conduct automated validation and screening of all submitted attestations to verify completeness, consistency with PECOS enrollment records, and the presence of required attestation elements. Attestations that pass automated validation would be processed for initial determination. Attestations that present indicators of incompleteness, inconsistency, or elevated compliance risk would be flagged for targeted documentation review, during which CMS or its contractors may request that the provider furnish supporting documentation from any or all of the categories described.

At the extended review stage, CMS and its contractors, including program integrity contractors, would employ risk-based methodologies to select a subset of attestations for more extensive compliance review. Such methodologies may include remote audits of provider records and documentation, site visits conducted by CMS or contractors to verify that the attested department meets the physical, financial, clinical, and administrative integration requirements of § 413.65, or

investigations of potential non-compliance identified through data analysis, referral, or other sources. The criteria and methodologies CMS would use to select attestations for extended review would be established through operational guidance and would be designed to focus oversight resources on providers and departments that present the highest risk of non-compliance with the provider-based requirements. We propose that failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of payments as described in § 413.65 (k).

We invite public comment on the appropriate scope and sequencing of documentation requirements, including whether the categories described should be further prioritized, consolidated, or phased in over time to facilitate provider compliance with the January 1, 2028 statutory deadline.

We solicit public comment on the proposed policies and processes described in this section. Specifically, we seek feedback from stakeholders regarding feasibility, operational impact, implementation considerations, potential burden, and any unintended consequences associated with these proposals. We encourage commenters to provide detailed rationale, data, examples, or alternative approaches that may assist CMS in evaluating and refining the final policy.

XXI. Payment for Direct and Indirect Graduate Medical Education (GME) Costs—Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

A. Background

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, “Affordable Care Act”), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Section 5506 of the Affordable Care Act instructs the Secretary to establish a process by regulation that redistributes slots from teaching hospitals that close to hospitals that meet certain criteria, with priority given to certain hospitals including those located in the same core based statistical area (CBSA), in a contiguous CBSA or in the same State as the closed hospital.

Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying

language at section 1886(d)(5)(B)(v) of the Act. These changes instruct the Secretary to establish a process to increase the full-time equivalent (FTE) resident caps at other hospitals based upon the FTE resident caps at teaching hospitals that closed on or after March 23, 2008. In the CY 2011 OPPI/ASC final rule with comment period (75 FR 72264), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct graduate medical education (GME) and indirect medical education (IME) FTE resident cap slots from the hospital that closed. We made certain additional

modifications to § 413.79 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply to teaching hospitals that closed between March 23, 2008, and August 3, 2010, and to teaching hospitals that close after August 3, 2010 (75 FR 72215).

B. Notice of Closure of Louis A. Weiss Memorial Hospital Located in Chicago, Illinois and the Application Process—Round 29

CMS learned of the closure of Louis A. Weiss Memorial Hospital, located in

Chicago, Illinois (CCN 140082).

Accordingly, we are providing notice of the closure of this teaching hospital and initiating another round of the application and selection process to redistribute the closed hospital's FTE resident caps. This round will be the 29th round ("Round 29") of the application and selection process. Table 78 contains the identifying information for the closed teaching hospital and its IME and direct GME FTE resident caps, which are part of the Round 29 application process under section 5506 of the Affordable Care Act.

TABLE 78: LOUIS A. WEISS MEMORIAL HOSPITAL FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422 ¹ , +/- ACA Section 5503 ² , and + ACA Section 5506 ³ adjustments)	Direct GME FTE Resident Cap (including +/- MMA Sec. 422, +/- ACA Section 5503, and + ACA Section 5506 adjustments)
140082	Louis A. Weiss Memorial Hospital	Chicago, IL	16984	August 9, 2025	81.69 - 1.41 sec. 422 reduction - 4.46 sec. 5503 reduction + 10.00 sec. 5506 increase = 85.82 ⁴	60.66 - 0.28 sec. 422 reduction - 3.59 sec. 5503 reduction + 10.00 sec. 5506 increase = 66.79 ⁵

1 Section 422 of the MMA, Public Law 108-173, redistributed unused IME and direct GME residency slots effective July 1, 2005.

2 Section 5503 of the Affordable Care Act of 2010, Pub. L. 111-148 and Pub. L. 111-152, redistributed unused IME and direct GME residency slots effective July 1, 2011.

3 Section 5506 of the Affordable Care Act of 2010, Pub. L. 111-148 and Pub. L. 111-152, redistributes IME and direct GME residency slots from teaching hospitals that close on or after March 23, 2008.

4 Louis A. Weiss Memorial Hospital's 1996 IME FTE resident cap is 81.69. Under section 422 of the MMA, the hospital received a reduction of 1.41 to its IME FTE resident cap, under section 5503 of the ACA, the hospital received a reduction of 4.46 to its IME FTE resident cap, and under section 5506 of the ACA, the hospital received an increase of 10.00 to its IME FTE resident cap: 81.69 - 1.41 - 4.46 + 10.00 = 85.82.

5 Louis A. Weiss Memorial Hospital's 1996 DGME FTE resident cap is 60.66. Under section 422 of the MMA, the hospital received a reduction of 0.28 to its DGME FTE resident cap, under section 5503 of the ACA, the hospital received a reduction of 3.59 to its DGME FTE resident cap, and under section 5506 of the ACA, the hospital received an increase of 10.00 to its DGME FTE resident cap: 60.66 - 0.28 - 3.59 + 10.00 = 66.79.

C. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Hospitals that wish to apply for and receive slots from the previously noted hospital's FTE resident caps must submit Round 29 applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™) between July 13, 2026, and October 13, 2026. The section 5506 application can be accessed at <https://mearis.cms.gov/public/home>.

CMS will only accept Round 29 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Refer to the "Resources" section for guidance regarding the application

submission process at <https://mearis.cms.gov/public/resources>.

- Technical support is available under "Useful Links" at the bottom of the MEARIS™ web page.

- Application related questions can be submitted to CMS using the form available under "Contact" at <https://mearis.cms.gov/public/resources>.

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received through MEARIS by the application deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme>. Hospitals should access this website for a list of additional section 5506 guidelines for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

XXII. Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of Personal Protective Equipment and Essential Medicines

In the "Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals" advance notice of proposed

rulemaking (91 FR 3851),¹⁸⁷ we sought public comment on potential options we could consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety, and to reflect the additional resource costs incurred when procuring these domestically manufactured items. We sought input on a possible new "Secure American Medical Supplies" friendly designation that could be earned by hospitals that demonstrate their commitment to domestic procurement. In addition, we sought input on potential ways such a designation could facilitate the creation of new, streamlined payment policies to support hospitals in their efforts. We also sought input on a potential new structural quality measure as part of the Hospital Inpatient Quality Reporting (IQR) Program that could promote hospital commitments to invest in domestic procurement to secure our nation's health and safety.

We are now seeking further public input on this issue after reviewing the comments on the ANPRM. Specifically, we are soliciting public comment on potential policy approaches for a payment adjustment, a methodology to calculate the price differential between domestic and non-domestic PPE and essential medicines, information sources of those price differentials, a definition of domestic essential medicine and PPE, and a process for verifying that a given essential medicine or PPE is "domestic."

A. Overview

We continue to believe that hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for domestically manufactured goods, which is foundational to safeguarding timely access and continuity of care for patients. Because hospitals are the primary purchasers and users of essential medicines and medical PPE, we believe a voluntary payment adjustment that reflects the additional marginal costs that hospitals face in procuring these products may help to sustain their domestic production and availability and thereby help to safeguard personnel and beneficiary safety over the long term.

We currently have a voluntary payment policy under the IPPS and OPSP for the additional resource costs that hospitals face in procuring

domestic National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 filtering facepiece respirators (FFRs). Building on public input from the ANPRM, we are considering expanding the existing IPPS payment policy to include other forms of domestic PPE and certain essential medicines.

1. Expanded Scope of PPE and Domestic Definition

For PPE, as discussed in section XXII.C., we are considering expanding the policy to include all domestic NIOSH-approved filtering face piece respirators that demonstrate compliance with the American Society for Testing and Materials (ASTM) Respirator Fit Capability Standard; domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards; and domestic gowns in compliance with FDA requirements and conforming to Association for the Advancement of Medical Instrumentation (AAMI) standards. We are considering defining the term "domestic" using the contract terms listed in the Make PPE In America Act, (section 70953 of Pub. L. 117–58), which identifies American-made PPE as domestically-made from domestic materials and components that are "grown, reprocessed, reused, or produced in the United States". Given the lack of available domestic nitrile butadiene rubber (NBR),¹⁸⁸ we are considering an exception for nitrile gloves which are made in the U.S. with foreign rubber. Future rulemaking may revisit this potential exception in the event that domestically produced NBR becomes available.

2. Potentially Eligible Essential Medicines and Domestic Definition

For essential medicines, as discussed in section XXII.D., we are seeking comment on including in an expanded policy certain FDA-approved medicines which have existing U.S. finished dosage form (FDF) production and do not contain API from countries listed on the "foreign adversaries" list at 15 CFR 791.4.¹⁸⁹ As discussed further in sections XXII.C. and XXII.D., in developing this potential subset of eligible essential medicines, we prioritized non-substitutable sterile injectables and generic antibiotics as per the prioritization framework developed by ASPR and Federal supply chain security offices, including within HHS

and the Department of War (DOW). We are seeking comment as to whether an essential medicine should be defined as domestic if the country of origin is the United States (U.S.), where country of origin is defined through incorporation by reference as the country in which "substantial transformation" of the final dosage form occurs via 19 CFR 134.1(b).

3. Domestic and Non-Domestic Cost Differential

As also discussed in sections XXII.C and XXII.D, we are considering whether the methodology for determining the amount of the payment adjustment should be based on the use of standardized cost differentials for eligible domestic PPE and essential medicines, which would be updated on an annual basis. We seek comment on the potential base cost differentials for eligible categories of PPE in section XXII.C. and the potential base cost differentials for eligible essential medicines in section XXII.D.

4. Manufacturer Attestation of Domestic Origin

Additionally, as discussed in section XXII.E., we are considering whether under a potential policy a manufacturer should voluntarily be able to provide an attestation to HHS that its product meets the applicable domestic definition. To make it easier for hospitals to identify domestic products, HHS would compile these attestations annually and create a public file of eligible products by National Drug Code (NDC) or Unique Device Identifier (UDI), as applicable, based on the information provided by the manufacturers. Only products in this file would be eligible for separate payment.

5. Potential Payment Adjustment Approaches

We are also seeking feedback on different potential approaches under the IPPS to separately pay for the additional resource costs that hospitals face when purchasing eligible domestic PPE and essential medicines. These approaches are discussed in section XXII.F.

6. Annual Spending Threshold

As discussed in section XXII.G., under any approach that may be considered, we believe it also may be prudent to consider establishing an appropriate maximum annual amount of aggregate separate payment under this policy and to prospectively allocate shares of that amount to individual hospitals before the start of the fiscal year. Under this approach, if the actual separate payment to a hospital for the fiscal year exceeds its allocated

¹⁸⁸ <https://www.madeinamerica.gov/waivers/nonavailability/6994cfd16e70851109b4247>.

¹⁸⁹ <https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-E/part-791/subpart-A/section-791.4>.

¹⁸⁷ Hereinafter referred to as "the ANPRM".

maximum amount, the excess amount would be reconciled at cost report settlement, as that excess amount would be considered still bundled into the MS-DRG payment and not separately payable.

B. Background and Summary of Prior Rulemaking

As discussed in the ANPRM, sufficient domestic availability of PPE and essential medicines in the health care sector is a critical component of emergency public health preparedness. In the spring of 2020, supply chains for PPE faced severe disruptions due to lockdowns that limited production and unprecedented demand spikes across multiple industries. Supplies of N95® FFRs, nitrile gloves, and isolation gowns were examples of PPE that experienced significant supply chain disruptions. So-called “just-in-time” supply chains that minimize stockpiling, in addition to reliance on overseas production, left U.S. hospitals unable to obtain enough PPE to protect health care workers. Similarly, shortages for critical medical products have persisted, with a recent report authored by the Senate Committee on Homeland Security and Governmental Affairs noting that the average drug shortage lasts about 1.5 years.¹⁹⁰ For pharmaceuticals, hospitals reported more than 40 drug shortages at the time they were surveyed—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.¹⁹¹ Historically, most shortages occur after quality-related breakdowns in manufacturing processes, as generic drug manufacturers face intense price competition, uncertain revenue streams, and high investment requirements to maintain mature manufacturing quality systems.¹⁹² Shortages of both essential medicines and reliable PPE jeopardize patient safety and health care quality, and it is therefore critical to ensure that quality PPE and essential medicines are

available to health care personnel and patients when needed. The COVID-19 pandemic illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. Sustaining domestic production of these important medical supplies is therefore critical in ensuring patients and health care personnel have the critical medical supplies they need.

In recent years we have solicited comment on, and based on feedback from interested parties, implemented payment adjustments to Medicare participating hospitals to reflect the additional costs of procuring domestically made surgical N95 FFRs and creating and maintaining buffer stocks of certain essential medicines.¹⁹³ In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72037), we implemented payment adjustments under the IPPS and OPPS to support a resilient and reliable domestic supply of NIOSH-approved® surgical N95 respirators. This payment adjustment is based on the IPPS and OPPS shares of the difference in cost between domestic and non-domestic NIOSH-approved surgical N95 FFRs and is available where those costs are separately tracked, reported, and appropriately claimed by the hospital on its cost report submitted to Medicare. As discussed in the CY 2023 OPPS/ASC final rule with comment period, the payment adjustment was intended to account for the marginal costs that hospitals face in procuring domestically made NIOSH-approved and FDA-certified surgical N95 FFRs. These marginal costs are due to higher per-unit acquisition prices that stem from higher costs of inputs and labor in the U.S. as compared to international suppliers, which make many N95 and other FFRs, as well as a demonstrated record of more consistent high-quality for domestically made products. Usage of the payment adjustments has been limited, and HHS conducted outreach to interested parties to better understand barriers to awareness and uptake and seek feedback on potential modifications that could increase effectiveness. For FY 2024, fewer than 100 hospitals reported the information necessary to determine the payment adjustment on their cost reports. This low adoption rate may have been partially attributable to administrative reporting burden concerns raised by interested parties.

¹⁹³ Hereafter referred to as “the N95 policy” and “the essential medicines policy,” respectively.

As noted in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72039), we received many comments urging us to expand this policy to cover other forms of PPE and critical medical supplies. A few commenters stated that other forms of PPE are susceptible to shortages similar to surgical N95 FFRs, and therefore investing in domestic production for these products was also important for future emergency preparedness. We stated that we would consider these comments, and other modifications to the payment adjustment, for future rulemaking as we gained more experience with our policy.

In addition to PPE, essential medicines are another critical component of preparedness. In the FY 2025 IPPS/Long-Term Care Hospital (LTCH) PPS final rule (89 FR 68986, 69387 through 69400), we finalized a separate payment under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of one or more essential medicines. Under this policy, essential medicines are defined as the medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (formally known as the Office of the Assistant Secretary for Strategic Preparedness and Response) and published in May 2022, and any subsequent revisions to that list of medicines.¹⁹⁴ The President's Executive Order 14336 further required that the ASPR provide the Assistant to the President and Homeland Security Advisor (APHSA), the Assistant to the President for Economic Policy (APEP), and the Office of Management and Budget (OMB) with an update to this list.¹⁹⁵

We solicited feedback and comments in the CY 2025 OPPS/ASC proposed rule (89 FR 59186, 59396 through 59399) on potential modifications to the surgical N95 FFR policy to increase hospital uptake, reduce reporting burden, and achieve the policy goal to maintain a baseline domestic production capacity of PPE to ensure

¹⁹⁴ The list is available at https://www.armi.usa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf and there have been no public revisions to the list yet.

¹⁹⁵ <https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/>.

¹⁹⁰ Senate Committee on Homeland Security & Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages, March 2023: <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report-FINAL-CORRECTED.pdf>.

¹⁹¹ Vizient, Beyond the shortage: The hidden cost of drug supply chain disruptions, June 2025: <https://www.vizientinc.com/newsroom/news-releases/2025/new-vizient-survey-finds-drug-shortages-cost-hospitals-nearly-900m-annually-in-labor-expenses>.

¹⁹² U.S. Department of Health and Human Services: Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States, April 2024: <https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf>.

that quality PPE is readily available to health care personnel when needed. As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93912, 94290 through 94295), commenters were supportive of a variety of modifications to the established policy, including modifications to the payment adjustment methodology calculation that would provide a national standard unit cost differential between domestic and non-domestic NIOSH-approved surgical N95 FFRs, stating that such a modification would minimize reporting burden for hospitals and ensure payments to hospitals are equitable. We note that some commenters differed in their view as to how the cost differential should be calculated. Commenters also stated that expanding the payment adjustment to more products would increase uptake of the payment adjustment by hospitals, strengthen the existing U.S. manufacturing base, incentivize other manufacturers to prioritize domestic production, and protect access to high-quality products. Commenters requested that CMS work with the Congress to give CMS authority to offset all the marginal costs incurred by the hospital in procuring domestically manufactured surgical N95 FFRs rather than just the Medicare share of these costs. Some commenters also indicated that hospitals have had difficulty ascertaining which products meet the definition of domestic under the surgical N95 FFR policy and were supportive of making publicly available a list of products eligible under the surgical N95 FFR policy.

As discussed in the CY 2025 OPPS/ASC final rule with comment period, several commenters urged CMS to expand the payment adjustment to include other PPE types and medical devices (89 FR 94295). Examples from commenters included isolation gowns, hair nets, beard covers, bouffant caps, shoe covers, face shields, ASTM level II and III surgical masks, powered air purifying respirators, elastomeric respirators, syringes, needles, catheters, and wound care dressings. Commenters indicated that many of these products are currently being purchased from non-domestic manufacturers and have been prone to shortages and quality issues. For example, a commenter cited safety concerns regarding the quality of

imported syringes and needles which they stated have had issues ranging from leaks to breakages that compromise patient safety.

In the ANPRM, we solicited comment on potential options we might consider for Medicare participating hospitals to help foster a more resilient supply chain for American-made PPE and essential medicines to secure our nation's health and safety and to reflect the additional resource costs incurred when procuring these domestically manufactured items. These potential options included the creation of a "Secure American Medical Supplies" friendly designation that could be earned by hospitals with a demonstrated commitment to procuring domestic PPE and domestic essential medicines, a potential separate Medicare payment to "Secure American Medical Supplies" friendly hospitals, and a structural measure that would require hospitals to attest to meeting the domestic procurement designation minimum percentages for PPE and essential medicines as part of the Hospital IQR Program.

Commenters generally continued to support CMS' efforts to foster a more resilient domestic supply chain for critical medical supplies and favored voluntary, non-budget-neutral payment approaches over quality measures or payments tied to hospital designations. Commenters raised concerns about administrative burden, and many hospitals highlighted challenges in identifying qualifying domestic products and tracking their use, as well as other costs associated with domestic purchasing. Commenters also urged creating a public list of eligible domestic products, standardizing the domestic cost differentials, and expanding the eligible product categories.

Several commenters emphasized that long-term, committed contracting arrangements (for example, 2- to 3-year or longer arrangements) between purchasers and manufacturers of domestic medical supplies would be necessary to increase the domestic manufacturing base. Some commenters stated that CMS would need to pay beyond the IPPS and OPPS shares of the additional costs in a non-budget neutral manner to shift purchasing, with several commenters suggesting that CMS work with Congress to achieve this objective. Some commenters supported the establishment of a resiliency¹⁹⁶ measure

to supplement or replace the quality measure discussed in the ANPRM. Several of these commenters advocated for any potential separate payment to be tied to demonstrated efforts on the part of hospitals and manufacturers to implement resiliency processes into their procurement practices.

C. Potential Eligible Domestic PPE Products and Cost Differentials

As described previously in section XXII.B., under the IPPS we currently make a payment adjustment for the additional resource costs that hospitals face in procuring domestic NIOSH-approved¹⁹⁷ surgical N95[®] respirators.¹⁹⁷ After consideration of the comments received on the ANPRM, to further support a level of supply resilience that is critical to protect the health and safety of personnel and patients, we are considering expanding the PPE products eligible for the separate IPPS payment adjustment to include all domestic NIOSH-approved FFRs that demonstrate compliance with the ASTM Respirator Fit Capability Standard, domestic medical gloves in compliance with FDA requirements and conforming to ASTM standards, and domestic gowns in compliance with FDA requirements and conforming to AAMI standards. We are not considering including other PPE products such as face shields, protective eyewear, surgical masks, and head and foot coverings at this time.

Given that the unique device identifier (UDI) codes for PPE, as applicable, may refer to packages of multiple items, our unit of analysis is a single item (that is, one glove). As previously noted, we are considering whether the methodology for determining the amount of the payment adjustment under any such expanded policy should be based on the use of standardized cost differentials for eligible categories of domestic PPE.

Potential eligible PPE items, per item differentials, and qualifying criteria under consideration are listed in Table 79. These potential PPE cost differentials were derived from public comments, prior discussions with manufacturers, and Federal procurement data. We invite public comments on approaches for determining the base cost differentials between domestic and non-domestic PPE items.

¹⁹⁶ In this context, we define "resiliency" in a manner consistent with the supply chain characteristics described by Executive Order 14017:

<https://www.federalregister.gov/documents/2021/03/01/2021-04280/americas-supply-chains>.

¹⁹⁷ N95 and NIOSH Approved are registered certification trademarks of the HHS in the U.S. and several other countries.

TABLE 79: DOMESTIC PPE ITEMS BEING CONSIDERED WITH BASE COST DIFFERENTIALS AND QUALIFYING CRITERIA

Eligible PPE Item	Domestic Differential Per Single Item	Required Compliance
Filtering Facepiece Respirators	\$0.38	- NIOSH-approved - ASTM Respirator Fit Capability Standards
Isolation gowns	\$0.82	- FDA Compliance - AAMI Standards
Nitrile exam gloves	\$0.05	- FDA Compliance - ASTM Standards

In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the most appropriate framework for determining if NIOSH-approved surgical N95 FFRs were considered domestic for purposes of the separate payment is the Berry Amendment (87 FR 72039 through 40). The Berry Amendment is a statutory requirement familiar to manufacturers that restricts the Department of Defense (DoD) from using funds appropriated or otherwise available to DoD for procurement of food, clothing, fabrics, fibers, yarns, other made-up textiles, and hand or measuring tools that are not grown, reprocessed, reused, or produced in the U.S. Berry Amendment restrictions are implemented by the DoD Federal Acquisition Regulation Supplement (DFARS) 252.225–7002, and the provision at 252.225–7002–1 states DoD cannot acquire specified “items, either as end products or components, unless the items have been grown, reprocessed, reused, or produced in the U.S.” With limited exceptions, the entire production process of an affected product, from the production of raw materials to the manufacture of all components to final assembly, must be performed in the U.S.¹⁹⁸

However, given that the inputs and constituent materials of some potentially eligible domestic PPE products (such as nitrile gloves) are not wholly defined by the Berry Amendment, we are considering defining domestic for purposes of this potential payment policy using the Make PPE In America Act domestic content requirements for Federal procurement contracts outlined in section 70953 of the Infrastructure Investment and Jobs Act. This statute defines American-made PPE as “personal protective equipment,

including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.” Those statutory requirements, which apply to procurement of PPE by the U.S. Departments of Health and Human Services, and Veterans Affairs, and Homeland Security, require the procurement of PPE, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the U.S. This Act is similar to the Berry Amendment but broader in the scope of PPE products it covers. PPE manufacturers are generally familiar with its requirements. The aforementioned NIOSH-approved FFRs that demonstrate compliance with the ASTM Respirator Fit Capability Standard, medical gloves in compliance with FDA requirements and conforming to ASTM standards, and gowns in compliance with FDA requirements conforming to AAMI standards eligible for Federal procurement would also be considered domestic for purposes of this potential policy and would therefore be eligible for the potential payment. On an annual basis, in connection with manufacturers’ attestations of eligible domestic PPE, a specific exception for NBR for nitrile gloves would be specified if applicable.

D. Potential Eligible Domestic Essential Medicines and Cost Differentials

The report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment*, as developed by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) with the Advanced Regenerative Manufacturing Institute’s (ARMI’s) Next Foundry for American Biotechnology, prioritized 86 essential medicines¹⁹⁹ from the Executive Order 13944 List of Essential

Medicines, Medical Countermeasures, and Critical Inputs, as developed under the Executive Order by the U.S. Food and Drug Administration (FDA).²⁰⁰

The ARMI List is a prioritized list of 86 medicines that are either critical for minimum patient care in acute settings or important for acute care with no comparable alternatives available. The medicines included in the ARMI List were considered, by consensus, to be most critically needed for typical acute patient care. In this context, acute patient care was defined as: rescue use or lifesaving use or both (that is, Intensive Care Units, Cardiac/Coronary Care Units, and Emergency Departments), stabilizing patients in hospital continued care to enable discharge, and urgent or emergency surgery. Development of the ARMI List focused on assessing the clinical criticality and supply chains of small molecules and therapeutic biologics. The development of the ARMI List was informed by meetings with multiple key pharmaceutical supply chain interested parties (for example, manufacturers, group purchasing organizations, wholesale distributors, providers, pharmacies), surveys and workshops with groups of clinicians and industry interested parties, public feedback on the Executive Order 13944 List (provided during a public comment period starting in October 2020), and other research. As discussed in section XXII.B., we previously finalized a separate payment under the IPPS to small, independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to a 6-month buffer stock of one or more of the ARMI List’s essential medicines.

For this potential payment policy, we are considering including certain FDA-approved medicines from the ARMI List

¹⁹⁸ Congressional Research Service: Buying American: Protecting U.S. Manufacturing Through the Berry and Kissell Amendments: sgp.fas.org/crs/misc/R44850.pdf.

¹⁹⁹ Hereinafter referred to as the “ARMI List” or “ARMI’s List.”

²⁰⁰ <https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs>.

which have existing U.S. FDF production, and do not contain API from countries listed on the “foreign adversaries” list at 15 CFR 791.4.²⁰¹ In developing the potential list of eligible essential medicines, we prioritized non-substitutable sterile injectables and

²⁰¹ <https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-E/part-791/subpart-A/section-791.4>.

generic antibiotics as per the prioritization framework developed by ASPR and Federal supply chain security offices, including within HHS and the DoD. Scheduled drugs, which are already predominantly manufactured domestically, as well as branded drugs were not considered in developing the potential list of eligible essential medicines. All drugs included in the

potential list have also been subject to shortage within the previous decade.²⁰² The priority matrix used for drug selection in developing the potential list of eligible essential medicines under consideration is shown in Table 80:

BILLING CODE 4169-69-P

²⁰² Shortages listed on ASHP database: <https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=All>.

TABLE 80: PRIORITY MATRIX FOR DRUG SELECTION IN DEVELOPING THE POTENTIAL LIST OF ELIGIBLE ESSENTIAL MEDICINES

	Critical Role	Shortage History
ACYCLOVIR	Essential for managing viral infections, particularly herpes-related infections, which can complicate other diseases, especially in immunocompromised individuals.	Shortages due to spikes in demand during viral outbreaks and disruptions in manufacturing. Issues such as limited raw material availability and regulatory compliance have also contributed.
Top prescribed penicillin-class antibiotics (AMOXICILLIN, AMPICILLIN, PENICILLIN G, PIPERACILLIN/TAZOBACTAM)	Broad-spectrum antibacterial crucial for treating a variety of infections, including those secondary to viral diseases.	Shortages have been driven by manufacturing delays, increased demand during respiratory illness seasons, and quality control problems. The complex production process and dependency on specific raw materials exacerbate these issues.
ATROPINE SULFATE	Used in surgery to stabilize breathing and heart rate, and as an antidote for nerve agents.	Recent shortages due to discontinuations.
AZITHROMYCIN	Macrolide antibiotic prescribed to treat bacterial infections including pneumonia.	Current shortage due to increased demand and API shortages.
CEFEPIME	Cephalosporin antibiotic used to treat a variety of bacterial infections.	Prone to multi-year shortages, now resolved.
CEFTRIAZONE	Cephalosporin antibiotic used for a variety of infections, including against both gram-positive and gram-negative organisms.	Prone to shortages due to increased demand, manufacturing delays, and discontinuations.
DOXYCYCLINE	Broad spectrum antibiotic effective against a range of bacterial infections.	Prone to occasional shortages over previous decade.
EPINEPHRINE	First-line treatment for anaphylaxis, severe asthma attacks, and cardiac arrest, making it indispensable in emergency settings.	Shortages due to production delays, increased demand during allergy seasons, and supply chain disruptions. The EpiPen shortage in 2018 highlighted the vulnerability of epinephrine supply chains.
LEVOFLOXACIN	Broad-spectrum fluoroquinolone antibiotic reserved for severe, hard-to-treat bacterial infections, and effective for penetrating deep tissues.	Prone to recent shortages due to discontinuations.
LINEZOLID	Oxazolidinone antibiotic effective against multidrug-resistant infections.	Prone to multi-year recent shortages.
MEROPENEM	Carbapenem antibiotic used to combat increased challenges with multidrug resistant infections.	Shortages due to increased demand.
METHYLPREDNISOLONE ACETATE and METHYLPREDNISOLONE SODIUM SUCCINATE	Corticosteroid vital for reducing severe inflammation and treating autoimmune reactions. It has been used extensively in managing severe COVID-19 cases to reduce cytokine storms.	Shortages of methylprednisolone have been linked to increased demand during pandemics, manufacturing issues, and raw material shortages. During the COVID-19 pandemic, its use in treating severe cases led to significant supply challenges.

	Critical Role	Shortage History
VALGANCICLOVIR	An antiviral medication used to prevent and treat Cytomegalovirus (CMV) in immunocompromised individuals, such as organ transplant recipients and people with AIDS.	Oral powders prone to recent shortages due to product discontinuations.
VANCOMYCIN HCL	Vancomycin is critical for treating severe Gram-positive bacterial infections, including MRSA. Infections with antibiotic-resistant bacteria are a significant risk during pandemics when healthcare systems are overwhelmed.	Shortages due to manufacturing disruptions, increased demand during infectious disease outbreaks, and issues with raw material supply. During the early 2010s, there were notable shortages due to increased global demand and the rise in antibiotic-resistant infections.

BILLING CODE 4169–69–C

As previously noted, we are seeking comment regarding whether the methodology for determining the amount of the payment adjustment under this potential policy should be based on the use of standardized cost differentials for eligible categories of domestic essential medicines. For each eligible essential medicine, we are seeking comment regarding whether it would be appropriate to use two separate possible base cost differentials, depending on whether both the FDF and API for the drug are manufactured domestically, or just the FDF is manufactured domestically. Each drug’s base cost differential could be subject to change on an annual basis to reflect inflation and changing pharmaceutical prices over time. We include in Table 81 a list of potential base cost differentials derived from economic analysis of wholesale acquisition costs and informed by public comments, consultations with pharmacists and government procurement specialists, and available literature to estimate costs of domestic production (including a 2022 study by ASPR that found domestic API is around 12 times more expensive than foreign API, and several studies identifying domestic generic costs as 35 to 50 percent higher than generics in India and China²⁰³). We invite public comments on approaches

for determining the base cost differentials between domestic and non-domestic essential medicines.

The cost differential for a given drug dosage would be relative to each particular drug’s unit of measurement, referred to here as base dosage. For instance, amoxicillin’s base dosage is a single 500 mg capsule; this means that the domestic cost differential for reimbursement would be \$0.12 per 500 mg amoxicillin if the drug is made in the U.S. with non-U.S. API, and \$0.25 per 500 mg amoxicillin if the drug is made in the U.S. with U.S. API. If a hospital purchases a bottle of 100 capsules of amoxicillin and each individual capsule contains 1 gram of amoxicillin, then the purchased drug dosage (1000 mg) divided by the drug base dosage (500 mg) would lead to a multiple of 2x per capsule, or 200x for the whole bottle. The NDC as used by the hospital would correspond to the entire bottle of 100 amoxicillin capsules, and would equate to a differential separate payment to the hospital of \$25 for U.S. FDF only. Similarly, if a 150 ml vial contains 100mg/5ml of linezolid, the purchased drug dosage is 3 gm linezolid which is a multiple of 3x over the base dosage listed in the Table 81 of 1 gm.

All combination drugs containing the eligible drug molecules would be

acceptable for a potential separate payment adjustment, based only on the dosage of eligible molecules (see Table 81 for examples).

Using the drug base dosage to calculate the differential separate payment amounts would have three primary benefits over alternative methodologies. First, it would provide flexibility with respect to new market entrants because the base rate would correspond to a product category as a whole, rather than a particular item. Second, this approach would be more resistant to gaming than alternative approaches because it does not rely on manufacturer submitted prices or temporary market conditions that are more liable to capture idiosyncratic factors, such as opportunistic price reporting, unrepresentative market conditions at the time of measurement, or atypically exquisite packaging. Lastly, it would be more transparent from the standpoint of hospitals, which would be able to determine the amount of separate payment for any NDC by applying the payment formula using the publicly available file of eligible products by NDC.

Specifically, we are considering the following domestic essential medicines for inclusion with the following base cost differentials and drug base dosages:

BILLING CODE 4169–69–P

²⁰³ Lu, Z.J.; Shih, Y.-C. T. Re-Shoring of Generic Drug Global Supply Chain: An Exploratory Economic Analysis. Preprints 2026, 2026021157. <https://doi.org/10.20944/preprints202602.1157.v1>; Mark Abdo, Douglas Throckmorton. 2020. “COVID–19 and Beyond: Oversight of the FDA’s Foreign Drug Manufacturing Inspection Process—

06/02/2020.” FDA. June 4, 2020. <https://www.fda.gov/news-events/congressional-testimony/covid-19-and-beyond-oversight-fdas-foreign-drug-manufacturing-inspection-process-06022020>; Shireesh Ambhaikar, Shantaram Shenai, V. Govindarajan, Pavan Gajare, P. K. Kulkarni, Shankar Suryanarayanan, Christopher Peterson, et

al. 2025. “Differences in the Cost of Manufacturing Pharmaceuticals in India for Differently Regulated Markets: A Comparative Analysis.” MedRxiv (Cold Spring Harbor Laboratory), April. <https://doi.org/10.1101/2025.04.16.25325941>.

**TABLE 81: DOMESTIC ESSENTIAL MEDICINES BEING CONSIDERED WITH
BASE COST DIFFERENTIALS AND DRUG BASE DOSAGES**

Eligible Drug Molecule	Drug Base Dosage	Base Cost Domestic Differential: U.S. FDF + non-U.S. API	Base Cost Domestic Differential: U.S. FDF + U.S. API
ACYCLOVIR	500 MG	\$1.50	\$ 6.00
AMOXICILLIN	500 MG	\$0.12	\$ 0.25
AMPICILLIN	500 MG	\$0.07	\$ 0.62
ATROPINE SULFATE	1 MG	\$0.95	\$ 7.20
AZITHROMYCIN	500 MG	\$0.95	\$ 2.88
CEFEPIME	1000 MG	\$0.25	\$ 2.29
CEFTRIAZONE	1000 MG	\$0.11	\$ 0.96
DOXYCYCLINE	100 MG	\$1.30	\$ 8.20
EPINEPHRINE	1 MG	\$0.35	\$ 3.15
LEVOFLOXACIN	5 MG	\$0.27	\$ 2.85
LINEZOLID	1000 MG	\$1.40	\$10.07
MEROPENEM	1000 MG	\$0.85	\$1.94
METHYLPREDNISOLONE ACETATE	100 MG	\$0.54	\$5.70
METHYLPREDNISOLONE SODIUM SUCCINATE	1000 MG	\$1.80	\$7.42
PENICILLIN G	1000 MG; 1.67 million units	\$0.29	\$2.10
PIPERACILLIN / TAZOBACTAM	500 MG	\$0.30	\$1.20
VALGANCICLOVIR	100 MG	\$0.30	\$0.57
VANCOMYCIN HCL	500 MG	\$2.75	\$6.05

BILLING CODE 4169-69-C

If we were to adopt such a policy, we would expect to add additional drugs in the future, increasing the number of drugs until the list eventually includes all non-scheduled generic drugs with domestic FDF production on the latest ARMI List. We would also expect that we may account for the production location of pharmaceutical precursors or key starting materials in addition to API and FDF locations.

For these essential medicines, we are considering that an essential medicine would be domestic if the country of origin is the U.S., where “country of origin” is defined through incorporation by reference as “substantial transformation” of the final dosage form (or the Active Pharmaceutical Ingredient) via 19 CFR 134.1(b). This is identical to the standard used by U.S. Customs and Border Protection, and thus represents a familiar definition for the pharmaceutical industry. This regulation defines “country of origin” as

the country of manufacture, production, or growth of any article of foreign origin entering the U.S. The regulation also specifies that further work or material added to an article in another country must effect a substantial transformation in order to render such other country the “country of origin.” “Substantial transformation” is defined by the International Trade Administration to mean that the good underwent a fundamental change in form, appearance, nature, or character.²⁰⁴ Under this approach, articles manufactured, produced, or grown in the U.S., or that otherwise undergo a substantial transformation in the U.S. would have a domestic country of origin for purposes of the potential payment.

²⁰⁴ For more information, see: <https://www.trade.gov/rules-origin-substantial-transformation>.

E. Public File of Potential Eligible Domestic PPE and Potential Eligible Domestic Essential Medicines

Under this potential policy, manufacturers of potentially eligible domestic PPE and essential medicines would voluntarily submit annual attestations to HHS that their products meet our domestic definitions. The annual attestations for potentially eligible domestic essential medicines would need to include country-of-origin information for FDF and API, as applicable, that demonstrates that the product was either wholly manufactured, produced, grown, or otherwise substantially transformed in the U.S. Repackaging, on its own, would not be interpreted as passing the “substantial transformation” test. For domestically produced drugs whose API is not produced domestically, submitters would attest that the API’s country of origin was not a country on the “foreign adversaries” list at 15 CFR

791.4 in order to be eligible. The annual attestations from PPE manufacturers would have to demonstrate that the product was in compliance with the “Make PPE in America” standards for domestic procurement, with the exception of NBR. We believe manufacturers are uniquely positioned to provide this information. We would welcome public feedback on these approaches to determining eligibility for domestic PPE and essential medicines for purposes of this potential payment policy, including whether alternatives to “country of origin” would be more appropriate for determining eligibility for domestic essential medicines, such as identifying the specific FDA-registered facilities responsible for producing the FDF and API.

Under this potential policy, HHS would compile the information provided by manufacturers and create an annual file of eligible domestic products and domestic cost differential estimates, including the NDC or UDI for the product, as applicable, manufacturer name, and part number. This public file would be intended to provide hospitals with a simple, reliable reference for identifying eligible domestic products and the estimated domestic cost differentials.

F. Potential IPPS Approaches to a Separate Voluntary Payment Adjustment for the IPPS Share of the Additional Resource Costs of Procuring Eligible Domestic PPE and Eligible Domestic Essential Medicines

As discussed previously in section XXII.B., we are requesting public comments on a potential separate payment adjustment under the IPPS for the additional resource costs hospitals incur when procuring domestically manufactured items. Based on a review of comments received on the ANPRM, we are considering using our authority under section 1886(d)(5)(I) of the Act to establish a voluntary separate IPPS payment adjustment for the IPPS share of the additional resource costs incurred by hospitals in procuring eligible domestic PPE and essential medicines, as discussed in greater detail in this section. To further support the strategic policy goal of sustaining a level of supply resilience for eligible domestic PPE and essential medicines that are critical to protect the health and safety of personnel and patients, consistent with the existing surgical N95 FFRs policy, we are considering if this potential IPPS payment adjustment should not be budget neutral.

High-quality domestic PPE and essential medicines are generally more expensive than foreign-made ones,

especially those produced by manufacturers with less mature manufacturing quality systems.²⁰⁵ These higher prices primarily stem from higher costs of manufacturing labor in the U.S. compared to costs in other countries, where most PPE and molecular precursors of pharmaceuticals are made, and high investment requirements to maintain mature manufacturing quality systems. These higher prices result in higher marginal costs for hospitals for procuring domestically made PPE and essential medicines. As discussed in the ANPRM (91 FR 3854), an ASPR review of publicly available individual and wholesale prices for both domestic and non-domestic nitrile gloves on manufacturer websites shows that the price of domestically manufactured nitrile gloves is approximately 1.5 to 3 times that of non-domestically manufactured nitrile gloves. A similar ASPR review of the publicly available prices of API from domestic and non-domestic sources reveals that domestic API are, on average, approximately 12 times as expensive as non-domestic alternatives. As previously discussed, we are requesting public comments on a potential separate payment adjustment under the IPPS for the IPPS share of the additional resource costs hospitals incur when procuring domestic PPE and essential medicines. We are also seeking feedback on potential approaches to calculating that separate payment, including the approaches discussed in this section.

One approach we are considering proposing in future rulemaking is a claims-based payment approach (Approach 1) and another is a cost-report payment approach (Approach 2). We first discuss the potential approaches as applied to domestic essential medicines and then discuss them as applied to domestic PPE as tracking domestic PPE use at the IPPS patient level may not be possible for hospitals, although we seek public input on this issue. To the extent tracking domestic PPE use at the IPPS patient level may not be possible for hospitals, we discuss two potential options for an allocation methodology under Approach 2 as applied to domestic PPE (Approach 2a and Approach 2b) that we might consider for future rulemaking.

²⁰⁵ U.S. Department of Health and Human Services: Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States, April 2024: <https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf>.

Under Approach 1 as applied to domestic essential medicines, the claims processing system would use the domestic cost differentials discussed in section XXII.D. to automatically calculate and pay the separate IPPS payment adjustment based on the domestic NDCs and units of those NDCs for eligible domestic essential medicines furnished to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the IPPS claim for that IPPS stay.

Under Approach 2 as applied as applied to essential medicines, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing individually on its IPPS claims. The payment is the same under either approach, but the hospital would not need to submit the NDCs on the claim under Approach 2. As with the current N95 policy, hospitals could request interim biweekly payments under Approach 2 and would be reconciled at cost report settlement. Biweekly payment amounts would be determined by the Medicare Administrative Contractor, consistent with existing policies and procedures using an estimate of the annual reimbursable amount for the year divided into 26 equal payments.

For PPE, to the extent that a hospital can track its use of domestic PPE for individual IPPS inpatients as it can for domestic essential medicines, Approach 1 and Approach 2 would operate similarly for domestic PPE as they would for domestic essential medicines. Under Approach 1, the claims processing system would use the domestic cost differentials discussed in section XXII.C. to automatically calculate and pay the separate IPPS payment adjustment based on the amount of eligible domestic PPE used in furnishing services to an IPPS inpatient during an IPPS hospital stay that a hospital voluntarily bills on the IPPS claim for that IPPS stay.

To implement this approach, we would create three new billing codes for this purpose: a billing code for eligible domestic N95 FFRs, a billing code for eligible domestic gloves, and a billing code for eligible domestic gowns.

Under Approach 2, a hospital would voluntarily use that same information to calculate the payment across all of its IPPS stays during its cost reporting period and report that aggregated information on its cost report instead of billing it individually on its IPPS claims. The payment is the same under

either approach (if domestic PPE use is tracked by the hospital at the IPPS patient level under Approach 2, such as by UDI for the product), but hospitals would not need to submit new PPE billing codes on the claim under Approach 2.

To the extent tracking domestic PPE use at the IPPS patient level may not be possible for a hospital, a reasonable allocation methodology would need to be used under Approach 2 to allocate the aggregate amount of domestic PPE purchased by the hospital to IPPS inpatients. We discuss two potential options for an allocation methodology under Approach 2 that we might consider for future rulemaking. Under either potential allocation option, a hospital would report on its cost report the aggregate amount of eligible domestic FFRs purchased, the aggregate amount of eligible domestic gloves purchased, and the aggregate amount of eligible domestic gowns purchased. We also discuss an illustrative example of how each approach might work for the domestic FFRs purchased by a hospital.

Under the first allocation option (Approach 2a), we could use the domestic cost differentials discussed in section XXII.C. and the amount of each type of eligible domestic PPE purchased to calculate the total domestic differential costs incurred by the hospital. To allocate a portion of the total domestic differential costs to IPPS inpatients for purposes of making a separate payment under Approach 2a, we would use the same method and cost data already reported on the hospital cost report that is used under the current N95 FFRs policy. Specifically, the separate payment would be calculated by multiplying the total domestic differential costs by the following fraction (Fraction 1):

- Total Medicare Part A hospital inpatient costs as reported on the cost report in Worksheet D–1 Part II, line 49,²⁰⁶ divided by
- Total costs for all inpatient routine services, ancillary services, outpatient services, and other reimbursable services as reported on the cost report in Worksheet C Part I line 202 column 5.

An alternative allocation approach (Approach 2b) could be to determine, for each category of PPE, a reasonable upper bound on the amount of eligible domestic PPE used in furnishing services to IPPS inpatients. Under this approach, in addition to reporting the aggregate amounts of eligible *domestic*

FFRs, eligible *domestic* gloves, and eligible *domestic* gowns purchased, a hospital would report the aggregate amounts of *total* FFRs, *total* gloves, and *total* gowns purchased—irrespective of whether the FFRs, gloves, and gowns are domestic or non-domestic.

Under Approach 2b, we would first proxy the *inpatient* portion of the *total* amount purchased for each category of PPE. In other words, because the total amount purchased by the hospital was used to furnish outpatient and inpatient services, we first need to proxy the portion that was used to furnish inpatient services. We seek public input on potentially using the hospital revenue information on Worksheet G–2 (or suggestions for other alternatives, revenue based or otherwise) to proxy the portion of the total amount purchased for each PPE category that was used to furnish inpatient services.²⁰⁷ If CMS were to use revenue, we would multiply the total purchased for each PPE category by the following fraction (Fraction 2) calculated from existing cost report information:

- The sum of the inpatient revenue reported on Worksheet G–2, Part I, column 1 (Inpatient), lines 1, 16, and 18, divided by
- The sum of the total revenue reported on Worksheet G–2, Part I, column 3 (Total), line 28.

Having proxied the *inpatient* portion of each PPE category, CMS could then proxy an upper bound on the *IPPS inpatient* portion of each PPE category by multiplying by a fraction (Fraction 3) that represents the portion of the hospital's inpatient services furnished to Medicare inpatients relative to all inpatients, calculated from existing cost report information as:

- The sum of the Medicare inpatient days reported on Worksheet S–3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable, divided by
- The sum of the inpatient days reported on Worksheet S–3, Part I, column 8 (Total All Patients), lines 1, 8 through 12, and subscripts as applicable.

The result of this calculation for each PPE category would be the estimated upper bound on the eligible domestic FFRs, gowns, and gloves, respectively, used in furnishing services to IPPS inpatients.

For each PPE category, we would then multiply the upper bound by the domestic cost differential discussed in

section XXII.C. to establish an IPPS limit for the separate payment to the hospital for that category of eligible PPE.

Using these IPPS limits, the separate payment to a hospital under Approach 2b would be calculated as the domestic cost differentials discussed in section XXII.C. multiplied by the aggregate amount of each type of domestic PPE purchased by the hospital, not to exceed the IPPS limit for that category of PPE for that hospital.

For purposes of illustrating the differences between Approach 2a and Approach 2b, we provide a hypothetical calculation of the separate IPPS payment under each approach for domestic FFRs purchased by General Hospital (GH). This calculation uses the following assumptions regarding GH's FFR purchases and cost report: (1) GH purchased 1 million FFRs; (2) 300,000 of those FFRs were domestic; (3) GH's total Medicare Part A hospital inpatient costs represent 10 percent of its total costs (Fraction 1); (4) GH's inpatient revenue represents 35 percent of its total revenue (Fraction 2); and (5) GH's IPPS days represent 25 percent of its total inpatient days (Fraction 3). The last three assumptions are approximately equal to the median values of those percentages across all IPPS hospitals based on cost report data.

Under Approach 2a, GH would report on its cost report the 300,000 domestic FFRs purchased by the hospital.

Using the potential domestic differential unit cost for FFRs of \$0.38 as discussed in Section XXII.C., the total domestic differential incurred by the hospital is \$114,000, which is equal to the 300,000 domestic FFRs purchased times the \$0.38 domestic differential unit cost.

Using the fact that GH's total Medicare Part A hospital inpatient costs represent 10 percent of its total costs (Fraction 1), the separate IPPS payment under Approach 2a would be \$11,400, which is equal to 10 percent of the \$114,000 total domestic differential.

Alternatively, under Approach 2b, GH would report on its cost report the 1 million total FFRs purchased and the 300,000 domestic FFRs purchased.

Using the fact that GH's inpatient revenue represents 35 percent of its total revenue (Fraction 2), CMS would proxy the portion of the 1 million FFRs used in furnishing services to inpatients as 350,000 FFRs, which is equal to 35 percent of the 1 million total FFRs.

Using the fact that GH's IPPS days represent 25 percent of its total inpatient days (Fraction 3), CMS would calculate an upper bound on the number of those 350,000 inpatient FFRs used in furnishing services to *IPPS*

²⁰⁶ Include the inpatient costs as reported in Worksheet E, Part A, lines 55, 55.01, and 56, if applicable.

²⁰⁷ Because ancillary costs for all payers are not cleanly subdivided on the cost report between inpatient and outpatient, we are considering using inpatient and outpatient revenue for this purpose.

inpatients as 87,500 FFRs, which is equal to 25 percent of the 350,000 inpatient FFRs.

Using the potential domestic differential unit cost for FFRs of \$0.38, CMS would calculate the IPPS payment limit as \$33,250, which is equal to the 87,500 FFRs times the \$0.38 domestic differential unit cost.

CMS would compare the total domestic differential of \$114,000 (calculated the same as under Approach 2a) with the IPPS payment limit of \$33,250 and the separate payment would be the lower of the two. In this illustrative example, the separate payment to GH under Approach 2b would be \$33,250 because the total domestic differential of \$114,000 exceeds the IPPS payment limit.

In summary, in this illustrative example GH would receive a separate IPPS payment of \$11,400 under Approach 2a or alternatively a separate payment of \$33,250 under Approach 2b.

G. Maximum Annual Amount of Aggregate Payments

Regardless of the payment approach, in conjunction with any such potential policy, we believe it may be prudent to establish an appropriate maximum annual amount of aggregate separate payments that would be available (e.g. \$500 million or \$1 billion) across all IPPS hospitals. To implement such an approach, we could prospectively allocate shares of this aggregate amount to individual hospitals before the start of the fiscal year. If the actual separate payment to a hospital for the fiscal year exceeds its allocated maximum amount, the excess amount would be reconciled at cost report settlement, as the payment for that hospital's excess cost would be considered still bundled into the MS-DRG payment and not separately payable. One potential mechanism for allocating the amount to individual hospitals would be the Medicare inpatient days as reported on Worksheet S-3, Part I, column 6 (Title XVIII), or column 6.01 (if applicable), lines 1, 8 through 12, and subscripts as applicable. A hospital's share of the Medicare inpatient days aggregated across all hospitals would be multiplied by the maximum annual amount of aggregate separate payment in order to determine its allocated amount. For example, if the maximum annual amount of aggregate separate payment under this potential policy were \$1 billion in a given fiscal year and a hospital's share of aggregated Medicare inpatient days was 0.03 percent based on historical cost reports, then the prospectively determined allocated maximum amount for that hospital for

that fiscal year would be \$300,000 ($=\$1 \text{ billion} \times 0.03 \text{ percent}$).

H. Solicitation of Additional Options: Domestic PPE and Essential Medicines

In addition to the approaches described earlier, we solicit general input on additional options from the public. Comments that include detailed information on economic impacts, timing, potential statutory authorities, and a discussion of trade-offs with respect to such options are especially useful to CMS. We are also requesting comment on the operational feasibility and difference of the approach for PPE versus essential medicine of the different aspects of the potential policy. We also seek comment and applicable data regarding current domestic production capacity, manufacturers' ability to expand output, expected expansion timelines, and barriers to scaling production. Please include references to research and data in comments where appropriate.

We note that because the current statutory authority for the existing payment adjustment under the OPPS for the additional resource costs that hospitals face in procuring domestic NIOSH-approved surgical N95 FFRs (section 1833(t)(2)(E) of the Act) requires those payments to be budget neutral (87 FR 72042, 72268 through 72269), we are not considering expanding and revising the current OPPS N95 policy. Instead, we are considering sunseting the existing surgical N95 FFRs policy, and also considering simultaneously prospectively removing the associated OPPS budget neutrality adjustment while we explore alternative outpatient approaches for the future.

We also note that after consideration of public feedback on the ANPRM, we are no longer exploring, at this time, a new "Secure American Medical Supplies" friendly designation or a new structural quality measure as part of the Hospital IQR Program.

XXIII. Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data

A. Background

Since January 1, 2021, CMS has required each hospital operating in the United States to provide clear, accessible pricing information online about the items and services they offer in two ways: (1) as a comprehensive machine-readable file (MRF) and (2) via a consumer-friendly display. The data we require hospitals to disclose in the MRF serves as a critical resource for

users, including employers, researchers and innovators, who may be leveraging the data with the goal of stimulating competition, generating new insights, and driving down healthcare costs. In parallel, the consumer-friendly display empowers consumers seeking healthcare services by making it easier to shop and compare prices across hospitals. Through past rulemaking cycles, requests for information (RFIs), interested parties' listening sessions, and evidence gathered from our compliance process, we continue to identify paths to further refine the hospital price transparency regulations.

The White House issued Executive Order 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information" on February 25, 2025 (90 FR 11005). Pursuant to this Executive Order, we will "continue to promote universal access to clear and accurate healthcare prices" and "identify opportunities to further empower patients with meaningful price information." We are committed to providing consumers with the information needed to make informed decisions about their healthcare, and on November 21, 2025, we issued the CY 2026 OPPS/ASC final rule with comment period to further advance this commitment (90 FR 53448). In the CY 2026 OPPS/ASC final rule with comment period, we finalized changes to the hospital price transparency regulations to help ensure that hospitals provide meaningful, accurate information about the amount they charge for healthcare items and services. We required hospitals to make their MRFs more useful and comparable by publishing actual dollar-based pricing data. Specifically, when a payer-specific negotiated charge is based on a percentage or algorithm, hospitals are required to encode the median, 10th percentile, and 90th percentile allowed amounts (as defined by CMS at 45 CFR 180.20), along with the number of claims used to calculate those figures, using remittance data from the prior 12 to 15 months. We also required hospitals to attest that their MRFs are true, accurate, and complete and that the hospital has included all applicable payer-specific negotiated charges in dollars that can be expressed as a dollar amount; and for payer-specific negotiated charges that cannot be expressed as a dollar amount in the MRF or are not knowable in advance, the hospital has provided in the MRF all necessary information available to the hospital for the public to be able to derive a dollar amount. Furthermore, we

required that the attestation identify a senior official designated to oversee the encoding of true, accurate, and complete data. Lastly, we finalized a requirement for hospitals to include their Type 2 National Provider Identifier(s) to improve standardization across hospitals. These changes went into effect January 1, 2026, with enforcement of these requirements starting April 1, 2026.

B. MRF RFI

We continue to make meaningful progress in standardizing the MRF to lay a strong foundation for transparency and consistency, and we believe that further enhancements to the format and content of the MRF will build on this progress to increase the utility and comparability of the data. We also continue to gain experience with the recent changes finalized in the CY 2026 OPPS/ASC final rule with comment period and continue to assess the extent to which they achieve the objectives outlined in Executive Order 14221. To inform potential enhancements, we have sought feedback from interested parties. On May 22, 2025, we posted the CMS Hospital Price Transparency Accuracy and Completeness RFI on the CMS Hospital Price Transparency website. The feedback gathered from this RFI further emphasized the importance of standardization of data within the MRF to promote accuracy and completeness. Responses also informed CMS' development of additional checks during our compliance review of MRFs. In addition, since the issuance of the CY 2026 OPPS/ASC final rule with comment period, we have received additional suggestions from users of the MRF (innovators, researchers, employers and consumers) through our hospital price transparency mailbox regarding ways to further standardize and improve the MRF data.

Over time, we have introduced several free text data elements (data elements in which unstructured, narrative information is entered) within the MRF and have required hospitals to encode a variety of supporting standard charge information within these data elements. This includes the requirement to encode a description of the standard charge methodology in a free text data element if 'other' is selected as the valid value for the methodology as well as the requirement to encode an explanation in a free text data element when the allowed amount calculations are required but there is no remittance data to perform those calculations. However, we have received feedback from interested parties that valuable

contextual information in these free text fields can be difficult for MRF users to interpret or parse. We have specifically received feedback regarding the need for more standardization of outlier provisions and additional contract terms, including, for example, outlier contract provisions that provide additional reimbursement for cases with exceptionally high costs, stop-loss contract clauses which provide additional reimbursement when a patient's treatment costs exceed a specific pre-negotiated threshold, rate-tiering arrangements where payers have categorized hospitals into different tiers based on cost and quality, and carve-out provisions which separate high-cost specialized services from standard bundled rates. Some interested parties noted that these provisions are common contracting practices between hospitals and payers, and that requiring hospitals to report these clauses in a more standardized format would help MRF users better understand when a standard charge applies, and circumstances in which it may not apply. Through compliance reviews, we have observed that this information is not uniformly encoded across hospital MRFs.

We seek interested parties' feedback about whether outlier, stop-loss, rate-tiering, and carve-out provisions are considered payer-specific negotiated charges at the item or service level, in which case they are already required to be encoded in the algorithm data element for each item or service, or whether they are more appropriately considered general contract provisions that apply broadly. When such provisions apply broadly across items and services, we are interested in feedback about specific requirements for standardization of such complex contracting methodologies that would facilitate hospital reporting of accurate and complete information. We have recently issued guidance and examples on how to encode the payer-specific negotiated charge algorithm data element, including the disclosure of outlier information, to support standardization and comparability of this information.²⁰⁸ However, given the importance of such provisions in hospital contracts and evidence gathered from our experience with compliance reviews and interested parties' feedback, which has shown the need to more clearly indicate whether and when such provisions apply in the MRFs, we anticipate providing additional guidance to support even more clear and accurate reporting of this

information and proposing additional requirements through future notice and comment rulemaking.

Interested parties have also identified challenges arising from variations in the name of a payer or a plan across hospitals' MRFs which makes it hard to identify the payer-specific negotiated charge for a specific payer-plan combination and makes comparison across hospitals more difficult. For example, we have seen variations in plan names such as Blue Cross, BlueCross, BC, and BCBS. Interested parties have provided a number of recommendations on how CMS should require more standardization including: publishing a standardized list of the top payer names, requiring a payer or plan unique identifier, for example, a tax identification number or employer identification number, and requiring additional clarifying information like product type and plan type.

Based on our observations while monitoring hospital compliance with the hospital price transparency requirement, as well as assessing recommendations from MRF users, we recognize the importance of requiring more standardization in the MRF to increase the utility of the data and, thereby, increasing competition. As such, we are seeking information from the public on how to strengthen the transparency and usability of the MRFs. Specifically, we welcome public comment on the areas of consideration outlined below:

1. Increasing Transparency of Outlier Provisions and Additional Contract Terms

- What information is needed for users of the MRF to fully understand contract terms related to outlier payments, stop-loss, rate-tiering, carve-outs, and other adjustments that occur across hospital items and services?

- How are hospitals currently reporting contract terms for outlier payments, stop-loss, rate-tiering, carve outs or other adjustments in the MRFs? Are the current formats sufficient for conveying these and other important contract terms? If not, what changes to the current formats, such as separate data elements, would be advised to accommodate the disclosure of such contract terms in a standard manner?

- Do outlier and carve-out contract terms typically apply to individual services, a category of services, or across the entire contract? Should rate-tiering standard charge information be reflected in the payer-specific negotiated charge?

- What additional contracting or payment adjustments affect payer-specific negotiated charges at the item

²⁰⁸ <https://www.cms.gov/files/document/hospital-price-transparency-faqs-encoding-algorithms.pdf>.

or service level, across items and services, or at the contract level, and should that information be encoded in the current data elements provided? If not, what changes to the current formats would be advised to capture this information in a standard manner?

2. Standardization To Enhance Utility of the MRF

- Are there challenges in parsing and categorizing the free text fields when analyzing MRFs? If so, what parameters or requirements would facilitate parsing and categorizing free text fields?

- Are there categories of information or topics consistently included in free text fields that may be standardized through the addition of new data elements? If so, what topic areas should be considered?

- Are there additional contract methodologies that should be reflected as valid values in the MRF, outside the current valid values of fee schedule, capitation, per diem, case rate and other?

- Should CMS require more structured reporting of payer, plan, product, network, and employer (as applicable) information across hospital MRFs, and if so, which elements should be required? Are there existing identifiers for payers and plans, to which hospitals have access, that should be incorporated in the MRF?

- What additional information should we consider to enhance the utility and comparability of the MRF data?

C. Consumer-Friendly Display Request for Public Comment

In the final rule that appeared in the November 27, 2019, **Federal Register** (84 FR 65524) titled “Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates: Price Transparency Requirements for Hospitals to Make Standard Charges Public” (the CY 2020 HPT final rule), we finalized the requirement for hospitals to display 300 total items and services, 70 of which CMS specified, in a consumer-friendly display. We allowed hospitals to choose the method to do so, either in a shoppable services file or using a price estimator tool. At the time, we provided limited specifications about the data requirements, allowing hospitals flexibility in the format used to display this information.

While we have not altered these consumer-friendly display requirements since issuing the CY 2020 HPT final rule, in an effort to implement Executive Order 14221 we engaged in a series of

listening sessions with consumers, consumer advocacy organizations, hospitals, and price estimator tool developers in June and July 2025. During these sessions, we gathered feedback on how effective the consumer-friendly display options were in supporting access to a real and comparable price. The consumers and consumer advocacy organizations shared the challenges of navigating different hospital consumer-friendly display formats to find meaningful price comparisons, as well as the need for a consistent set of requirements across the shoppable services file and the price estimator tool, as the applicable regulatory requirements differ. So as to streamline and standardize requirements for the consumer-friendly display, some interested parties have recommended that CMS no longer deem hospitals compliant with the consumer-friendly display requirements if they offer a price estimator tool, as provided at 45 CFR 180.60(a)(2). Some interested parties also indicated the platforms and formats of price estimator tools vary widely across hospitals, making it difficult to find and compare information. Given the variability of price estimator tools across hospitals, deeming hospitals compliant with the consumer-friendly display requirements if they offer a price estimator tool may limit CMS’ ability to address consumers’ requests to increase the comparability and usefulness of this information.

Hospitals, consumers, consumer advocacy organizations, and price estimator tool developers also provided feedback on what additional contextual information is important to the consumer to understand a real price, for example, knowing whether the price displayed includes facility or professional service charges. Interested parties from hospitals also indicated that consumers want to know what services are and are not included in the price displayed, as well as the ancillary services that would be billed with the shoppable service. Further, interested parties offered suggestions on how to go beyond standardizing data formats, suggesting a requirement to post more comprehensive information, such as standard service packages, inclusive of standard codes and ancillary services.

In addition, and as mentioned above, in the CY 2020 HPT final rule, we required hospitals to display 70 CMS-specified items and services as part of the total 300 items and services. Since the initial requirement, we have heard feedback from interested parties that some of these items and services may not be particularly useful to consumers or are not universally applicable across

all hospitals, such as the add-on CPT code 29826 for shaving of shoulder bone using an endoscope, which may not be considered a shoppable service by consumers or furnished by all hospitals subject to the hospital price transparency requirements. We have also received feedback that some of the required items and services may be out-of-date as this list has not been updated since the CY 2020 HPT final rule. Interested parties have offered suggestions about items and services that may be better suited for the CMS-specified items and services.

Finally, we frequently observe, through compliance reviews, that there are differences between the data in a hospital’s consumer-friendly display and MRF for the same items and services. Specifically, we have noted that standard charges in a hospital’s consumer-friendly display do not always match the standard charges for the same items and services listed in the hospital’s MRF. We are seeking feedback to better understand the circumstances leading to differences in the information across the two formats. Furthermore, a few interested parties, particularly consumer advocates, have observed that hospitals are able to provide information about discounted cash prices in their price estimator tool, even where there is no information about discounted cash prices encoded in the hospital’s MRF. We are seeking clarification to better understand why a hospital would be able to provide information about a discounted cash price in the price estimator tool, yet attest in their MRF, by not encoding the information, that they have not established a discounted cash price for that item or service.

From our interactions with consumers, hospitals, and price estimator tool developers, we understand the need to strengthen the comparability of the data included in the consumer-friendly display to enhance consumers’ ability to shop for care and obtain pricing information in advance of scheduled services. As such, we are seeking information from the public on how to enhance the comparability of the consumer-friendly display data to inform future rulemaking. Specifically, we welcome public comment on the following questions:

- Should we revisit the number and types of CMS-specified shoppable services? What are the advantages and disadvantages of increasing or decreasing the number of shoppable services? Are there specific shoppable services that CMS should include,

exclude, or update on the list of 70 CMS-specified items and services?

- What would be the advantages and/or disadvantages of requiring hospitals to submit a shoppable services file? Alternatively, what would be the advantages and/or disadvantages of removing the deemed compliance for the price estimator tools? Does the current incongruity in how hospitals display shoppable services, with some posting a shoppable services file and others utilizing a price estimator tool, make it more difficult for consumers to actually compare prices for shoppable services across different hospitals? What positive or negative effects would consumers experience if the price estimator tool alone were no longer considered compliant?

- For hospitals that satisfy the consumer-friendly display requirements through a price estimator tool, what mechanisms could be used to make the underlying data available in a separate file?

- Are there circumstances in which the standard charges in a hospital's shoppable services file would not match the information for the same items and services listed in the hospital's MRF? Why would a hospital be able to provide a discounted cash price in its price estimator tool but not in its MRF?

- Which data elements are important for consumers to make comparisons between hospitals? Would a standard shoppable services file template make the information more comparable? How could a shoppable services file indicate the ancillary services that are included in or excluded from the price?

- How should hospitals present ancillary items, implants, and bundled services so consumers better understand total expected costs? What approaches most effectively distinguish included versus excluded services?

- What additional information should we consider to enhance the comparability of the consumer-friendly display data between hospitals?

XXIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

1. Background

In sections XIV. and XV. of this proposed rule, we discuss the proposed requirements for the Hospital Outpatient Quality Reporting Program. The Hospital Outpatient Quality Reporting Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting Program. We refer readers to the CY 2026 OPPS/ASC final rule with comment period (90 FR 54029 through 54037) for detailed discussions of the previously finalized Hospital Outpatient Quality Reporting Program ICRs which are currently under review for approval under OMB control number 0938–1109 (expiration date June 30, 2026).

In this proposed rule, we propose to: (1) remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) incorporate electronic clinical quality measures (eCQMs) into the existing validation process for chart-abstracted measures beginning with eCQM data from the CY 2027 reporting period affecting the CY 2030 payment determination; (3) reduce the validation selection pool from 500 to up to 400 HOPDs beginning with validation affecting the CY 2030 payment determination; and (4) remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation noncompliance, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination.

Additionally, as part of our proposal to incorporate eCQMs into the existing validation process for chart-abstracted measures beginning with CY 2027 eCQM data affecting the CY 2030 payment determination, we would: (1)

modify the number of chart-abstracted cases required for validation from 12 per quarter to a maximum of 8 per quarter per measure beginning with validation affecting the CY 2030 payment determination; (2) replace the previously finalized 2-year validation cycle with a 3-year validation cycle, where hospitals selected for validation based on CY 2027 data affecting the CY 2029 payment determination would not be selected again for validation of the same data affecting the CY 2030 payment determination; (3) determine eCQM validation scores using the same methodology currently used to score chart-abstracted measure validation; (4) revise the policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval; and (5) extend the educational review process established for chart-abstracted measure validation to eCQM validation.

In the CY 2026 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the Hospital Outpatient Quality Reporting Program by utilizing the Bureau of Labor Statistics (BLS) median hourly wage rate for Medical Records Specialists (90 FR 54029). Specifically, we used the industry-specific wage for Medical Records Specialists working in “general medical and surgical hospitals”, as this categorization aligns the closest with the Hospital Outpatient Quality Reporting Program care setting. The most recent data from BLS’ May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of \$28.59 per hour for Medical Records Specialists working in “general medical and surgical hospitals” (SOC 29–2072).²⁰⁹ We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$28.59 \times 2 = \$57.18$) to estimate total cost burden is reasonably accurate. Accordingly, unless otherwise specified, we calculate cost burden to hospitals using a wage plus benefits estimate of \$57.18 per hour throughout the discussion in this section of this proposed rule for the

²⁰⁹ U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at <https://data.bls.gov/oes/#/industry/622100/2025>. Accessed: May 18, 2026.

Hospital Outpatient Quality Reporting Program.

In the CY 2026 OPPI/ASC final rule with comment period, our burden estimates assumed that approximately 3,200 hospital outpatient departments (HOPDs) will report data to the Hospital Outpatient Quality Reporting Program (90 FR 54029). For this proposed rule, based on the most recent available data from the CY 2026 Hospital Outpatient Quality Reporting Program payment determination, we estimate that 3,000 HOPDs will report data to the Hospital Outpatient Quality Reporting Program for the CY 2027 reporting period/CY 2029 payment determination and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

As discussed in section XIV.B. of this proposed rule, we propose removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. For this measure, HOPDs are required to abstract data from patient charts as well as report the measure electronically via CMS' Hospital Quality Reporting (HQR) system. According to the current Hospital Outpatient Quality Reporting Program Specifications Manual, the sample size requirement for HOPDs with populations of 900 patients or less is 63 cases annually, and the requirement for HOPDs with populations of greater than 900 patients is 96 cases annually.²¹⁰ To be conservative, we base our burden estimates on an estimate of 96 cases per HOPD annually. Under OMB control number 0938–1109, the currently approved burden is 2.92 minutes (0.049 hours) per case for chart-abstraction and 10 minutes (0.167 hours) per HOPD to report the measure via the HQR. Therefore, we estimate that this proposal would result in a decrease in burden for all 3,000 HOPDs of 14,612 hours [(0.049 hours × 96 cases × 3,000 HOPDs) + (0.167 hours × 3,000 HOPDs)] at a savings of \$835,514 (14,612 hours × \$57.18) beginning with the CY 2027 reporting period.

3. Information Collection Burden Estimate for the Proposed Validation of eCQMs Beginning With Validation of CY 2027 Data Affecting the CY 2030 Payment Determination

As discussed in section XV.D. of this proposed rule, we propose to incorporate eCQMs into the Hospital Outpatient Quality Reporting Program's existing validation process for chart-abstracted measures. We assume HOPDs would only need to upload one PDF file per case to CMS' HQR system, and therefore estimate a burden of 1 minute (0.067 hours) per case per HOPD and propose to validate up to 32 eCQM cases annually from four calendar quarters of eCQM data (up to 8 cases × 4 quarters) for each eCQM with mandatory reporting, starting with validation of CY 2027 eCQM data affecting the CY 2030 payment determination. For purposes of estimating burden in this proposed rule, we assume 400 HOPDs would be selected for validation as discussed in section XXIV.A.4. of this proposed rule. If the proposed reduction of the validation selection pool from 500 to 400 HOPDs is not finalized in the CY 2027 OPPI/ASC final rule with comment period, we will revise our burden estimates in that final rule with comment period using the requirement for selection of 500 HOPDs currently approved under OMB control number 0938–1109. We note submission of medical documentation would occur in the CY immediately following the CY of the data being submitted (for example, CY 2027 data would be submitted in CY 2028, and CY 2028 data would be submitted in CY 2029). For the CY 2028 reporting period, in which HOPDs would be selected for validation of the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM, we estimate an increase in burden of 213 hours across the 400 HOPDs selected for eCQM validation (0.0167 hours × 4 quarters × 8 cases × 400 HOPDs) at a cost of \$12,198 (213 hours × \$57.18). For the CY 2029 reporting period and subsequent years, in which HOPDs would be selected for validation of both the STEMI and Emergency Care Access & Timeliness eCQMs, we estimate an increase in burden of 427 hours across the 400 HOPDs selected for eCQM validation (0.0167 hours × 4 quarters × 16 cases × 400 HOPDs) at a cost of \$24,397 (427 hours × \$57.18).

As discussed in section XV.D. of this proposed rule, we propose policies which would align the proposed incorporation of eCQMs into the existing validation process for chart-abstracted measures beginning with CY 2027 eCQM data affecting the CY 2030

payment determination. Specifically, we propose to modify the number of cases selected for chart-abstracted measure validation under the Hospital Outpatient Quality Reporting Program to align with the proposed number of cases selected for eCQM validation. We also propose to validate up to 32 randomly selected patient cases annually for each chart-abstracted measure. Under these proposals, we would validate up to 32 randomly selected patient cases for chart-abstracted clinical process of care measures (up to 8 cases per quarter), starting with validation of CY 2027 data affecting the CY 2030 payment determination. Submission of medical documentation will occur in the CY immediately following the CY of the data being submitted (for example, CY 2027 data will be submitted in CY 2028). As currently approved under OMB control number 0938–1109, selected HOPDs are required to submit medical documentation for validation for 48 cases (12 cases per quarter), for which we estimate an information collection burden of 15 minutes (0.25 hours) per case, or 12 hours per HOPD (0.25 hours/case × 48 cases). For the CY 2028 reporting period, in which HOPDs would be selected for validation of both the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients and the Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival measures, we estimate the burden associated with these proposals for the 400 HOPDs selected for validation to be 6,400 hours (0.25 hours × 64 cases × 400 HOPDs) at a cost of \$365,952 (6,400 hours × \$57.18). For the CY 2029 reporting period, in which HOPDs would be selected for validation of only the Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation Within 45 Minutes of Arrival measures, we estimate the burden associated with these proposals for the 400 HOPDs selected for validation to be 3,200 hours (0.25 hours × 32 cases × 400 HOPDs) at a cost of \$182,976 (3,200 hours × \$57.18). We discuss the revised information collection burden for all HOPDs selected for chart-abstracted measure validation in section XXIV.A.4. of this proposed rule where we discuss our proposal to modify the validation

²¹⁰ CMS. (2025). Hospital OQR Program Specifications Manual Release Notes version 19.0. Available at https://qualitynet.cms.gov/files/69274c02ec892eacec2209b5?filename=OQR_SpecManual_v19.0a.pdf.

selection pool from 500 HOPDs to 400 HOPDs.

Additionally, we propose to replace the previously finalized 2-year validation cycle with a 3-year validation cycle beginning with CY 2027 data affecting the CY 2030 payment determination, under which validation results for a single year of data would be applied to the applicable payment determination 3 years later. Under this proposal, HOPDs selected for chart-abstracted measure validation based on CY 2027 data, affecting the CY 2029 payment determination, would not be selected again for validation of the same data affecting the CY 2030 payment determination. We also propose to determine eCQM validation scores using the methodology currently used to score chart-abstracted measure validation; revise our policy to allow the results of educational reviews for all four quarters of chart-abstracted measure validation to be reflected in the final validation score prior to the calculation of the confidence interval; and extend the educational review process established for chart-abstracted measure validation to eCQM validation. These proposed changes to the HOPD selection and targeting methodology, validation cycles, scoring methodology, validation scoring, and the educational review process would not affect information collection burden as neither the amount of data nor frequency of data submission is impacted.

4. Information Collection Burden Estimate for the Proposed Modification of the Validation Selection Pool From 500 to up to 400 HOPDs Beginning With Validation of CY 2027 Data Affecting the CY 2030 Payment Determination

As discussed in section XV.D.2.a. of this proposed rule, we propose to reduce the number of hospitals selected at random for validation from 450 HOPDs to up to 200 HOPDs and to increase the number of hospitals selected by targeting criteria from 50

HOPDs to up to 200 HOPDs, for a total of up to 400 HOPDs selected each year beginning with validation of CY 2027 data affecting the CY 2030 payment determination. For purposes of estimating burden in this proposed rule, we assume HOPDs would be required to submit medical record documentation for 32 cases as discussed in section XXIV.A.3. of this proposed rule. If the proposed modification to modify the number of required cases from 48 to 32 cases per chart-abstracted measure is not finalized in the CY 2027 OPPI/ASC final rule with comment period, we will revise our burden estimates using the requirement of 48 cases currently approved under OMB control number 0938–1109. As discussed in section XXIV.A.3. of this proposed rule, for the CY 2028 reporting period, we estimate these two proposals would result in a revised total burden of 6,400 hours (0.25 hours $\times$ 4 quarters $\times$ 16 cases $\times$ 400 HOPDs) at a cost of \$365,952 (6,400 hours $\times$ \$57.18) if finalized; an increase of 400 hours and \$22,872 from our currently approved burden of 6,000 hours and \$343,080. For the CY 2029 reporting period, we estimate these two proposals would result in a revised total burden of 3,200 hours (0.25 hours $\times$ 4 quarters $\times$ 8 cases $\times$ 400 HOPDs) at a cost of \$182,976 (3,200 hours $\times$ \$57.18) if finalized; a decrease of –2,800 hours and \$160,104 from our currently approved burden estimate.

5. Information Collection Burden Estimate for the Proposed Removal of the Requirement for Hospitals To Resubmit Medical Documentation as Part of a Validation Reconsideration Request, Beginning With Data From the CY 2026 Reporting Period Affecting the CY 2028 Payment Determination

As discussed in section XV.E. of this proposed rule, we propose to remove the requirement for HOPDs to resubmit medical documentation as part of their request for reconsideration of validation noncompliance, beginning with data

from the CY 2026 reporting period affecting the CY 2028 payment determination. Instead, we would re-use the medical documentation previously submitted by the HOPD during the validation process. The removal of this requirement would not affect burden related to validation requirements, as reconsideration is an optional administrative activity, and HOPDs would still be required to submit the same number of requested medical records to validate the accuracy of eCQM data (the extent to which data abstracted from the submitted medical record matches the data submitted in the QRDA I file). Additionally, as currently approved under OMB control number 0938–1109, consistent with regulations under the Paperwork Reduction Act of 1995, 5 CFR 1320.4, the burden associated with filing a Reconsideration Request is excluded from our calculation of information collection burden because this collection occurs during the conduct of an administrative action.

6. Summary of Information Collection Burden Estimates for the Hospital OQR Program

Tables 82 through 84 summarize the information collection burden changes under OMB control number 0938–1109. We estimate that the proposed measure removal and modifications to the validation process in this proposed rule would result in a net decrease in information collection burden of 16,985 hours at a savings of \$971,221 annually for all 3,000 program-eligible HOPDs beginning with the CY 2029 reporting period/CY 2031 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109. With respect to any costs/burdens unrelated to data submission, we refer readers to the regulatory impact analysis in section XXVII. of this proposed rule.

TABLE 82: SUMMARY OF PROPOSED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period							
Activity	Estimated time per record (minutes)	Number of reporting quarters per year	Number of HOPDs reporting	Average number records per HOPDs per quarter	Annual burden (hours) per HOPD	Proposed annual burden (hours) across HOPDs	Previously finalized annual burden (hours) across HOPDs	Net difference in annual burden hours
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
	Total Change in Information Collection Burden Hours: -14,612							
	Total Cost Estimate: Updated Hourly Wage (\$57.18) x Change in Burden Hours (-14,612) = -\$835,514							

TABLE 83: SUMMARY OF PROPOSED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Reporting Period							
Activity	Estimated time per record (minutes)	Number of reporting quarters per year	Number of HOPDs reporting	Average number records per HOPDs per quarter	Annual burden (hours) per HOPD	Proposed annual burden (hours) across HOPDs	Previously finalized annual burden (hours) across HOPDs	Net difference in annual burden hours
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
Implement Updates to Chart-Abstracted Measure Validation	15	4	400	16	8	6,400	6,000	400
Implement eCQM Validation	1	4	400	8	0.533	213	0	213
	Total Change in Information Collection Burden Hours: -13,999							
	Total Cost Estimate: Updated Hourly Wage (\$57.18) x Change in Burden Hours (-13,999) = -\$800,444							

TABLE 84: SUMMARY OF PROPOSED HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2031 PAYMENT DETERMINATION

Activity	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Reporting Period							
	Estimated time per record (minutes)	Number of reporting quarters per year	Number of HOPDs reporting	Average number records per HOPDs per quarter	Annual burden (hours) per HOPD	Proposed annual burden (hours) across HOPDs	Previously finalized annual burden (hours) across HOPDs	Net difference in annual burden hours
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	3,000	96	4.7	0	14,112	-14,112
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Measure Reporting)	10	1	3,000	1	0.167	0	500	-500
Implement Updates to Chart-Abstracted Measure Validation	15	4	400	8	8	3,200	6,000	-2,800
Implement eCQM Validation	1	4	400	16	1.067	427	0	427
	Total Change in Information Collection Burden Hours: -16,985							
	Total Cost Estimate: Updated Hourly Wage (\$57.18) x Change in Burden Hours (-16,985) = -\$971,221							

B. ICRs for the Rural Emergency Hospital (REH) Quality Reporting Program

1. Background

In section XVI. of this proposed rule, we summarize the previously approved requirements for the REH Quality Reporting Program. We are not proposing any changes to the previously finalized REH Quality Reporting Program policies in this proposed rule. The REH Quality Reporting Program is generally aligned with the CMS quality

reporting program for HOPDs, known as the Hospital Outpatient Quality Reporting Program. We refer readers to the CY 2026 OPPI/ASC final rule with comment period (90 FR 54037 through 54041) for detailed discussions of the previously finalized REH Quality Reporting Program ICRs, which have been approved under OMB control number 0938-1454 (expiration date December 31, 2026).

In the CY 2026 OPPI/ASC final rule with comment period, we calculated reporting burden estimates for the REH

Quality Reporting Program by utilizing the BLS median hourly wage rate for Medical Records Specialists (90 FR 54037). Specifically, we used the industry-specific wage for Medical Records Specialists working in the “general medical and surgical hospitals” industry, as this categorization aligns the closest with the REH Quality Reporting Program care setting. The most recent data from BLS’ May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of \$28.59

per hour for Medical Records Specialists working in “general medical and surgical hospitals” (SOC 29–2072).²¹¹ We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, doubling the hourly wage rate ($\$28.59 \times 2 = \$57.18$) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to REHs using a wage plus benefits estimate of \$57.18 per hour throughout the discussion in this section of this rule for the REH Quality Reporting Program.

In the CY 2026 OPPI/ASC final rule with comment period, our burden estimates were based on the 38 acute care and critical access hospital conversions to REH status as of April 11, 2025 (90 FR 54037). For this proposed rule, based on the actual number of acute care and critical access hospital conversions to REH status as of April 6, 2026, we estimate that 48 REHs will report data to the REH Quality Reporting Program during the CY 2027 reporting period unless otherwise noted. While the exact number of REHs required to submit data may vary due to status changes to and from an REH, as reiterated in section XVI. of this proposed rule, REHs are required by statute to submit quality data. Therefore, we assume that all 48 REHs will submit data under the REH Quality Reporting Program for the CY 2027 reporting period and subsequent years.

2. Revised Information Collection Burden Estimates for Currently Approved Measures

Our currently approved information collection burden estimates of 464 hours at a cost of \$26,532 (using revised wage rates) are based on an estimate of 38 REHs reporting data for the REH Quality Reporting Program. This burden is entirely associated with the reporting of chart-abstracted measures as REHs have the option to report either the Median Time for Discharged Emergency Department (ED) Patients measure or the Emergency Care Access & Timeliness eCQM to meet program requirements, and the estimated burden for the Median Time for Discharged ED Patients is greater than the estimated burden for

the Emergency Care Access & Timeliness eCQM. As discussed in section XXIV.B.1. of this proposed rule, we are updating our assumption of the number of REHs that will submit data under the REH Quality Reporting Program from 38 REHs to 48 REHs, an increase of 10 REHs. Our currently approved burden estimates assume that for chart-abstracted measures where patient-level data are submitted directly to CMS, REHs require 2.9 minutes, or 0.049 hours per case per measure to collect and submit the data for each submitted case. We further assume that each REH will abstract and submit data from 63 cases per quarter, for a total of 252 cases per year. Therefore, we estimate each REH requires 12.2 hours ($0.049 \text{ hours} \times 252 \text{ cases}$) at a cost of approximately \$698 ($12.2 \text{ hours} \times \$57.18$) to collect and report data for the Median Time for Discharged ED Patients measure. For the increase of 10 REHs, we estimate an increase in annual chart-abstractation burden of 122 hours ($12.2 \text{ hours} \times 10 \text{ REHs}$) at a cost of \$6,976 ($122 \text{ hours} \times \$57.18$).

C. ICRs for the Ambulatory Surgical Center (ASC) Quality Reporting Program

1. Background

In sections XIV. and XVII. of this proposed rule, we discuss the proposed requirements for the ASC Quality Reporting Program. We refer readers to the CY 2026 OPPI/ASC final rule with comment period (90 FR 54041 through 54045) for detail regarding the previously finalized ASC Quality Reporting Program ICRs which are currently under review for approval under OMB control number 0938–1270 (expiration date June 30, 2026). We propose to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination.

In the CY 2026 OPPI/ASC final rule with comment period, we calculated reporting burden estimates for the ASC Quality Reporting Program by utilizing the BLS median hourly wage rate for Medical Records Specialists (90 FR 54042). Specifically, we used the industry-specific wage for Medical Records Specialists working in the “general medical and surgical hospitals” industry, as this categorization aligns the closest with the ASC Quality Reporting Program care setting. The most recent data from BLS’ May 2025 National Occupational Employment and Wage Estimates reflects a median hourly wage of \$28.59 per hour for Medical Records Specialists

working in “general medical and surgical hospitals” (SOC 29–2072).²¹² We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, doubling the hourly wage rate ($\$28.59 \times 2 = \$57.18$) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to ASCs using a wage plus benefits estimate of \$57.18 per hour throughout the discussion in this section of this rule for the ASC Quality Reporting Program.

Based on the most recent analysis of the CY 2026 payment determination data, we found that of the 6,930 ASCs that were actively billing Medicare, 4,399 were required to participate in the ASC Quality Reporting Program. Of the 2,531 ASCs not required to participate in the program, 650 ASCs did so and met full requirements. On this basis, we estimate that 5,149 ASCs ($4,399 + 650$) will submit data for the ASC Quality Reporting Program for the CY 2027 reporting period/CY 2029 payment determination and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination

As discussed in section XIV.B. of this proposed rule, we propose removal of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. For this measure, ASCs are required to both abstract data from patient charts as well as report the measure electronically via the HQR system. Regarding the number of cases required for chart-abstractation, based on the current ASC Quality Reporting Program Specifications Manual, we estimate that each participating ASC will abstract and submit data for the minimum yearly sample size of 63 annually.²¹³ Under OMB control number 0938–1270, the currently approved burden is 2.92 minutes (0.049

²¹¹ U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at: <https://data.bls.gov/oes/#/industry/622100/2025>. Accessed: May 18, 2026.

²¹² U.S. Bureau of Labor Statistics. (2026). Occupational Outlook Handbook, Medical Records Specialists. Available at: <https://data.bls.gov/oes/#/industry/622100/2025>. Accessed: May 18, 2026.

²¹³ https://qualitynet.cms.gov/files/692dbe71ec892eacec22890b?filename=ASC_v15.0a_FullSpecMan.pdf.

hours) per case for chart-abstraction and 10 minutes (0.167 hours) per ASC to report the measure via the HQR. Therefore, we estimate that this proposal would result in a decrease in burden for all 5,149 ASCs of 16,753 hours [(0.049 hours × 63 cases × 5,149 ASCs) + (0.167 hours × 5,149 ASCs)] at a savings of \$957,937 (16,753 hours × \$57.18).

3. Summary of Information Collection Burden Estimates for the ASC Quality Reporting Program

Table 85 summarizes the information collection burden changes for OMB control number 0938–1270. We estimate the proposed measure removal in this proposed rule would result in a decrease in information collection burden of 16,753 hours at a savings of

\$957,937 annually for all 5,149 program-eligible ASCs beginning with the CY 2027 reporting period/CY 2029 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270. With respect to any costs/burdens unrelated to data submission, we refer readers to the regulatory impact analysis in section XXVII. of this proposed rule.

TABLE 85: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION
COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029
PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Reporting Period								
Activity	Estimated time per record (minutes)	Number of reporting quarters per year	Number of ASCs reporting	Average number records per ASC per quarter	Annual burden (hours) per ASC	Proposed annual burden (hours) across ASCs	Previously finalized annual burden (hours) across ASCs	Net difference in annual burden hours
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Chart Abstraction)	2.92	1	5,149	63	3.1	0	15,895	-15,895
Remove Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure (Reporting)	10	1	5,149	1	0.167	0	858	-858
Total Change in Information Collection Burden Hours: -16,753								
Total Cost Estimate: Updated Hourly Wage (\$57.18) x Change in Burden Hours (-16,753) = -\$957,937								

D. ICRs for the Implementation of Section 6225 of the Consolidated Appropriations Act, 2026 for the Requirements for Provider-Based Status (§ 413.65)

The requirements for a determination that a facility or an organization has provider-based status are in the regulations at § 413.65. Section 6225 of the CAA, 2026 added paragraph (23) to section 1833(t) of the Act, and prohibits Medicare payments for items and

services furnished on or after January 1, 2028, unless off-campus outpatient departments of a provider meet certain conditions. New section 1833(t)(23)(A) of the Act requires, as a condition of receiving payment, that off-campus outpatient departments of a provider obtain and bill under separate NPIs and that main providers submit provider-based attestations in accordance with provisions at § 413.65. New section 1833(t)(23)(B)(i) of the Act requires the Secretary, through notice and comment

rulemaking, to establish a process for each provider with an off-campus outpatient department to submit an initial and subsequent attestation, for the review of each such attestation and for the determination, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether each off-campus outpatient department is compliant with the requirements described in subparagraph (A). In addition, new section 1833(t)(23)(C) defines an “off-

campus outpatient department of a provider” for purposes of paragraph (23) as a department of a provider (as defined in § 413.65) that is not located on the campus (also defined in § 413.65) of the main provider or is not within the distance described in such definition of campus from a remote location of a hospital (also defined in § 413.65).

As discussed in greater detail section XX. of this proposed rule, we propose modifications to the provider-based regulations at § 413.65 to implement the new requirements of section 6225 of the CAA, 2026. Among those proposals, we propose to revise § 413.65(b) to add a reference to the new mandatory attestation requirement for an off-campus outpatient department of a provider required by section 6225 of the CAA, 2026 and propose a maximum 5-year timeframe for any subsequent attestation(s). In addition, we propose to establish a standardized attestation form for provider-based determinations, in connection with the provisions of section 6225 of the CAA, 2026, and propose that providers would submit the attestation through a centralized electronic system. The standardized form would replace the current MAC-specific templates. We also propose to eliminate the mandatory requirement for off-campus provider-based facilities or organizations to supply supporting documentation at the time of attestation. Under our proposal, until the standardized form and centralized electronic system are finalized, providers may continue to submit attestations using the current process in satisfaction of section 6225 of the CAA, 2026.

The collection of information requirements for the existing regulations at § 413.65 that govern the requirements for a determination that a facility or an organization has provider-based status is associated with OMB control number 0938–0798 (expiration date December 31, 2027). For the existing attestation requirement in § 413.65(b)(3), OMB has currently approved 2,500 hours of burden at a cost of approximately \$327,150 based on accounting for information collection burden experienced by approximately 250 main providers. This estimated burden is based on the expectation that it would take a main provider 10 hours per attestation and each main provider would submit 1 attestation. In this proposed rule, we describe the burden changes regarding collection of information, under OMB control number 0938–0798.

The burden associated with this new attestation requirement continues to be the time for the main provider to report

the facility’s status to CMS and furnish the necessary documentation to support a provider-based determination. We believe this is reasonable as the information submitted by the provider is typically information that the provider already has regarding their business. However, as discussed in greater detail in section XX.3. of this proposed rule, under the proposal to establish a standardized attestation form for provider-based determinations that providers would submit through a centralized electronic system, we expect there would be a reduction in administrative burden for providers, and a more efficient review process for MACs and CMS. We anticipate that this reduction in administrative burden for providers would decrease the time required to submit each attestation by 25 to 75 percent.

As discussed in section XX.C. of this proposed rule, under existing regulations the attestation process was required only if the main provider sought a CMS determination of provider-based status. However, under the provisions of section 6225 of the CAA, 2026, Medicare payments will be prohibited unless off-campus outpatient departments of a provider meet certain conditions, including that the main provider has submitted an initial provider-based status attestation that the off-campus outpatient department is compliant with the requirements described in section § 413.65 (or a successor regulation); and the main provider has submitted a subsequent attestation within the timeframe specified by the Secretary. As a result of this new mandatory attestation requirement, we expect there to be an increase in both the number of main providers submitting attestations and the number of attestations submitted by each main provider. Under these new provider-based status attestation requirements, it is estimated that 1,832 main providers would take 5 hours per attestation, and, on average, each main provider would submit 9 attestations for provider based departments. Therefore, we have calculated the burden as follows: 16,488 responses times 5 hours per response = 82,440 burden hours. We believe that an executive officer will be making the attestation because an executive officer is in the best position to have access to the business information required to make the attestation. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2024) at http://www.bls.gov/oes/current/oes_nat.htm# for Category 11–0000 for the position of Top Executives,

the mean hourly wage for a top executive is \$67.24. We have added 100 percent for fringe and overhead benefits, which calculates to \$134.48 per hour. We estimate the total cost is \$11,086,531 (82,440 hours × \$134.48 per hour). The estimated number of attestations has increased due to section 6225 of the CAA, 2026 requiring providers submit attestations for all off-campus provider-based departments. As such, the estimated number of attestations has increased from 250 to 16,488 and the estimated total cost has increased from \$327,150 to \$11,086,531.

E. ICRs for Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPTS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services (84 FR 61142, 61446 through 61456).²¹⁴ As part of the CY 2021 OPPTS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, 86236 through 86248). Through the CY 2023 OPPTS/ASC final rule with comment period, we added an eighth service category to the list of OPD services requiring prior authorization (87 FR 71748, 72224 through 72233.) The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to expand the Botulinum Toxin Injection service category to include additional codes requiring prior authorization. To improve readability and brevity, as we indicated earlier in the preamble, effective dates were removed and the section numbering in the regulatory text was updated. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) have been renumbered as (a)(1) through (8). The additional Botulinum Toxin Injection codes would be added to existing codes located at proposed revised § 419.83 (a)(2) and would require prior authorization beginning for service dates on or after July 1, 2027.

The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by

²¹⁴ See also Correction Notice issued January 3, 2020 (85 FR 224).

providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. The request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the additional Botulinum Toxin Injection codes will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (Medicare Administrative Contractor) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task would be 30 minutes, which is equivalent to that for normal prepayment or postpayment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we

estimate a cost of \$5 per request for mailing medical records. Based on CY 2024 data for the new services, we estimate that annually, there would be 17,699 initial requests mailed during a year. In addition, we estimate there would be 5,808 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated at \$117,537 (23,507 mailed requests × \$5). We also estimate that an additional 3 hours per provider would be required to attend educational meetings, train staff on what services require prior authorization, and review training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS 2024 rate for Healthcare Support Workers, All Other,²¹⁵ we estimate an average median clerical hourly rate of \$22.14 with a loaded rate of \$44.28. The prior authorization program for the new services will not create any new documentation requirements. Instead, it will only require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff will

need to spend more time completing the documentation that will be needed in the absence of the prior authorization policy. The hourly rate reflects the time required for the additional clerical work of submitting the prior authorization request. We believe providers will need to educate their staff on what services are included in the prior authorization process. Following this education, the staff will know which services need prior authorization and will not need additional time or resources to determine whether a service requires prior authorization. We estimate that the total annual number of submissions would be 78,358 (54,851 submissions via fax or electronic means + 23,507 mailed submissions). The annual burden hours for the new services, allotted across all providers, would be 41,555 hours (0.5 hours × 78,358 submissions plus 3 hours × 792 providers for education). The annual burden cost would be \$1,957,592 (41,555 hours × \$44.28 plus \$117,537 for mailing costs). The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval.

Table 86 is a chart reflecting the total burden and associated costs for the provisions included in this proposed rule.

TABLE 86: TOTAL BURDEN FOR NEW SERVICES

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Addition of Additional Services for Hospital OPD Prior Authorization Process	+41,555	+\$1.96 M

* Numbers rounded.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by the date and time specified in the **DATES** section of this rule.

XXV. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR

59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled “Copayment Capped at the Inpatient Deductible of \$1,364.00” where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled “Drug Pass-Through

Expiration during Calendar Year” where we flag, through the use of an asterisk, each drug for which pass-through payment is expiring during the calendar year on a date other than December 31. In the CY 2026 final rule with comment period (90 FR 54058), we retained these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled “Drug Pass-Through Expiration during Calendar Year” to include devices, so that the column reads: “Drug and Device Pass-Through

²¹⁵ https://www.bls.gov/oes/current/oes_nat.htm.

Expiration during Calendar Year” where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82131), we deleted the column titled “Copayment Capped at the Inpatient Deductible” and instead added a new column for “Adjusted Beneficiary Copayment” to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also added another column for notes. The “Note” column contains multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

In addition, for CY 2024, we updated the format of the OPPS Addenda A, B, and C by adding another column for “IRA Coinsurance Percentage” to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the IRA.

In the CY 2026 OPPS/ASC proposed rule, we proposed that for CY 2026 and subsequent years to keep the same format for the addenda A, B, and C, and we did not propose any additional changes for CY 2026 (90 FR 33837). In the CY 2026 OPPS/ASC final rule with comment period, we finalized our policy as proposed (90 FR 54058).

For CY 2027, we are not proposing any changes relating to the format for the addenda A, B, and C.

To view the Addenda to this proposed rule pertaining to CY 2027 proposed payment rates under the OPPS, we refer readers to the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices> select “CMS–1850–P” from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled “2027 NPRM OPPS Addenda” in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2027 proposed payment rates under the ASC payment system, we refer readers to the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical->

center-asc/asc-regulations-and-notices; select “CMS–1850–P” from the list of regulations. The ASC Addenda to this proposed rule are contained in a zipped folder titled “2027 NPRM Addendum AA, BB, DD1, DD2, EE, and FF” in the related links section at the bottom of the page.

XXVI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule; and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXVII. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2027. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2025 through and including December 31, 2025, and processed through June 30, 2026, and update HCRIS cost report information.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2027, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2027. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be

performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. In the CY 2024 OPPS/ASC final rule with comment period, we finalized a policy to extend the 5-year interim period by an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting (88 FR 81960). As discussed in section XIII. of this proposed rule, we propose to extend our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2027). The ASC impacts discussed below reflect our application of the hospital market basket update for CY 2027.

In addition, this proposed rule is necessary to make policy changes for facilities reporting data under the Hospital OQR and ASCQR Programs. The primary objective of these quality reporting programs is to promote higher quality, more efficient health care for Medicare beneficiaries by collecting and reporting on quality-of-care metrics. This information is made available to consumers, both to empower Medicare beneficiaries and inform decision making, as well as to incentivize healthcare facilities to make continued improvements.

B. Overall Impact of Provisions of This Proposed Rule

We have examined the impacts of this rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13132, “Federalism”; Executive Order 13563, “Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive

impacts; and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President’s priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, the Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

We estimate that the total increase in Federal Government expenditures under the OPSS for CY 2027, compared to CY 2026, due to the changes to the OPSS in this proposed rule, will be approximately \$1.82 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2027 we estimate that the OPSS expenditures, including beneficiary cost-sharing, for CY 2027 will be approximately \$110.9 billion, which is approximately \$9.5 billion higher than estimated OPSS expenditures in CY 2026. We also estimate that the proposed 3.0 percentage point adjustment for the 340B Remedy Offset is expected to reduce overall OPSS payments by \$2.3 billion in CY 2027. Table 88 of this proposed rule displays the distributional impact of the CY 2027 changes in OPSS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2027 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. However, under the proposed 340B drug payment policy for CY 2027, we would pay for drugs acquired through the 340B Drug program at ASP minus 33.4 percent.

We estimate that the proposed update to the conversion factor will increase total OPSS payments by 2.4 percent in

CY 2027. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including ECHs, and the proposed payment adjustment for cancer hospitals would not increase total OPSS payments because these changes to the OPSS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2026 and CY 2027, considering all budget-neutral payment adjustments, proposed changes in estimated total outlier payments, the application of the frontier State wage adjustment, the proposed payment adjustment for imaging without contrast services furnished at excepted off campus PBDs, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act will increase total estimated OPSS payments by 1.9 percent. We note that, as previously discussed in section V.B.7 of this proposed rule, we propose to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies by 3.0 percentage points in CY 2027. We estimate that this reduction would reduce OPSS spending by approximately \$2.3 billion in CY 2027.

We estimate the total increase (from changes to the ASC provisions in this proposed rule, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2027 compared to CY 2026, to be approximately \$520 million. Tables 89 and 90 of this proposed rule display the redistributive impact of the CY 2027 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPSS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2027 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2027 on the CMS website with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to

the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient>. On the website, select “Regulations and Notices” from the left side of the page and then select “CMS–1850–P” from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 88 of this proposed rule. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Proposal To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider Based Departments (PBDs)

In section X.A. of this proposed rule, we discuss our CY 2027 proposal to control for unnecessary increases in the volume of outpatient services by paying for imaging without contrast services furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). Specifically, we proposed to pay for HCPCS codes billed with modifier “PO” and assigned to and paid through imaging without contrast APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate).

To develop an estimated impact of this policy, we began with CY 2025 outpatient claims data used, for claim lines with HCPCS codes assigned for payment through imaging without contrast APCs 5521 through 5524 and

composite imaging without contrast APCs 8004, 8005, and 8007 that contained modifier “PO” because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPSS. We then simulated payment for the remaining claim lines as if they were paid at the PFS-equivalent rate, removing a portion of the payment associated with rural sole community hospitals based on our finalized exception for those hospitals. An estimate of the proposed policy that

includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2027 Mid-Session review budget approximates the estimated decrease in total payments at \$260 million, with Medicare OPSS payments decreasing by \$190 million and beneficiary copayments decreasing by \$70 million in CY 2027.

This estimate is utilized for the accounting statement displayed in Table 87 of this proposed rule because the impact of this proposed CY 2027 policy, which is not budget neutral, is combined with the impact of the OPD

update, which is also not budget neutral, to estimate changes in Medicare spending under the OPSS as a result of the changes in this proposed rule.

We note our estimates may differ from the actual effect of the proposed policy due to offsetting factors, such as changes in provider behavior. We note that by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of imaging without contrast services provided in the excepted off-campus PBD setting.

TABLE 87: ESTIMATED EFFECT OF CHANGES TO IMAGING WITHOUT CONTRAST SERVICES WHEN FURNISHED AT EXCEPTED OFF-CAMPUS PROVIDERS (IN \$ MILLIONS)

CY	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027 – 2036
Part B Trust Fund benefits	(260)	(690)	(770)	(840)	(920)	(1,010)	(1,120)	(1,220)	(1,320)	(1,430)	(9,580)
Premium offset	70	170	190	210	230	260	280	310	330	360	2,410
Net Part B Trust Fund impact	(190)	(520)	(580)	(630)	(690)	(750)	(840)	(910)	(990)	(1,070)	(7,170)
Beneficiary cost-sharing	(70)	(180)	(200)	(210)	(240)	(260)	(280)	(310)	(340)	(360)	(2,450)

c. Estimated Effects of OPSS Changes on Hospitals

Table 88 shows the estimated impact of the proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children’s hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 88, and we discuss them separately below, because CMHCs are paid only for partial hospitalization and intensive outpatient program services under the OPSS and are a different provider type from hospitals. In the CY 2025 OPSS/ASC final rule with comment period (89 FR 94269 through 94270), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2027, we propose to maintain the same APC structure and we propose to continue our CY 2026 methodology for calculating rates by applying the 40

percent Medicare Physician Fee Schedule (MPFS) Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs.

The estimated increase in the total payments made under the OPSS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2027 is 3.2 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.2 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is a proposed 0.8 percentage point for CY 2027 (which is also the

productivity adjustment for FY 2027 in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19850)) resulting in the proposed CY 2027 OPD fee schedule increase factor of 2.4 percent. We are using the OPD fee schedule increase factor of 2.4 percent in the calculation of the proposed CY 2027 OPSS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 88 of this proposed rule.

To illustrate the impact of the CY 2027 changes, our analysis begins with a baseline simulation model that uses the CY 2026 relative payment weights, the CY 2026 final OPSS wage indexes that include reclassifications, and the final CY 2026 conversion factor. Table 88 shows the estimated redistribution of the increase or decrease in payments for CY 2027 over CY 2026 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2026 and CY 2027

(Column 2); the wage indexes and the provider adjustments (Column 3); the effect of the proposed payment adjustment for drugs acquired through the 340B Program (Column 4); the combined impact of all of the changes described in the preceding columns plus the 2.4 percent OPD fee schedule increase factor update to the conversion factor (Column 5); the additional estimated impact for the proposed payment adjustment for imaging without contrast services furnished at excepted off campus PBDs (Column 6); the estimated impact taking into account all payments for CY 2027 relative to all payments for CY 2026, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 7).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we propose to maintain the current adjustment percentage for CY 2027. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected passthrough payment for CY 2027 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change, or what proportion of OPPS payments to the hospital are for services compared to drugs), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule redistribute money during implementation will also depend on changes in volume, practice patterns, and the mix of services billed between CY 2026 and CY 2027 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2027 would increase Medicare OPPS payments by an estimated 1.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 1.8 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers. We note that providers not considered "new providers" for purposes of the 340B remedy offset

would receive an adjustment to their OPPS payment rates of minus 3.0 percent, which we estimate reduces overall provider payment by 2.9 percent.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 88 shows the total number of facilities (3,471), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2025 hospital outpatient and CMHC claims data to model CY 2026 and CY 2027 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2026 or CY 2027 payment and entities that are not paid under the OPPS. The latter entities include CAHs, IHS and tribal hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,362), excluding the hold harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 39 CMHCs at the bottom of the impact table (Table 88) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals would experience an increase of 0.1, with the impact ranging from a decrease of 0.3 to an increase of 0.4, depending on the number of beds. Rural hospitals would

experience a decrease of 0.1 percent overall. Major teaching hospitals would experience a decrease of 0.3 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration, the updates for the wage indexes with the FY 2027 IPPS post-reclassification wage indexes, the rural adjustment, the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year and using a CY 2026 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2027 scaled weights and a CY 2026 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2025 and CY 2027.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2027 changes in wage index policy, discussed in section II.C. of this proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2027, as described in section II.E. of this proposed rule. We modeled a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2027 is 0.88, which is higher than the PCR target adopted in the CY 2026 OPPS/ASC final rule with comment period (90 FR 53501). We note that, in accordance with section 16002 of the 21st Century Cures Act, we apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we discuss in section II.F. of this proposed rule.

Column 3 also includes the effects of the proposed COLA factors for providers located in Hawaii and Alaska, which would apply to the non-labor portion of OPPS payments. This proposal is

discussed in detail in section X.C of this proposed rule.

Column 4: Effect of the Proposed Payment Adjustment for 340B Drugs

Column 4 demonstrates the total payment effect of the proposed payment adjustment for drugs acquired under the 340B Program from ASP plus 6 percent to ASP minus 33.4 percent. This column includes both the reduced payment for 340B acquired drugs and the increase to the conversion factor for budget neutrality purposes, which increases payment for all non-drug OPPS services. For rural sole community hospitals, this column shows a 5.7 percent increase, reflecting no payment adjustment for drugs (because these providers are proposed to be exempt from these reductions) and an 8.44 percent increase for non-drug services.

We also note that the proposed 340B drug payment policy described in this column can significantly affect an OPPS provider's estimated CY 2027 payment depending on the proportion of a provider's payment represented by drugs purchased through the 340B Drug Program. For providers that are excepted from the 340B drug payment proposal and for non-340B hospitals, we would generally expect an increase in these providers' estimated 2027 OPPS payments under this column, as they would receive an increase to their non-drug service payments through the budget neutral adjustment to the OPPS conversion factor due to this policy but no change to their drug payments. However, for 340B hospitals, estimated payment changes due to this policy would depend on the volume of 340B drugs the provider furnishes and how that compares to the volume of non-drug services provided by the provider. For most 340B providers, the decreased 340B drug payments will outweigh the increased payments for non-drug services.

Column 5: All Budget Neutrality Changes Combined With the Market Basket Update

Column 5 demonstrates the combined impact of all the proposed changes previously described and the proposed update to the conversion factor of 2.4 percent. Overall, these changes would increase payments to urban hospitals by 1.9 percent and to rural hospitals by 6.4 percent. Rural sole community hospitals would receive an estimated increase of 8.8 percent while other rural hospitals would receive an estimated increase of 2.5 percent.

Column 6—Proposed Off-Campus PBD Imaging Without Contrast Payment Policy

Column 6 displays the estimated effect of our proposed CY 2027 policy to pay for imaging without contrast services assigned to APCs 5521 through 5524 and composite imaging without contrast APCs 8004, 8005, and 8007 when billed with modifier "PO" at a PFS-equivalent rate. We note that the numbers provided in this column isolate the estimated effect of this proposed policy adjustment relative to the numerator of Column 5. Therefore, the numbers reported in Column 6 show how much of the difference between the estimates in Column 5 and the estimates in Column 7 are a result of the off-campus PBD imaging without contrast policy.

Column 7: All Changes With Outlier—Proposed CY 2027 Update

Column 7 depicts the full impact of the proposed CY 2027 policies on each hospital group by including the effect of all changes for CY 2027 and comparing them to all estimated payments in CY 2025. Column 7 shows the combined budget neutral effects of Columns 2 and 3 and 4; the effect of the off-campus provider-based department drug administration policy; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this proposed rule; the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XV. of this proposed rule); and other rule adjustments to the CY 2027 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2026 update (and assumed, for modeling purposes, to be the same number for CY 2027), we included 64 hospitals in our model because they had both CY 2024 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2027 would increase payments to all facilities by 1.9 percent for CY 2027. We modeled the independent effect of all changes in Column 7 using the final relative payment weights for CY 2026 and the proposed relative payment weights for CY 2027. We used the final conversion factor for CY 2026 of \$91.415 and a CY 2027 conversion factor of \$102.004 discussed in section II.B. of this proposed rule.

Column 7 contains simulated outlier payments for each year. We used the 1

year charge inflation factor used in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19808) of 7.3 percent (1.07310) to increase charges on the CY 2025 claims, and we used the overall CCR in the April 2026 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2026. Using the CY 2025 claims and a 7.3 percent charge inflation factor, we currently estimate that outlier payments for CY 2026, using a multiple threshold of 1.75 and a fixed-dollar threshold of \$6,225, would be approximately 1.19 percent of total payments. The estimated current outlier payments of 1.19 percent are incorporated in the comparison in Column 7. We used the same set of claims and a charge inflation factor of 15.1 percent (1.15154) and the CCRs in the April 2026 OPSF, with an adjustment of 0.977497 (91 FR 19808), to reflect relative changes in cost and charge inflation between CY 2026 and CY 2027, to model the proposed CY 2027 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of \$7,150. The charge inflation and CCR inflation factors are discussed in detail in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19807 through 19811).

Overall, we estimate that facilities would experience an increase of 1.9 percent under this proposed rule in CY 2027 relative to total spending in CY 2026. This projected increase (shown in Column 7) of Table 88 of this proposed rule reflects the proposed 2.4 percent OPD fee schedule increase factor, removing the 0.19 difference in estimated outlier payments between CY 2026 (1.19 percent) and CY 2027 (1.0 percent), including the 0.4 percent decrease due to the payment adjusted for drug administration at off campus PBDs, plus 0.12 percent for the change in the pass-through payment estimate between CY 2026 and CY 2027. We estimate that the combined effect of all changes for CY 2027 would increase payments to urban hospitals by 1.3 percent. Overall, we estimate that rural hospitals would experience a 5.9 percent increase as a result of the combined effects of all the changes for CY 2027.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes include a decrease of 3.1 percent for major teaching hospitals and an increase of 6.0 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 3.2 percent.

In our analysis, we also have categorized hospitals by type of

ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 1.4 percent, proprietary hospitals would experience an increase of 10.3 percent, and	governmental hospitals would experience a decrease of 1.3 percent. Reduction for Providers Subject to the 340B Remedy Offset In column 8 we have included additional information to account for	estimated payment changes in the CY 2027 OPPS for providers subject to the 340B Remedy Offset which we propose will be a 3.0 percent point decrease in CY 2027. BILLING CODE 4169-69-P

TABLE 88: ESTIMATED IMPACT OF PROPOSED CY 2027 CHANGES FOR SERVICES PROVIDED IN THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Nu mbe r of Hos pital s	APC Recali bratio n (all change s)	New Wage Index and Provi der Adjus tment s	340B Adjus tment	All Budg et Neut ral Chan ges (com bine d cols 2-4) with Mar ket Bask et Upda te	Paym ent Adjus tment for Imagi ng w/o Contr ast at Off Camp us Provi ders	All CY 2027 Pro pose d Cha nges	Impa ct of Adjus tment only for Provi ders Subje ct to 340B Reme dy Offse t
ALL PROVIDERS *		3,471	0.0	0.1	0.0	2.5	-0.4	1.9	-2.9
ALL HOSPITALS		3,362	0.1	0.0	-0.1	2.4	-0.4	1.8	-2.9
	(excludes hospitals held harmless and CMHCs)								
URBAN HOSPITALS		2,693	0.1	0.0	-0.5	1.9	-0.4	1.3	-2.9
	LARGE URBAN (>1M)	1,274	0.1	-0.2	-0.9	1.4	-0.4	1.0	-2.9
	OTHER URBAN (<=1 M)	1,419	0.1	0.1	-0.3	2.3	-0.4	1.6	-2.9
RURAL HOSPITALS		669	-0.1	0.5	3.5	6.4	-0.1	5.9	-3.0
	SOLE COMMUNITY	329	-0.2	0.7	5.7	8.8	0.0	8.3	-3.0
	OTHER RURAL	340	-0.1	0.2	-0.1	2.5	-0.3	2.0	-3.0
BEDS (URBAN)									
	0 - 99 BEDS	918	0.4	0.1	4.8	7.9	-0.2	7.5	-2.7
	100 - 199 BEDS	741	0.3	0.1	3.0	6.0	-0.3	5.4	-2.9
	200 - 299 BEDS	426	0.4	-0.2	2.0	4.6	-0.5	4.1	-2.9
	300 - 499 BEDS	377	0.3	-0.1	0.3	2.9	-0.4	2.3	-2.9
	500 + BEDS	231	-0.3	0.0	-5.2	-3.2	-0.5	-4.0	-2.9

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Nu mbe r of Hos pital s	APC Recali bratio n (all change s)	New Wage Index and Provi der Adjus tment s	340B Adjus tment	All Budg et Neut ral Chan ges (com bine d cols 2-4) with Mar ket Bask et Upda te	Paym ent Adjus tment for Imagi ng w/o Contr ast at Off Camp us Provi ders	All CY 2027 Pro pose d Cha nges	Impa ct of Adjus tment only for Provi ders Subje ct to 340B Reme dy Offse t
BEDS (RURAL)									
	0 - 49 BEDS	315	0.0	0.8	4.6	8.0	0.0	7.0	-2.9
	50 - 100 BEDS	196	-0.1	0.3	3.9	6.6	0.0	6.2	-3.0
	101 - 149 BEDS	89	-0.2	0.1	2.0	4.4	-0.2	4.3	-3.0
	150 - 199 BEDS	39	-0.2	0.7	3.9	6.9	-0.2	6.2	-3.0
	200 + BEDS	30	-0.3	0.8	2.7	5.6	-0.2	5.2	-3.0
REGION (URBAN)									
	NEW ENGLAND	122	0.0	1.5	-0.7	3.1	-0.6	2.5	-3.0
	MIDDLE ATLANTIC	290	0.0	-0.4	-1.2	0.7	-0.8	-0.1	-2.9
	SOUTH ATLANTIC	445	0.2	0.0	-0.2	2.3	-0.4	2.0	-2.9
	EAST NORTH CENTRAL	410	0.0	-0.8	-0.9	0.6	-0.6	0.0	-3.0
	EAST SOUTH CENTRAL	163	-0.1	0.3	-3.0	-0.4	-0.4	-0.7	-3.0
	WEST NORTH CENTRAL	173	-0.1	0.9	-1.6	1.6	-0.2	0.4	-3.0
	WEST SOUTH CENTRAL	442	0.4	-1.0	1.5	3.3	-0.4	3.1	-2.9
	MOUNTAIN	222	0.2	-0.3	1.0	3.4	-0.2	2.6	-2.9
	PACIFIC	376	0.2	0.5	-0.4	2.7	-0.2	2.0	-2.9
	PUERTO RICO	50	0.5	-1.3	4.8	6.5	0.0	6.6	0.0
REGION (RURAL)									
	NEW ENGLAND	20	-0.3	2.5	4.1	9.0	0.0	8.9	-3.0
	MIDDLE ATLANTIC	46	-0.3	-0.6	1.3	2.8	-0.2	2.7	-3.0
	SOUTH ATLANTIC	109	0.0	0.8	2.9	6.2	-0.4	6.0	-3.0
	EAST NORTH CENTRAL	112	-0.1	-0.6	3.4	5.1	-0.2	5.0	-2.9
	EAST SOUTH CENTRAL	125	-0.1	0.3	1.0	3.6	-0.1	3.8	-3.0

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Nu mbe r of Hos pital s	APC Recali bratio n (all change s)	New Wage Index and Provi der Adjus tment s	340B Adjus tment	All Budg et Neut ral Chan ges (com bine d cols 2-4) with Mar ket Bask et Upda te	Paym ent Adjus tment for Imagi ng w/o Contr ast at Off Camp us Provi ders	All CY 2027 Pro pose d Cha nges	Impa ct of Adjus tment only for Provi ders Subje ct to 340B Reme dy Offse t
	WEST NORTH CENTRAL	73	-0.2	0.8	5.6	8.7	0.0	8.0	-3.0
	WEST SOUTH CENTRAL	120	0.4	-0.8	5.0	7.0	-0.2	7.1	-3.0
	MOUNTAIN	39	-0.2	1.2	5.6	9.1	0.0	7.5	-2.9
	PACIFIC	24	-0.3	3.1	3.2	8.7	0.0	5.4	-3.0
	PUERTO RICO	1	2.7	4.7	8.1	19.0	0.0	11.9	0.0
TEACHING STATUS									
	NON-TEACHING	1,993	0.3	0.1	3.5	6.4	-0.3	6.0	-2.9
	MINOR	905	0.3	0.1	1.1	3.9	-0.4	3.2	-3.0
	MAJOR	464	-0.3	-0.1	-4.3	-2.4	-0.5	-3.1	-2.9
DSH PATIENT PERCENT									
	0	10	-0.1	-1.3	8.1	9.1	-0.4	9.0	-2.5
	> 0 - 0.10	232	0.5	-0.3	6.9	9.7	-0.3	9.3	-2.9
	>= 0.10 - 0.16	266	0.5	0.2	6.6	10.0	-0.5	9.3	-2.8
	>= 0.16 - 0.23	538	0.5	-0.2	6.4	9.3	-0.5	9.0	-2.9
	>= 0.23 - 0.35	1,126	0.0	0.2	-0.7	1.9	-0.4	1.2	-2.9
	>= GE 0.35	776	-0.3	-0.1	-5.8	-3.9	-0.3	-4.5	-2.9
	DSH NOT AVAILABLE **	414	0.5	-0.2	6.8	9.8	-0.4	9.5	-2.8
URBAN TEACHING/ DSH									
	TEACHING & DSH	1,204	0.0	0.0	-1.9	0.4	-0.5	-0.3	-2.9
	NO TEACHING/DSH	1,086	0.4	0.0	3.3	6.2	-0.3	5.8	-2.9

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	APC Recalibration (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes (combined cols 2-4) with Market Basket Update	Payment Adjustment for Imaging w/o Contrast at Off Campus Providers	All CY 2027 Proposed Changes	Impact of Adjustment only for Providers Subject to 340B Remedy Offset
	NO TEACHING/NO DSH	10	-0.1	-1.3	8.1	9.1	-0.4	9.0	-2.5
	DSH NOT AVAILABLE**	393	0.6	-0.2	6.8	9.8	-0.4	9.5	-2.8
TYPE OF OWNERSHIP									
	VOLUNTARY	1,970	0.0	0.0	-0.5	2.0	-0.4	1.4	-2.9
	PROPRIETARY	990	0.9	-0.4	7.4	10.6	-0.2	10.3	-2.9
	GOVERNMENT	402	-0.3	0.2	-3.0	-0.8	-0.3	-1.3	-2.9
CMHCs		39	-0.5	-1.9	8.1	8.1	0.0	8.4	-0.2

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all CY 2027 OPPS policies and compares those to the CY 2026 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2027 hospital inpatient wage index. The rural SCH adjustment proposes to continue our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 0.9994 because the proposed CY 2027 target payment-to-cost ratio is higher than the CY 2026 PCR target.

Column (4) shows the impact of the proposed 340B drug payment adjustment and the corresponding increase in non-drug service payment.

Column (5) shows the impact of all budget neutrality adjustments and the addition of the 2.4 percent OPD rate update factor (proposed IPPS market basket percentage increase of 3.2 percent reduced by proposed 0.8 percentage point for the productivity adjustment).

Column (6) shows the separate impact of the payment adjustment for imaging without contrast APC services furnished at excepted off campus providers.

Column (7) shows the combined impact of columns 5 and 6, plus additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.

The column for providers subject to the 340B Remedy Offset shows the separate impact of applying the proposed 3.0 percentage point reduction to the OPPS conversion factor update as part of the 340B Remedy Offset.

		(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
		Number of Hospitals	APC Recalculation (all changes)	New Wage Index and Provider Adjustments	340B Adjustment	All Budget Neutral Changes (combined cols 2-4) with Market Basket Update	Payment Adjustment for Imaging w/o Contrast at Off Campus Providers	All CY 2027 Proposed Changes	<i>Impact of Adjustment only for Providers Subject to 340B Remedy Offset</i>
These 3,471 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.									
We estimate that 3,217 providers would be subject to the reduction to payments that result from the 340B remedy offset.									
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.									

BILLING CODE 4169-69-C**d. Estimated Effects of OPPS Changes on CMHCs**

The last line of Table 88 demonstrates the isolated impact on CMHCs, which furnished only partial hospitalization and intensive outpatient program services under the OPPS during CY 2025. As discussed in section VIII.C. of this proposed rule, we propose for CY 2027 to continue paying CMHCs using APCs 5851 through 5854. We modeled the impact of this APC policy, assuming CMHCs will continue to provide the same PHP and IOP care as seen in the CY 2025 claims used for ratesetting in this proposed rule. We did not exclude days with one or two services from our modeling for CY 2027, because our proposed rule policy would pay the per diem rate for APC 5853 for such days in CY 2027. As a result of the proposed PHP APC changes for CMHCs, we estimate that CMHCs would experience a 0.5 percent decrease in CY 2027 payments relative to their CY 2026 payments (shown in Column 2). For a detailed discussion of our proposed PHP and IOP policies, please see section VIII. of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2027 wage index values, which result in an estimated decrease of 1.9 percent to CMHCs.

Column 5 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2027 and the proposed FY 2027 wage index updates, and proposed 340B payment policy, would result in an estimated increase of 8.1 percent.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and decrease for services for which the OPPS payments would fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H. of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18 percent for all services paid under the OPPS in CY 2027. The estimated aggregate beneficiary coinsurance reflects general system adjustments. We note that the individual payments, and therefore copayments, associated with services

may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII. of this proposed rule. Hospitals, CMHCs, and ASCs will be affected by the changes in this proposed rule. Additionally, the payment policies we established for IOP services affect RHCs and FQHCs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 88. However, the proposed payment amount for OPPS APC 5861 will affect payments to RHCs and FQHCs since under sections 1834(o)(5)(A) and 1834(y)(3)(A) of the Act payment for IOP services in these settings is required to be equal to the payment determined for IOP services in the hospital outpatient department.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of \$1.82 billion in program

payments for OPPS services furnished in CY 2027. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in proposed rule would increase these Medicaid beneficiary payments by approximately \$40 million in CY 2027. Currently, there are approximately 11.8 million dual-eligible beneficiaries, which represent approximately 40 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 12 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 58 percent Federal payments and 42 percent State payments. Therefore, for the estimated \$40 million Medicaid increase, approximately \$25 million would be from the Federal Government and \$15 million would be from State governments.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this proposed rule.

2. Estimated Effects of CY 2027 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are setting the CY 2027 ASC relative payment weights by scaling the final CY 2027 OPPS relative payment weights by the proposed CY 2027 ASC scalar of 0.809. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 89 and 90.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. In the CY 2024 OPPS/ASC final rule with comment period, we extended this 5-year interim period an additional 2 years through CYs 2024 and 2025. In the CY 2026 OPPS/ASC final rule with comment period, we extended the interim period an additional year through 2026. As discussed in further detail in section XIII. of this proposed rule, we propose an extension of our utilization of the hospital market basket update as the

update factor to the ASC payment system for 1 additional year (through CY 2027). Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economywide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2027 payment determinations would be based on the application of a 2.0 percentage point reduction to the hospital market basket update for CY 2027. We calculated the proposed CY 2027 ASC conversion factor by adjusting the CY 2026 ASC conversion factor (\$56.322) by 1.0016 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2026 and CY 2027, which includes our policy to limit wage index declines of greater than 5 percent, and by applying the CY 2027 hospital market basket update factor of 2.4 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by a productivity adjustment of 0.8 percentage point). The proposed CY 2027 ASC conversion factor is \$57.766 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2027 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2026 and CY 2027 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2027 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as

ophthalmology, digestive system, or orthopedic procedures. The combined effect of the final update to the payments on an individual ASC would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the proposed CY 2027 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2024 claims data. Table 89 depicts the estimated aggregate percent change in payment by surgical specialty by comparing estimated CY 2026 payments to estimated CY 2027 payments, and Table 90 shows a comparison of estimated CY 2026 payments to estimated CY 2027 payments for items and procedures that we estimate would receive the most Medicare payment in CY 2026.

In Table 89, we have aggregated the surgical HCPCS codes by specialty group and then estimated the effect on aggregated payment for surgical specialty. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 89.

- Column 1—Surgical Specialty Group indicates the surgical specialty into which ASC procedures are grouped. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

- Column 2—Estimated CY 2026 ASC Payments were calculated using CY 2025 ASC utilization data (the most recent full year of ASC utilization) and CY 2026 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2026 ASC payments.

- Column 3—Estimated CY 2027 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty that is attributable to the proposed update to ASC payment rates for CY 2027 compared to CY 2026.

As shown in Table 89, for the six specialty groups that account for the most ASC utilization and spending, we

estimate that the proposed update to ASC payment rates for CY 2027 would result in a 1 percent decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 6 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 6 percent increase in aggregate payment amounts for nervous system procedures, a 2 percent decrease in aggregate payment amounts for digestive system procedures, a 5 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 1 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than the proposed 2.4 percent increase, depending on if

payment weights in the OPPTS APCs after application of the ASC weight scaler that correspond to the applicable services increased or decreased, if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 1 percent decrease in eye surgical procedure payments and a 2 percent decrease in gastrointestinal surgical procedure payments. The decrease in expenditures for these surgical specialties is attributable to the 2.4 percent hospital market basket update being offset by the reduction in the ASC weight scaler. The reduction in the ASC weight scaler from 0.872 in CY 2026 to our proposed 0.809 for CY 2027 is attributable to the increase in device portions under the ASC payment system as a result of the increase in OPPTS payment rates for clinical services for CY 2027 and out policy to treat device portions of device-intensive procedures as constant

between the OPPTS and ASC payment system. The increase in proposed CY 2027 OPPTS payment rates for clinical services is a result of the OPPTS budget neutrality adjustment from the proposed 340B drug payment policy. Therefore, surgical specialties that predominantly consist of procedures designated as device-intensive under the ASC payment system will see an increase in expenditures greater than the 2.4 percent hospital market basket update whereas surgical procedures that have relatively few device-intensive procedures will see a relatively smaller increase or decrease in CY 2027 expenditures. The increases in expenditures for musculoskeletal, nervous system, and cardiovascular surgical specialties groups is a result of the higher share of device-intensive procedures that are assigned to this surgical specialty group. For estimated changes for selected procedures, we refer readers to Table 89.

TABLE 89: ESTIMATED IMPACT OF THE PROPOSED CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2026 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2026 ASC Payments (in Millions) (2)	Estimated CY 2027 Percent Change (3)
Total	\$8,349	2
Eye	\$2,120	-1
Musculoskeletal	\$2,019	6
Nervous System	\$1,580	6
Gastrointestinal	\$1,059	-2
Cardiovascular	\$635	5
Genitourinary	\$365	1

Table 90 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2027. The table displays 30 of the procedures receiving the greatest estimated CY 2026 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending

order by estimated CY 2026 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2026 ASC Payments were calculated using CY 2024 ASC utilization (the most recent full year of ASC utilization) and the CY

2026 ASC payment rates. The estimated CY 2026 payments are expressed in millions of dollars.

- Column 4—Estimated CY 2027 Percent Change reflects the percent differences between the estimated ASC payment for CY 2026 and the estimated payment for CY 2027 based on the final update.

TABLE 90: ESTIMATED IMPACT OF THE PROPOSED CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2026 ASC Payment (in millions) (3)	Estimated CY 2027 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	\$1,383	-2
27447	Total knee arthroplasty	\$529	5
63685	Ins/rplc spi npg/rcvr pocket	\$421	15
27130	Total hip arthroplasty	\$284	6
45385	Colonoscopy w/lesion removal	\$273	-2
45380	Colonoscopy and biopsy	\$253	-2
23472	Reconstruct shoulder joint	\$215	7
43239	Egd biopsy single/multiple	\$174	-2
63650	Implant neuroelectrodes	\$161	6
64590	Ins/rpl prph sac/gstr npg/r	\$131	8
66991	Xcapsl ctrc rmvl insj 1+	\$125	10
64483	Njx aa&/strd tfrm epi l/s 1	\$108	-3
66982	Xcapsl ctrc rmvl cplx wo ecp	\$103	-2
64635	Destroy lumb/sac facet jnt	\$103	-3
29827	Sho arthrs srg rt&tr cuf rpr	\$97	36
36902	Intro cath dialysis circuit	\$90	-1
64628	Trml dstrj ios bvn 1st 2 l/s	\$75	7
64493	Inj paravert f jnt l/s 1 lev	\$74	-3
0627T	Perq njx algc fluor lmbr 1st	\$73	9
66821	After cataract laser surgery	\$67	-2
G0105	Colorectal scrn; hi risk ind	\$64	-2
65820	Relieve inner eye pressure	\$57	-2
64561	Implant neuroelectrodes	\$56	8
64555	Implant neuroelectrodes	\$54	10
15823	Revision of upper eyelid	\$51	-4
G0121	Colon ca scrn not hi rsk ind	\$47	-2
62323	Njx interlaminar lmbr/sac	\$44	-2
64721	Carpal tunnel surgery	\$42	-3
33285	Insj subsq car rhythm mntr	\$41	4
27279	Arthrd si jt perq/min nvas	\$40	7

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2027 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the procedures we are finalizing to add to the ASC CPL for CY 2027. First, other than certain preventive services where coinsurance and the Part B deductible are waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPSS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive

services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPSS. Therefore, the beneficiary coinsurance amount under the ASC payment system will usually be less than the OPSS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPSS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPSS copayment amount

for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPSS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For those additional procedures that we finalized to designate as office-based in

CY 2027, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPps and ASC Payment System

As required by OMB Circular A–4 (available on the Office of Management

and Budget website at <https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf>, we have prepared accounting statements to illustrate the impacts of the OPps and ASC changes in this proposed rule. The first accounting statement, Table 91, illustrates the classification of expenditures for the CY 2027 estimated hospital OPps incurred benefit impacts associated with the proposed CY 2027 OPD fee schedule increase and the proposed policy for imaging without

contrast services furnished at excepted off-campus PBDs. The second accounting statement, Table 92, illustrates the classification of expenditures associated with the 2.4 percent CY 2027 update to the ASC payment system, based on the provisions of the proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 91: ACCOUNTING STATEMENT: CY 2027 ESTIMATED HOSPITAL OPps TRANSFERS FROM CY 2026 TO CY 2027 ASSOCIATED WITH THE CY 2027 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	\$1.82 billion
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPps

TABLE 92: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2026 TO CY 2027 AS A RESULT OF THE PROPOSED CY 2027 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	\$170 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	\$170 million

3. Effects of Proposed Changes in Requirements for the Hospital Outpatient Quality Reporting Program

a. Background

We refer readers to the CY 2026 OPps/ASC final rule with comment period (90 FR 54071 and 54072) for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting Program for the CY 2026 reporting period and subsequent years. Of the 2,984 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2026 payment determination for the Hospital Outpatient Quality Reporting Program, we determined that 35 HOPDs did not meet the program requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 47 HOPDs elected not to participate.

b. Impact of CY 2027 OPps/ASC Proposed Rule Proposals

We propose to: (1) remove the Appropriate Follow-Up Interval for

Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination; (2) incorporate electronic clinical quality measures (eQMs) into the existing validation process for chart-abstracted measures beginning with eQm data from the CY 2027 reporting period affecting the CY 2030 payment determination; (3) reduce the validation selection pool from 500 to up to 400 HOPDs beginning with validation affecting the CY 2030 payment determination; and (4) remove the requirement for hospitals to resubmit medical documentation as part of their request for reconsideration of validation, beginning with data from the CY 2026 reporting period affecting the CY 2028 payment determination.

As part of the proposal to incorporate eQMs into the existing validation process for chart-abstracted measures, we would also update our data validation policies for chart-abstracted measures, including modifying the number of chart-abstracted measure cases required for validation from 12 per

quarter to up to 8 per quarter per measure beginning with validation affecting the CY 2030 payment determination.

We refer readers to section “XXIV. Collection of Information” of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the Hospital Outpatient Quality Reporting Program for the estimated 3,000 program-eligible HOPDs. As shown in summary Table 84 in section XXIV.A.6. of this proposed rule, we estimate a total information collection and reporting burden net decrease of 16,985 hours at a savings of \$971,221 annually associated with our proposals beginning with the CY 2029 reporting period/CY 2031 payment determination compared to our information collection burden estimates which are currently under review for approval under OMB control number 0938–1109 (expiration date June 30, 2026).

In addition to the reduced information collection burden associated with the proposals in this proposed rule, we believe there would be administrative cost savings associated with the proposed removal of the requirement for HOPDs to resubmit medical documentation as part of their request for reconsideration of validation noncompliance. Regarding the proposed incorporation of eQMs into the existing validation process for chart-abstracted measures, with more than 98 percent of HOPDs eligible to participate in the Hospital Outpatient Quality Reporting Program affiliated with hospital systems that are already familiar with the eQCM validation process under the Hospital Inpatient Quality Reporting Program, we anticipate their experience with eQCM validation for the Hospital Inpatient Quality Reporting Program would minimize the additional costs beyond the information collection burden discussed in section XXIV.A. of this proposed rule associated with eQCM validation by leveraging existing or similar personnel and processes.

We do not believe the remaining proposals would result in any additional economic impact beyond that discussed in section “XXIV. Collection of Information” of this proposed rule.

4. Effects of Requirements for the Rural Emergency Hospital (REH) Quality Reporting Program

We refer readers to the CY 2026 OPPTS/ASC final rule with comment period (90 FR 54072 and 54073) for the previously discussed effects of changes to the REH Quality Reporting Program for the CY 2026 reporting period and subsequent years. For the CY 2027 reporting period, we have estimated there will be 48 REHs required to report under the REH Quality Reporting Program based on acute care and critical access hospital conversions to REH status as of April 6, 2026. We note that this estimate is an increase of 10 REHs from our estimate of 38 provided in the CY 2026 OPPTS/ASC final rule with comment period, resulting in an increase in total information collection burden for the REH Quality Reporting Program of 122 hours and \$6,976 (90 FR 54072). We are not proposing any changes to our previously finalized REH Quality Reporting Program policies in this proposed rule.

5. Effects of Proposed Changes in Requirements for the Ambulatory Surgical Center (ASC) Quality Reporting Program

a. Background

We refer readers to the CY 2026 OPPTS/ASC final rule with comment period (90 FR 54073) for the previously estimated effects of changes to the ASC Quality Reporting Program for the CY 2026 reporting period and subsequent years. Based on the most recent analysis of the CY 2026 payment determination data, we found that, of the 6,930 ASCs that were actively billing Medicare, 4,399 were required to participate in the ASC Quality Reporting Program. Of the 2,531 ASCs not required to participate in the program, 650 ASCs did so and met full requirements. On this basis, we estimate that 5,149 ASCs (4,399 + 650) will submit data for the ASC Quality Reporting Program for the CY 2027 reporting period and subsequent years unless otherwise noted. We note that this estimate is an increase of 559 ASCs from our estimate of 4,590 provided in the CY 2026 OPPTS/ASC final rule with comment period (90 FR 54073) due to more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2027 OPPTS/ASC Proposed Rule Proposals

We propose to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2027 reporting period/CY 2029 payment determination. We refer readers to section “XXIV. Collection of Information” of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the ASC Quality Reporting Program for the estimated 5,149 program-eligible ASCs. As shown in summary Table 85 in section XXIV.C.3. of this proposed rule, we estimate a total information collection and reporting burden decrease of 16,753 hours at a savings of \$957,937 annually associated with our proposal for the CY 2027 reporting period/CY 2029 payment determination and subsequent years compared to our information collection burden estimates which are currently under review for approval under OMB control number 0938–1270 (expiration date June 30, 2026). We do not believe this proposal would result in any additional economic impact beyond those discussed in section “XXIV. Collection of Information” of this proposed rule.

6. Effects of Addition of New Codes for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPTS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which requires the Secretary to develop “a method for controlling unnecessary increases in the volume of covered OPD services” (84 FR 61142, November 12, 2019).²¹⁶ As part of the CY 2021 OPPTS/ASC final rule with comment period, we added additional service categories to the prior authorization process (85 FR 85866, December 29, 2020). Through the CY 2023 OPPTS/ASC final rule with comment period, we added an eighth service category to the list of OPD services requiring prior authorization (87 FR 71748, 72224 through 72233, November 23, 2022). The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we propose to expand the Botulinum Toxin Injection service category to include additional codes requiring prior authorization. To improve readability and brevity, as we indicated earlier in section XVIII. of this proposed rule, effective dates were removed and the section numbering in the regulatory text was updated. The former paragraphs (a)(1)(i) through (v), (a)(2)(i) and (ii), and (a)(3) have been renumbered as (a)(1) through (8). The additional Botulinum Toxin Injection codes would be added to the existing codes located at proposed revised § 419.83(a)(2) and would require prior authorization beginning for service dates on or after July 1, 2027.

The addition of these services is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the healthcare sector to require prior authorization for these additional codes is dependent on the number of claims affected. Table 94, Overall Economic Impact on the Health Sector, lists an estimate of the overall economic impact on the health sector for the new services. The values populating Table 93 were obtained from the cost reflected in Table 94, Annual Private Sector Costs, and Table 95, Estimated Annual

²¹⁶ See also Correction Notice issued January 3, 2020 (85 FR 224).

Administrative Costs to CMS. Tables 94 and 95 combine to convey the overall economic cost impact to the health sector for the new services, which is illustrated in Table 93.

Based on the estimate, the overall economic cost impact is approximately \$9.6 million in the first year for the new services. The 5-year impact is approximately \$48 million, and the 10-year impact is approximately \$95.9 million. Additional administrative

paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of \$25 million. We believe there are likely to be other benefits that result from the prior authorization requirement for the new services, though many of those benefits are difficult to quantify. For instance,

we expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We will solicit public comments on the potentially increased costs and benefits associated with this proposed provision for the new services.

TABLE 93: OVERALL ECONOMIC COST IMPACT ON THE HEALTH SECTOR

	Year 1	5 Years	10 Years
Private Sector Costs	\$1,957,592	\$9,787,962	\$19,575,924
Medicare Costs	\$7,632,439	\$38,162,195	\$76,324,390
Total Economic Impact to Health Sector	\$9,590,031	\$47,950,157	\$95,900,314

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of \$10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and

payment rules and regulations could be significant, as the proposed rule may change the billing practices of those providers. The purpose of the statute and this proposed rule is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the additional OPD services to be a condition that we must mitigate. We believe that the effect would be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding the new services would offer additional protection to a provider's cash flow as the provider would know in advance if the Medicare requirements were met.

b. Anticipated Specific Cost Effects

(1) Private Sector Costs

We do not believe that this proposed rule would significantly affect the number of legitimate claims submitted for the new services. However, we expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the additional services will be equivalent to that of submitting documentation and clerical activities associated with prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 94: ANNUAL PRIVATE SECTOR COSTS

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests- Initial Submissions	41,299	0.5	20,649	\$914,351
Fax and Electronic Submitted Requests- Resubmissions	13,552	0.5	6,776	\$300,041
Mailed in Requests- Initial Submissions	17,699	0.5	8,850	\$391,865
Mailed in Requests- Resubmissions	5,808	0.5	2,904	\$128,589
Mailing Costs	23,507	5		\$117,537
Provider Demonstration- Education	792	3	2,376	\$105,209
Total			41,555	\$1,957,592

(2) Administrative Costs to CMS

CMS would incur additional costs associated with processing the prior authorization requests for the new

services. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by \$95, the estimated cost to review each

request. The combined cost also includes other elements such as appeals, education, outreach, and system changes.

TABLE 95: ANNUAL ESTIMATED ADMINISTRATIVE COSTS TO CMS

Additional Services	Estimated Annual Administrative Cost
Botulinum Toxin Injections	\$7,632,439

(3) Estimated Beneficiary Costs

We expect a reduction in the utilization of the new Medicare OPD services when such utilization does not comply with one or more of Medicare’s coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although this proposed rule permits utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and, thus, are not eligible for Medicare payment. We

lack the data to quantify these costs as well.

(4) Estimated Benefits

There will be quantifiable benefits for this proposed rule because we expect a reduction in the unnecessary utilization of the new Medicare OPD services subject to prior authorization. It is difficult to project the exact decrease in unnecessary utilization; however, based on a 25 percent savings percentage, we estimate an overall gross savings of \$25 million. These savings represent a Medicare benefit from more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the

additional OPD services would help ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary’s condition. This would require the facility to collaborate closely with the practitioner early in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient, or the patient does not meet the Medicare requirements, would likely be reduced by requiring a provider to submit clinical documentation as part of its prior authorization request.

We solicit comments on the potential additional burden associated with applying prior authorization requirements to these additional botulinum toxin injection codes, including any impacts on providers and beneficiaries.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this

proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$119.10 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is \$952.80 (8 hours × \$119.10). Therefore, we estimate that the total cost of reviewing this regulation is \$2,898,418 (\$952.80 × 3,042).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great

majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than \$9.0 million to \$47.0 million in any 1 year). (For details, see the SBA's website at <http://www.sba.gov/content/small-business-size-standards> (refer to the 620000 series or Sector 62, Health Care and Social Assistance).)

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title "Hospitals" and corresponding NAICS code 622 in determining impacts for small entities for this rule. The NAICS code 622 has a size standard of \$47 million.²¹⁷ Table 96 shows the number of firms, revenue, and estimated impact per hospital category.

²¹⁷ https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%281%29%20%281%29_0.pdf.

TABLE 96: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOSPITALS FOR NAICS CODE 622

NAICS	NAICS Description	Enterprise Size (\$1,000)	Number of Firms	Receipts (\$1,000)	Average Receipts Per Firm (\$1,000)
622	Hospitals	<100	68	3,235	48
622	Hospitals	00-499	176	47,198	268
622	Hospitals	500-999	61	43,484	713
622	Hospitals	1,000-2,499	36	55,875	1,552
622	Hospitals	2,500-4,999	43	160,867	3,741
622	Hospitals	5,000-7,499	45	285,858	6,352
622	Hospitals	7,500-9,999	77	653,169	8,483
622	Hospitals	10,000-14,999	158	1,852,000	11,722
622	Hospitals	15,000-19,999	173	2,919,720	16,877
622	Hospitals	20,000-24,999	154	3,391,347	22,022
622	Hospitals	25,000-29,999	128	3,342,680	26,115
622	Hospitals	30,000-34,999	126	3,876,502	30,766
622	Hospitals	35,000-39,999	87	3,061,225	35,186
622	Hospitals	40,000-49,999	162	6,839,652	42,220
622	Hospitals	50,000-74,999	276	15,547,026	56,330
622	Hospitals	75,000-99,999	144	11,728,762	81,450
622	Hospitals	100,000+	1,222	1,300,730,378	1,064,427
622	Hospitals	Total	3,136	1,354,538,978	431,932

Source: Data obtained from United States Census Bureau table “us_6digitnaics_rcptsize_2022” (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx.

Notes: The ‘Average Receipts Per Firm’ is calculated as the Receipts (\$1,000)/Number of Firms. The ‘Total’ row represents all the hospital firms under NAICS 622. Overall receipts (revenue) for the 3,136 firms (NAICS 622) are approximately \$1,355 billion.

TABLE 97: ESTIMATED IMPACT ON SMALL BUSINESSES*

	Total Facilities	Estimated Small Businesses	Total Impact (\$1 million)	Estimated Impact to Small Businesses	Estimated Average Impact per Small Business
OPPS Hospitals	3,481	1,605	\$1,830	\$32,900,000	\$20,498
ASCs	6,179	5,560	\$170	\$59,200,000	\$10,647

* Based on the assumptions that small firms represent 46.1 percent of OPPS Hospitals and account for approximately 1.8 percent of total industry revenues, and, small firms represent 90.0 percent of ASCs and account for approximately 34.8 percent of total industry revenues using the SBA size standards,

For purposes of the RFA, approximately half of all hospitals are considered to be small entities. As shown in Table 96, hospitals with enterprise size of \$49 million or less (1,494) are approximately 48 percent of total firms (3,136). Because roughly half

of hospitals qualify as small entities under the RFA, the impacts described in this proposed rule generally affect small entities. Individuals and States are not included in the definition of a small entity. MACs are also not considered to be small entities because they do not

meet the SBA definition of a small business.

HHS interprets the RFA to consider economic effects “significant” when more than 5 percent of providers incur impacts of at least 3 to 5 percent or more of total revenue or total costs. This

proposed rule includes a number of proposed policy changes that can significantly increase or decrease estimated 2027 payments at an individual level, including changes such as the proposed exceptions to the 340B drug payment proposal and the payment adjustment for imaging without contrast services furnished at provider based departments. Based on this impact analysis, we estimate that the policies proposed in this rule would affect more than 5 percent of hospitals with changes in Medicare revenue of at least 3 to 5 percent.

Therefore, the Secretary has certified that this proposed rule will have a significant economic impact on a substantial number of small entities.

For example, we estimate that a majority of the 3,481 OPPS providers included in the impact analysis presented in Table 88 would experience average payment increases of approximately 2.0 percent. We attribute those changes primarily to the proposed change in estimated outlier payments, changes in estimated pass through spending, and the proposed OPPS update. Across hospital categories, we estimate that impacts would range from an increase of 8.8 percent for rural sole community hospitals to an estimated decrease of 4.2 percent for hospitals with a DSH patient percentage greater than 35 percent.

As shown in Tables 91 and 92, we estimate that this proposed rule would result in aggregate transfers of approximately \$1.82 billion to OPPS providers and \$170 million to ASCs. In Table 97, we estimate the impact of this rule on small entities by applying the SBA size standards and approximating the share of affected firms and revenues attributable to small entities. Specifically, we assume that small firms represent 46.1 percent of affected entities and account for approximately 1.8 percent of total industry revenues. Using these assumptions, we estimate that of the 3,481 OPPS providers, approximately 1,605 are small entities. Applying the 1.8 percent revenue share, we estimate that approximately \$32.9 million of the OPPS impacts would accrue to small entities, which corresponds to an average impact of approximately \$20,498 per small OPPS provider.

This proposed rule includes a range of proposals. We describe the applicable statutory provisions, identify the proposed policies, present the rationale for these proposals, and, where appropriate, in the corresponding sections of this proposed rule.

In addition, section 1102(b) of the Act requires us to prepare a regulatory

impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in the impact analysis of this proposed rule, this rule is expected to generally increase OPPS payments to the approximately 511 small rural hospitals. Therefore, the Secretary has certified that this proposed rule will have a significant impact on the operations of a substantial number of small rural hospitals.

The analyses presented in this section and throughout the preamble of this proposed rule constitute our initial regulatory flexibility analysis. We invite public comment on our estimates and our assessment of the impact of the proposed policies on small entities.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2027, that threshold is approximately \$193 million.

This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$193 million in any 1 year.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism

implication. As reflected in Table 88 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would decrease by 1.3 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

H. E.O. 14192, “Unleashing Prosperity Through Deregulation”

Executive Order 14192, entitled “Unleashing Prosperity Through Deregulation” was issued on January 31, 2025, and requires that “any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations”. This rule is expected to be an E.O. 14192 regulatory action. We estimated that this rule will generate \$6.23 million in annualized cost at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 1, 2026.

List of Subjects

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 2. Section 413.65 is amended—

■ a. In paragraph (a)(2) by adding the definition of “Off-campus outpatient department of a provider” in alphabetical order;

■ b. By revising paragraphs (b)(3)(ii) and (iii);

■ c. By adding paragraph (b)(6);

■ d. By revising paragraphs (e) introductory text, (g)(1)(i) and (ii), (h) introductory text, and (k).

The additions and revisions read as follows:

§ 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) * * *

(2) * * *

* * * * *

Off-campus outpatient department of a provider means a department of a provider that is not located on the campus of the main provider (as defined in this section) or within 250 yards of a remote location of a hospital (as defined in this section).

* * * * *

(b) * * *

(3) * * *

(ii) If the facility is not located on the campus of the potential main provider or within 250 yards of a remote location of a hospital, the attesting provider would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to maintain documentation of the basis for its attestations to CMS and to furnish such information upon request.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as

described in paragraph (b)(3)(i) of this section, CMS or its agents will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS or its agents at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

* * * * *

(6) As of January 1, 2028, for each off-campus outpatient department of a provider, excluding those described in paragraphs (m) or (n) of this section, a provider must submit an initial attestation for provider-based status within the 2-year period prior to furnishing services, and a subsequent attestation within a period not to exceed 5 years thereafter.

* * * * *

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider or within 250 yards of a remote location of a hospital must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

* * * * *

(g) * * *

(1) * * *

(i) Any facility or organization that is located on the main hospital campus or within 250 yards of a remote location of a hospital and is treated by CMS under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by CMS under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

* * * * *

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider or within 250 yards of a remote location of a hospital and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

* * * * *

(k) *Temporary treatment as provider-based.* If a provider submits an attestation of compliance with the

requirements for provider-based status, as described in paragraph (b) of this section, for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits an attestation until the date that CMS determines that the facility or organization does not meet the provider-based rules. CMS may, at any time, initiate an extended review to validate the attestation of compliance, including through site visits, remote audits, desk reviews, investigations, or any other means CMS determines appropriate. As part of such a review, the provider must submit supporting documentation sufficient to demonstrate compliance with the provider-based requirements set forth in this section, in the form and manner and within the timeframe specified by CMS. Failure to submit requested documentation within the timeframe specified by CMS may result in a determination of non-compliance and recovery of payments as described in this paragraph (k). If CMS determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b–8, and 1395hh.

■ 4. Section 416.171 is amended by revising paragraphs (a)(2)(iii) through (viii) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2027, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2028 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period

ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section was reduced by 2.0 percentage points for ASCs that failed to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2027, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2028 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(v) of this section, was reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2027, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2028 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 5. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 6. Adding § 419.23 to subpart B to read as follows:

§ 419.23 Special rule for off-campus outpatient department of a provider.

(a) No payment may be made under this part for items and services furnished on or after January 1, 2028, by an off-campus outpatient department of a provider (as defined in paragraph (b) of this section) unless—

(1) Such department has obtained, and such items and services are billed under, a National Provider Identifier that is separate from such identifier for such provider;

(2) Such provider has submitted an initial attestation for provider-based status in accordance with § 413.65(b)(6) of this chapter; and

(3) After such provider has submitted an initial attestation under paragraph (a)(2) of this section, such provider has submitted a subsequent attestation within the timeframe specified in and in accordance with § 413.65(b)(6) of this chapter.

(b) For purposes of this section, off-campus outpatient department of a provider is defined at § 413.65(a)(2) of this chapter.

■ 7. Section 419.32 is amended by—

■ a. Revising paragraph (b)(1)(iv)(B)(12); and

■ b. Adding paragraph (b)(1)(iv)(B)(13).
The revision and addition read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(12) For calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 0.5 percentage point reduction, except that the 0.5 percentage point reduction shall not apply to hospital outpatient items and services, not including separately payable drugs or biologicals, furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later.

(13) Beginning in calendar year 2027, a multifactor productivity adjustment (as determined by CMS), and 3.0-percentage point reduction, except that the 3.0-percentage point reduction shall not apply to hospital outpatient items and services furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until the estimated payment reductions made in accordance with paragraph (b)(1)(iv)(B)(12) of this section and this paragraph

(b)(1)(iv)(B)(13) for all applicable hospital outpatient items and services reaches \$7.769 billion, as further described in each calendar year's rule.

* * * * *

■ 8. Section 419.43 is amended by adding paragraph (l) to read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(l) *Cost-of-living adjustment.* An additional adjustment is made for hospitals located in Alaska and Hawaii to account for the higher cost-of-living in those States.

9. Section 419.46 is amended by revising paragraphs (f)(2), (f)(3) introductory text, (f)(4), and (g)(2)(vii) and (viii) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(f) * * *

(2) A hospital meets the validation requirements with respect to a calendar year if it achieves:

(i) An overall reliability score of at least 75-percent for chart-abstracted measure validation, as determined by CMS; and

(ii) Beginning with validation affecting the CY 2030 payment determination, an overall reliability score of at least 75-percent for eCQM validation, as determined by CMS.

(3) CMS will select a random sample of up to 200 hospitals, beginning with validation affecting the CY 2030 payment determination, or 450 hospitals, for validation affecting payment determinations prior to CY 2030, for validation purposes, and will select up to an additional 200 hospitals, beginning with validation affecting the CY 2030 payment determination, or 50 hospitals for validation affecting payment determinations prior to CY 2030, for validation purposes based on the following criteria:

* * * * *

(4) Hospitals that are selected and receive a score for validation may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation were incorrectly scored, the corrected validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(2) * * *

(vii) Except as provided in paragraph (g)(2)(viii) of this section, a copy of all materials that the hospital submitted to comply with the requirements of the affected Hospital OQR Program payment determination year; and

(viii) If the hospital is requesting reconsideration on the basis that CMS determined it did not meet the affected payment determination year's validation requirement set forth in paragraph (f)(2) of this section, the hospital must provide:

(A) A written justification for each appealed data element classified during the validation process as a mismatch. Only data elements that affect a hospital's validation score are eligible to be reconsidered; and

(B) Any evidence that supports the hospital's reconsideration request, including, as applicable, copies of patient charts, emails, and other documents. The hospital is not required to resubmit materials previously submitted to CMS unless specifically requested by CMS.

* * * * *

■ 10. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* The following service categories comprise the list of hospital outpatient department services requiring prior authorization:

- (1) Blepharoplasty.
- (2) Botulinum toxin injections.
- (3) Panniculectomy.

- (4) Rhinoplasty.
- (5) Vein ablation.
- (6) Cervical Fusion with Disc Removal.
- (7) Implanted Spinal Neurostimulators.
- (8) Facet Joint Interventions.

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 11. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 12. Section 427.303 is amended by revising paragraph (b)(1)(iv) to read as follows:

§ 427.303 Determination of total number of billing units.

* * * * *

(b) * * *

(1) * * *

(iv) Separately payable billing units in claim lines billed with the “TB” modifier and successor billing modifiers to identify 340B units, for claims with dates of service on or after January 1, 2025.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 13. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 14. Section 488.5 is amended by adding paragraph (a)(21) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(21) For accrediting organizations seeking or maintaining CMS approval of accrediting programs for hospitals, Critical Access Hospitals, and Rural Emergency Hospitals, the application must include a description of the policies and procedures the organization will use to assess compliance with the EMTALA-administrative requirements set forth at § 489.20 (l), (m), (q), and (r) during accreditation and reaccreditation surveys, including—

(i) Procedures for reviewing required EMTALA signage;

(ii) Procedures for verifying that transfer records are maintained and retained for at least 5 years;

(iii) Procedures for verifying the on-call physician lists are maintained as required;

(iv) Procedures for verifying a central log of individuals presenting to the emergency department is maintained as required;

(v) Procedures for reporting identified noncompliance with § 489.20 to CMS in accordance with CMS oversight requirements; and

(vi) Procedures for reporting identified noncompliance with § 489.24 subsequently identified during survey to CMS in accordance with CMS oversight requirements.

* * * * *

Robert F. Kennedy, Jr.,
Secretary, Department of Health and Human Services.

[FR Doc. 2026–13656 Filed 7–2–26; 8:45 am]

BILLING CODE 4169–69–P



FEDERAL REGISTER

Vol. 91

Tuesday,

No. 128

July 7, 2026

Part III

Department of Energy

10 CFR Part 430

Energy Conservation Program: Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment; Proposed Rule

DEPARTMENT OF ENERGY**10 CFR Part 430****[EERE–2025–BT–STD–0001]****RIN 1904–AF72****Energy Conservation Program: Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment****AGENCY:** Office of Critical Minerals and Energy Innovation, Department of Energy.**ACTION:** Notice of proposed rulemaking and announcement of webinar.

SUMMARY: The U.S. Department of Energy (“DOE” or “the Department”) proposes to update the Department’s current rulemaking methodology titled, “Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment” (“Process Rule”). Specifically, DOE proposes to: make Appendix A binding on DOE for certain actions; amend objectives and considerations consistent with recent Executive orders and Department policies; add a definition of “significant energy savings”; re-instate the comparative analysis requirement, described as a “walk up” approach; include certain economic thresholds; re-instate the description of clear and convincing evidence; and revert to language from the 2020 Process Rule text, with minor edits, in several sections. In addition to requesting written comments on its proposal, DOE will also hold a public meeting to discuss this proposal and obtain additional input.

DATES:

Comments: DOE will accept comments, data, and information regarding all aspects of this notice of proposed rulemaking (“NOPR”) no later than August 6, 2026.

Meeting: DOE will hold a public meeting via webinar on Wednesday, July 15, 2026, from 1 to 4 p.m. ET. See section VI of this document, “Public Participation,” for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at www.regulations.gov under docket number EERE–2025–BT–STD–0001.

Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2025–BT–STD–0001 and/or regulatory information number (“RIN”) 1904–AF72, by any of the following methods:

(1) *Email:* ProcessRule2025STD0001@ee.doe.gov. Include the docket number EERE–2025–BT–STD–0001 and/or RIN 1904–AF72 in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.

(2) *Postal Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop CM–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. If possible, please submit all items on a compact disc (“CD”), in which case it is not necessary to include printed copies.

(3) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies. No telefacsimiles (“faxes”) will be accepted. For detailed instructions on submitting comments and additional information on this process, *see* section VI (Public Participation) of this document.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at www.regulations.gov/docket/EERE-2025-BT-STD-0001. The docket web page contains instructions on how to access all documents, including public comments, in the docket. *See* section VI of this document for information on how to submit comments through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Appliance Standards Program, U.S. Department of Energy, Office of Critical Minerals and Energy Innovation, Building Technologies Office, CM–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Email:

ApplianceStandardsQuestions@ee.doe.gov.

Mr. Pete Cochran, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Telephone: (202) 586–4798. Email: Peter.Cochran@hq.doe.gov.

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: ApplianceStandardsQuestions@ee.doe.gov. A plain language summary of the rule is also available on the Federal e-Rulemaking Portal at www.regulations.gov.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Summary of the Proposal
- II. Authority and Background
 - A. Authority
 - B. Background
- III. Discussion of General Comments
 - A. General Support for or Opposition to Standards
 - B. General Support for or Opposition to Changes to the Process Rule
- IV. Discussion of Comments and Proposed Revisions to Individual Sections of the Process Rule
 - A. Objectives (Section 1)
 - B. Scope (Section 2)
 - C. Application (Section 3)
 - D. Setting Priorities for Rulemaking Activity (Section 4)
 - E. Coverage Determination Rulemakings (Section 5)
 - F. Significant Energy Savings
 - 1. Background
 - 2. Proposed Threshold for Significant Energy Savings
 - G. Process For Developing Energy Conservation Standards (Section 6)
 - 1. Early Assessment and Pre-NOPR Stages
 - 2. Comment Periods
 - 3. Factors To Be Considered in Selecting a Proposed Standard
 - a. Private Impacts on Consumers
 - b. Impacts on the Environment
 - H. Policies on Selection of Standards (Section 7)
 - 1. Market Competition and Innovational
 - 2. Analytic Approaches To Address Balancing Factors in EPCA
 - 3. Selection of Standard Level
 - I. Test Procedures (Section 8)
 - 1. Early Assessment and Pre-NOPR Stage
 - 2. Comment Periods
 - 3. 180-Day Period
 - 4. Industry Standards
 - 5. General
 - J. ASHRAE Equipment (Section 9)
 - 1. Limited Circumstances and Clear and Convincing Evidence
 - K. Direct Final Rules (Section 10) and Negotiated Rulemaking
 - L. Principles for Distinguishing Between Effective and Compliance Dates (Section 11)

- M. Other Comments
- N. Topics Considered in Other Processes
 - 1. Analytical Methodology
 - 2. Product-Specific Comments
- O. Severability
- V. Procedural Issues and Regulatory Review
 - A. Review Under Executive Order 12866
 - B. Review Under Additional Executive Orders and Presidential Memoranda
 - C. Review Under the Regulatory Flexibility Act
 - D. Review Under the Paperwork Reduction Act of 1995
 - E. Review Under the National Environmental Policy Act of 1969
 - F. Review Under Executive Order 13132
 - G. Review Under Executive Order 12988
 - H. Review Under the Unfunded Mandates Reform Act of 1995
 - I. Review Under the Treasury and General Government Appropriations Act, 1999
 - J. Review Under Executive Order 12630
 - K. Review Under the Treasury and General Government Appropriations Act, 2001
 - L. Review Under Executive Order 13211
 - M. Review Under the Information Quality Bulletin for Peer Review
- VI. Public Participation
 - A. Participation in the Webinar
 - B. Procedure for Submitting Prepared General Statements for Distribution

- C. Conduct of the Webinar
- D. Submission of Comments
- VII. Approval of the Office of the Secretary

I. Summary of the Proposal

In this NOPR, DOE is proposing revisions to the Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment, codified in the Code of Federal Regulations (“CFR”) at 10 CFR part 430, subpart C, appendix A, (“Appendix A” or the Process Rule), which DOE generally uses to prescribe energy conservation standards and test procedures for both consumer products and commercial equipment pursuant to the Energy Policy and Conservation Act of 1975 (EPCA), as amended (42 U.S.C. 6291, *et seq.*; 42 U.S.C. 6311, *et seq.*). These proposed changes are intended to provide increased certainty in DOE’s rulemaking processes for impacted stakeholders, and to better inform the Secretary in making his or her

determination under EPCA regarding both whether to regulate and, when choosing to regulate, what standard level to select. In addition, as discussed further below, the proposed process changes reflect the best reading of the statute, consistent with *Loper Bright Enters v. Raimondo*, 603 U.S. 369 (2024), and *Michigan v. EPA*, 576 U.S. 743 (2015).

In this document, DOE proposes to make appendix A binding on DOE for certain actions; amend objectives and considerations consistent with statute and recent Executive Orders and Department policies; add a definition of “significant energy savings”; re-instate the comparative analysis requirement, described as a “walk up” approach; include certain economic thresholds; re-instate the description of clear and convincing evidence; and revert to language from the 2020 Process Rule text, with minor edits, in several sections. These proposed revisions are summarized in Table I.1.

Table I.1 List of Proposed Revisions in this Document Organized by Process Rule Section

Section	Proposed Revisions
1. Objectives	- Proposes to clarify that consensus proposals can proceed to a direct final rule, and that direct final rules would follow the procedural requirements specified in EPCA - Proposes to add objectives consistent with recent Executive Orders
2. Scope	None
3. Application	Proposes that Appendix A be binding on DOE for certain actions
4. Setting Priorities	Proposes to amend factors for consideration in prioritization and to change the request for comment requirement to be based on if circumstances weigh toward doing so
5. Coverage Determinations	Proposes to re-instate language from 2020 Process Rule
6. Process for Developing Energy Conservation Standards	- Proposes to reinstate the 2020 Process Rule requirements regarding Early Assessment, Pre-NOPR stages, and comment periods. - Proposes to re-instate determination of significant savings of energy with revised thresholds compared to the 2020 Process Rule - Proposes to make minor amendments to factors for consideration in selecting proposed standards including removing impacts on the environment and adding consideration of consumer choice and certain consumer economic impacts
7. Policies on Selection of Standard	- Proposes to re-instate section on considerations in assessing economic justification - Proposes to re-instate a walk up comparative analysis - Proposes to define certain consumer economic thresholds
8. Test Procedure	Proposes to re-instate language from the 2020 Process Rule including on rulemaking stages and timelines, comment periods, and adoption of industry standards, and corrects a formatting error
9. ASHRAE Equipment	Proposes to re-instate 2020 Process Rule language including that DOE will adopt the standard levels or industry test procedure contained in ASHRAE Standard 90.1 except in very limited circumstances and to define the term “clear and convincing evidence”
10. Direct Final Rules	Proposes to revert this section to the 2020 Process Rule language while including existing clarification regarding direct final rules in section 1
Negotiated Rulemaking	Proposes to reinstate this section from the 2020 Process Rule with minor edits
11. Principles for Distinguishing Between Effective and Compliance Dates	Proposes to distinguish between prescribed, effective, and compliance date
12.-16. Analytical Methodology Sections	Proposes to amend some of these sections; detailed analytic updates will be addressed separately via the analytic framework update effort.

In addition, on January 20, 2025, the President issued Executive Order 14154, “Unleashing American Energy” (E.O. 14154). 90 FR 8353 (Jan. 29, 2025). That order stated the policy of the United

States with regard to energy production and management. Among the stated elements of this policy, sections 1(f) through (h) of E.O. 14154 cite the intent to safeguard the American people’s

freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads, and

to promote market competition and innovation within the manufacturing and appliance industries; to ensure that the global effects of a rule, regulation, or action shall, whenever evaluated, be reported separately from its domestic costs and benefits, in order to promote sound regulatory decision making and prioritize the interests of the American people; and to guarantee that all Executive departments and agencies (agencies) provide opportunity for public comment and rigorous, peer-reviewed scientific analysis. Section 6 of the Executive order also specifies policies for prioritizing accuracy in environmental analyses, specifically instructing that for Federal regulatory processes, “all agencies shall adhere to only the relevant legislated requirements for environmental considerations and any considerations beyond those requirements are eliminated.” Section 6 of the Executive order also provides instructions regarding consideration of greenhouse gas emissions and the “social cost of carbon.”

Consistent with E.O. 14154, the Department, among other actions, is evaluating existing policy regarding its approach for consideration of new or amended energy conservation standards and test procedures for consumer products and certain commercial and industrial equipment. The Department has tentatively determined that the changes proposed herein will provide certainty in DOE’s rulemaking processes for impacted stakeholders and will allow the Secretary to make the best-informed determinations under EPCA regarding the regulation of covered products and equipment.

In addition to the specific issues discussed in this NOPR, DOE welcomes comment on all other aspects of the Process Rule that interested parties believe could be improved or should be maintained.

II. Authority and Background

A. Authority

The Energy Policy and Conservation Act, Public Law 94–163, as amended (“EPCA”),¹ authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317, as codified). Title III, Part B² of EPCA established the Energy

Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309, as codified). Title III, Part C³ of EPCA, added by Public Law 95–619, Title IV, section 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. (42 U.S.C. 6311–6317, as codified). Under EPCA, DOE’s energy conservation program consists essentially of four parts: (1) testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291; 42 U.S.C. 6311), test procedures (42 U.S.C. 6293; 42 U.S.C. 6314), labeling provisions (42 U.S.C. 6294; 42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6295; 42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6296; 42 U.S.C. 6316).

Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, water use (as applicable), or estimated annual operating cost of each covered product and covered equipment during a representative average use cycle or period of use, and the statute further requires that the test procedure not be unduly burdensome to conduct. (42 U.S.C. 6293; 42 U.S.C. 6314). Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their product complies with the applicable energy conservation standards and as the basis for any representations regarding the energy use or energy efficiency of the product. (42 U.S.C. 6293(c); 42 U.S.C. 6295(s); 42 U.S.C. 6314(d); and 42 U.S.C. 6316(a)). Similarly, DOE must use these test procedures to determine whether the products or equipment comply with the applicable energy conservation standards adopted pursuant to EPCA. (42 U.S.C. 6295(s); 42 U.S.C. 6316(a)).

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products. EPCA requires that any new or amended energy conservation standard for covered products (and at least certain types of equipment) must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A); 42 U.S.C.

6313(a)(6)(A)–(C); 42 U.S.C. 6316(a)). Furthermore, for covered consumer products and certain covered equipment, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B); 42 U.S.C. 6316(a)). For other covered equipment subject to ASHRAE Standard 90.1, the statute states that if DOE determines that a standard higher than the ASHRAE level is appropriate, the Department must determine that such standard would result in significant additional conservation of energy and be supported by clear and convincing evidence. (42 U.S.C. 6313(a)(6)(A)–(C)).

Moreover, DOE may not prescribe a standard: (1) for certain products, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B); 42 U.S.C. 6313(a)(6)(A)–(C); 42 U.S.C. 6316(a)). In determining whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i); 42 U.S.C. 6313(a)(6)(B)(ii); 42 U.S.C. 6316(a)). DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on the manufacturers and consumers;

(2) The savings in operating costs, throughout the estimated average life of the products (*i.e.*, life-cycle costs), compared with any increase in the price of, or in the initial charges for, or operating and maintaining expenses of, the products which are likely to result from the imposition of the standard;

(3) The total projected amount of energy, or as applicable, water, savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors DOE considers relevant. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII)) Furthermore, the new or amended standard must result in a significant conservation of energy (42 U.S.C. 6295(o)(3)(B); 42 U.S.C. 6313(a)(6)(A)–(C); and 42 U.S.C. 6316(a)) and comply

¹ All references to EPCA in this document refer to the statute as amended through Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflects the last statutory amendments that impact parts A and A–1 of EPCA.

² For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

³ For editorial reasons, upon codification in the U.S. Code, Part C was redesignated as Part A–1.

with any other applicable statutory provisions.

Further, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii); 42 U.S.C. 6316(a)).

Additionally, EPCA provides that a rule prescribing an energy conservation standard for a type (or class) of covered products shall specify a level of energy use or efficiency higher or lower than that which applies (or would apply) for such type (or class) for any group of covered products which have the same function or intended use, if the Secretary determines that covered products within such group: (A) consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard from that which applies (or will apply) to other products within such type (or class). (42 U.S.C. 6295(q)(1)) In making a determination under this paragraph concerning whether a performance-related feature justifies the establishment of a higher or lower standard, the Secretary shall consider such factors as the utility to the consumer of such a feature, and such other factors as the Secretary deems appropriate. (*Id.*)

In 2020, DOE previously exercised permissible discretion in amending and making binding the Department's Process Rule. Since then, recent Supreme Court decisions—notably *Loper Bright Enterprises v. Raimondo* (603 U.S. 369 (2024))—provide further guidance on how agencies should interpret and apply applicable statutes. The decision in *Loper* not only bolsters the discretion exercised by the 2020 final rule but also supports this proposal as consistent with the “best read” of EPCA. In addition, other decisions, such as *Michigan v. EPA*, 576 U.S. 743 (2015), further support DOE's proposed application of the balancing factors under at 42 U.S.C. 6295(o)(2)(B)(i). EPCA expressly requires that DOE “shall . . . determine whether the benefits of the standard exceed its burdens” and lists a broad array of seven balancing factors the Secretary

must consider. *Id.* The procedures proposed here, and the proposal to make them binding on actions that may result in more stringent standards, will enhance the Department's ability to gather and weigh the relevant evidence needed to support a reasoned decision under EPCA's broad and inherently consumer-protective balancing factors. *See id.* (directing Secretary expressly to consider, *inter alia*, the economic impact on manufacturers and consumers, the comparative life-time operating cost savings versus increases in product purchase and maintenance costs, and any lessening in utility as a result of new standards); *see also id.* 42 U.S.C. 6295(o)(3)(B) (forbidding the establishment of new standard if it will not result in “significant conservation” of energy or water); *cf. Michigan*, 576 U.S. at 752 (noting irrationality of ignoring costs under even the vague “appropriate and necessary” standard).

B. Background

In July of 1996, DOE published a final rule in the **Federal Register** that codified DOE's “Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products” at 10 CFR part 430, subpart C, appendix A. 61 FR 36974 (July 15, 1996) (“July 1996 Final Rule”). The goal of the Process Rule was to increase transparency by elaborating on the procedures, interpretations, and policies that would guide the Department in establishing new or revised energy conservation standards for consumer products.

On February 14, 2020, DOE published a final rule in the **Federal Register** (“February 2020 Final Rule”) that significantly revised the Process Rule. 85 FR 8626. This rule made the specified rulemaking procedures binding on DOE and revised certain provisions to ensure consistency with existing statutory requirements. Other changes included expanding early opportunities for public input on the Appliance Program's priority setting and rulemaking activities, setting a significant energy savings threshold for updating standards, establishing a 180-day window between test procedure final rules and standards proposals, specifying DOE's approach to adoption of industry test standards in its test procedures, and delineating procedures for rulemaking under the separate direct final rule and negotiated rulemaking authorities. DOE also published a companion final rule in the **Federal Register** on August 19, 2020 (“August 2020 Final Rule”), that clarified how DOE would conduct a comparative

analysis across all trial standard levels when determining whether a particular trial standard level was economically justified. 85 FR 50937.

Subsequently, DOE published further amendments to the Process Rule, some of which reversed or modified amendments made in the February 2020 and August 2020 Final Rules. DOE published the first of these final rules in the **Federal Register** on December 13, 2021 (“December 2021 Final Rule”). 86 FR 70892. DOE published a second final rule with additional amendments to certain sections of the Process Rule in the **Federal Register** on April 8, 2024 (“April 2024 Final Rule”). 89 FR 24340. These amendments, among other things, reverted the Process Rule back to the non-binding status of the July 1996 Final Rule to allow DOE to tailor its rulemaking process to best fit the unique circumstances of a particular rulemaking and provide DOE with flexibility to be able to better meet statutory review requirements, and removed the significant energy savings threshold. 86 FR 70896–70906.

The following paragraphs summarize the origins and historical amendments to the individual sections of the Process Rule.⁴

(1) *Objectives*—This section was established in the July 1996 Final Rule and lays out the overall purpose of the Process Rule and its specific provisions. The February 2020 Final Rule made various editorial changes to this section.

(2) *Scope*—This section was established in the July 1996 Final Rule and identifies the types of rulemakings to which the Process Rule applies. This section was amended in the February 2020 Final Rule to clarify that the Process Rule applies to energy conservation standards and test procedures for both covered consumer products and commercial and industrial equipment.

(3) *Application*—This section was added in the February 2020 Final Rule and specified that the Process Rule would be binding on DOE. This section was subsequently amended in the December 2021 Final Rule to state that DOE has discretion to depart from the general guidance in Appendix A when it deems necessary or appropriate, with the stipulation that DOE will provide interested parties with notice of the deviation and an explanation.

(4) *Setting Priorities for Rulemaking Activity*—This section was established in the July 1996 Final Rule and

⁴ The full text of the current Process Rule is available at www.ecfr.gov/current/title-10/chapter-II/subchapter-D/part-430/subpart-C/appendix-A/Appendix%20A%20to%20Subpart%20C%20of%20Part%20430.

identifies the factors that DOE applies when determining its regulatory plans and formulation of inputs for the Regulatory Agenda. This section was amended in the February 2020 Final Rule to specify that DOE would offer an opportunity to provide input on prioritization of rulemakings through a request for comment as DOE begins preparation of its Regulatory Agenda each spring.

(5) *Coverage Determination Rulemakings*—This section was established in the February 2020 Final Rule and describes the process DOE would follow to establish coverage for consumer products and industrial equipment. Subsequent amendments in the December 2021 Final Rule and April 2024 Final Rule allow DOE to seek early stakeholder input through preliminary rulemaking documents prior to a proposed coverage determination, removed a previous requirement that final coverage determinations be published prior to the initiation of any test procedure or energy conservation standard rulemaking and at least 180 days prior to publication of a test procedure NOPR, and removed the previously required 180-day period between finalization of DOE test procedures and issuance of a NOPR proposing new or amended energy conservation standards.

(6) *Process for Developing Energy Conservation Standards*—This section was established in the July 1996 Final Rule and describes the process to be used in developing energy conservation standards for covered products and equipment other than those covered equipment subject to ASHRAE/IES Standard 90.1. The February 2020 Final Rule created an “early assessment” process for seeking stakeholder input prior to commencing a rule and committed to an initial rulemaking stage prior to a proposed rule (e.g., a framework document or preliminary analysis). This rule also established a threshold of “significant energy savings” of 0.3 quads or 10-percent site savings over 30 years. Subsequent amendments in the December 2021 and April 2024 Final Rules removed the energy savings threshold requirement and the requirement for a separate early assessment request for information (“RFI”) but clarified that DOE will issue one or more documents during the pre-NOPR stage of a rulemaking.

(7) *Policies on Selection of Standards*—This section was established in the July 1996 Final Rule and describes Department policies concerning the selection of new or revised standards. The July 1996 Final Rule provided that DOE would

implement the statutory mandate that any new or amended standard is designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. The February 2020 Final Rule made minor amendments to align with revisions elsewhere in the Process Rule, while the August 2020 Final Rule added a clarification that DOE would conduct a comparative analysis across all trial standard levels when determining whether a level was economically justified. The December 2021 Final Rule amended this section to remove the requirement for a comparative analysis.

(8) *Test Procedures*—This section was established in the original July 1996 Final Rule and describes the process by which DOE would establish test procedures for covered products and equipment. The February 2020 Final Rule added an early assessment process for test procedures and generally committed that DOE would adopt consensus industry test procedures unless not consistent with EPCA. Consistent with other amendments in that rule, this section was also amended to require that DOE finalize a test procedure 180 days in advance of a standards proposal. The December 2021 Final Rule clarified that DOE may revise consensus industry test procedure standards for compliance, certification, and enforcement purposes, and revised application of the 180-day period to apply to the period between finalization of a test procedure and close of the comment period of a standards proposal (rather than publication of the proposal).

(9) *ASHRAE Equipment*—This section was created by the February 2020 Final Rule and describes the process DOE will follow for conducting rulemakings for equipment subject to the “ASHRAE trigger” provisions in EPCA that apply when ASHRAE Standard 90.1 is amended with respect to standards, test procedures, or design requirements applicable to such equipment. The April 2024 Final Rule added provisions to clarify application of the 6- and 7-year-lookback provisions for periodic review of standards and test procedures for ASHRAE equipment.

(10) *Direct Final Rules*—This section was established in the February 2020 Final Rule and describes how DOE would comply with EPCA requirements specific to publication of direct final rules, including the Department’s interpretation of the term “fairly representative of relevant points of view” as it applies to interested stakeholders. It also stated that a negotiated rulemaking may not result in

a direct final rule. The December 2021 Final Rule amended this section to clarify that DOE will implement its direct final rule authority under EPCA on a case-by-case basis including its evaluation of the meaning of “fairly representative”, subject to the circumstances of a particular rulemaking. It also removed the prohibition on a negotiated rulemaking culminating in a direct final rule.

(11) *Principles for Distinguishing Between Effective and Compliance Dates*—This section was established in the February 2020 Final Rule and provides clarification as to the distinction between the effective and compliance dates of a final rule. This section has not been amended since its original establishment.

(12) *Principles for the Conduct of the Engineering Analysis*—This section was established in the July 1996 Final Rule, and other than minor editorial changes, was not substantively amended in subsequent rulemakings.

(13) *Principles for the Analysis of Impacts on Manufacturers*—This section was established in the July 1996 Final Rule, and other than minor editorial changes, was not substantively amended in subsequent rulemakings.

(14) *Principles for the Analysis of Impacts on Consumers*—This section was established in the July 1996 Final Rule, and other than minor editorial changes, was not substantively amended in subsequent rulemakings.

(15) *Consideration of Non-Regulatory Approaches*—This section was established in the July 1996 Final Rule and identifies how DOE will consider the effects of non-regulatory efforts by manufacturers, utilities, and other interested parties to produce substantial efficiency improvements. Revisions in the February 2020 Final Rule removed a section discussing the Department’s pursuit of voluntary programs where it appears that highly efficient products can obtain a significant market share but that less efficient products cannot be eliminated altogether because, for instance, of unacceptable adverse impacts on a significant subgroup of consumers.

(16) *Cross-Cutting Analytical Assumptions*—This section was established in the July 1996 Final Rule and sets out the sources and general principles that DOE expects to continue relying upon in selecting values for certain cross-cutting analytical assumptions. This section was amended in the February 2020 Final Rule to specify that DOE would use two time lengths—30 years and another time length that is specific to the standard being considered, such as the useful

lifetime of the product under consideration, as well as a 9-year regulatory timeline as a sensitivity case. That rule also specified that DOE will endeavor to use robust price forecasting

techniques in projecting future prices of products.

On April 17, 2025, DOE published in the **Federal Register** an RFI seeking comments and information from interested parties to assist DOE in

identifying potential modifications to its Process Rule (“April 2025 RFI”). 90 FR 16093. DOE received comments in response to the April 2025 RFI from the interested parties listed in Table II.1.

BILLING CODE 6450–01–P

Table II.1 Commenters with Written Submissions in Response to the April 2025 RFI

Commenter(s)	Abbreviation	Comment No. in the Docket	Commenter Type
AHRI, AMCA, AHAM, CTA, HPBA, HARDI, NAM, NAMA, NAFEM, NEMA, PHCC, PMI, PTI ⁵	Joint Commenters	24	Trade Associations
Air Conditioning Contractors of America	ACCA	38	Trade Association
Air-Conditioning, Heating, and Refrigeration Institute	AHRI	28	Trade Association
American Gas Association, American Public Gas Association, National Propane Gas Association	Joint Gas Associations	25	Utility Associations
American Public Power Association	APPA	20	Utility Association
Anonymous	Anonymous	4	Individual
Anonymous	Anonymous	5	Individual
Anonymous	Anonymous	6	Individual
Anonymous	Anonymous	10	Individual
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Consumer Federation of America, National Consumer Law Center	Joint Advocates	31	Advocates
ASHRAE	ASHRAE	12	Trade Association
AUX Air USA	AUX	7	Manufacturer
Bradford White Corporation	BWC	34	Manufacturer
Burnham Holdings, LLC	BHI	16	Manufacturer
Ceres, Inc.	Ceres	22	Advocates
Don Voight	Voight	3	Individual
Edison Electric Institute	EI	35	Utility Association
Hawaii State Energy Office; Washington State Department of Commerce	State Agencies	33	State Agencies
Heidi King Consulting	Heidi King Consulting	30	Consultant
Lennox International Inc.	Lennox	26	Manufacturer
Manufactured Housing Institute	MHI	21	Trade Association
Mark Strauch	Strauch	18	Individual
National Association of Home Builders	NAHB	19	Trade Association
National Electrical Manufacturers Association	NEMA	23	Trade Association
National Multifamily Housing Council and National Apartment Association	NMHC and NAA	29	Trade Association
National Rural Electric Cooperative Association	NRECA	17	Utility Association
North American Association of Food Equipment Manufacturers	NAFEM	13	Trade Association
Northwest Energy Efficiency Alliance	NEEA	36	Advocates

ONE Gas, Inc.	ONE Gas	37	Utility
Pacific Gas and Electric Company; San Diego Gas and Electric; Southern California Edison	CA IOUs	32	Utilities
Pool & Hot Tub Alliance	PHTA	27	Trade Association
Rinnai America Corporation	Rinnai	11	Manufacturer
Solaray Corporation	Solaray	8	Manufacturer
Teresa Sabol Spezio, PhD, PE	Spezio	9	Individual
The Rehancement Group, Inc.	TRG	2	Consultant
WM Technologies LLC	WM Technologies	14	Manufacturer
Zero Zone, Inc.	Zero Zone	15	Manufacturer

BILLING CODE 6450-01-C

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.⁶

DOE received one comment pertaining to issues outside of the scope of this rulemaking and which, therefore, are not addressed in this document.⁷

III. Discussion of General Comments**A. General Support for or Opposition to Standards**

A number of commenters indicated general support for existing energy conservation standards. (Anonymous, No. 4 at p. 1; Anonymous, No. 6 at p. 1; Ceres, No. 22 at p. 6; Lennox, No. 26 at p. 1; Rinnai, No. 11 at p. 2)

An individual commented that existing energy conservation standards still allow for a significant number of choices for consumers. (Anonymous, No. 6 at p. 1) Another individual commented that energy conservation standards drive engineering innovation, including for lighting and water-using products. (Anonymous, No. 3 at p. 1)

Several individuals commented on operating cost savings associated with energy conservation standards. An

individual commented that energy efficient appliances reduce operating costs for consumers and asked DOE to continue enforcing standards. (Anonymous, No. 3 at p. 1) The individual also suggested DOE review studies documenting the value of energy conservation standards. (Anonymous, No. 3 at p. 1) Another individual commented that less-efficient appliances will cost consumers more to operate regardless of energy source or price and that DOE should continue to establish energy conservation standards to save consumers money. (Anonymous, No. 9 at p. 1) A third individual commented that E.O. 14154 is focused on reducing energy costs and burdens on consumers and that increasing energy efficiency is one of the best ways to reduce energy costs for consumers. The individual also commented that regulations should be backed by strong data and analysis and that research demonstrates that the energy savings associated with standards can be worth it, even if there is a higher up-front cost. (Anonymous, No. 10 at pp. 1–2).

Lennox commented to support the goals of DOE's appliance efficiency program to maximize improvements in energy savings for consumers that are technologically feasible and economically justified for finished products at the system level. (Lennox, No. 26 at p. 1).

Rinnai commented to support national energy efficiency standards and the principle of Federal preemption, which prevents State-level mandates that would destabilize markets and erode consumer choice. (Rinnai, No. 11 at p. 2).

An individual expressed opposition to energy conservation standards, commenting that efficiency standards have had a negative impact on reliability and that it would be preferable to have greater choice for lighting and appliances. (Anonymous, No. 5 at p. 1).

In response, DOE is not making any proposals with respect to the Appliance Standards Program itself, but instead, the Department is proposing certain revisions to the process by which it carries out its obligations under EPCA to adopt new or revised energy conservation standards and test procedures, as discussed in section IV of this document.

B. General Support for or Opposition to Changes to the Process Rule

This section discusses the comments in general support for or opposition to revising the current Process Rule. Specific comments related to specific Process Rule revisions are discussed in section IV of this document.

Several commenters expressed general support for revising the current Process Rule, as discussed in the following paragraphs.

BHI commented that DOE's existing rulemaking process is opaque, overly complex, and subject to agenda-driven manipulation. The commenter added that the resulting rules are often delayed, based on flawed analysis, and poorly documented, and that they impose undue regulatory burden and uncertainty on the industry, while leaving DOE open to litigation. (BHI, No. 16 at p. 2) BHI attached comments submitted to previous rulemakings⁸ to illustrate the need for revisions. (BHI, No. 16 at pp. 1–2) BHI acknowledged that implementing the Process Rule changes as changes recommended in their comments for periodic reviews of standards as required under EPCA would likely result in an increased frequency with which new standards cannot be justified for a particular product. According to the commenter,

⁸ BHI attached previously submitted comments that were summarized as part of the rulemakings corresponding to the following dockets: Docket EERE 2019–BT–STD–0036, EERE–2021–BT–STD–003, EERE–2018–BT–STD–0018 related to Boilers, the Process Rule, and Non-Condensing Technology, respectively.

⁶ The Air-Conditioning, Heating, and Refrigeration Institute (AHRI); Air Movement and Control Association (AMCA) International; Association of Home Appliance Manufacturers (AHAM); Consumer Technology Association (CTA); Hearth, Patio & Barbecue Association (HPBA); Heating, Air-Conditioning, Refrigeration Distributors International (HARDI); National Association of Manufacturers (NAM); National Automatic Merchandising Association (NAMA); North American Association of Food Equipment Manufacturers (NAFEM); National Electrical Manufacturers Association (NEMA); Plumbing-Heating-Cooling Contractors Association (PHCC); Plumbing Manufacturers International (PMI); and Power Tool Institute (PTI).

⁷ The parenthetical reference provides a reference for information located in this rulemaking docket, Docket No. EERE–2025–BT–STD–0001, which is maintained at: www.regulations.gov. The references are arranged as follows: (commenter name, comment docket ID number at page of that document).

⁸ (TRG, No. 2 at pp. 1–4).

increasing standards for a particular product over time results in an appliance's efficiency approaching its theoretical limit, thereby suggesting that previous standards have done what EPCA intended; any process for standard setting should account for the reality that trivial energy gains will result in cost increases to consumers that yield little to no real-world payback by way of decreases in utility bills. (BHI, No. 16 at p. 6)

The Joint Commenters stated that the Process Rule should be clear, transparent, and reflect stakeholder consensus so that it will not be subject to policy swings by changing Administrations. (Joint Commenters, No. 24 at p. 3).

The Joint Gas Associations commented that the Process Rule should be revised to ensure protection of consumer choice, promote market competition and innovation, maintain fuel neutrality, and reduce regulatory burdens. (Joint Gas Associations, No. 25 at p. 7).

NRECA commented in support of DOE's efforts to revise the Process Rule in ways that would lead to more common sense outcomes when updating energy conservation standards. NRECA added that the Process Rule should be revised to enhance consumer choice and affordability. (NRECA, No. 17 at p. 2).

Rinnai commented that the Process Rule should be revised to ensure discipline, transparency, and public accountability. (Rinnai, No. 11 at p. 3).

DOE also received comments generally supporting revisions to return, fully or partially, to the Process Rule as amended at the beginning of 2020 (*i.e.*, the "2020 Process Rule"), as further discussed in the following paragraphs.

BHI, MHI, WM Technologies and Zero Zone commented that DOE should return to the 2020 Process Rule. (BHI, No. 16 at p. 2; MHI, No. 21 at p. 2; WM Technologies, No. 14 at pp. 1, 3; Zero Zone, No. 15 at p. 1). MHI noted that standards for water heaters, gas furnaces, showerheads, electric spas, and freezers would have been avoided with the 2020 Process Rule. (MHI, No. 21 at p. 2).

AHRI, BWC, the Joint Commenters, and Lennox commented in support of revising the Process Rule and of any changes largely consistent with the 2020 Process Rule. (AHRI, No. 28 at p. 1; BWC, No. 34 at p. 1; Joint Commenters, No. 24 at p. 2; Lennox, No. 26 at p. 2). Specifically, Lennox stated that they support re-instituting the five key Process Rule measures from the 2020 Process Rule: (1) DOE's compliance with the Process Rule must be mandatory and binding on DOE; (2) test

procedures should be finalized by DOE 180 days before proposing new energy conservation standards; (3) reasonable and mandatory minimum public comment periods should be provided; (4) minimum threshold values for significant energy savings should be reinstated; and (5) comparative analysis across trial standard levels should be reinstated. (Lennox, No. 26 at p. 2). BWC added that the 2020 Process Rule was not a "one-size-fits-all" approach and provided DOE with extensive regulatory flexibility. (BWC, No. 34 at p. 3).

Several commenters opposed changes to the current Process Rule and generally stated that the current Process Rule is adequate. (Joint Advocates, No. 31 at p. 1; State Agencies, No. 33 at pp. 1–2; Ceres, No. 22 at p. 6; Anonymous, No. 4 at p. 1).

The Joint Advocates added that the current Process Rule already provides detailed rulemaking guidance that addresses the topics discussed in the April 2025 RFI. For example, the Joint Advocates argued that the current Process Rule already includes consumer choice and market competition and innovation protections; it also considers manufacturer impacts, including regulatory burden, and it provides detailed guidance on cost and benefit analysis and the public comment and review process. (Joint Advocates, No. 31 at p. 1).

The State Agencies added that the current Process Rule appropriately provides guidance and should not be modified. The State Agencies argued that repeated changes to the Process Rule have led to market uncertainty. In addition, the State Agencies further argued that any changes to the Process Rule would increase regulatory burden and recommended that DOE should not pursue any further rulemakings related to Process Rule, including a separate analytical methodology RFI. (State Agencies, No. 33 at pp. 1–2).

An individual commented that there was a lack of evidence to suggest that there are substantial flaws in existing rules or the current process to establish them. (Anonymous, No. 4 at p. 1).

AUX stated that the current Process Rule is essential to fostering innovation, ensuring affordable and environmentally-friendly products, and balancing regulatory certainty and flexibility for manufacturers without overburdening manufacturers. AUX added that the existing Process Rule has driven innovation in residential HVAC, leading to more-efficient products that often exceed standards and providing significant cost savings to consumers. (AUX, No. 7 at pp. 1–2).

The CA IOUs stated that they support the objectives of the Process Rule and recommended that any changes should enhance these goals while aligning with EPCA's purpose of achieving cost-effective energy savings. The CA IOUs emphasized the importance of maintaining flexibility to address appliance-specific issues, complying with EPCA and the Administrative Procedure Act, and ensuring equitable implementation. The commenters suggested that DOE should evaluate issues on a case-by-case basis within the context of each individual rulemaking rather than being pre-determined by a set of generalized assumptions. The CA IOUs further cautioned against frequent changes to the Process Rule, which create uncertainty, instead urging DOE to prioritize consistency and to focus on improvements grounded either in established practices or ones widely supported by stakeholders. (CA IOUs, No. 32 at pp. 1–2).

NEEA commented that DOE should maintain a consistent Process Rule to provide a predictable and accessible regulatory process and prevent additional regulatory burden. (NEEA, No. 36 at p. 1).

In response, DOE has reviewed the current Process Rule, the 2020 Process Rule, and the general comments received in response to the April 2025 RFI. Based on this review and an evaluation of comments received on specific Process Rule topics, DOE is proposing revisions to the current Process Rule to return largely to the 2020 Process Rule with some modifications, as discussed in further detail in section IV of this document.

IV. Discussion of Comments and Proposed Revisions to Individual Sections of the Process Rule

The following sections discuss comments received relating to individual sections of the Process Rule, DOE's responses, and the proposed revisions to the Process Rule. DOE requests comments, data, and information regarding these proposals and all aspects of this notice of proposed rulemaking.

A. Objectives (Section 1)

This section was established in the July 1996 Final Rule and lays out the overall purpose of the Process Rule and its specific provisions. The February 2020 Final Rule made various editorial changes to this section. The December 2021 Final Rule added support for proposals developed in accordance with the Negotiated Rulemaking Act (5 U.S.C. 561 *et seq.*).

DOE did not receive any comments specific to the Objectives section of the Process Rule, other than general comments related to negotiations, as discussed in section IV.K of this document.

As discussed in the April 2025 RFI, DOE requested information to ensure consistency with recently issued Executive orders while continuing to satisfy the Department's statutory obligations. 90 FR 16093 (April 17, 2025). Consistent with this goal, DOE is proposing to include a new section in the Objectives section of the Process Rule to clearly specify the Department's goals of preserving availability of any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding as prescribed by EPCA. Such goals also safeguard the American people's freedom to choose from a variety of goods and appliances (including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads); promote market competition and innovation within the manufacturing and appliance industries; ensure that the global effects of a rule, regulation, or action shall, whenever evaluated, be reported separately from its domestic costs and benefits (energy savings and efficiency), in order to promote sound regulatory decision making and prioritize the interests of the American people; and guarantee opportunities for public comment and rigorous, peer-reviewed scientific analysis. (42 U.S.C. 6295(o)-(p)). These objectives also support the policies specified in Executive Order 14154.

Consistent with the statutory requirements of EPCA, DOE additionally has the goal of eliminating counterproductive requirements that raise the costs of home appliances.⁹ DOE is proposing to include this goal within the objectives section of the Process Rule.

B. Scope (Section 2)

This section was established in the July 1996 Final Rule and identifies the types of rulemakings to which the Process Rule applies. This section was amended in the February 2020 Final Rule to clarify that the Process Rule applies to both covered consumer

products and commercial and industrial equipment, except covered ASHRAE equipment, which is governed separately under section 9 of the appendix.

The Joint Gas Associations stated that a revised process Rule should apply to both consumer products and industrial and commercial equipment, except for ASHRAE equipment. (Joint Gas Associations, No. 25 at p. 30).

In response, DOE notes that the current Process Rule has this same scope as recommended by Joint Gas Associations, with ASHRAE covered separately in its own section. DOE is not proposing any revisions to the Scope section of the Process Rule.

C. Application (Section 3)

This section was added to the Process Rule by the February 2020 Final Rule and specified that the Process Rule would be binding on DOE. This section was subsequently amended in the December 2021 Final Rule to provide DOE with discretion to depart from the general guidance in Appendix A when it deems it necessary or appropriate to do so, with the stipulation that DOE will provide interested parties with notice of the deviation and an explanation.

In the April 2025 RFI, DOE requested comments on whether reintroducing a provision making the Process Rule mandatory would better enable the Department to comply with its obligations under the statute and applicable Executive orders. 90 FR 16093, 16100 (April 17, 2025).

In response to the April 2025 RFI, many commenters supported mandatory application of the Process Rule, generally to provide certainty to stakeholders. (Joint commenters, No. 24 at p. 3; AHRI, No. 28 at p. 13; Joint Gas Associations, No. 25 at pp. 7, 10–11; ASHRAE, No. 12 at p. 2; BWC, No. 34 at p. 1; MHI, No. 21 at p. 3; NAHB, No. 19 at p. 5; NEMA, No. 23 at pp. 2–3; NAFEM, No. 13 at p. 7; ONE Gas, No. 37 at p. 2; Rinnai, No. 11 at pp. 3, 11–12; WM Technologies, No. 14 at p. 3; Zero Zone, No. 15 at p. 3; BHI, No. 16 at p. 2) AHRI and BHI noted that mandatory application should reduce litigation risk. (AHRI, No. 28 at p. 13; BHI, No. 16 at p. 2).

Several of the commenters supporting mandatory application also acknowledged that some changes or flexibility may need to be included. PHTA stated that some areas should have well thought out deviations. (PHTA, No. 27 at p. 1) The Joint Commenters stated that any flexibility needed should be built into the rule. (Joint Commenters, No. 24 at p. 3) NAFEM stated that its recommended

revisions should be included if the rule becomes mandatory. (NAFEM, No. 13 at p. 7) Lennox stated that if made binding, the Process Rule should require DOE to actively explore negotiated rulemakings for all major new standards. (Lennox, No. 26 at pp. 11–12).

In addition, Zero Zone emphasized the value of public comment in making any changes to the Process Rule. (Zero Zone, No. 15 at p. 3) BHI suggested that Congress should cement this rule as law to avoid the pendulum swinging between Administrations. (BHI, No. 16 at p. 2).

Two commenters opposed mandatory application of the Process Rule. The Joint Advocates stated that an overly rigid approach could result in missed energy and water savings opportunities, delay rulemakings, and increase potential for procedural litigation. (Joint Advocates, No. 31 at p. 4) The State Agencies stated that flexibility is needed, and that making the Process Rule mandatory would increase regulatory burden. They noted that if the Process Rule is to be made mandatory, additional opportunities for public comment should be provided to make sure all potential provisions are carefully considered. (State Agencies, No. 33 at p. 2).

Upon review, DOE has tentatively determined that there is a reasonable basis for making the Process Rule binding for certain actions, while retaining greater flexibility for other actions. Any ECS-related action undertaken by DOE must adhere to the requirements outlined by EPCA. *See* 42 U.S.C. 6295; 42 U.S.C. 6311–6313. When the Secretary must make a statutory determination (e.g., regarding whether to regulate; or whether a proposed standard is technologically feasible and economically justified; or whether the benefits of a proposed standard exceed its burdens), DOE may offer the public additional transparency regarding circumstances when the Department will follow the requirements under EPCA more narrowly or will follow additional procedures. The Secretary has discretion under EPCA to implement additional procedures in support of careful consideration of statutory factors that weigh heavily in his determinations.

In the Process Rule, DOE is proposing that all procedures for regulatory actions (actions that may increase ECS stringency relative to existing requirements) will be binding requirements for the Department, which will provide much-needed certainty to stakeholders and will reflect the Secretary's careful consideration and

⁹ See "Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis" (Available at: <https://www.whitehouse.gov/presidential-actions/2025/01/delivering-emergency-price-relief-for-american-families-and-defeating-the-cost-of-living-crisis/>).

weighing of the balancing factors for economic justification and other requirements under EPCA. (See 42 U.S.C. 6295(o)). This approach recognizes, per EPCA, that regulatory changes often increase manufacturer costs and usually result in the need for design modifications that necessitate substantial investments of engineering resources, production line conversions, and other related manufacturing alterations or revisions to testing regimes. (See 42 U.S.C. 6295(o)(2)(B)(i), (m)). EPCA acknowledges the time, detailed analysis, and notice required in prescribing new or amended standards by establishing a minimum allowable period between further regulatory rulemakings; clearly articulated factors for a determination of economic justification; and required procedures for notice, comment, and transparency of record. (See 42 U.S.C. 6295(l), (m), (o), (p)). It behooves DOE to proceed with caution when enacting efficiency standards that may adversely affect consumers by pricing them out of the market for new or replacement appliances or eliminating useful characteristics of covered products. (See 42 U.S.C. 6295(o)(2)(B)(i)). New standards are also likely to present more challenges when evaluating economic effects, including lack of pertinent data on consumer response and reliance on assumptions. When reweighing evidence in other actions, such as for certain deregulatory actions, however, hindsight may provide a wealth of information. Moreover, DOE must meet strict evidentiary standards when issuing rules, including more stringent energy conservation standards, under 42 U.S.C. 6293, 6294, or 6295. Under 42 U.S.C. 6306(b)(2), when petitioned by an aggrieved party, a court may not affirm a rule unless DOE's rule is supported by "substantial evidence." Likewise, 42 U.S.C. 6313(b)(6)(A)(ii)(II) requires "clear and convincing evidence" to support a heightened standard for certain commercial equipment. This is true even when the Department has limited information to evaluate such complex factors as "the economic impact of the standard on the manufacturers and on the consumers of the products" and a comparison of the "operating costs throughout the estimated average life of the covered product" against "any increase in the price . . . or maintenance expenses of[] the covered products" with respect to products that may not be brought to market until some years after the regulatory action is finalized. (42 U.S.C. 6295(o)(2)(B)(i); see, e.g., *id.* 42 U.S.C. 6295(l)(2), (m)(4), (n)(5) (requiring

delays of up to five years before new standards may be enforced on manufacturers))

As noted previously and as EPCA acknowledges, regulatory actions typically justify the need for early stakeholder involvement and ample opportunities for public input. That is why it is crucial that DOE regulatory actions provide sufficient opportunity for public input so that stakeholders have adequate time to analyze and provide thoughtful comments, data, and information to the agency before it finalizes a proposed regulatory action. Not only does a properly structured process provide regulatory certainty and prevent the imposition of unnecessary or unjustified costs on manufacturers, but it also ensures that consumers do not face excessive costs or the loss of important performance-related features. This holds true for both energy conservation standards and test procedure rulemakings, because if a test procedure does not properly measure a covered product's energy efficiency or energy use, energy conservation standards may be set at an inappropriate level. And it is important to remember that EPCA establishes the minimum requirements to issue new rules. For example, EPCA requires a comment period of not less than 60 days for proposed standards and test procedures. (42 U.S.C. 6295(p)(2), 6293(b)(2)). But there is no maximum comment period limit for a proposed standards rule and the limit for a proposed test procedure rule is 270 days. *Id.* Similarly, EPCA only requires that DOE publish a notice of proposed rulemaking before issuing a final rule or final determination not to amend standards. (42 U.S.C. 6295(p)(1)). But again, that is the minimum requirement. And while these procedural requirements may be sufficient for revisiting a determination not to amend standards that was made less than 3 years ago in a market where there has been no technological advances in efficiency, for all the reasons discussed previously, a more comprehensive, structured process is warranted before implementing rules that impose new obligations and costs on regulated parties and consumers. Consequently, the proposed Process Rule sets forth procedural elements (including early assessment opportunities and preliminary documents), temporal spacing between key elements, and minimum comment periods to facilitate rulemakings that are robust and best meet all applicable statutory requirements. Making these procedures binding on DOE would further safeguard the achievement of

these important objectives. While DOE acknowledges the concerns raised by some commenters about an overly rigid approach, the Department has tentatively determined that the Process Rule, as proposed to be amended in this NOPR, contains sufficient flexibility to address those stakeholder concerns.

Certain actions, in contrast, may present a very different set of situations that may warrant a different approach and may not necessitate the same level of advance outreach, lengthened comment periods, or lead time, as compared to regulatory actions. In some circumstances, where DOE determines that deregulation is appropriate, it may be that DOE has recognized, with the benefit of hindsight and additional real-world information gathered as a new standard or test procedure is implemented, or a test procedure later determined to be unduly burdensome to conduct (in violation of 42 U.S.C. 6293(b)(3) or 42 U.S.C. 6314(a)(2)). In such instances, consumers may experience a reduction in product choice, a loss of valuable features, and/or an unjustified increase in first costs. Alternatively, an unanticipated change in market conditions or error in analysis may result in hardships or barriers to compliance for manufacturers. Deregulatory actions are intended to remedy these suboptimal outcomes, and in some cases, DOE does not believe that there is the same need for procedural protections for deregulatory actions as there is for regulatory actions, for the reasons that follow. Over time, DOE has exercised discretion in expediting certain deregulatory actions. For example, DOE has conducted test procedure rulemakings on an expedited timeline to address limited-scope issues (e.g., the rulemaking to amend test cloth specifications for clothes dryer and clothes washer testing was initiated with a NOPR¹⁰ and did not have a pre-proposal document).

First, deregulatory actions are not likely to require costly changes to manufacturing lines or production facilities, as would be expected to accompany more stringent standards. In contrast to regulatory actions, deregulation may reduce costs, and potential savings may trickle down to consumer, especially in highly competitive markets. A newly deregulated area frees industry from associated compliance mandates and presents more business options, which will of course entail the independent weighing of potential costs and benefits by industry before taking action.

¹⁰ See, FR 87903 (Nov. 5, 2024), which led to a final rule publication at 90 FR 5519 (Jan. 17, 2025)

Second, because deregulatory actions open up new, less burdensome options to manufacturers (and indirectly to consumers), those same procedural safeguards (e.g., preliminary documents, required spacing of rulemaking steps, and extended comment periods) may not be necessary. With the increased flexibility that comes from deregulation, industry and consumers may choose to maintain course or adjust, but are not compelled to take any action, unlike with regulatory actions, which by their nature limit choice and force action. Furthermore, DOE believes that there is also a temporal element to deregulatory actions, in that there is value in providing substantive relief to consumers and manufacturers as soon as possible. Accordingly, following all of the procedural steps proposed in the Process Rule would in certain circumstances run counter to providing deregulatory relief as soon as possible. Finally, DOE may choose to add to the standards determination process thresholds rooted in EPCA's required considerations for economic justification. When those thresholds, which reflect the Secretary's discretion in weighing EPCA's balancing factors, indicate a determination not to further regulate, DOE may consider that analysis sufficient under the requirements of EPCA and may choose to forego more detailed analyses. (42 U.S.C. 6295(o)). Though such an action is not deregulatory, it offers the kind of certainty and timely notice contemplated by EPCA, and these considerations may outweigh the additional procedural steps merited for increases in stringency. Consequently, DOE proposes not to make all Process Rule provisions binding on the Department for actions that are not likely to increase stringency for affected entities (e.g., certain deregulatory actions or determinations not to further regulate). In such instances, the Department may choose to apply those provisions as may be appropriate in any particular action so as to maintain flexibility and to provide relief without undue delay in appropriate cases.

Moreover, in contrast to a regulatory action imposing new standards that will result in estimated, but uncertain, impacts on the market, it will often be the case that DOE has a wealth of information to rely on in making a deregulatory decision with respect to a test procedure or standard under consideration. Both the Department and stakeholders will have data and experience gathered during the implementation of an existing standard that will provide greater certainty

without the need for an extended period of evidence building and development of estimates and projections.

DOE has not identified any statutory or other legal impediments to a bifurcated approach to the binding nature of the Process Rule that distinguishes between regulatory and other actions. DOE has discretion to set its own procedures for conducting rulemaking proceedings, as long as such procedures also incorporate any relevant statutory requirements set forth in EPCA (e.g., a minimum 60-day comment period for NOPRs). In crafting those procedures, DOE is at liberty to tailor those procedures to address identified concerns (as discussed previously) or to provide a more flexible and expedited process where the same concerns are not found to exist.

It is DOE's view that this approach would allow DOE to best meet the statutory requirements of EPCA, including preventing the unavailability of performance-related features. (42 U.S.C. 6295(o)(4)). DOE also believe that this approach is consistent with numerous comments on the April 2025 RFI which generally supported mandatory application of the Process Rule but acknowledged the potential need for flexibility in certain situations. Furthermore, this approach is consistent with the objectives set forth in various Executive orders and Presidential memoranda. For example, section 2(f) of Executive Order (E.O.) 14154, "Unleashing American Energy," 90 FR 8353 (Jan. 29, 2025), states that it is the policy of the United States to safeguard the American people's freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads, and to promote market competition and innovation within the manufacturing and appliance industries. In addition, the Presidential memorandum titled "Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis," 90 FR 8245 (Jan. 28, 2025), directs agencies to take appropriate actions to, among other things, "eliminate counterproductive requirements that raise the cost of home appliances."

In summary, DOE has tentatively concluded that a bifurcated approach to the binding nature of the Process Rule which distinguishes between regulatory and other actions would be appropriate for several reasons. DOE believes that it best suits the Department's model outcome for deregulatory situations, in that it would allow DOE to provide expedited relief to stakeholders in terms

of cost savings, reduced regulatory burdens, and protection of performance-related features. Along these lines, it would also be consistent with the views of many commenters and would allow DOE to implement what it believes is the best reading of the statutory provisions of EPCA, including applicable evidentiary standards, as well as practical differences between regulatory and deregulatory actions such as informational asymmetries. It would also support the Administration's priorities in terms of advancing appliance affordability and preserving consumer choice.

As such, DOE proposes to revise section 3 of the Process Rule to specify its mandatory application as described in this section. DOE requests comment on this proposal and on any alternate approaches to mandatory application that best achieve transparency and opportunities for public comment while allowing for flexibility for certain deregulatory actions.

D. Setting Priorities for Rulemaking Activity (Section 4)

This section was established in the July 1996 Final Rule and identifies the factors that DOE applies when determining its regulatory plans and formulation of inputs for the Regulatory Agenda. This section was amended in the February 2020 Final Rule to specify that DOE would offer the opportunity to provide input on prioritization of rulemakings through a request for comment as DOE begins preparation of its Regulatory Agenda each spring.

In the April 2025 RFI, DOE generally requested comments and information on whether and how the Process Rule should be amended to specify rulemaking prioritization and timelines, consistent with EPCA's requirements. 90 FR 16093, 16100 (April 17, 2025).

The Joint Advocates stated that the current Process Rule already describes the prioritization process for rulemaking activity, so no amendment is needed. (Joint Advocates, No. 31 at p. 4).

The State Agencies stated that EPCA already establishes timelines for standards to be revised. The State Agencies added that the current Process Rule allows for reasonable timelines, and that the Process Rule should not be amended to provide specific rulemaking prioritization and timelines. They further stated that any potential changes must be justified by DOE after thorough consideration of impacts and burdens. (State Agencies, No. 33 at p. 2).

The Joint Gas Associations stated that DOE should focus on the potential energy savings and the potential economic benefits as an initial screen

for determining its priorities. The Joint Gas Associations argued that such focus is important, because if DOE determines the proposed regulatory activity does not provide sufficient energy savings or is not cost-effective, there is no need to review the other factors. The Joint Gas Associations also supported stakeholder input in the rulemaking process and with regard to setting priorities, and they stated that commenting on the Regulatory Agenda would provide stakeholders with a chance to weigh in on these priorities. (Joint Gas Associations, No. 25 at pp. 35–36).

Upon review, DOE has tentatively determined that DOE's statutory review requirements and the current Process Rule adequately describe the prioritization setting framework as recommended by commenters. Specifically, DOE is statutorily required to review energy conservation standards and test procedures at intervals specified by EPCA. Additionally, DOE acknowledges the benefits of considering energy savings and potential economic benefits in prioritizing rulemakings, as recommended by the Joint Gas Associations, which are already specified in section 4 of the Process Rule.

As discussed in section IV.A of this document, DOE is proposing to specify that the Department's objectives include protecting consumer choice in covered products and equipment and eliminating counterproductive requirements that increase the costs of appliances. DOE is proposing to include these objectives in the list of factors DOE will consider when establishing rulemaking priorities, and requests comment on their inclusion.

Section 6 of Executive Order 14154 specifies policies for prioritizing accuracy in environmental analyses, specifically instructing that for Federal regulatory processes, "all agencies shall adhere to only the relevant legislated requirements for environmental considerations and any considerations beyond those requirements are eliminated." Consistent with this direction, DOE is proposing to remove the consideration of environmental factors as specified in section 4(a)(2) of the Process Rule and to instead refer to potential social and private costs and benefits.

DOE has also considered the requirement to request comment as DOE begins preparation of its Regulatory Agenda each spring. DOE's rulemaking reviews are largely driven by statutory timelines, with consideration of the factors outlined in section 4 of the Process Rule. DOE's goal is to limit

regulatory burden for stakeholders, and the Department has tentatively determined that there is little additional benefit provided by the current request for comment specified in section 4 of the Process Rule. Therefore, DOE is proposing to clarify in the Process Rule that DOE will request comment on rulemaking prioritization only when circumstances weigh towards doing so. Such circumstances may include Executive Orders or other Administration initiatives or meaningful shifts in policy on which the Department would benefit from broad and early public comment. Consequently, this would move from being a prescriptive annual publication from DOE for stakeholder review to a discretionary action considered on a case-by-case basis, thereby limiting the burden associated with reviewing DOE's rulemaking documents while providing the benefit of public comment when needed. DOE notes that stakeholders may contact DOE regarding rulemaking priorities, independent of a published request for comment.

E. Coverage Determination Rulemakings (Section 5)

This section was established in the February 2020 Final Rule and describes the process DOE would follow to establish coverage for new consumer products and industrial equipment under the applicable statutory criteria of EPCA. Subsequent amendments in the December 2021 Final Rule and April 2024 Final Rule allowed DOE to seek early stakeholder input through preliminary rulemaking documents prior to a proposed coverage determination, removed a previous requirement that final coverage determinations be published prior to the initiation of any test procedure or energy conservation standard rulemaking and at least 180 days prior to publication of a test procedure NOPR, and removed the previously required 180-day period between finalization of DOE test procedures and issuance of a NOPR proposing new or amended energy conservation standards.

In the April 2025 RFI, DOE generally requested comments and information on whether and how the Process Rule should be amended to specify rulemaking prioritization and timelines, consistent with EPCA's requirements. 90 FR 16093, 16100 (April 17, 2025). Timing of coverage determinations falls within the scope of this request.

Lennox commented that DOE should require that coverage determinations be finalized at least 180 days prior to the publication of a TP NOPR for newly-covered products/equipment. The

commenter argued that it is a misuse of DOE, manufacturer, and other stakeholder resources to attempt to address substantive regulatory issues until the products have been clearly and specifically defined. (Lennox, No. 26 at p. 11).

Lennox also commented that coverage determination comment periods should be at least 60 days. (Lennox, No. 26 at p. 8–9).

In response, as discussed previously, DOE is largely proposing to revert to the language in the 2020 Process Rule, including for the section on coverage determinations. As mentioned, the 2020 Process Rule required that final coverage determinations be published prior to the initiation of any test procedure or energy conservation standard rulemaking and at least 180 days prior to publication of a test procedure NOPR. DOE understands that the 180 day-period provides regulated entities with both regulatory certainty and time to reallocate capital in preparation for compliance requirements. With regard to the comment period, both the current and 2020 Process Rule include a comment period of at least 60 days, so DOE is not proposing any changes specific to this requirement.

Several commenters discussed the process that they believe DOE should follow to establish coverage for consumer products and industrial equipment, as described in this section. On this topic, Strauch commented that DOE should focus on covered products required by statute under EPCA and not expand coverage to other consumer products and industrial equipment. (Strauch, No. 18 at p. 1).

The Joint Gas Associations supported a Process Rule that limits any expansion of coverage to those narrow circumstances that satisfy the statutory requirements and purpose of EPCA. (The Joint Gas Associations, No. 25 at p. 33).

Lennox and WM Technologies stated that standards should apply to only the finished product/system level, and not to sub-systems or components. Lennox and WM Technologies further stated that component-level regulation increases burden (e.g., regulatory complexity, consumer costs) and/or limits innovation. WM Technologies added that component-level and finished-product-level tests are different from each other and could produce test results that are not compatible. (Lennox, No. 26 at pp. 1, 4–5; WM Technologies, No. 14 at pp. 2–3)

In response, both the current and the 2020 Process Rule state that DOE has discretion to conduct proceedings to

determine whether additional products or equipment should be covered or whether to reduce the scope of coverage under EPCA if certain statutory requirements are met, including if such coverage is necessary or appropriate to carry out the purpose of EPCA. Section 5 of appendix A. Furthermore, the statute includes definitions for the terms “consumer product” and “industrial equipment” that determine the product level subject to regulation. Finally, DOE plans to consider issues related to component-level regulation on a case-by-case basis. At this time, DOE does not believe it is necessary to provide additional context with respect to the statutory requirements and is not proposing any additional changes to the Coverage Determination Rulemakings section of the Process Rule.

F. Significant Energy Savings

1. Background

Under EPCA, any new or amended energy conservation standard must result in significant conservation of energy or, in the case of ASHRAE equipment, significant additional conservation of energy.¹¹ (42 U.S.C. 6295(o)(3)(B); 42 U.S.C. 6313(a)(6)(A)(ii)(II); 42 U.S.C. 6316(a)). However, EPCA does not define “significant” as it relates to the amount of energy savings projected to result from an energy conservation standard. While DOE has generally addressed the significance of energy savings on a case-by-case basis in the context of individual energy conservation standards rulemakings, DOE has twice established sets of numerical thresholds to determine whether energy savings are significant.

In a final rule published in the **Federal Register** on December 22, 1982, DOE adopted three tests for determining whether an energy conservation standard would result in significant energy savings. 47 FR 57198 (December 1982 Final Rule). The first test deemed energy savings significant if the standard would result in the saving of 10,000 barrels per day (bpd) of oil or the saving of natural gas equivalent to 10,000 bpd of oil over the period of the average life of the product. The second test deemed energy savings significant if the standard would result in the saving of one percent of national electricity use over the period of the average life of the product. The third test deemed energy

savings significant if the standard would reduce product energy consumption by 16.67 percent. *Id.* at 47 FR 57209. In *Natural Resources Defense Council v. Herrington*, 768 F.2d 1355 (D.C. Cir. 1985), the court held that, while Congress gave DOE considerable discretion to define significant energy savings, DOE’s three tests were inconsistent with the purposes of EPCA. *Id.* at 1383.

In 2017, DOE once again initiated inquiry on the topic of a significant energy savings threshold in a request for information (RFI) published in the **Federal Register** on December 18, 2017. 82 FR 59992, 59997. Subsequently, in the February 2019 Process Rule NOPR, DOE proposed a threshold-based analysis for determining whether energy savings are significant. 84 FR 3910, 3923 (Feb. 13, 2019). Subsequent to the February 2019 NOPR, DOE published in the **Federal Register** a notice of data availability (NODA) on July 26, 2019, which presented its energy savings data in terms of site energy usage. 84 FR 36037 (July 2019 NODA).

DOE’s proposal generated significant comments both in support and in opposition, with the most salient points presented in the paragraphs that follow. (These comments are summarized in the February 2020 final rule, followed by DOE’s responses. *See* 85 FR 8626, 8656–8676 (Feb. 14, 2020).)

Commenters supporting the significant energy savings threshold argued that it would support consistency across energy conservation standards rulemakings, alleviate unnecessary regulatory burdens and uncertainty on industry, assist the Department and industry with resource allocation, and help mitigate consumer cost impacts. *Id.* at 85 FR 8656–8658.

Commenters opposing the significant energy savings threshold argued that it was inconsistent with the *Herrington* decision, that it would sacrifice energy and cost savings, and that any such level would be arbitrary. *Id.* at 85 FR 8658–8662. It was also argued that a simple threshold does not account for the importance of saving energy at different times of day, such as at times of peak grid demand. *Id.* at 85 FR 8660.

After considering comments received and applying a uniform approach with respect to the energy usage examined, DOE decided to adopt a significant energy savings threshold in the February 2020 Process Rule final rule, but it adjusted the numerical value of the threshold to account for concerns raised by commenters. In that rule, DOE adopted two tests for determining whether an energy conservation standard would result in significant

energy savings. The primary test deemed energy savings significant if the standard would result in a 10-percent reduction in site energy use over a 30-year period. *Id.* at 85 FR 8675. The second test deemed energy savings significant if the standard would save 0.3 quads of site energy use over a 30-year period. DOE found that these thresholds would have significantly reduced rulemaking burden over the history of the energy conservation standards program while retaining over 95 percent of the energy savings. *Id.* DOE explained its conclusion that the adopted approach was consistent with the court’s holding in *Herrington*. *See id.* at 85 FR 8669. The final rule pointed to that portion of the court’s decision in *Herrington* noting that DOE could establish a threshold for significant energy savings as long as the selected level reasonably accommodates the policies of EPCA. *Id.* at 85 FR 8675. This language in the *Herrington* opinion is particularly noteworthy because it provides a judicial interpretation as to the best reading of EPCA vis-à-vis the “significant conservation of energy” provision. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), it is the province of Article III courts to determine the best reading of ambiguous statutory provisions. Consequently, the *Herrington* court’s pronouncement as to the permissibility of a threshold for significant energy savings suggests that DOE is on firm ground in proposing such a threshold as part of the Process Rule.

However, before these significant energy savings tests were ever utilized in a DOE rulemaking, the Department changed course and eliminated these tests from its regulations in the December 2021 Final Rule, thereby reverting once again to assessing on a case-by-case basis whether a new or amended energy conservation standard would result in significant conservation of energy. 86 FR 70892, 70893 (Dec. 13, 2021). As discussed in the April 2021 Process Rule NOPR, DOE proposed to remove the current numerical threshold for determining whether energy savings are significant for a number of reasons; however, DOE did not claim that establishing a threshold was outside its authority under EPCA. 86 FR 18901, 18905 (April 12, 2021).

In light of E.O. 14154, “Unleashing American Energy,” 90 FR 8353 (Jan. 29, 2025), and the Presidential Memorandum of January 20, 2025, “Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis,” 90 FR 8245 (Jan. 28, 2025), DOE has decided to once again examine the potential for using

¹¹ For ASHRAE equipment, the baseline for comparison is the potential energy savings from the industry standard (*i.e.*, ASHRAE Standard 90.1). Thus, DOE can only issue a more-stringent standard if the additional energy savings are significant. (*See* 42 U.S.C. 6313(a)(6)(A)(ii)(II)).

tests or numerical thresholds in determining whether energy savings from a standard would be significant. Specifically, section 2(f) of E.O. 14154 provides that it is the policy of the United States “to safeguard the American people’s freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads, and to promote market competition and innovation within the manufacturing and appliance industries.” 90 FR 8353, 8353 (Jan. 29, 2025). Furthermore, the Presidential Memorandum of January 20, 2025, in relevant part, orders the heads of all Executive departments and agencies to “eliminate counterproductive requirements that raise the cost of home appliances.” 90 FR 8245, 8245 (Jan. 28, 2025).

For these reasons, in the April 2025 RFI, DOE requested comments on ways to reduce regulatory burden, mentioning the threshold value for energy savings as an example of such an opportunity. 90 FR 16093, 16097 (April 17, 2025). DOE received several comments in response to the April 2025 RFI related to whether DOE should establish criteria or thresholds to define the term “significant energy savings.” Two commenters opposed adding a significant energy savings threshold. (ASHRAE, No. 12 at pp. 2–3; NEEA, No. 36 at pp. 1–2). ASHRAE stated that there is no widely agreed to definition and that DOE should focus on achieving efficiency improvements on an individual basis, and NEEA stated that smaller incremental jumps are less burdensome and suggested assessing burden on an individual product basis. (*Id.*) Several commenters were supportive of a threshold. (AHRI, No. 28 at p. 11; BWC, No. 34 at pp. 4–5; BHI, No. 16 at pp. 2–3; Joint Gas Associations, No. 25 at p. 27; Lennox, No. 26 at pp. 2–4; MHI, No. 21 at p. 3; Strauch, No. 18 at p. 1; NAHB, No. 19 at p. 4; NEMA, No. 23 at pp. 4–5; NRECA, No. 17 at p. 2; ONE Gas, No. 37 at p. 5; Rinnai, No. 11 at p. 9; Strauch, No. 18 at p. 1; Zero Zone, No. 15 at p. 3) BWC, MHI, NAHB, and NEMA supported the thresholds from the February 2020 Process Rule. (BWC, No. 34 at pp. 4–5; MHI, No. 21 at p. 3; NAHB, No. 19 at p. 4; NEMA, No. 23 at pp. 4–5) Lennox supported a threshold of 0.3 quads or a 5-percent improvement in site energy savings. (Lennox, No. 26 at pp. 2–4) The Joint Gas Associations recommended that DOE utilize source energy when evaluating critical energy policy decisions and include the

anticipated reduction of source energy consumption and impact of overall source energy consumption in the market sector, noting that gas products are at a disadvantage when using site savings due to differing site-to-source factors. (Joint Gas Associations, No. 25 at p. 19–21, 27) In addition, the Joint Gas Associations stated that any energy savings associated with fuel switching should not be permitted to be used to justify a standard. (Joint Gas Associations, No. 25 at p. 21).

Energy conservation standards that reduce consumer choice and raise costs while delivering minimal energy savings to the consumer and the Nation are counterproductive as contrary to the statutory considerations outlined in EPCA. Establishing a reasonable, consistent methodology for determining significant energy savings ensures compliance with both the requirements of EPCA, as well as the policies and objectives set forth in these additional Executive Actions, and is responsive to the majority of stakeholder comments.

2. Proposed Threshold for Significant Energy Savings

One of the complicating factors in establishing tests or thresholds for determining significant energy savings has always been the vast difference in energy use amongst covered products and equipment. For example, the regulated site energy use of covered products and equipment ranges from less than 1 quad over a 30-year period to over 500 quads.¹² In *Herrington*, the court acknowledged that DOE may reasonably regard energy savings as not significant for a high-consumption appliance, even if the same amount would be significant for a low-consumption appliance. *Natural Resources Defense Council v. Herrington*, 768 F.2d 1355, 1376 (D.C. Cir. 1985). As a result, the court held that EPCA does not forbid DOE from setting a significant energy savings threshold as a percentage of the energy consumed by a covered product or equipment, provided that the selected level reasonably accommodates the policies of EPCA. *Id.* Keeping in mind these important considerations, DOE has tentatively concluded that a percentage-based threshold is the best way to reduce regulatory burdens while meeting the policy objectives of EPCA.

As for the specific percentage, DOE agrees with the court in *Herrington* that a significant energy savings threshold must show some awareness of the range

of energy savings Congress thought worth pursuing. *Id.* at 1377. Since the inception of the program, DOE has issued 86 rules establishing energy conservation standards for covered products and equipment with a total site energy savings of 83.5 quads.¹³ Without a significant energy savings threshold in place, DOE has generally adopted standards unless the energy savings would be genuinely trivial.¹⁴ For example, DOE has adopted standards that would result in 0.016 (Ceiling Fan light Kits), 0.02 (Microwave Ovens), and 0.044 (Beverage Vending Machines) quads of site energy savings over a 30-year period.¹⁵ Because the criterion for significant energy savings has, therefore, been almost without meaning (other than that trivial energy savings are not significant), DOE has essentially established standards based solely on what is economically justified and technologically feasible under EPCA. As a result, the energy savings from these standards are already close to the upper range of energy savings that is even achievable under EPCA, let alone the amount of energy savings that Congress thought was worth pursuing as “significant.”

Knowing that a reasonable threshold for significant energy savings can help achieve the energy conservation objective of EPCA while reducing regulatory burden, DOE evaluated potential energy savings percentage thresholds based on what percentage of energy savings from past standards rulemakings would have been retained under a new, proposed threshold. In conducting this evaluation, however, it rapidly became apparent that it would be difficult to accommodate the policies of EPCA solely using a percentage threshold. For example, on January 17, 2001, DOE published standards for consumer water heaters that were projected to result in 4.6 quads of source energy savings. 66 FR 4474, 4475. However, those energy savings only represented a 4-percent reduction in energy use of consumer water heaters over the analysis period. As a result, similar to the February 2020 Final Rule, DOE is proposing a second threshold that would be based on the cumulative amount of energy saved over the 30-year

¹³ See supporting table available in www.regulations.gov/docket/EERE-2025-BT-STD-0001. This includes final rules published from 1989 to 2025.

¹⁴ See, e.g., *Energy Conservation Program: Energy Conservation Standards for Dehumidifiers*, 81 FR 38338, 38346 (June 13, 2016)(finding energy savings to be nontrivial and, therefore, “significant” within the meaning of section 325 of EPCA).

¹⁵ See supporting table available in www.regulations.gov/docket/EERE-2025-BT-STD-0001.

¹² The range is based on the standby energy use for microwave ovens compared to the energy use of electric motors.

analysis period. The second threshold would account for situations where standards result in significant energy savings in absolute terms that may be achieved through small percentage reductions in energy use for covered products and equipment that use more energy (e.g., water heaters and central air conditioners and heat pumps).

In proposing these thresholds, DOE notes that the choice of site energy vs. source (or primary) energy is important. Site energy consumption refers to energy use at the site of the relevant equipment. For electricity from the grid, source (or primary) energy consumption is equal to the heat content of the fuels used to generate that electricity (which accounts for losses associated with the generation, transmission, and distribution of electricity).

For natural gas, oil, and propane, source energy is equivalent to site energy. Full-fuel-cycle (FFC) energy includes source energy and all energy consumed in extracting, processing, and transporting or distributing primary fuels, which are referred to as upstream activities. For natural gas, FFC energy includes leakage in upstream activities. This distinction is important, as some covered products and equipment may only use a single type of fuel (e.g., central air conditioners and heat pumps (electricity)), while others may use multiple types of fuel (e.g., water heaters (gas, oil, and electricity)). As the National Academies report¹⁶ noted, for products that use multiple fuel types or when more than one fuel can be used for the same application, comparison of just the site energy will lead to incorrect inferences about the potential for energy conservation. The report stated that for these products, measuring full-fuel-cycle energy consumption would provide a more complete picture of energy used, allowing comparison across many different products. Based on ensuring an equitable treatment of different energy sources, DOE has tentatively determined that a significant energy savings threshold based on FFC rather than site energy use is appropriate. DOE also notes that a threshold based on FFC energy savings is consistent with DOE's historic practice of presenting projected energy savings from a rule in terms of FFC savings.

Similar to the approach taken in the February 2020 Process Rule final rule,

DOE has evaluated how various potential significant energy savings thresholds would have impacted DOE's past rulemakings. 85 FR 8626, 8675 (Feb. 14, 2020). Based on this evaluation, DOE notes that a threshold based on a 10-percent reduction in FFC energy use over a 30-year period or a 2 quad reduction in FFC energy use over a 30-year period would retain 91.5 percent of the energy savings from the program while eliminating 35 percent of the rulemakings (30 of 86 rulemakings).¹⁷ This is a clear indication that establishing a threshold for significant energy savings can yield enormous benefits and reduce burdens without frustrating the energy conservation purposes of EPCA. Manufacturers typically incur significant conversion costs to redesign models for compliance with new or amended standards, and higher production costs associated with amended standards are passed on to consumers as higher up-front purchase costs. As discussed earlier in this paragraph, DOE estimates that without a threshold, 35 percent of DOE's rulemakings have imposed those costs on the market, while contributing to less than 9 percent of the total energy savings from the program.

Further, DOE notes that failure to meet the threshold in a rulemaking for a covered product or equipment does not foreclose the possibility of a future rulemaking for that same product/equipment achieving significant energy savings. One of the purposes of a threshold for significant energy savings is to prevent a process where DOE amends an energy conservation standard every time there is an incremental improvement in energy efficiency for a covered product or equipment which does not rise to a "significant" level. For example, the 2017 final rule for walk-in coolers and freezers was estimated to save 0.85 quads FFC over 30 years, representing an 8-percent reduction in FFC energy use. 82 FR 31808 (July 10, 2017). These energy savings would not meet the threshold of significant energy savings proposed in this NOPR. However, DOE's next walk-in coolers and freezers final rule published in 2024 was estimated to save 1.6 quads FFC over 30 years, representing a 6-percent reduction in FFC energy use. 89 FR 104616 (Dec. 23,

2024).¹⁸ These values also would not meet the proposed thresholds for significant energy savings, but the combined energy use reduction of the two final rules would represent over 2 quads of FFC energy savings. This example indicates how the proposed energy savings thresholds would allow DOE to continue establishing amended energy conservation standards, when appropriate, while avoiding the burdensome process of the market complying with frequent incremental changes to DOE's standards. DOE has tentatively determined that this balance of achieving significant energy savings while limiting the burden of rulemakings with lower energy savings, either on a percentage or quads basis, ensures that DOE's actions are consistent with EPCA while providing certainty as to how DOE will apply statutory requirements.

Based upon this analysis, DOE proposes to amend the current Process Rule to include the provisions regarding significant energy savings from the 2020 Process rule, but to consider "significant energy savings" as at least a 10-percent reduction in FFC energy use over a 30-year period or a 2 quad reduction in FFC energy use over a 30-year period. DOE also proposes to add this language specific to ASHRAE equipment and "significant additional conservation of energy" in section 9. DOE requests comment on these proposed thresholds and may also consider alternative thresholds ranging from 5 to 15 percent or from 0.5 quads to 5 quads FFC energy reduction over a 30-year period. These other thresholds and an analysis of their application to past DOE rulemakings can be found in the rulemaking docket.¹⁹ As discussed earlier in this section, DOE has tentatively determined that these proposed thresholds best balance the energy savings associated with the program while limiting the burden associated with rulemakings projected to save less energy, either on a percentage or quads basis. DOE also requests comment on its tentative determination that thresholds should be based on FFC energy use.

As discussed, DOE plans to review its analytical methods for evaluating potential new or amended standards as part of a separate process. To the extent that DOE's analytical methods may change in a way that would impact any eventual energy savings threshold (e.g.,

¹⁶ National Research Council (2009), *Review of Site (Point-of-Use) and Full-Fuel-Cycle Measurement Approaches to DOE/EERE Building Appliance Energy-Efficiency Standards: Letter Report*. Washington, DC: The National Academies Press (Available at: www.nationalacademies.org/publications/12670).

¹⁷ This evaluation is based on the FFC energy savings as presented in the final rules published from 1989 through 2025. The conversion of site to FFC energy use and energy savings varies by rulemaking based on both the energy source considered for the product or equipment at issue and on the site-to-FFC multipliers current at the time of that analysis.

¹⁸ This final rule was subsequently withdrawn by DOE on May 20, 2025, after the President signed a resolution of disapproval under the Congressional Review Act. 90 FR 21391.

¹⁹ See supporting table available in www.regulations.gov/docket/EERE-2025-BT-STD-0001.

analyzing energy savings over a time period other than 30 years), DOE would consider any corresponding adjustments needed to the energy savings thresholds in a subsequent proceeding. DOE requests comment and information on any such alternative analysis and corresponding adjustments, either as part of this proceeding or the separate proceeding focusing on analytical methodologies.

DOE also recognizes that EPCA established separate sections for consumer products and for certain industrial equipment,²⁰ recognizing the distinct uses and markets for these categories of equipment and products. Additionally, the model redesign cycles and product and equipment lifetimes also may be distinct between these categories, impacting the tradeoff of energy savings and burden associated with amended standards. DOE may consider an alternate approach under which it establishes different thresholds for covered products and equipment. To illustrate that approach, for example, DOE could alternatively specify that “significant energy savings” for covered products means at least a 10-percent reduction in energy use over a 30-year period or a 1 quad reduction in FFC energy use over a 30-year period; whereas for covered equipment significant energy savings may mean at least a 10-percent reduction in energy use over a 30-year period or a 2 quad reduction in FFC energy use over a 30-year period. DOE requests comment on whether such an alternative approach may be appropriate, as well as the specific thresholds that should be applied, for example thresholds in the range from 5 to 15 percent or from 0.5 quads to 5 quads FFC energy reduction over a 30-year period.²¹

DOE also requests comment on further alternative approaches, such as setting distinct thresholds, in terms of percentage and total FFC energy use reduction over a 30-year period (or as noted earlier over alternative analysis periods), according to the type of covered products and equipment in residential, commercial, and industrial sectors. For example, would there be a benefit to establishing separate thresholds for consumer heating and cooling equipment as compared to consumer appliances (e.g., refrigerators, dishwashers, and clothes washers and dryers)? DOE specifically requests comments on whether specific

thresholds should be applied to: (1) consumer heating and cooling products; (2) consumer appliances (such as refrigerators, dishwashers, and washers and dryers); (3) consumer water heating products; (4) consumer electronics; (5) other covered products; (6) commercial heating and cooling equipment; (7) commercial water heating equipment; (8) commercial refrigeration equipment; and (9) other covered equipment. DOE requests comment on this further disaggregated threshold approach, and on whether the 10-percent and 2 quads FFC energy use reduction over a 30-year period, or higher or lower alternatives, may be appropriate for each product or equipment grouping. DOE also acknowledges that implementation of such an approach may require further clarification regarding specific product classifications. DOE requests comment on whether further implementation guidance would be helpful and any recommendations from affected stakeholders on how to best implement such an alternate approach.

G. Process For Developing Energy Conservation Standards (Section 6)

This section was first established in the July 1996 Final Rule and describes the process DOE follows in developing energy conservation standards for covered products and equipment other than those covered equipment subject to ASHRAE/IES Standard 90.1. The February 2020 Final Rule created an “early assessment” process for seeking stakeholder input prior to commencing a rule and committed to an initial rulemaking stage prior to a proposed rule (e.g., an advanced notice of proposed rulemaking (“ANOPR”) or a framework document and preliminary analysis). This rule also established a threshold for “significant energy savings” of 0.3 quads or 10 percent site savings over 30 years. Subsequent amendments in the December 2021 and April 2024 Final Rules removed the energy savings threshold requirement and the requirement for a separate early assessment RFI but clarified that DOE will issue one or more documents during the pre-NOPR stage of a rulemaking, which could include a framework document, RFI, notice of data availability (“NODA”), preliminary analysis, or ANOPR.

1. Early Assessment and Pre-NOPR Stages

Several commenters supported reinstating an early assessment stage in the process for developing energy conservation standards or in general support of a formal early assessment process for both energy conservation

standards and test procedure rulemakings.²²

AHRI expressed support for an early assessment process for the amendment of existing standards. (AHRI, No. 28 at p. 8). NAHB recommended that DOE reinstate the early assessment process for soliciting stakeholder feedback well in advance of commencing an energy conservation standards rulemaking, as this reduces regulatory burden. (NAHB, No. 19 at p. 3). The Joint Gas Associations stated that a formal early assessment process can increase the efficiency of DOE’s rulemaking process, as it could lead to a prompt, early decision in favor of more productive use of rulemaking resources. (Joint Gas Associations, No. 25 at p. 25). NEMA stated that the scope of coverage for a rulemaking should be thoroughly researched and addressed in a robust RFI phase to ensure clarity and consideration of all relevant data and stakeholder input before the NOPR is issued. NEMA also stated that this would reduce the likelihood of a rule that is inconsistent with the statute and, thus, vulnerable to legal challenge. NEMA recommended re-adoption of the approach in the 2020 Process Rule to mandate use of an early assessment RFI and either an ANOPR or a framework document with a preliminary analysis. (NEMA, No. 23 at pp. 7–8).

Several commenters also expressed support for requiring a pre-NOPR stage in the process for developing energy conservation standards; however, there was no consistency in recommending what that stage should be. Commenters stated that this requirement can be fulfilled with either an ANOPR or framework document with a preliminary analysis (AHRI, No. 28 at p. 8), an ANOPR or a preliminary analysis (APPA, No. 20 at p. 4; EEI, No. 35 at p. 4), or an ANOPR or a framework document or a preliminary analysis (NAHB, No. 19 at pp. 3–4). The Joint Gas Associations stated that the Process Rule should include multiple avenues such as an ANOPR, NODA, RFI, or NOPR/SNOPR and that DOE should explain why it determined which publication was appropriate (e.g., NODA instead of ANOPR). (Joint Gas Associations, No. 25 at p. 26).

In response, DOE agrees with commenters that a formal early assessment provides an important opportunity for public input and provides regulatory certainty to stakeholders. As such, DOE is proposing to return to the language in the 2020 Process Rule regarding early assessment.

²⁰ 42 U.S.C. 6291–6309 and 42 U.S.C. 6311–6317, respectively.

²¹ See supporting table available in www.regulations.gov/docket/EERE-2025-BT-STD-0001.

²² See also section IV.J.1 of this document with regard to early assessments for test procedures.

While commenters did not all agree on what stages of a rulemaking should follow an early assessment, DOE has tentatively decided that specifying limited pathways as opposed to numerous options provides more regulatory certainty to stakeholders. As such, DOE also proposes to return to the language in the 2020 Process Rule regarding publishing either a Framework Document and Preliminary Analysis, or an ANOPR. DOE requests comment on these proposals.

DOE notes that the procedural requirements of section 6 of Appendix A do not apply to direct final rules. The procedural requirements for direct final rules are specified in EPCA. (42 U.S.C. 6295(p)(4)).

2. Comment Periods

When developing energy conservation standards, the current Process Rule specifies that the length of the public comment period for pre-NOPR rulemaking documents may vary depending on the circumstances of the particular rulemaking and will be determined on a case-by-case basis. At the NOPR stage, the current Process Rule specifies that there will be no less than 60 days for public comment on the NOPR, with at least one public hearing or workshop, consistent with EPCA requirements. (42 U.S.C. 6295(p)(2); 42 U.S.C. 6306; 42 U.S.C. 6316(a)-(b)). See Sections 6(a)(6) and 6(b)(2) of appendix A. In contrast, the February 2020 Process rule had included a minimum comment period of 75 calendar days for pre-NOPR and NOPR rulemaking documents. 85 FR 8626, 8705–8706 (Feb. 14, 2020).

The April 2025 RFI requested comments on whether and how the Process Rule should be amended to modify public comment and review procedures for rulemakings, consistent with EPCA's requirements. 90 FR 16093, 16098 (April 17, 2025).

In response to the April 2025 RFI, several commenters expressed support for mandatory minimum comment periods in the Process Rule. AHRI stated that taking the time to allow for meaningful input is more likely to result in a streamlined process and better outcomes, and it may also reduce the likelihood of litigation. (AHRI, No. 28 at p. 9). BWC stated that a mandatory minimum comment period is ultimately beneficial to DOE, as it will allow stakeholders the full amount of time to potentially identify inaccuracies, issues, or errors that can then be adjusted and make both test procedures and energy conservation standards for covered products more robust. (BWC, No. 34 at p. 3). The Joint Gas Associations stated

that the minimum statutorily specified opportunities for public input are generally inadequate and that longer comment periods should be the norm and specified in the Process Rule. (Joint Gas Associations, No. 25 at pp. 24–25).

Several commenters recommended specific comment period lengths. BWC recommended that DOE re-adopt the February 2020 Process Rule provisions, which would extend the mandatory length of comment periods to 75 days for both NOPR and pre-NOPR notices. (BWC, No. 34 at p. 2). AHRI stated that 75 days is an appropriate length of time to gather comments in early phases of a rulemaking, but 60 days should be the minimum. AHRI further stated that if DOE believes a particular step dictates a shorter or longer comment period, it can deviate from the Process Rule and provide an explanation in the notice. (AHRI, No. 28 at pp. 9–10). AHRI also stated that if DOE shortens the comment period to 60 days, DOE should continue to freely grant reasonable requests for extension. (AHRI, No. 28 at p. 10). Rinnai recommended minimum public comment periods of 60 days for initial notices and 45 days for supplemental notices. (Rinnai, No. 11 at pp. 3, 5, 10). Lennox stated that the comment periods specified in the Process Rule should be binding so as to allow for a reasonable minimum comment period in order for stakeholders to properly review and respond to the document in question. (Lennox, No. 26 at p. 2). Lennox recommended that NOPRs have comment periods of at least 60 days from the date of publication in the **Federal Register**. Lennox also recommended that pre-NOPR documents have comment periods of at least 60 days (for the first pre-NOPR notice in a docket) or 30 days (for subsequent notices if those subsequent notices do not raise material new issues that require engineering or technical analysis). Lennox also recommended that SNOPIs and other post-NOPR documents have comment periods of at least 30 days. (Lennox, No. 26 at pp. 8–9).

Other commenters stated that public comment periods specified in the existing Process Rule are sufficient. The State Agencies stated that the current public comment and review process is robust, accessible, transparent, and has resulted in thousands of comments from across the Nation to inform DOE proceedings. The State Agencies also requested that if DOE does propose changing the public comment periods, that it also provide justification and an opportunity for additional public comment on how the proposed changes to the Process Rule would result in an

improved public comment and review process. (State Agencies, No. 33 at p. 2). NEEA recommended that DOE should maintain the current public comment and review process as codified in the Process Rule that allows for early and meaningful public engagement. The commenter stated that the current rule embeds EPCA's statutory comment requirements and provides structured opportunities for stakeholder input throughout the rulemaking process, including at the proposal stage and, in some cases, earlier through pre-rulemaking notices or stakeholder meetings. NEEA expressed opposition to any changes that would diminish the structure, duration, or significance of public comment periods. (NEEA, No. 36 at p. 2).

ACCA stated that minimum public comment periods alone are not sufficient if the procedures themselves remain opaque or are overly reliant on technical modeling that is inaccessible to small businesses. (ACCA, No. 38 at p. 3).

In response, DOE has reviewed the comments received regarding the appropriate comment periods for various documents. DOE has tentatively determined that a minimum 75-day comment period best addresses the public comments received, as it ensures stakeholders will be provided with a meaningful opportunity for public comment on every rulemaking document. Though several public comments indicate that a 60-day comment period is typically sufficient for a NOPR, commenters representative of a wide swath of affected entities also support reinstatement of the 75-day comment period. Therefore, DOE proposes to reinstate the comment periods from the 2020 Process Rule. Additionally, DOE already makes available its analytical models and technical documentation, with at least one public hearing or workshop, for all stakeholders to review during the comment period. DOE has tentatively determined that this approach is sufficiently accessible to all interested parties. Further consideration of analytical methodologies will be addressed in a separate process, as discussed in section IV.N.1 of this document.

3. Factors To Be Considered in Selecting a Proposed Standard

Section 6 of the Process Rule includes a list of factors to be considered in selecting a proposed standard. This list is largely the same in the current Process Rule as in the 2020 Process Rule, but DOE is proposing to re-instate the language in the 2020 Process Rule

for consistency. In addition, DOE is proposing minor wording changes to certain of the factors, including those discussed in the subsequent paragraphs, consistent with statutory requirements and best practices.

a. Private Impacts on Consumers

Section 6(a)(5)(iv)(B) of the Process Rule specifies that at the pre-NOPR stage, DOE will consider various factors when selecting a proposed standard, including an analysis of private impacts on consumers, including estimates of energy savings, consideration of subgroups, and other assessments of the range of impacts. As discussed, Executive Order 14154 states that it is the policy of the Department to safeguard the American people's freedom to choose from a variety of goods and appliances, including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads. Consistent with this Executive order, DOE is proposing to add protection of consumer choice to the list of factors DOE will assess in considering the private impacts on consumer of any potential standards level. As discussed in section IV. H of this document, DOE is also proposing to add consideration of certain private economic impacts to the existing paragraph.

b. Impacts on the Environment

Section 6(a)(5)(iv)(F) of the Process Rule specifies that at the pre-NOPR stage, DOE will consider various factors when selecting a proposed standard, including an analysis of environmental impacts and estimated impacts on emissions of carbon and relevant criteria pollutants. Under EPCA, the Secretary has discretion to weigh "other factors the Secretary considers relevant." (42 U.S.C. 6295(o)(2)(B)(i)(VII)). Previously, the Secretary made a determination this consideration of environmental and emissions impacts was relevant. Currently, however, given other considerations germane to 42 U.S.C. 6295(o), the Secretary has tentatively determined that the specifics of section 6(a)(5)(iv)(F) of the Process Rule as written are no longer relevant as an additional factor for his consideration, and instead, DOE is proposing that this factor simply refer to "Other factors the Secretary considers relevant." This proposal is also consistent with the policies specified in the Executive order. More specifically, section 6 of Executive Order 14154 specifies policies for prioritizing accuracy in environmental analyses, specifically instructing that for Federal regulatory processes, all agencies shall adhere to

only the relevant legislated requirements for environmental considerations, and any considerations beyond those requirements are eliminated.

H. Policies on Selection of Standards (Section 7)

This section was established in the July 1996 Final Rule and describes the Department policies concerning the selection of new or revised standards. The February 2020 Final Rule made minor amendments to align with revisions elsewhere in the Process Rule, while the August 2020 Final Rule added a clarification that DOE would conduct a comparative analysis across all trial standard levels when determining whether a level was economically justified. The December 2021 Final Rule amended this section to remove the requirement for a comparative analysis and to remove a section related to considerations in assessing economic justification.

1. Market Competition and Innovation

The April 2025 RFI requested comment on whether and how the Process Rule should be updated to provide additional detail on how DOE's rulemaking process can promote market competition and innovation within the manufacturing and appliance industries and on DOE's historical analysis of potential impacts of any lessening of competition under 42 U.S.C. 6295(o)(2)(B)(i)(V). 90 FR 16093, 16098 (April 17, 2025).

DOE received several comments in support of using standards to promote market competition.

Lennox commented that DOE should support domestic manufacturers by promulgating reasonable standards and enforcing compliance to prevent the entry of low-cost, non-compliant imports. (Lennox, No. 26 at p. 5)

NEMA commented that competition benefits from reasonable and consistent efficiency rules that provide a stable and level playing field. NEMA further stated that predictability and consistency in the Appliance Standards Program are essential to reduce regulatory burden. In addition, the commenter argued that sudden changes can jeopardize investments made and inventory already created, which rely on current standards and test procedures. NEMA added that the testing of products and certification is highly beneficial in protecting manufacturers and consumers against misrepresentations of performance. (NEMA, No. 23 at pp. 3–4, 6)

Ceres commented that Federal appliance standards are critical for

regulatory clarity, market consistency, and innovation incentives and provide a reduction in complexity and cost associated with meeting a patchwork of State-level regulations. Ceres added that for manufacturers, this consistency simplifies product design, production planning, and distribution logistics, thereby enabling more efficient economies of scale and streamlining compliance processes compared to having to meet different local energy efficiency rules. (Ceres, No. 22 at p. 1)

The Joint Advocates commented that efficiency standards promote market competition and innovation and cited a study²³ showing that regulations can enhance competition by creating market pressure that motivates innovation, leveling the playing field during transitions, and providing certainty that investments in efficiency improvements will be valued in the future. The Joint Advocates also pointed to another study²⁴ which concluded that as standards take effect, the price of older, but still-compliant products drops, and manufacturers are then incentivized to innovate so they can introduce new premium models with novel features and higher efficiency, resulting in better products that benefit all consumers. (Joint Advocates, No. 31 at p. 3)

DOE also received several comments indicating that changes to the Process Rule are not needed to promote competition and innovation.

Ceres, the Joint Advocates, Lennox, and the State Agencies commented that the existing Process Rule and/or current statute is sufficient to protect competition and innovation. (Ceres, No. 22 at p. 1; Joint Advocates, No. 31 at p. 2; Lennox, No. 26 at p. 5; State Agencies, No. 33 at p. 2)

Specifically, Ceres stated that the current statute already promotes market competition and innovation by directing DOE not to consider new standards or amendments that cannot be scaled to meet the market and energy conservation needs. Ceres added that completely changing the current Process Rule would ultimately reduce market competition and product availability across the Nation and put U.S.

²³ M. E. Porter & C. van der Linde, "Toward a New Conception of the Environment-Competitiveness Relationship," *Journal of Economic Perspectives*, 1995, Vol. 9, No. 4, pp. 97–118 (Available at: www.aeaweb.org/articles?id=10.1257/jep.9.4.97) (Last accessed July 31, 2025).

²⁴ A. Brucal & M.J. Roberts, "Do energy efficiency standards hurt consumers? Evidence from household appliance sales," *Journal of Environmental Economics and Management*, 2019, Vol. 96, pp. 88–107 (Available at: www.sciencedirect.com/science/article/pii/S0095069617307647) (Last accessed July 31, 2025).

manufacturers at a disadvantage in the global marketplace. (Ceres, No. 22 at pp. 1–2)

The Joint Advocates commented that the Process Rule already includes market competition and innovation protections, including the requirement to consult with both the U.S. Attorney General and the Department of Justice in evaluating any lessening of market competition, as well as the requirement to consider the practicability to manufacture, install, and service a given technology before giving it further consideration in a rulemaking. The Joint Advocates added that the Process Rule further states that DOE will not consider technology options that cannot be scaled to meet the market need or that are proprietary. (Joint Advocates, No. 31 at pp. 2–3)

The State Agencies commented that any potential changes to the Process Rule must be analyzed across the full range of technologies covered by the Appliance Standards Program and must consider manufacturer innovation. The State Agencies stated that consideration of market competition and innovation needs no further elaboration within the Process Rule and is only appropriate at the individual rulemaking level. (State Agencies, No. 33 at pp. 1–2)

DOE received several comments recommending specific changes to the Process Rule to promote competition and innovation.

ACCA commented that recent policies have favored electrification, ignoring the energy resilience benefits of dual-fuel systems and significant barrier to full electrification. The commenter stated that such policies risk increasing market concentration, as fewer manufacturers are capable of producing compliant units and fewer contractors are equipped to install them correctly. ACCA added that pursuing full electrification could also raise costs, reduce service availability, and unintentionally burden grid infrastructure with additional seasonal loads. (ACCA, No. 38 at p. 2)

APPA stated that standards can create market distortions that negatively impact competition and innovation. APPA commented that as smart and artificial intelligence technologies become more prevalent, DOE should ensure that regulations do not eliminate innovative technologies or worsen supply chain issues. Specifically, with rising demand and existing challenges for distribution transformers such as higher costs and longer procurement times, the commenter urged DOE to avoid adopting standards that worsen these issues for minimal efficiency gains. APPA further stated that

standards should not create situations where only one U.S. manufacturer has patents to make the product or key components of a product. (APPA, No. 20 at pp. 2–3)

Similarly, EEI commented that regulations should not eliminate innovative technologies. As an example, EEI stated that DOE should use annual energy metrics, where possible, instead of separate standby, off, and active-mode metrics. EEI explained that annual energy metrics support innovation by allowing manufacturers to consider trading off higher standby energy use for a “smart appliance” with lower overall annual energy use. (EEI, No. 35 at pp. 3–4)

NEMA commented that the Process Rule should explicitly require DOE to consider how a rule will affect investment and whether it will harm U.S. industry, innovation, and ultimately consumers. NEMA added that DOE should consider the impact its decisions have on investment by American companies related to innovation. (NEMA, No. 23 at pp. 3–4, 6)

After reviewing the comments received, DOE has tentatively determined that the current Process Rule Objectives should be amended to include additional provisions stating that it is DOE’s policy to promote market competition and innovation consistent with the requirements of EPCA. *See* section IV.A of this document for further discussion. DOE remains cognizant of these issues and notes that the current statute and Process Rule already include mechanisms to consider the potential impacts from industry concentration, manufacturing capacity, employment, and other relevant issues. In response to ACCA, DOE notes that potential standards for products using different fuels are evaluated separately with their own economic justification. In response to APPA, DOE notes that the screening analysis already considers impacts related to proprietary technologies. In response to EEI, DOE notes that it will consider the appropriate metric in individual rulemakings, keeping in mind the requirements in EPCA related to standby mode and off mode energy use at 42 U.S.C. 6295(gg). In response to NEMA, DOE notes that it has received more specific comments related to how DOE should analyze manufacturer impacts, as discussed in section IV.N.2 of this document; the Department will analyze these issues in a separate proceeding.

2. Analytic Approaches To Address Balancing Factors in EPCA

The April 2025 RFI requested comments on whether and how the Process Rule should be updated to provide additional detail on how DOE’s rulemaking process satisfies the statutory requirements for establishing new or amended energy conservation standards. 90 FR 16093, 16099 (April 17, 2025). DOE received comments related to how the Process Rule should approach analyzing the potential effects of efficiency levels, including incorporation of the statutory factors, which inform the agency’s choice of a standard level.

Several commenters supported the provisions in the current Process Rule. The Joint Advocates and the State Agencies stated that the current Process Rule and EPCA already outline the detailed statutory criteria that DOE must follow in each rulemaking. (Joint Advocates, No. 31 at p. 1; State Agencies, No. 33 at p. 2) NEEA recommended that DOE should maintain its current approach in the Process Rule to assess economic viability. Specifically, the commenter encouraged DOE to maintain a comprehensive assessment of economic impacts that considers life-cycle cost savings, avoided energy system costs, macroeconomic impacts, and economic impacts to consumers. NEEA further recommended against redefining “economically justified” to have a narrow focus on short payback periods or “first cost analysis,” which would undervalue long-term economic benefits. NEEA added that overlooking broader energy system costs and macroeconomic impacts will limit the ability to accelerate production of energy-intensive industries and limit economic growth potential. (NEEA, No. 36 at p. 3)

Several other commenters made specific recommendations regarding additional thresholds or evaluations DOE should make when assessing potential standards.

The Joint Gas Associations generally support an approach where DOE evaluates the cost-effectiveness of a standard versus its possible level of enhanced efficiency and added that any process of evaluation must include balancing potential energy savings with the cost of implementation. (Joint Gas Associations, No. 25 at p. 26)

When selecting a standard level, in addition to including a definition for “significant energy savings” (*See* section IV.F of this document for additional discussion on this issue), AHRI commented that the Process rule

should also incorporate other factors including: (1) a cost-benefit analysis for consumers and manufacturers into the definition of “significant energy savings”; (2) thresholds or benchmarks that explain how DOE evaluates marginal energy savings in relation to consumer burden, product costs, and feature trade-offs; and (3) a methodology for comparing energy savings as it relates to the cost of compliance, particularly for products where existing efficiency levels are already high or marginal gains in energy savings require a steep expense. (AHRI, No. 28 at p. 11)

NAFEM commented that the Process Rule should specify a clear rule regarding payback period (“PBP”) that can satisfy EPCA’s requirement that standards be economically justified. The commenter argued that lengthy PBPs (sometimes exceeding the product’s average lifetime) are impractical and not economically justified for small businesses that often operate on short planning horizons and may never recoup the cost of higher-efficiency equipment. NAFEM added that lengthy PBPs would lead small businesses to repair old equipment or purchase less-efficient refurbished units, thereby undermining EPCA’s energy efficiency goals. (NAFEM, No. 13 at pp. 5–6)

NAHB commented that standards should be set strictly based on cost-effectiveness to the consumer. NAHB added that greater weight should be given to the 7-percent discount rate, as a 3-percent is not realistic in the real estate development context. (NAHB, No. 19 at p. 5)

ONE Gas commented that DOE should implement a *de minimis* threshold for consumer savings at both the individual covered product and national levels. ONE Gas added that the *de minimis* test should be applied in the Framework Document phase and resolved at the Preliminary Analysis phase. (ONE Gas, No. 37 at p. 5)

Rinnai commented that the Process Rule should include provisions requiring DOE to conduct an affordability analysis and not set standards if some populations, such as low- or middle-income households, face net costs or excessive payback periods. (Rinnai, No. 11 at p. 12, 13) In addition, Rinnai stated that the Process Rule should require a quantitative assessment of impacts on low-income and senior households, with explicit criteria that flag when negative outcomes exceed defined thresholds. (Rinnai, No. 11 at p. 8) Further, Rinnai commented that the Process Rule should require that a standard not be set if analysis shows marginal or negative life-cycle cost outcomes, payback periods close to the

product lifespan, or disproportionate burdens on low-income or senior consumers. (Rinnai, No. 11 at p. 9)

The Joint Gas Associations commented that DOE’s rules should not harm any customers and should not increase costs for low-income and senior households. The Joint Gas Associations added that the Process Rule should include some criteria for fully evaluating the cost impacts on customers, in particular low-income and senior households. (Joint Gas Associations, No. 25 at pp. 17–18) The Joint Gas Associations further commented that the Process Rule should require a minimum²⁵ three-year payback period threshold for DOE to propose a new or revised standard. (Joint Gas Associations, No. 25 at p. 27)

The Joint Gas Associations recommended that the Process Rule should state that DOE will utilize source energy when evaluating critical energy policy decisions and that it will seek comments on the best method to use when evaluating energy efficiency measures, which may not always be the existing site-to-source conversion. (Joint Gas Associations, No. 25 at pp. 19–21) In addition, the Joint Gas Associations stated that any energy savings associated with fuel switching should not be permitted to be used to justify a standard. (Joint Gas Associations, No. 25 at p. 21)

APPA commented that DOE should ensure that standards do not result in significantly higher upfront costs or greater total system energy losses. (APPA, No. 20 at p. 2)

ACCA recommended that the Process Rule should incorporate field-based efficiency data and installation quality metrics in the Department’s cost-benefit analysis and determination of significant conservation of energy. (ACCA, No. 38 at p. 2) In response, DOE anticipates further additions and refinements to the Department’s life-cycle cost analysis and payback period methodology, as well as all energy conservation standards rulemaking analytical methodologies, will be addressed in the forthcoming Analytic Framework update. Further public input will be invited on suggestions to update and improve the agency’s subgroup and distributional impact analyses, such as those involving low-income senior citizens and small entities. Further public comment is also solicited in response to this proposal.

²⁵ DOE understands the reference to a “minimum three-year payback period” in this comment to mean that DOE should only establish standards with estimated payback periods of three years or less.

Statutory Factors and Analysis

Pursuant to EPCA, any new or amended energy conservation standard for covered products (and at least certain types of equipment) must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A); 42 U.S.C. 6316(a)). In determining whether a standard is economically justified, EPCA requires DOE, to the greatest extent practicable, to consider the following seven factors: (1) The economic impact of the standard on the manufacturers and consumers; (2) the savings in operating costs, throughout the estimated average life of the products (*i.e.*, life-cycle costs), compared with any increase in the price of, or in the initial charges for, or operating and maintaining expenses of, the products which are likely to result from the imposition of the standard; (3) the total projected amount of energy, or as applicable, water, savings likely to result directly from the standard; (4) any lessening of the utility or the performance of the products likely to result from the standard; (5) the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard; (6) the need for national energy and water conservation; and (7) other factors DOE finds relevant. (42 U.S.C. 6295(o)(2)(B)(i); (p)). As part of its consideration of these seven factors, DOE conducts and publishes an analysis in a technical support document (also known as a regulatory impact analysis (RIA)). This analysis accompanies the proposed and final rules in fulfillment of the agency’s statutorily required responsibilities to provide the public with the opportunity to comment on DOE’s consideration of the factors for economic justification, technological feasibility, and other factors required by EPCA. (*See* 42 U.S.C. 6295(p)). Furthermore, the new or amended standard must result in a significant conservation of energy (42 U.S.C. 6295(o)(3)(B); 42 U.S.C. 6313(a)(6); and 42 U.S.C. 6316(a)) and comply with any other applicable statutory provisions.

The Secretary determines whether a standard achieves the maximum improvement in energy efficiency²⁶ given that the standard must be both technologically feasible and economically justified. This determination is made after conducting analysis required by EPCA and considering views and comments

²⁶ “or in the case of showerheads, faucets, water closets, or urinals, water efficiency” 42 U.S.C. 6295(o)(2).

furnished with respect to a proposed standard. To best inform this determination, DOE proposes a “walk up” approach to evaluating prospective standards. By taking a “walk up” approach, DOE can compare each progressively more stringent standard (each increase in energy efficiency and each incremental increase in costs) to both the status quo and the standard just below it. This allows the agency and interested public to assess at each possible standard level the incremental increases in energy or water savings relative to the incremental increases in costs, including those arising out of changes in consumer choice and satisfaction. The 2020 Process Rule referred to this framework as the “comparative” approach. To reflect the general framework of that comparative approach, as well forthcoming analytic updates consistent with 42 U.S.C. 6295(o)(2)(B), this proposal refers to this concept as a “walk up.”

As part of the EPCA analysis, DOE must estimate benefits of possible higher efficiency standards, including those the statute directs DOE to consider estimated energy savings and potential operating cost savings over the average life of a covered product. (42 U.S.C. 6295(o)(2)(B)(i)(II)–(III), (VII)). In estimating these anticipated benefits, DOE must also anticipate consumer behavioral changes that may temper or increase energy or cost savings, such as increased product usage (often referred to as the “rebound effect”), refurbishing of old products or purchase of used products, or substitution effects like using more energy- or water-intensive settings more frequently in response to negative impacts on product performance, or reduced costs to controlling HVAC systems due to Apps.²⁷ (42 U.S.C. 6295(o)(2)(B)(i)(I)). In addition, under EPCA, DOE must estimate the costs of possible higher efficiency standards, including those the statute directs DOE to consider: increases in price, initial installation and maintenance costs; lessening of the utility or performance (such as potential negative impacts on product cleaning performance or differences in the brightness (lumens), hue or colors of light bulbs); lessening of market competition, such as increases in market consolidation or other changes in price-setting power, and other economic impacts to manufacturers and consumers. (42 U.S.C. 6295(o)(2)(B)(i)(I)–

II), (IV–VII)). In estimating these anticipated costs, DOE would be analyzing consumer welfare impacts and losses to consumers and producers from foregone consumption of good the market would otherwise offer (also known as dead weight loss in economic terms), and the behavioral changes that are likely to result from possible standards. Consumer welfare in economic terms refers to the general satisfaction and well-being consumers derive from their purchases and use of products. In other words, DOE’s statutory considerations regarding impacts to consumers and manufacturers, increases in prices, maintenance costs, changes in utility and performance all translate to consumer welfare impacts and related changes in consumer behavior. Under EPCA, DOE further considers losses to society when producers are willing to offer a product at a particular price and consumers are willing to purchase that product at that particular price and that exchange will no longer occur as a result of a proposed standard. In particular, under EPCA, DOE may not prescribe new standards where the standard would likely result in domestic unavailability “in any covered product (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary’s finding.” (42 U.S.C. 6295(o)(4)). The unavailability of any of these characteristics translates once again to consumer welfare impacts and potential losses to society when the market is willing to make an exchange but for the standard. In other words, the loss of features such as consistently illuminated clocks in microwaves,²⁸ the window in an oven door,²⁹ or glass

²⁸ In the most recent energy conservation standards rulemaking for microwave ovens, DOE “screened out” from its analysis any consideration of automatic power-down of the clock display as a technology option for reducing the standby power of microwave ovens due to its impact on consumer utility. DOE found that while it is uncertain the extent to which consumers value the function of a continuous display clock, the loss of such function may result in significant loss of consumer utility. 78 FR 36316, 36362 (June 20, 2023).

²⁹ In the most recent energy conservation standards rulemaking for conventional cooking products, DOE screened out from its analysis any consideration of energy savings that could be achieved through removal of the glass window in the oven door, in part due to the loss of consumer utility, possible adverse impacts on cooking certain types of delicate food items, and potential safety concerns. See section 4.2.1.3 of the Technical Support Document accompanying the February 14, 2024, direct final rule (89 FR 11434), available at www.regulations.gov/document/EERE-2014-BT-STD-0005-12819.

doors on beverage coolers,³⁰ changes to the layout of residential refrigerators and clothes washers and dryers, and dishwashers would limit consumer choices and impact consumer satisfaction and well-being. The agency “screened out” these feature losses from consideration in prior analyses, and requests comment on how such screening can be improved. DOE’s forthcoming analytic framework RFI and update will also offer the public an opportunity to suggest methodological and data changes the better capture these consumer impacts.

The main difference between the “walk down approach” and the “walk up approach” is that the walk down approach starts at the most stringent possible standard and “walks down” to different levels of stringency, presumptively stopping at the most-stringent standard that DOE determines is economically justified. This approach favors technological feasibility over economic justification, resulting in more stringent standards than may be appropriate under EPCA’s balancing factors. In other words, under the walk down approach, DOE does not interpret the statute as requiring a netting of the benefits and costs in moving to a more progressively stringent standard. Meanwhile, the proposed approach “walks up” from the *status quo* to increasing levels of stringency. This approach allows both DOE and the public to compare easily a proposed standard’s proposed energy and operating savings and economic impacts to the status quo and to the standard just below. For example, if the installation costs of a proposed water heater standard would increase by 106 percent relative to the status quo, the walk up approach would ensure that this impact is shown clearly on the cost side of the ledger. Also, other behavioral impacts that would temper estimated energy savings would be included, such as when consumers choose to repair or move to secondary markets when faced with such up-front costs. In other words, the walk up approach allows for balancing technological feasibility and economic justification with parity. At each increment of increased stringency,

³⁰ In the most recent energy conservation standards rulemaking for miscellaneous refrigeration products, DOE screened out from its analysis any consideration of energy savings that could be achieved through the replacement of glass doors with solid doors, finding that solid doors would be much less desirable to consumers and the loss of the glass doors would have an adverse impact on consumer utility. See section 4.2.1.1 of the Technical Support Document accompanying the May 7, 2024, direct final rule (89 FR 38762), available at www.regulations.gov/document/EERE-2020-BT-STD-0039-0037.

²⁷ See, for example, DOE’s previous consideration of potential negative impacts on clothes washer performance that could alter consumers’ usage patterns at certain higher efficiency levels considered for the analysis. (89 FR 19026, 19117; March 15, 2024).

the agency must consider costs. In addition, with the agency's forthcoming analytic update, the agency's cost and benefits estimates are expected to expand beyond engineering concepts to further capture economic concepts such as consumer welfare and behavioral change impacts. When technology is not feasible, then incremental cost can be very high or even infinite. While DOE conducts an engineering-based technological feasibility check as part of its existing process the agency acknowledges that feasibility in economic terms is also related to costs. Given this, the economic justification analysis also has some collinearity to technological feasibility. For instance, it may be that at higher TSLs, from an engineering perspective, the required technological feasibility has been determined 'feasible' but that from an economic perspective the production costs are so high as to prevent widespread availability or consumption. Such technology would clearly not be found to be economically justified and from a lay person's market perspective might not be considered feasible. When technology is feasible, it may still fail at economic justification, and EPCA requires both conditions to be satisfied. The seven EPCA factors lay out different aspects of potential economic impacts to affected parties. DOE's analytic framework RFI will delve further into methodological and conceptual tools aimed at a more complete and updated analysis of these factors:

1. The economic impact of the standard on the manufacturers and consumers: this factor broadly lays out economic impacts to manufacturers and consumers should be taken into consideration in setting conservation standards regardless of whether those impacts may be readily quantifiable or not. Readily quantifiable effects include potential energy and water savings assuming that consumers' distribution of consumption of energy and water do not change over time appreciably. Currently, DOE folds some of these impacts into the agency's life-cycle and payback period analysis. Manufacturers' compliance costs are also readily quantifiable using information collected through government data collections, public comment, DOE's tear-down and other engineering efforts, purchase of proprietary information and others. There are other economic effects that are more difficult to capture on both consumer and manufacturer sides. Estimating changes in consumers' consumption of substitute (e.g., used and refurbished appliances) and complimentary goods (e.g., dryers if

purchasing washers; detergent choices) as a result of a conservation standard is more difficult. For example, if a clothes washer energy and water conservation standard were to adversely impact cleaning or rinsing performance, consumers that experience any such negative impacts on product performance could potentially alter their usage patterns, for example by using more energy-intensive settings more frequently (e.g., Extra-Hot temperature setting); using more water-intensive cycle options (e.g., Deep Fill option; extra rinse cycles); using non-regulated cycles (e.g., Heavy Duty cycle); or re-washing clothing that has not been cleaned sufficiently. Such changes to consumer usage patterns may counteract the energy and water savings that DOE has estimated would be achieved at the higher efficiency level (89 FR 19026, 19117; March 15, 2024). Similarly, if the same standard also affects how clothing is washed, then consumers may buy more powerful and expensive detergent (complimentary good) in reaction. Alternatively, if a new clothes washer standard materially increases purchase and installation costs for that appliance, consumers may choose not to purchase a clothes dryer when those purchases are very often bundled as complimentary goods. This change could result in losses to society from foregone market exchanges and losses in consumer satisfaction where preferences would typically lean towards a bundled purchase. In addition, new standards may cause manufacturers to divert resources away from improving features that consumers want. While not exhaustive, the above examples illustrate that quantitative estimates of potential energy and water savings and compliance costs may not capture important effects readily.

2. The savings in operating costs, throughout the estimated average life of the products (i.e., life-cycle costs), compared with any increase in the price of, or in the initial charges for, or operating and maintaining expenses of, the products which are likely to result from the imposition of the standard: DOE is already explicitly taking this factor into consideration in the agency's life-cycle cost analysis and payback period analysis and recognizes there are elements of consumer behavior and welfare, as well as considerations of the useful life of the appliance, that are not currently captured in this analysis.

3. The total projected amount of energy, or as applicable, water savings likely to result directly from the standard: DOE already explicitly takes this factor into consideration in the agency's lifecycle analysis and national

impact analysis and recognizes there are elements of consumer behavior and welfare, such as in earlier stated examples, that may affect these estimates that are not currently captured in this analysis.

4. Any lessening of the utility or the performance of the products likely to result from the standard: consumers value different attributes of products differently. Some may value the energy and/or water efficiency savings more than the cycle time in clothes washers. Others may value cycle time more than the energy and/or water efficiency savings. Others may place value in how effectively any residual detergent is rinsed from the clothing, or how much moisture is removed from the clothing during the final spin portion of the wash cycle. If changes in energy and/or water conservation standards were to lead to a reduction in certain aspects of cleaning or rinsing performance, then consumers may be less satisfied with their clothes washers. These types of effects may be more difficult to assess quantitatively than potential energy and/or water savings and compliance costs and nonetheless should be addressed. On the other hand, consumer purchases often reveal preferences for such functions, and by statute, DOE must consider these changes in utility and performance relative to products in existence at the time a regulation being contemplated.

5. The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard: lessening of competition is a concern that DOE takes seriously. Increases in market power or significant market consolidation would likely further reduce consumer choices and lead to material increases in the prices of covered products. DOE currently applies a market concentration index (HHI) in evaluating the lessening of market competition. While this index is a helpful indicator, DOE is considering other indicators of lessening competition. Market competition can decline when fewer manufacturers participate in the market or fewer manufacturers choose to produce some product categories. When consumer purchases do not decrease by much as prices rise (in economic terms: demand is relatively inelastic) and competition decreases, manufacturers are able to set prices higher without sharply reducing the number of units sold. For example, consumers often replace large appliances such as water heaters, heat pumps, air conditioners, or refrigerators when they break down, which may result in less price flexibility for the consumer. The result is greater benefits

for manufacturers (who sell fewer units at a higher price), reduced benefits for consumers (who buy fewer units at a higher price), and some loss to society (units that could have been produced and sold at lower prices are not produced and benefit no one). To account for the impacts of reduced competition, DOE is considering analysis that more formally incorporates consumer responsiveness to changes in price (price-elasticity of demand) and the likely price impacts in markets where high consolidation already exists.

6. The need for national energy and water conservation: enhanced energy efficiency, where economically justified, improves the Nation's energy security and strengthens the economy. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. DOE conducts a utility impact analysis to estimate how standards may affect the Nation's needed power generation capacity.

7. Other factors DOE finds relevant: In the past, the Secretary has exercised discretion under factor seven for considerations such as impacts of standards to certain subgroups such as small manufacturers or low-income senior citizens. DOE's comparative analysis can be applied to such distributional outcomes as well, and DOE continues to explore other discretionary considerations. One such consideration may be to explicitly state that the Secretary has determined that any proposed standard for which costs (including consumer welfare losses and losses to society from lost market exchanges) exceed benefits (including energy and operating cost savings) will presumptively be considered as not economically justified. More generally, the Secretary has sufficient discretion to apply a "walk up approach" under EPCA.

Energy Conservation and the Energy Paradox

The potential for appliance and other covered product buyers to voluntarily forego improvements in energy efficiency that seemingly offer savings exceeding their initial costs is one example of what is often termed the "energy efficiency gap" or "energy efficiency paradox." Economic theory predicts that, holding all else equal, individuals will purchase more expensive energy-efficient appliances and other covered products if they expect future savings on energy expenditures to offset the higher upfront

purchase costs.³¹ If buyers fully internalize the expected energy savings that result from higher efficiency in their appliances and other covered products purchase decisions, manufacturers will presumably supply any improvements that buyers demand, and appliances and other covered products prices will fully reflect future energy cost savings that consumers would realize from owning—and potentially reselling—more energy-efficient models if secondary markets exist. In this case, a regulation that induces increased energy efficiency of appliances and other covered products will impose net private costs on appliance and other covered product owners and can only result in social benefits through correcting other market failures (*e.g.*, imperfect information or internalizing other negative spillover effects). If instead, regulations are issued based on the premise that consumers systematically "undervalue" cost savings generated by improvements in energy efficiency when choosing among competing models, then more stringent energy efficiency standards may lead manufacturers to adopt improvements in energy efficiency that buyers would not choose despite the cost savings they offer.

Whether the value of the resulting realized energy savings will improve consumer welfare depends on if and why consumers appear to undervalue future energy expenditures. If the apparent "undervaluation" is due to factors that are missing from the analysis—*e.g.*, tradeoffs with product functions and attributes such as cleaning performance, increased cycle times when in energy saver mode or changes in the starkness, warmth, or hue of light bulbs—these hidden or missing costs may be offsetting some or all of the value of energy savings and may not result in additional social benefits. The appearance of such a gap, between the level of energy efficiency that would minimize consumers' overall expenses and what they actually purchase, is typically based on engineering calculations that compare the initial cost of providing higher energy efficiency to the discounted present value of the resulting savings in future energy costs, and such analyses will not typically capture the above variables. If instead undervaluation is

³¹ These additional up-front costs include more than just the cost of the technology necessary to improve energy economy; because consumers have a scarcity of resources, it also includes the opportunity cost of any other desirable features that consumers give up when they choose the more energy-efficient appliances and other covered products.

due to consumer or manufacturer inattention to future energy costs resulting from a market failure such as an information asymmetry, then the value of energy savings is a social benefit of the regulation. How potential buyers value improvements in the energy efficiency of new appliances and other covered products is therefore an important issue when assessing the benefits and costs of government regulation. There is a large empirical literature examining this issue that comes to varying conclusions about the extent that consumers value these future energy expenditures. As noted in the Office of Management and Budget (OMB) Circular A-4 (2003),³² "individual preferences of the affected population should be a guiding principle in the regulatory analysis." This literature and its implications for DOE's analysis will be explored further in DOE's analytic framework update effort.

Walk Up Analysis

A "walk up" analysis takes a step-wise approach to estimating increasing levels of energy conservation and the related impacts on consumers and manufacturers. Starting at the status quo (baseline), the agency would analyze the increases in benefits (including energy savings) and costs (including manufacturer costs) associated with progressively more stringent TSLs. DOE would use these estimates to identify a preferred option that is technically feasible and economically justified. For the "walk up" analysis the Secretary could determine economic justification by relying on either incremental effects or by relying on net benefits. Both methods examine economic justification by comparing the monetized benefits and costs at different TSLs. Once these analyses are complete, the Secretary may consider these estimates along with additional factors as noted above in determining whether to set a standard and if so, what level of stringency to propose. DOE requests comment on all aspects of the proposed walk up approach.

Illustrative Example

In the following illustrative example, DOE presents an incremental walk up approach under three scenarios: (1) where DOE is not accounting for consumer welfare and market loss (dead weight loss) impacts; (2) where DOE captures some but not all consumer

³² Office of Management and Budget. (2003). Circular A-4: Regulatory Analysis: https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4.

welfare and market lost impacts or such impacts are relatively small; (3) where DOE robustly estimates consumer welfare and market loss impacts and those impacts are substantial. In addition, DOE presents a simple net benefits scenario.

The numbers used in the tables are for illustration only and do not reflect estimates for any particular policy.

Table 1 shown below compares monetized energy savings with monetized cost increases associated with tighter energy efficiency levels but does not include all the economic impacts envisioned by the statute (e.g., consumer welfare and dead weight loss). For example, in going from the world without a standard (the baseline) to a proposed TSL 1, assume benefits of \$100 (i.e., estimated energy and operating cost savings), and costs of \$75 (i.e., cost increase and lost consumer satisfaction from reduced choices). The incremental net benefit of moving to TSL 1 equals \$25. It follows that going from TSL 1 to TSL 2 has incremental benefits of \$50 while the cost is \$25 for

an incremental net benefit of \$25. Similarly, TSL 3 has an incremental net benefit of \$0 and TSL 4 an incremental net benefit of –\$25 (see table 1 of this document). In this scenario DOE might choose TSL 3 without considering certain impacts to consumer welfare and losses from foregone market exchanges.

In the second scenario, if consumer welfare effects such as more handwashing of dishes, dislike of lightbulb colors and behavioral changes in response to cost increases, are relatively small in comparison to the energy savings, then including these effects may not change incremental net benefits substantially (See Table 2 of this document). Even in this scenario, TSL 3 is no longer desirable.

On the other hand, in the third scenario if consumer effects are substantial enough to cause consumers to delay the purchase of covered products, or buy used or refurbished covered products, or engage in other major behavioral changes (see example in Table 3 of this document where the costs double when taking into account

consumer effects), then this could significantly change the preferred TSL. In the illustrative example in Table 3, the agency’s preferred alternative may be to not regulate.

This illustrative example demonstrates how important the appropriate analytic framework is for analyzing DOE’s EPCA factors as part of either the standard selection process or in informing the determination of whether to amend an existing regulation. In cases where consumer and market impacts prove difficult to quantify, DOE may need to rely on a strong qualitative record and/or public comment to inform the Secretary’s determination. Regardless of quantification or monetization, such impacts should be DOE’s analysis and should carry weight in the consideration of what constitutes economic justification. The forthcoming analytic framework RFI will solicit comment on methodology and data efforts that may better capture these impacts.

BILLING CODE 6450–01–P

Table 1: Incremental Effects without Consumer Effects

Alternative	Energy savings (percent increase in savings)	Operating cost savings over product life	Increased cost of product over product life	Incremental Benefits relative to less stringent option	Incremental Costs relative to less stringent option	Incremental Net Benefits relative to less stringent option
Baseline	0	0	0			
TSL 1	10%	100	75	100-0=100	75-0 = 75	100-75 = 25
TSL 2	15%	150	100	150-100=50	100-75=25	50-25 = 25
TSL 3	20%	200	150	200-150=50	150-100=50	50-50 = 0
TSL 4	25%	235	210	235-200=35	210-150=60	35-60= -25

Agency may choose a higher standard.

Table 2: Incremental Effects with Minor Consumer Effects

Alternative	Operating cost savings over product life	Increased cost of product over product life	Consumer Effects	Incremental Benefits relative to less stringent option	Incremental Costs relative to less stringent option	Incremental Net Benefits relative to less stringent option
Baseline	0	0	0			
TSL 1	100	75	5	$100-0=100$	$(75+5)-0=80$	$100-80=20$
TSL 2	150	100	10	$150-100=50$	$(100+10)-80=30$	$50-30=20$
TSL 3	200	150	15	$200-150=50$	$(150+15)-110=55$	$50-55=-5$
TSL 4	235	210	20	$235-200=35$	$(210+20)-165=65$	$35-65=-30$

Agency may choose a lower standard.

Table 3: Incremental Effects with Major Consumer Effects

Alternative	Operating cost savings over product life	Increased cost of product over product life	Consumer Effects	Incremental Benefits relative to less stringent option	Incremental Costs relative to less stringent option	Incremental Net Benefits relative to less stringent option
Baseline	0	0	0			
TSL 1	100	75	75	$100-0=100$	$(75+75)-0=150$	$100-150=-50$
TSL 2	125	100	100	$125-100=25$	$(100+100)-150=50$	$25-50=-25$
TSL 3	200	150	150	$200-150=50$	$(150+150)-200=100$	$50-100=-50$
TSL 4	235	210	210	$235-200=35$	$(210+210)-300=120$	$35-120=-85$

BILLING CODE 6450-01-C

Agency may choose not to regulate.

Net Benefits

Under this approach, the preferred TSL would be the standard level that maximizes the benefit of increasing the efficiency standard stringency when considering the costs of that increase. In other words, when the net benefit is maximized, the Secretary can presumptively make the determination that a proposed standard is both

technologically feasible and economically justified. Under this option, TSL 1 would be the agency's preferred TSL. DOE request comment on whether the net benefit approach should be the presumptive application of the "walk up" framework.

Following public comment and peer review, DOE plans to issue analytic guidance that will aid the agency in quantifying potentially important consumer and manufacturer effects that

are not currently quantified and offer transparency to the public on the details of the agency's updated EPCA analytic approach.

3. Selection of Standard Level

In addition to addressing "balancing the factors in EPCA" as described in the previous section, DOE also considered how to evaluate EPCA's statutory requirements when constructing standard levels for consideration. Many

of the comments received in response to the April 2025 RFI discussed in section IV.H.2 of this NOPR are also relevant in evaluating how to construct candidate standard levels. DOE has included those comments again in the paragraphs that follow for consideration in this section. Several commenters supported the provisions in the current Process Rule. The Joint Advocates and the State Agencies stated that the current Process Rule and EPCA already outline the detailed statutory criteria that DOE must follow in each rulemaking. (Joint Advocates, No. 31 at p. 1; State Agencies, No. 33 at p. 2) NEEA recommended that DOE should maintain its current approach in the Process Rule to assess economic viability. Specifically, the commenter encouraged DOE to maintain a comprehensive assessment of economic impacts that considers life-cycle cost savings, avoided energy system costs, macroeconomic impacts, and economic impacts to consumers. NEEA further recommended against redefining “economically justified” to have a narrow focus on short payback periods or first-cost analysis, which would undervalue long-term economic benefits. NEEA added that overlooking broader energy system costs and macroeconomic impacts will limit the ability to accelerate production of energy-intensive industries and limit economic growth potential. (NEEA, No. 36 at p. 3)

Several other commenters made specific recommendations regarding additional thresholds or evaluations DOE should make when assessing potential standards.

The Joint Gas Associations generally support an approach where DOE evaluates the cost-effectiveness of a standard versus its possible level of enhanced efficiency and added that any process of evaluation must include balancing potential energy savings with the cost of implementation. (Joint Gas Associations, No. 25 at p. 26)

When selecting a standard level, in addition to including a definition for “significant energy savings” (See section IV.F of this document for additional discussion on this issue), AHRI commented that the Process rule should also incorporate other factors including: (1) a cost-benefit analysis for consumers and manufacturers into the definition of “significant energy savings”; (2) thresholds or benchmarks that explain how DOE evaluates marginal energy savings in relation to consumer burden, product costs, and feature trade-offs; and (3) a methodology for comparing energy savings as it relates to the cost of compliance,

particularly for products where existing efficiency levels are already high or marginal gains in energy savings require a steep expense. (AHRI, No. 28 at p. 11)

NAFEM commented that the Process Rule should specify a clear rule regarding payback period (“PBP”) that can satisfy EPCA’s requirement that standards be economically justified. The commenter argued that lengthy PBPs (sometimes exceeding the product’s average lifetime) are impractical and not economically justified for small businesses that often operate on short planning horizons and may never recoup the cost of higher-efficiency equipment. NAFEM added that lengthy PBPs would lead small businesses to repair old equipment or purchase less-efficient refurbished units, thereby undermining EPCA’s energy efficiency goals. (NAFEM, No. 13 at pp. 5–6)

NAHB commented that standards should be set strictly based on cost-effectiveness to the consumer. NAHB added that greater weight should be given to the 7-percent discount rate, as 3-percent is not realistic in the real estate development context. (NAHB, No. 19 at p. 5)

ONE Gas commented that DOE should implement a *de minimis* threshold for consumer savings at both the individual covered product and national levels. ONE Gas added that the *de minimis* test should be applied in the Framework Document phase and resolved at the Preliminary Analysis phase. (ONE Gas, No. 37 at p. 5)

Rinnai commented that the Process Rule should include provisions requiring DOE to conduct an affordability analysis and not set standards if some populations, such as low- or middle-income households, face net costs or excessive payback periods. (Rinnai, No. 11 at p. 12, 13) In addition, Rinnai stated that the Process Rule should require a quantitative assessment of impacts on low-income and senior households, with explicit criteria that flag when negative outcomes exceed defined thresholds. (Rinnai, No. 11 at p. 8) Further, Rinnai commented that the Process Rule should require that a standard not be set if analysis shows marginal or negative life-cycle cost outcomes, payback periods close to the product lifespan, or disproportionate burdens on low-income or senior consumers. (Rinnai, No. 11 at p. 9) DOE notes that suggestions of this nature can also be offered in response to the Department’s forthcoming Analytic Framework update RFI.

The Joint Gas Associations commented that DOE’s rules should not harm any customers and should not increase costs for low-income and

senior households. The Joint Gas Associations added that the Process Rule should include some criteria for fully evaluating the cost impacts on customers, in particular low-income and senior households. (Joint Gas Associations, No. 25 at pp. 17–18) The Joint Gas Associations further commented that the Process Rule should require a minimum³³ three-year payback period threshold for DOE to propose a new or revised standard. Joint Gas Associations, No. 25 at p. 27)

APPA commented that DOE should ensure that standards do not result in significantly higher upfront costs or greater total system energy losses. (APPA, No. 20 at p. 2)

Upon review of the comments, DOE notes that it is addressing procedural aspects of the Process Rule in this notice. DOE further notes that with the current Process Rule and statutory criteria, rulemaking analyses apply a primarily engineering-based approach to: (a) balance the potential energy savings against the cost of implementation; (b) perform a cost-benefit analysis for both consumers and manufacturers, including marginal energy benefits and a comparison of those benefits against the cost of compliance; (c) consider payback periods in addition to other factors such as total life-cycle cost; (d) consider discount rates determined from actual asset and debt holdings for both consumers and businesses (in addition to discount rates specified by the Office of Management and Budget); and (e) consider the potential impacts to certain consumer subgroups such as low-income or senior households.

In addition, DOE has tentatively proposed implementing presumptive thresholds on certain consumer economic-related metrics. However, the Secretary retains discretion under EPCA to weigh the seven factors and make a determination that a rule that meets these thresholds (e.g., lower percent net cost, lower percent increase in total installed cost, and lower simple payback period as a percentage of average lifetime) would not be considered economically justified. The proposed thresholds provide clarity and certainty to stakeholders regarding how the Secretary proposes to weigh EPCA criteria at 42 U.S.C. 6295(o) related to economic justification.

Specifically, DOE reviewed key analytical metrics assessed during an energy conservation standards

³³ DOE understands the reference to a “minimum three-year payback period” in this comment to mean that DOE should only establish standards with estimated payback periods of three years or less.

rulemaking and has tentatively determined that the following three factors, consistent with EPCA, best reflect protecting consumer choice and affordability, and are applicable across rulemakings:

- Maximum increase in installed cost relative to the baseline total installed cost (%).
- Maximum percentage of consumers for whom the standard level is projected to result in net costs (%).
- Maximum simple payback period relative to average product lifetime (%).

These factors are already analyzed in each rulemaking as part of the life-cycle cost and payback period analysis, and relate to one or two of the factors EPCA prescribed for determining whether a standard is economically justified:

1. The economic impact of the standard on the manufacturers and on the consumers of the products subject to the standard; and
2. The savings in operating costs throughout the estimated average life of the product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the products that are likely to result from the imposition of the standard.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(II)).

Given that these economic thresholds are factors that DOE already considers as required by EPCA, and that the Secretary weighs in determining economic justification, DOE has tentatively determined that adopting presumptive thresholds relating to economic justification is justified under EPCA, just as setting a threshold for significant energy savings is allowable.

DOE is proposing the following thresholds as a basis for determining whether a potential standard level is not economically justified (*i.e.*, a potential standard exceeding the threshold would not be justified) consistent EPCA:

- Up to 10% increase in installed cost relative to the baseline.
- Up to 20% of consumers projected to incur net costs as a result of a new or amended standard.
- Maximum simple payback period as a percentage of average useful lifetime of a covered product of up to 50%.

DOE welcomes comments and feedback on these proposed thresholds, including whether higher or lower thresholds would be appropriate in support of the Secretary's determination regarding economic justification. Regarding payback period, DOE requests comment on alternative threshold approaches, including whether a specific duration, such as five years, would be more appropriate, or a combination threshold that applies both

payback period as a percentage of average lifetime and a duration of five years, whichever duration is less. Based on comments, DOE may adopt a value that is higher or lower than the value proposed for each of these metrics, or DOE may adopt a similar metric that would also or better achieve the goals of consumer choice or affordability. DOE notes that, at any adopted level, these thresholds would each represent a point in the analysis for identifying a potential standard level as not being economically justified. As noted earlier, the Secretary retains discretion under EPCA to weigh the seven factors. Additionally, DOE is separately conducting an analytic update to address methodological approaches in energy conservation standards rulemakings. To the extent that any methodological changes would impact the proposed metrics to be considered for economic justification, DOE would evaluate whether the numerical thresholds proposed in this NOPR require adjustment.

DOE proposes that these metrics be applied after the completion of an LCC analysis in order to inform the Secretary's determination regarding whether to regulate in consideration of whether EPCA's requirement for economic justification can be met. The threshold determination can also inform DOE's assessment of which efficiency levels in each product class could become part of a trial standard level. DOE welcomes feedback on how such thresholds could best be implemented. DOE notes that the proposed threshold approach is also consistent with E.O. 14154, "Unleashing American Energy," 90 FR 8353 (Jan. 29, 2025), and the Presidential Memorandum of January 20, 2025, "Delivering Emergency Price Relief for American Families and Defeating the Cost-of-Living Crisis," 90 FR 8245 (Jan. 28, 2025).

In conjunction with the proposed threshold approach, the proposed walk-up approach described earlier in this section builds on both DOE's engineering analysis and the prior comparative framework. DOE anticipates this proposed framework will allow the agency to estimate a wider array of impacts resulting from candidate trial standard levels and is a better read of the balancing factors required to determine economic justification under EPCA. In particular, the walk up approach, paired with DOE's forthcoming analytic update, will address methodological approaches to modeling behavior changes driven by changes in energy conservation standards. Ultimately, DOE anticipates the Secretary will be able to utilize

estimates that better reflect EPCA's balancing factors for economic justification, as well as the incremental impacts of each candidate standard in making determinations regarding whether and what to regulate and at what level.

As stated previously, the December 2021 Final Rule removed a section related to considerations in assessing economic justification. 86 FR 70892, 70908. DOE did not receive any comments directly related to this section, but is also proposing to amend the Process Rule to add back in this section as it appeared in the 2020 Process Rule in order to provide additional clarity to stakeholders in terms of how the Secretary makes decisions regarding economic justification, beyond the proposed threshold approach described in this section.

I. Test Procedures (Section 8)

This section was established in the original July 1996 Final Rule and describes the process by which DOE would establish test procedures for covered products and equipment. The February 2020 Final Rule added an early assessment process for test procedures and generally committed that DOE would adopt consensus industry test procedures unless not consistent with EPCA. Consistent with other amendments in that rule, this section of the Process Rule was also amended to require that DOE finalize a test procedure 180 days in advance of a standards proposal. The December 2021 Final Rule clarified that DOE may revise consensus industry test procedure standards for compliance, certification, and enforcement purposes, and modified application of the 180-day period between finalization of a test procedure and issuance of a standards proposal by instead specifying a 180-day period between finalization of a test procedure and the close of the standards proposal comment period. The April 2024 Final Rule removed the requirement for an early assessment stage, instead specifying that DOE would publish one or more preliminary documents (*e.g.*, an RFI or a NODA) related to the test procedure.

1. Early Assessment and Pre-NOPR Stage

In response to the April 2025 RFI, DOE received two comments³⁴ in general support of a formal early assessment process for both energy conservation standards and test

³⁴ (Joint Gas Associations, No. 25 at p. 25) and (NEMA, No. 23 at pp. 7–8).

procedure rulemakings, which were summarized in section IV.G.1 of this document.

As DOE discussed in section IV.G.1 of this document, DOE has tentatively determined to amend the current Process Rule provisions to revert to the 2020 Process Rule requirement of an early assessment stage, and for test procedures where the early assessment indicates that DOE should proceed with a rulemaking, the 2020 Process Rule language also provides additional opportunities for early public input, such as an RFI or NODA.

2. Comment Periods

When developing test procedures, the current Process Rule specifies that the length of the public comment period for pre-NOPR rulemaking documents may vary depending on the circumstances of the particular rulemaking and will be determined on a case-by-case basis. At the NOPR stage, the current Process Rule specifies that there will be no less than 60 days for public comment on the NOPR, with at least one public hearing or workshop. (*See* 42 U.S.C. 6293(b)(2) and 42 U.S.C. 6306). *See* sections 8(a)(6) and 8(b)(2) of appendix A. The February 2020 Process rule did not include provisions specific to comment period lengths for test procedure rulemakings.

In commenting on the April 2025 RFI, AHRI stated that DOE should provide at least 30 days for comment on a pre-NOPR test procedure document and urged DOE to provide a 75-day comment period on the NOPR to allow interested parties time to evaluate proposed test procedure changes including collecting and analyzing test data, as lab time is hard to come by. (AHRI, No. 28 at pp. 9–10)

DOE has tentatively determined that reinstating language regarding test procedures from the 2020 Process Rule will allow for sufficient opportunities for early input, as discussed in the previous section. DOE also notes that guardrails are provided by the statutory requirement to provide a minimum 60-day comment period on test procedure NOPRs, while allowing DOE the ability to offer longer comment periods should there be extenuating circumstances, such as the need for additional laboratory time mentioned by AHRI. As such, DOE is not proposing changes to the 2020 Process Rule language to more directly address comment periods.

3. 180-Day Period

The February 2020 Process Rule specified that test procedure rulemakings establishing methodologies used to evaluate proposed energy conservation standards will be finalized

at least 180 days prior to publication of a NOPR proposing new or amended energy conservation standards. 85 FR 8626, 8708 (Feb. 14, 2020). The December 2021 Final Rule modified the calculation of the 180-day period. 86 FR 70892, 70912 (Dec. 13, 2021). Accordingly, the current Process Rule provides that except as provided in paragraph (e)(2) of section 8 of Appendix A, new test procedures and amended test procedures that impact measured energy use or efficiency will be finalized at least 180 days prior to the close of the comment period for a NOPR or a notice of proposed determination (“NOPD”). *See* section 8(e)(1) of appendix A. The exceptions are for test procedures developed by consensus or test procedures limited to calculation changes. *See* section 8(e)(2) of appendix A.

On this topic, the Joint Advocates stated that the current Process Rule already specifies the timing between the finalization of a test procedure and the end of the comment period for an ECS NOPR, which allows stakeholders to gain familiarity with new test procedures prior to providing comments on proposed standards. (Joint Advocates, No. 31 at p. 4)

In contrast, AHRI, the Joint Gas Associations, BWC, Lennox, NEMA, Rinnai, and Zero Zone generally supported a return to prior language in the Process Rule and expansion of the spacing between test procedure and standards rulemakings to 180 days between the issuance or publication of a test procedure final rule and the issuance or publication of an energy conservation standards NOPR. (AHRI, No. 28 at p. 12; BWC, No. 34 at pp. 2–3; Joint Gas Associations, No. 25 at p. 29; Lennox, No. 26 at pp. 2, 10–11; NEMA, No. 23 at pp. 8–9; Rinnai, No. 11 at pp. 3–5; Zero Zone, No. 15 at p. 3) Lennox stated that this full 180-day period is necessary because manufacturers’ assessment of test procedures can involve extensive equipment testing, with significant lab set-up and evaluation time. (Lennox, No. 26 at pp. 2, 10–11) The Joint Gas Associations stated that adopting this proposal will ensure that the test procedures are technically correct, that they can be repeated, and that the new or amended standards can be meaningfully reviewed. (Joint Gas Associations, No. 25 at p. 29) AHRI specified that this spacing requirement would apply to test procedures that impact energy use or efficiency. (AHRI, No. 28 at p. 12)

EEI and BHI generally stated that DOE should finalize test procedures well before a proposed change to the

corresponding standard. (EEI, No. 35 at p. 4; BHI, No. 16 at p. 3) EEI stated that changes to the test procedure after that point should be limited to issues that do not impact estimated energy use, cost, or design, thereby allowing stakeholders to clearly understand potential impacts and comment appropriately. (EEI, No. 35 at p. 4) BHI stated that DOE has a record of poor judgment in deciding what constitutes minor changes. (BHI, No. 16 at p. 3)

APPA stated generally that DOE should finalize test procedures for products well before it issues an ANOPR or proposal for those products. (APPA, No. 20 at p. 4) Similarly, NAHB stated that DOE should finalize test procedures prior to issuing an ANOPR or proposal for new standards—both for existing and new test procedures, because significant changes to test procedures can significantly impact the analyses performed for standards. (NAHB, No. 19 at p. 4) NAHB also supported DOE finalizing all new or amended test procedures that impact measured energy use or efficiency 180 days prior to close of a comment period, so that stakeholders can clearly understand potential impacts and comment appropriately. (NAHB, No. 19 at p. 5)

In response, DOE has tentatively determined to amend the language in the current Process Rule to match the 2020 Process Rule language that provides 180 days between a test procedure final rule and issuance of a standards NOPR. DOE requests comments on this issue.

As discussed, section 8(e)(2) of appendix A provides exceptions to the 180-day period for test procedures developed by consensus (*See* section 8(e)(2)(i) of appendix A) or test procedures limited to calculation changes (*See* section 8(e)(2)(ii) of appendix A). The current regulatory text in this section of Appendix A contains a formatting error whereby one of the provisions relevant to test procedures developed by consensus is printed in section 8(e)(2)(ii) of appendix A, which pertains to test procedures limited to calculation changes. In this NOPR, DOE proposes to correct this formatting error. As proposed, revised section 8(e)(2)(i) of appendix A would contain the provisions specific to test procedure amendments limited to calculation changes; and section 8(e)(2)(ii) of appendix A would contain the provisions specific to test procedures developed by consensus. These proposed changes are technical in nature only.

4. Industry Standards

The February 2020 Final Rule stated that DOE will adopt industry test standards as DOE test procedures for covered products and equipment, unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA), or estimated operating costs of that equipment during a representative average use cycle. 85 FR 8626, 8708 (Feb. 14, 2020). The December 2021 Final Rule modified that provision. 86 FR 70892, 70928 (Dec. 13, 2021). Specifically, the current Process Rule provides that DOE will adopt industry test procedure standards as DOE test procedures for covered products and equipment, but only if DOE determines that such procedures would not be unduly burdensome to conduct and would produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA), or estimated operating costs of that equipment during a representative average use cycle. DOE may also adopt industry test procedure standards with modifications or craft its own procedures as necessary to ensure compatibility with the relevant statutory requirements, as well as DOE's compliance, certification, and enforcement requirements. *See* section 8(d) of appendix A.

Several commenters indicated full support for DOE adopting industry standards. (AHRI, No. 28 at pp. 5–6; BHI, No. 16 at p. 3; BWC, No. 34 at p. 3; NEMA, No. 23 at p. 9) BWC strongly supported harmonization of DOE test procedures with industry standards to avoid redundant testing and reduce burdens on manufacturers. BWC encouraged DOE participation in industry working groups to raise concerns during the development of test procedures, thereby minimizing future conflicts. (BWC, No. 34 at p. 3) BHI stated that the 2020 Process Rule required DOE to use consensus test procedures with minimum modification; BHI added that this would streamline the rulemaking process, increase regulatory certainty, and reduce potential introduction of errors. (BHI, No. 16 at p. 3) NEMA recommended DOE return to the approach to industry standards reflected in the 2020 Final Rule and adopt consensus industry test standards without modification unless inconsistent with the law or impracticable. (NEMA, No. 23 at p. 9)

AHRI supported adopting consensus and proven test procedures already in use by industry and others as methods

of test for all applicable products and equipment. The commenter stated that the 2020 Process Rule deferred only to those consensus procedures that are fully consistent with applicable law, thereby streamlining rulemaking and regulatory burden. AHRI added that this policy promotes innovation, accelerates market adoption, fosters competition, and reduces burden. (AHRI, No. 28 at pp. 5–6) However, AHRI stated that the Process Rule should clarify how reliance on consensus standards interacts with DOE's test-procedure-waiver process.³⁵ The commenter stated that when an existing procedure fails to address a specific product configuration, manufacturers may request a waiver, prompting DOE to amend its procedure. AHRI added that if DOE principally relies on consensus standards, those standards are not subject to the same waiver prompt. AHRI stated that DOE should, therefore, establish a mechanism to ensure that products granted waivers are subsequently incorporated into updated procedures—either through the consensus standards body or, if necessary, via DOE action. (AHRI, No. 28 at p. 6) AHRI also recommended that DOE consider including an opportunity for DOE to adjust and address test procedure amendments on an expedited basis, such as a petition from stakeholders. The commenter stated that an expedited process would not be intended to address sweeping changes to the method of test but could fix errors or address burdensome practical challenges in execution of the test that had not been anticipated during the rulemaking stage. (AHRI, No. 28 at pp. 8–9)

Other commenters indicated that DOE should consider industry standards but could make changes. (CA IOUs, No. 32 at p. 2; Joint Gas Associations, No. 25 at p. 32; Rinnai, No. 11 at pp. 13–14) The Joint Gas Associations stated they are wary of a revised Process Rule mandating that industry standards must be used in test procedures in instances not already addressed in the statute. The Joint Gas Associations recommended that when making a determination on test procedures, the Department should give consideration to the applicable industry standard and work with stakeholders before automatically mandating the use of a particular

³⁵ DOE's current test procedure waiver process includes a provision which directs DOE to publish a NOPR to amend its test procedures so as to eliminate any need for the continuation of such waiver, as soon as practicable after the granting of any waiver. As soon thereafter as practicable, DOE will publish in the **Federal Register** a final rule. 10 CFR 430.27(l).

industry standard. (Joint Gas Associations, No. 25 at p. 32) Rinnai supported use of industry standards when developing test methods, but the commenter stated that DOE should modify or decline to adopt an industry standard if doing so is necessary to ensure accuracy, consumer transparency, or alignment with EPCA. Rinnai stated that the Process Rule should provide flexibility to consider such standards, solicit stakeholder input, and adopt them only when supported by clear and convincing evidence. (Rinnai, No. 11 at pp. 13–14) The CA IOUs stated that adopting industry test procedures is widely regarded as best practice, but the commenters acknowledged that these may not fully align with EPCA requirements and may need to be modified or enhanced to ensure they comply with law and are enforceable by being repeatable, reproducible, representative, and reasonable. (CA IOUs, No. 32 at p. 2)

DOE has a long history of monitoring the committees developing consensus standards, which allows DOE to evaluate whether the standards meet both industry's needs to minimize burden and provide representations to consumers and DOE's needs to comply with EPCA requirements and support repeatability and reproducibility to ensure a level playing field for manufacturers. This participation can also allow industry standards to incorporate the substance of waivers and address calculation changes. For this reason, upon review of comments, DOE is proposing to reinstate much of the language from the 2020 Process Rule, which limits changes to industry standards to those required for compliance with EPCA.

5. General

The April 2025 RFI requested comments on whether and how the Process Rule should be updated to provide additional detail on how DOE's rulemaking process satisfies the statutory requirements for establishing new or amended test procedures. 90 FR 16093, 16099 (April 17, 2025).

DOE received several comments related to general requirements for test procedures. AHRI stated that the Process Rule should clarify EPCA requirements that test procedures are to be representative of average use, not unduly burdensome, and repeatable and that the Process Rule should require DOE to demonstrate that test procedures do not result in indirect performance mandates. (AHRI, No. 28 at p. 3) NAFEM stated that the Process Rule should take into account real world

operating conditions and requirements, particularly related to food safety. (NAFEM, No. 13 at pp. 4–5) Heidi King Consulting stated that any test procedure must appropriately reflect the purpose of the product and its features, and that DOE should carefully consider when it is appropriate to assess energy performance at the product level versus the component level. (Heidi King Consulting, No. 30 at p. 4)

Upon review and in consideration of comments received, DOE has tentatively determined to reinstate the 2020 Process Rule language.

J. ASHRAE Equipment (Section 9)

Section 9 of the Process Rule was created by the February 2020 Final Rule and describes the process DOE will follow for conducting rulemakings for equipment subject to the “ASHRAE trigger” provisions in EPCA that apply when ASHRAE Standard 90.1 is amended with respect to standards, test procedures, or design requirements applicable to such equipment. The April 2024 Final Rule added provisions to clarify application of the 6- and 7-year lookback provisions for periodic review of standards and test procedures in the context of ASHRAE equipment.

1. Limited Circumstances and Clear and Convincing Evidence

The circumstances under which DOE will adopt a more-stringent standard than the ASHRAE standard or a different test procedure are laid out in the statute. DOE will issue a more-stringent standard than the ASHRAE Standard 90.1 level if DOE determines, supported by clear and convincing evidence, that the more-stringent standard would result in significant additional conservation of energy and is technologically feasible and economically justified. (42 U.S.C. 6313(a)(6)(A)(ii)(II)). DOE will adopt an updated test procedure for covered ASHRAE equipment so as to be consistent with related amendments to ASHRAE Standard 90.1, unless such test standard would not meet the requirements of 42 U.S.C. 6314(a)(2)–(3) (*i.e.*, a test procedure reasonably designed to reflect energy efficiency, energy use, and estimated operating cost of a type of industrial equipment (or class thereof) during a representative average use cycle and is not unduly burdensome to conduct). (42 U.S.C. 6314(a)(4)(B)). If DOE makes such finding, by rule and supported by clear and convincing evidence, the Department may establish an amended test procedure that does meet these statutory requirements. (42 U.S.C. 6314(a)(4)(C)).

To reflect these statutory requirements, the February 2020 Process included the statement that DOE will adopt the revised ASHRAE levels or the industry test procedure, except in very limited circumstances. The February 2020 Process Rule also included a description of what qualifies as clear and convincing evidence.³⁶ 85 FR 8626, 8708 (Feb. 14, 2020). Both the statement and the clear and convincing description were subsequently removed from the Process Rule in the April 2024 Final Rule, deferring instead to the statutory language. 89 FR 24340, 24354 (April 8, 2024). *See* section 9(a) and (b) of appendix A.

The Joint Gas Associations stated that a revised Process Rule should define the process used to adopt ASHRAE Standard 90.1 equipment standards and define a mechanism for when a more-stringent equipment efficiency standard over the ASHRAE level may be pursued. (Joint Gas Associations, No. 25 at pp. 31–32)

ASHRAE and the Joint Gas Associations commented that DOE should adopt language explaining that DOE will adopt the revised ASHRAE levels or industry test procedure, except in very limited circumstances. The Joint Gas Associations argued that this was the intent contemplated by EPCA. (ASHRAE, No. 12 at p.2; Joint Gas Associations, No. 25 at pp. 31–32)

The Joint Gas Associations stated that for consideration of standards more stringent than the ASHRAE levels, DOE should be required to meet a very high bar to meet the “clear and convincing evidence” threshold and should seek public comment to assist it in making that determination. The commenters stated that to meet the “clear and convincing evidence” threshold, DOE should be required to determine that there is no substantial doubt that the

more-stringent standard would result in significant additional conservation of energy, is technologically feasible and economically justified, or that the industry test procedures do not meet EPCA requirements. (Joint Gas Associations, No. 25 at pp. 31–32)

In response, DOE agrees that the intention of EPCA was for the Department to only adopt standard levels more stringent than those in ASHRAE Standard 90.1 in very limited circumstances. As such, for clarity, DOE is proposing to add that language back into the Process Rule and to largely reinstate the 2020 Process Rule language related to ASHRAE, in combination with the previous description of clear and convincing evidence. Specifically, DOE proposes to add the following language in section 9(e) of the Process Rule:

For ASHRAE equipment, DOE will adopt the revised standard levels or the industry test procedure contained or referenced in the latest version of ASHRAE Standard 90.1, as contemplated by EPCA, except in very limited circumstances.

With respect to DOE’s consideration of standards more-stringent than the ASHRAE Standard 90.1 levels or changes to the industry test procedure, DOE will do so only if it can meet a very high bar to demonstrate that it has met a “clear and convincing evidence” threshold. Clear and convincing evidence would exist only where the specific facts and data available to DOE regarding a particular ASHRAE amendment demonstrates that there is no substantial doubt that a standard more stringent than that contained in the ASHRAE Standard 90.1 amendment is permitted because it would result in a significant additional amount of energy savings and is technologically feasible and economically justified, or, in the case of test procedures, that the industry test procedure does not meet the EPCA requirements. DOE will make this determination only after seeking data and information from interested parties and the public to help inform the Agency’s views, and DOE will take this step prior to publishing a proposed rule to adopt more-stringent standards or a different test procedure.

DOE has tentatively determined that this language reflects the intent of EPCA while providing additional clarity to stakeholders and ensuring the appropriate level of deference to the ASHRAE process. DOE emphasizes that in discussing the need for “clear and convincing evidence” in the context of more-stringent standard levels for ASHRAE equipment, the Department is simply explaining the existing

³⁶ The February 2020 Final Rule stated that with respect to DOE’s consideration of standards more-stringent than the ASHRAE levels or changes to the industry test procedure, DOE will do so only if it can meet a very high bar to demonstrate the “clear and convincing evidence” threshold. Clear and convincing evidence would exist only where the specific facts and data made available to DOE regarding a particular ASHRAE amendment demonstrates that there is no substantial doubt that a standard more stringent than that contained in the ASHRAE Standard 90.1 amendment is permitted because it would result in a significant additional amount of energy savings, is technologically feasible and economically justified, or, in the case of test procedures, that the industry test procedure does not meet the EPCA requirements. DOE will make this determination only after seeking data and information from interested parties and the public to help inform the Agency’s views. DOE will seek from interested stakeholders and the public data and information to assist in making this determination, prior to publishing a proposed rule to adopt more-stringent standards or a different test procedure. 85 FR 8626, 8708 (Feb. 14, 2020).

requirements of the statute, rather than seeking to change or reinterpret those requirements.

Rather than changing the definition in question, DOE has found this language consistent with how that term has historically been interpreted and defined in the civil context in Federal Circuit and District Courts throughout the United States. Recently, the term “clear and convincing evidence” was addressed in a pair of cases involving DOE. In *American Public Gas Ass’n v. United States Department of Energy*, the D.C. Circuit stated, “The requirement of ‘clear and convincing evidence’ as a prerequisite to informal rulemaking is unusual, perhaps unique; we are aware of no other authorization for rulemaking subject to this heightened evidentiary standard. The standard is familiar, however, from other areas of the law: clear and convincing evidence requires a factfinder (in this case the Secretary) to have an ‘abiding conviction’ that her findings (in this case that a more stringent standard would result in significant additional conservation of energy, would be technologically feasible, and is economically justified) are ‘highly probable’ to be true. *Colorado v. New Mexico*, 467 U.S. 310, 316, 104 S.Ct. 2433, 81 L.Ed.2d 247 (1984).” 22 F.4th 1018, 1025 (D.C. Cir. 2022); see also *Am. Pub. Gas Ass’n v. U.S. Dep’t of Energy*, 72 F.4th 1324, 1336 (D.C. Cir. 2023).

In addition, the Ninth Circuit Court of Appeals has defined the “clear and convincing” standard as requiring the evidence “to be so clear as to leave no substantial doubt [and] sufficiently strong to command the unhesitating assent of every reasonable mind.” *Ittella Foods, Inc. v. Zurich Ins. Co.*, 98 F. App’x 689, 691 (9th Cir. 2004) (internal citations omitted). Similarly, the Eighth Circuit Court of Appeals has defined, “clear and convincing evidence” as “leav[ing] no substantial doubt.” *Hunt v. Pan Am. Energy*, 540 F.2d 894, 901 (8th Cir. 1976), and the Second Circuit Court of Appeals stated, “[c]lear and convincing proof is highly probable and leaves no substantial doubt,” *Dongguk Univ. v. Yale Univ.*, 734 F.3d 1113, 123 (2d Cir. 2013) (internal citations omitted).³⁷ Further, the *Handbook of*

Federal Evidence, which consists of materials designed to aid in understanding Federal evidentiary rules, also defines “clear and convincing evidence” in civil cases as requiring that “evidence be so clear as to leave no substantial doubt” and describes this standard of proof to only be sustained if the evidence induces a reasonable belief that the facts asserted are highly probably true. (*Handbook of Federal Evidence*, section 301:5 Burden of Persuasion, Incidence and Measure in Civil Cases (8th ed. 2018)).

Regarding any argument that the “clear and convincing evidence” standard is a term of legal art, of which Congress was aware when they adopted the language, and that DOE does not have the power to redefine “clear and convincing evidence” to make it closer to “beyond a reasonable doubt,” as exhibited in the above paragraph, DOE is not redefining the standard, and DOE’s provision for “clear and convincing evidence” is consistent with how it has been regularly defined in Federal Courts for many years. Accordingly, DOE agrees with NRDC that Congress was cognizant of the common law and accepted definition of “clear and convincing evidence” when implementing 42 U.S.C. 6313(a)(6)(A)(ii)(II); the definition of “clear and convincing evidence” as evidence that is so clear as to leave “no substantial doubt” can be traced to a 1899 California Supreme Court decision, decided far before 42 U.S.C. 6313(a)(6)(A)(ii)(II) was enacted. *Sheehan v. Sullivan*, 126 Cal. 189, 193 (1899) (defining clear and convincing evidence as clear, explicit, and unequivocal; so clear as to leave no substantial doubt). Again, this language has been reiterated by Federal Courts in the many years since.

and convincing evidence is evidence that leaves no substantial doubt . . . establishes not only that the proposition at issue is probable, but also that it is highly probable.”); *Hanna Coal Co., Inc. v. I.R.S.*, 218 B.R. 825, 829 n.2 (W.D. Va. 1997) (“Clear and convincing evidence leaves no substantial doubt in your mind. It is proof that establishes in your mind, not only [that] the proposition at issue is probable, but also that it is highly probable.”); *Gentry v. Hershey Co.*, 687 F. Supp. 2d 711, 724 (M.D. Tenn. 2010) (“Evidence is clear and convincing when it leaves no serious or substantial doubt about the correctness of the conclusions drawn.”); *Sala v. United States*, 552 F. Supp. 2d 1157, 1162 (D. Colo. 2007) (“Clear and convincing evidence leaves no substantial doubt in your mind. It is proof that establishes in your mind, not only [that] the proposition at issue is probable, but also that it is highly probable.”); *Tobinick v. Novella*, 108 F. Supp. 3d 1299, 1309 (S.D. Fla. 2015) (“The burden of proof by clear and convincing evidence requires a finding of high probability. The evidence must be so clear as to leave no substantial doubt. It must be sufficiently strong to command the unhesitating assent of every reasonable mind.”).

DOE requests comment on this proposal.

2. Timelines and Triggers

In the February 2020 Final Rule, the 2020 Process Rule expounded upon the timelines in EPCA for amending standards for ASHRAE equipment, combining timelines for standards and test procedures. 85 FR 8626, 8708 (Feb. 14, 2020). The April 2024 Final Rule added provisions to separately address standards and test procedures and to clarify application of EPCA’s 6- and 7-year lookback provisions for periodic review of standards and test procedures for ASHRAE equipment. 86 FR 70892, 70928–70929 (Dec. 13, 2021).

The Joint Gas Associations stated that the Department should continue to follow the statutory timelines and procedural requirements in EPCA for ASHRAE equipment when adopting the ASHRAE Standard 90.1 levels, rather than those set forth in any Process Rule. (Joint Gas Associations, No. 25 at pp. 31–32) The Joint Advocates noted that for ASHRAE equipment, the Process Rule separately defines the timelines for ASHRAE trigger rulemakings. (Joint Advocates, No. 31 at p. 4) ASHRAE stated that faster adoption by DOE of amended energy conservation standards in ASHRAE Standard 90.1 would lead to lower energy costs for consumers and businesses, and the commenter added that such approach is in alignment with both OMB Circular A–119 and the National Technology Transfer and Advancement Act (“NTTAA”), Public Law 104–113 (which directs Federal agencies to adopt voluntary industry consensus standards unless inconsistent with the law or impractical). (ASHRAE, No. 12 at p. 2)

In response and in consideration of the comments received, DOE has tentatively determined to largely reinstate the 2020 Process Rule language.

The Scope section of the current Process Rule (section 2) states that ASHRAE equipment is governed separately under section 9; as such, the other provisions in the Process Rule do not apply.

The Joint Gas Associations stated that in the event that DOE conducts a rulemaking to establish more-stringent standards for covered ASHRAE equipment, DOE should follow the procedures established in a revised Process Rule, while still complying with EPCA’s ASHRAE-specific deadlines. (Joint Gas Associations, No. 25 at pp. 31–32) ASHRAE stated that DOE should strictly adhere to the “7 Factor Test” if promulgating energy conservation

³⁷ Federal District Courts in circuits around the country have provided similar definitions of “clear and convincing evidence” in the civil context. See *Mandel v. Boston Phoenix, Inc.*, 492 F. Supp. 2d 26, 29 (D. Mass. 2007) (“The meaning of the term ‘clear and convincing evidence’—evidence so clear as to leave no substantial doubt.”)—is equally familiar and well-defined.”); *Jersey Const., Inc. v. Pennoni Assoc., Inc.*, Civ. A. No. 91–7331, 1993 WL 2999 (E.D. Pa. Feb. 4, 1993) (citing *Joseph’s v. Pizza Hut of Am. Inc.*, 733 F. Supp. 222, 223–24 (W.D. Pa. 1989), *aff’d*, 899 F.2d 1217 (3d Cir. 1990) (“Clear

standards levels beyond ASHRAE Standard 90.1. (ASHRAE, No. 12 at p. 2)

In response, DOE notes that although the full Process Rule does not currently apply to ASHRAE equipment, ASHRAE equipment have express rulemaking timelines specified in EPCA, as well as EPCA provisions related to the 7 Factor Test for economic justification. Additionally, the clear and convincing evidence threshold for rulemakings regarding ASHRAE equipment that would go beyond the levels set forth in ASHRAE Standard 90.1 may require additional consideration throughout the rulemaking process as compared to a rulemaking for non-ASHRAE equipment. As such, DOE has tentatively determined that additional language in the Process Rule may be needed. DOE is requesting information and comments on possible improvements or considerations for ASHRAE equipment.

The April 2024 Final Rule clarified in section 9(a)(3) of the Process Rule that publication of ASHRAE Standard 90.1 is the “trigger” for DOE reviewing standards. 89 FR 24340, 24362 (April 8, 2024).

ASHRAE stated that the trigger for when DOE must consider updating energy conservation standards for covered ASHRAE equipment is when the full version of ASHRAE Standard 90.1 is updated and published. (ASHRAE, No. 12 at p. 2)

In response, DOE agrees that this is consistent with DOE’s historical interpretation of what constitutes a trigger.

The February 2020 Final Rule specified that DOE’s review in considering amended standards based on action by ASHRAE to amend ASHRAE Standard 90.1 was strictly limited to the specific equipment class for which ASHRAE made a change. 85 FR 8626, 8708 (Feb. 14, 2020). The current Process Rule does not include such statement. Instead, the April 2024 Final Rule amended section 9(a)(3) of the Process Rule to state that DOE considers an amendment of standard levels in ASHRAE Standard 90.1 to be only those changes resulting in an increase in stringency of standard levels relative to the current Federal standards or the adoption of a design requirement. 89 FR 24340, 24362 (April 8, 2024).

The Joint Gas Associations stated that DOE’s review in adopting amendments based on action by ASHRAE should be strictly limited to the specific standards for the specific equipment for which ASHRAE has made a change. (Joint Gas Associations, No. 25 at pp. 31–32)

DOE agrees that this is historically the way that DOE has proceeded; therefore,

DOE has tentatively determined that it will largely revert to this language as established in the 2020 Process Rule. DOE requests comment on this approach, and also on whether additional language regarding this topic would be appropriate in the Process Rule.

K. Direct Final Rules (Section 10) and Negotiated Rulemaking

The Direct Final Rule section was established in the February 2020 Final Rule and describes how DOE would comply with EPCA requirements specific to publication of direct final rules, including the Department’s interpretation of the term “fairly representative of relevant points of view” as it applies to interested stakeholders. 85 FR 8626, 8708 (Feb. 14, 2020). The December 2021 Final Rule amended this section to clarify that DOE will implement its direct final rule authority under EPCA on a case-by-case basis including its evaluation of the meaning of “fairly representative,” subject to the circumstances of a particular rulemaking. 86 FR 70892, 70929 (Dec. 13, 2021). *See* section 10 of appendix A.

The February 2020 Final Rule also included a separate section related to negotiated rulemakings, which specified that they could not result in a direct final rule. 85 FR 8626, 8708–8709 (Feb. 14, 2020). The December 2021 Final Rule removed that section, instead inserting in the Objectives section of the Process Rule (section 1) a statement that the Department encouraged consensus proposals, including those developed in accordance with the Negotiated Rulemaking Act (“NRA”), Public Law 104–320 (5 U.S.C. 561, *et seq.*). It also clarified in section 10 of the Process Rule that consensus recommendations developed in accordance with the NRA may result in a direct final rule. 86 FR 70892, 70925, 70929 (Dec. 13, 2021). *See* sections 1(g) and 10 of appendix A.

Several commenters expressed support for negotiated rulemakings and urged that the Process Rule should maintain procedures for their use. Lennox stated that negotiated rulemakings should be a preferred route for energy efficiency rulemaking by DOE. (Lennox, No. 26 at p. 3) Lennox further stated that the Process Rule should require DOE to actively explore negotiated rulemakings for all major new standards. (Lennox, No. 26 at p. 11–12) BWC stated that DOE should be allowed to use a negotiated rulemaking process during the early stages, involving stakeholders who represent relevant viewpoints. (BWC, No. 34 at p. 4) The Joint Gas Associations supported

including procedures for negotiated rulemakings in the Process Rule that provide for a convener and promote full stakeholder participation throughout the rulemaking process. The Joint Gas Associations stated that if used appropriately, negotiated rulemakings can be an effective and efficient means of promulgating new energy conservation standards. (Joint Gas Associations, No. 25 at p. 35) Rinnai supported the use of a negotiated process that allows DOE to identify and address technical, economic, and practical concerns early in the process. Rinnai further stated that participation should include regional utilities, national and small manufacturers, consumer representatives, and State/local energy officials. (Rinnai, No. 11 at pp. 13–14)

Several commenters recommended that negotiated rulemakings utilize a neutral convener. The Joint Gas Associations recommended that a revised Process Rule should make clear that, prior to initiating a negotiated rulemaking, DOE will appoint a convener to: (i) identify persons who will be significantly affected by a proposed rule; and (ii) conduct discussions with such persons to identify their issues of concern and to ascertain whether the establishment of a negotiated rulemaking committee is feasible and appropriate in the particular rulemaking. The Joint Gas Associations also supported DOE incorporating provisions to ensure there is opportunity for public comment before the negotiated rulemaking committee. The Joint Gas Associations stated that the use of a facilitator and the opportunity for comprehensive public input will ensure the participation of all relevant interests in the process. (Joint Gas Associations, No. 25 at p. 35) Rinnai stated that for negotiated rulemakings to be effective, there should be a neutral convener to assess the feasibility of a negotiated rulemaking and to identify all parties significantly affected by the rule. Rinnai further stated that all stakeholders should be able to provide public comment on committee drafts and deliberations before consensus is finalized into regulation. (Rinnai, No. 11 at p. 13)

Several commenters supported the use of direct final rules (“DFR”) after a consensus is reached during a negotiated rulemaking. BWC stated that if consensus is reached, DOE can issue a DFR, bypassing many administrative steps and saving time and resources. (BWC, No. 34 at p. 4) Rinnai recommended codifying in the Process Rule that DFRs are only appropriate

where a representative cross-section of stakeholders—including utilities, consumers, small businesses, and small manufacturers—have actively participated in developing the proposed standard and affirmatively support its adoption without further comment. (Rinnai, No. 11 at p. 13) Rinnai also stated that negotiations should be required to represent a consensus inclusive across various constituencies and be subject to public scrutiny. Rinnai further stated that negotiations should include robust engagement with the full diversity of impacted stakeholders, particularly small and mid-sized manufacturers, distributors, professional installers, and end users. (Rinnai, No. 11 at p. 14) The Joint Gas Associations stated that at a minimum, the DFR process should include larger concerns and small businesses in the regulated industry/manufacturer community, energy advocates, energy utilities, consumers, and States. The Joint Gas Associations stated that a representative group, with respect to all proposed standards applicable to appliances that use natural gas, must include gas distribution utilities and their customers. Furthermore, the Joint Gas Associations stated that any rules established through a DFR or a negotiated rulemaking process must still adhere to the other principles in EPCA, such as being economically justified, technologically feasible, and demonstrate significant conservation of energy. The Joint Gas Associations recommended that a revised Process Rule should reflect and formalize this inclusive approach. (Joint Gas Associations, No. 25 at pp. 33–34)

Rinnai stated that no stakeholder recommendation should be used as the primary basis for a proposed rule unless it includes participants that represent all segments of the affected industry (including small manufacturers and utilities) and includes a mechanism for dissenting views to be formally submitted. (Rinnai, No. 11 at p. 14)

Rinnai stated that analysis supporting negotiations should be required to include a competitive impact assessment (*i.e.*, examining how any stakeholder recommendation may benefit one or more participating entities). The commenter stated that this review should examine whether the proposal would create market distortions, impose barriers to entry, or provide disproportionate advantages to specific market participants or technologies. Rinnai recommended that findings should be publicly disclosed to ensure transparency and guard against regulatory capture. (Rinnai, No. 11 at p. 14)

Upon review, DOE has tentatively determined that largely returning to the language in the 2020 Process Rule regarding Direct Final Rules and the Negotiated Rulemaking Process will provide more clarity to stakeholders on how DOE will implement these mechanisms. DOE has also tentatively determined, based on review of stakeholder comments, that the text in the Objectives section of the Process Rule encouraging the development of consensus proposals, including—in certain circumstances and after careful consideration of fair representation—negotiated proposals, is appropriate, and is further proposing to add language noting that these proposals may proceed to a direct final rule in appropriate cases.

DOE is requesting information and comments on possible improvements or considerations for the process of negotiated rulemaking under EPCA. DOE is also requesting comments on considerations for direct final rules.

L. Principles for Distinguishing Between Effective and Compliance Dates (Section 11)

This section was established in the February 2020 Final Rule and provides clarification as to the distinction between the effective and compliance dates of a final rule. 85 FR 8626, 8709 (Feb. 14, 2020). This section has not been amended since its original establishment.

While DOE did not receive any comments related to this section, DOE has tentatively determined that it would also be beneficial to clarify the prescribed date of a rule as compared to the effective and compliance dates. As noted in the current Process Rule, the effective date is the date a rule is legally operative after being published in the **Federal Register**. Under the Administrative Procedure Act, the effective date must be at least 30 days after the date of publication in the **Federal Register**. (5 U.S.C. 553(d)). For some rules, a longer period is required (*e.g.*, 60 days for a major rule under the Congressional Review Act (5 U.S.C. 801(a)(3)) and 120 days for a direct final rule issued under 42 U.S.C. 6295(p)(4)). The compliance date, on the other hand, is the specific date when manufacturers are required to use a new test procedure to make energy efficiency representations or to meet a new energy conservation standard. For test procedures, the compliance date is typically 180 days after publication in the **Federal Register**. (42 U.S.C. 6293(c)(2)). For standards, the compliance date is typically three or five years after publication in the

Federal Register for covered products but can vary under certain circumstances. (42 U.S.C. 6295(m)(4)).

In addition to effective and compliance dates, the date a rule is prescribed is also a significant date in EPCA. For instance, under EPCA, petitions for review of a rule are required to be filed “within 60 days after the date on which such rule is prescribed.” (42 U.S.C. 6306(b)(1)). DOE’s longstanding interpretation has been that the prescribed date of a rule is the date the rule is published in the **Federal Register**. This view is consistent with the court’s determination in *Natural Resources Defense Council v. Abraham* that “publish” and “prescribe” are “interchangeable” terms in EPCA. 355 F.3d 179, 196 (2d Cir. 2004). DOE proposes to add language clarifying that the prescribed date for a rule issued under EPCA, including direct final rules, is the date the rule is published in the **Federal Register**.

M. Other Comments

DOE received several other comments not directly linked to any specific section of the Process Rule. The Department summarizes and addresses these comments in the paragraphs that follow. However, DOE is not proposing any revisions in relation to these comments for the reasons explained.

In the April 2025 RFI, DOE requested comments and information on whether any changes to the Process Rule should be made, consistent with statutory requirements, to reduce the regulatory burden associated with test procedure and/or energy conservation standards rulemakings. 90 FR 16093, 16097 (April 17, 2025).

DOE received two comments related to changing timelines of rulemakings in response to regulatory burden. BWC stated that DOE should evaluate the cumulative regulatory burden on manufacturers early in the rulemaking process, because manufacturers producing multiple covered products can be overwhelmed by simultaneous rulemakings. BWC stated that DOE should accept comments from manufacturers facing cumulative regulatory burdens and consider delaying rulemakings if manufacturers are overstretched by other ongoing DOE efforts. (BWC, No. 34 at p. 4) NAFEM commented that the Process Rule should require DOE to align regulatory schedules across Federal agencies and State regulations to reduce uncertainty and manufacturer burden in terms of re-tooling product lines and costs for agency re-approvals, costs for re-testing equipment and products, and costs to

modify sales and marketing literature. NAFEM argued that overlapping and conflicting timelines create economic hardship, especially for small manufacturers. (NAFEM, No. 13 at pp. 3–4)

In response, DOE notes that it must comply with statutory requirements for the timing of rulemakings, and any adjustments to rulemaking timelines to address regulatory burden must be done in compliance with the statutory deadline for a given product. As such, DOE is unable to address these requested changes to regulatory timelines generally as part of the Process Rule.

Several other commenters discussed how to analyze cumulative regulatory burden; these comments will be summarized and addressed in a separate proceeding focused on the analytical methodologies used in DOE's rulemaking process.

The April 2025 RFI asked whether and how the Process Rule should be updated to provide additional detail on how DOE's rulemaking process ensures protection of consumer choice in prescribing regulations for covered consumer products and commercial/ industrial equipment as directed by EPCA. 90 FR 16093, 16097 (April 17, 2025)

Several commenters stated that EPCA and/or the current Process Rule already prioritize the interests of American consumers and consumer choice and that no changes to the Process Rule are needed. (NEEA, No. 36 at p. 3; Ceres, No. 22 at pp. 2–4; Lennox, No. 26 at p. 3; State Agencies, No. 33 at p. 1; Joint Advocates, No. 31 at p. 2) Ceres added that the current Process Rule provides market certainty critical for manufacturers to determine appliance costs for consumers. Ceres stated that without national standards, manufacturers would have to navigate individual State requirements to offer their products across the country, and that this may prevent some manufacturers from selling products in individual States, thereby creating serious variances in costs and products available from State to State. (Ceres, No. 22 at pp. 2–4)

NAHB expressed support for standards that reduce energy consumption and allow markets to offer a robust range of products that meet consumer preferences for functionality, cost, efficiency, and aesthetics. NAHB stated that EPCA requires DOE to consider this exact impact, but that the recent residential furnaces and consumer water heaters rulemakings will adversely impact consumer choice. Accordingly, the commenter

recommended that compliance with these standards should be postponed. (NAHB, No. 19 at pp. 2–3)

DOE agrees that its role in implementing EPCA should include thorough assessment of the interests of American consumers and domestic manufacturers, but DOE is open to comments regarding additional ways DOE can address these interests. DOE notes that many other commenters discussed consumer choice specifically in relation to adding more clarification of how DOE interprets the EPCA provisions related to features, product classes, and unavailability.³⁸ These comments may be considered in a separate proceeding related to that topic, if appropriate. In response to NAHB, DOE notes that the referenced rulemakings have already been completed and any change to the compliance date is outside the scope of this Process Rule proceeding.

Rinnai recommended requiring identification and documentation of lessons learned for any rule that is withdrawn under the Congressional Review Act (“CRA”) or judicial invalidation. (Rinnai, No. 11 at p.11)

In response, DOE notes that its actions addressing rules being withdrawn as a result of CRA or judicial invalidation are based on the requirements of the CRA or the specific judicial decision. As such, DOE is not proposing additional language in the Process Rule.

PHTA recommended that any amendments to the certification, compliance, enforcement sections of Part 429 (which require a change to the reporting requirements for manufacturers to demonstrate compliance) be completed within the test procedure or energy conservation standard rulemaking, and not a separate certification rulemaking. (PHTA, No. 27 at p. 2)

DOE notes that information collected in certification reports is subject to approval from Office of Information and Regulatory Affairs (“OIRA”), consistent with the requirements of the Paperwork Reduction Act (“PRA”). DOE establishes reporting requirements consistent with the PRA and OIRA requirements for the entire range of covered products. DOE is considering how to best limit regulatory burden associated with its appliance standards program, including

approaches to limit the paperwork and reporting burden associated with compliance certification reporting requirements. DOE will propose any such action as part of a separate proceeding related to certification requirements.

Zero Zone recommended that DOE review how it applies uncertainty levels to analysis, test reporting and certification, and standard levels. (Zero Zone, No. 15 at pp. 1–2)

In response, DOE notes that uncertainty levels are assessed on a case-by-case basis in individual energy conservation standards and test procedure rulemakings, as needed. Given the fact-specific nature of such inquiry, DOE does not believe that a generalized statement in the Process Rule would add significant value.

APPA and EEI stated that DOE should work with Congress to reform the 3-year-lookback provision for “no new standards” determinations, perhaps by providing that a new analysis should only be required if there is a significant shipments increase. (APPA, No. 20 at p. 3; EEI, No. 35 at p. 3) APPA commented that DOE should also work with Congress to revise the “six-year-lookback” (for energy conservation standards) and “seven-year-lookback” (for test procedures) requirements contained in the Energy Independence and Security Act of 2007 (“EISA 2007”) amendments to EPCA and consider changing it to six or seven years after the compliance date of a new standard. APPA argued that this would provide more time to evaluate the real-world effects of new standards before considering any amendments. (APPA, No. 20 at pp. 3, 5)

DOE acknowledges receipt of these comments and will consider further updates to the Process Rule to reflect any future amendments to EPCA, if adopted by Congress.

Lennox stated that the Process Rule should acknowledge DOE's “error correction” provisions and that these error correction provisions should be strengthened. (Lennox, No. 26 at p. 11)

In response, DOE's error correction provisions are not part of the Process Rule and DOE has tentatively decided to continue addressing them separately. See 10 CFR 430.5. The error correction provisions describe an optional process that the Secretary may choose to follow for a final rule that establishes or amends energy conservation standards, prior to publication of such rule in the **Federal Register**. Because this is an optional procedure and because DOE is proposing in this notice that the Process Rule would be binding on DOE, DOE has tentatively determined that

³⁸ (ACCA, No. 38 at p. 1; AHRI, No. 28 at pp. 2–3; APPA, No. 20 at p. 5; BHI, No. 16 at pp. 2–5; Heidi King Consulting, No. 30 at p. 4; Joint Advocates, No. 31 at p. 2; Joint Gas Associations, No. 25 at pp. 14–16; NAFEM, No. 13 at pp. 7–8; NEMA, No. 23 at pp. 5–6; NRECA, No. 17 at p. 2; Rinnai, No. 11 at pp. 3, 6–7, 11–12; Strauch, No. 18 at pp. 1–2; ONE Gas, No. 37 at pp. 3–4; WM Technologies, No. 14 at p. 2).

addressing error correction provisions separately is appropriate. However, DOE is requesting additional comments on whether the Process Rule should reference the optional separate error correction provisions.

Several commenters discussed stakeholder engagement and transparency.

ACCA stated that DOE should provide plain-language summaries of proposed standards and technical analyses. The commenter added that DOE should expand opportunities for contractors, installers, and service professionals—those closest to real-world performance—to contribute data and recommendations during rulemakings. ACCA suggested that DOE should establish a small business review panel within the program, modeled on the Small Business Administration's Small Business Regulatory Enforcement Fairness Act ("SBREFA") panels, to evaluate impacts early in the rulemaking process. (ACCA, No. 38 at p. 3)

APPA recommended that DOE increase its use of internet platforms and hybrid meetings to maximize stakeholder input and reduce the cost of rulemaking processes. (APPA, No. 20 at pp. 4–5) EEI recommended that DOE should increase its use of internet platforms including hosting hybrid or internet-only webinars during comment periods. (EEI, No. 35 at p. 4) NAHB encouraged DOE to focus on publicizing and justifying its rationale for decision making throughout the rulemaking process; NAHB noted that webinars and other public forums to solicit input can increase confidence in the fairness and transparency of the rulemaking process. (NAHB, No. 19 at p. 5) Rinnai recommended requiring disclosure of all modeling assumptions, engagement with stakeholders through technical workshops, and publishing intermediate results. Rinnai also recommended requiring stakeholder webinars within 10 days of releasing major data sets or modeling changes. (Rinnai, No. 11 at p. 10)

NRECA commented that DOE should account for key issues raised by stakeholders and incorporate the information provided in its rulemakings. (NRECA, No. 17 at p. 2) APPA commented that DOE should ensure that it carefully evaluates information and analyses submitted by stakeholders. (APPA, No. 20 at pp. 4–5) NAFEM commented that DOE should participate in increased dialogue with industry. (NAFEM, No. 13 at p. 8)

Rinnai recommended requiring public availability of all life-cycle cost ("LCC") model files and key assumptions.

(Rinnai, No. 11 at p. 10) Zero Zone stated that DOE should be required to share its models and allow stakeholder review. (Zero Zone, No. 15 at p. 4)

NEMA recommended that DOE consider soliciting pre-NOPR information at the earliest possible time, in order to guide the way forward, help avoid wasting resources later, and reduce the likelihood of a rule that is inconsistent with the statutory scheme and, thus, vulnerable to legal challenge. (NEMA, No. 23 at p. 8)

The Joint Gas Associations stated that the Department should use updated qualitative and quantitative analytical methods that fully document for the public that its decisions are sound. These commenters added that any results should be fully explained and capable of being reproduced by stakeholders. (Joint Gas Associations, No. 25 at p. 18)

AHRI, NAFEM, and Zero Zone suggested that DOE should be required to provide masked test data to all stakeholders, and AHRI and NAFEM suggested that unmasked test data should be provided to the relevant manufacturer. (AHRI, No. 28 at pp. 2, 7; NAFEM, No. 13 at pp. 6–7; Zero Zone, No. 15 at pp. 2, 4) Zero Zone added that a Professional Engineer should be required to review and approve the results. (Zero Zone, No. 15 at p. 4)

The Joint Advocates stated that the Process Rule currently specifies opportunity for public comment, and DOE makes supporting materials publicly available, including technical support documents, government regulatory impact models, and the national impact analysis ("NIA") and LCC spreadsheets. Accordingly, the Joint Advocates concluded that there is no need to amend these sections of the Process Rule. (Joint Advocates, No. 31 at pp. 3–4) NEEA stated that DOE should continue to publish its analyses and field formal comment periods and stakeholder input opportunities across key rulemaking stages. Additionally, NEEA recommended DOE continue to prioritize transparency, accessibility, and consistency in how it solicits and incorporates public feedback, and the commenter opposed any changes that would diminish the structure, duration, or significance of public comment windows. (NEEA, No. 36 at p. 2) NEEA recommended DOE maintain its current commitment to transparent, peer-reviewed cost-benefit analysis, including the publication of assumptions, data, and modeling tools. (NEEA, No. 36 at p. 3)

Upon review, DOE agrees that the current Process Rule already specifies appropriate opportunities for public

comment and stakeholder engagement. While DOE makes all spreadsheet models and technical support documents publicly available for stakeholder review, the Department welcomes the opportunity to further increase transparency and reproducibility as part of the rulemaking record. DOE recognizes that in isolation such documents may be difficult to navigate without clear documentation manuals and access to underlying methodology and data. DOE will explore opportunities to increase transparency further through the Analytic Framework update. DOE already engages with stakeholders via public hearings (including hybrid meetings) and provides opportunities for stakeholders to submit relevant real-world performance data and information and provide recommendations. DOE responds to key issues raised by stakeholders and incorporates information provided in its rulemakings, where appropriate. DOE also has the ability to make additional materials available or to conduct additional stakeholder engagement as necessary. To the extent that commenters raised topics related to analytical methodologies, DOE further discusses such comments in section IV.N.1 of this document, and the Department will address these methodologies in a separate process. As such, DOE is not proposing any revisions in response to these comments at this time.

N. Topics Considered in Other Processes

1. Analytical Methodology

DOE received several comments in response to the April 2025 RFI pertaining to the analysis conducted in support of the development of energy conservation standards, including comments on the methodology and development of input values related to the general approach,³⁹ as well as comments pertaining to specific analyses, including: (1) the engineering analysis;⁴⁰ (2) the markups analysis;⁴¹ (3) the energy use and life-cycle cost analysis;⁴² (4) the environmental

³⁹ (BHI, No. 16 at pp. 5–6; BWC, No. 34 at p. 5; Joint Commenters, No. 24 at pp. 3–4; AHRI, No. 28 at pp. 2, 7–8, 11–12; Joint Gas Associations, No. 25 at pp. 23–24, 37–38; APPA, No. 20 at p. 1; Joint Advocates, No. 31 at pp. 2–3; EEI, No. 35 at p. 2; State Agencies, No. 33 at p. 2; Heidi King Consulting, No. 30 at pp. 1–3; Lennox, No. 26 at pp. 6–7)

⁴⁰ (Joint Gas Associations, No. 25 at p. 22; Strauch, No. 18 at p. 1; NAFEM, No. 13 at p. 8)

⁴¹ (Joint Gas Associations, No. 25 at p. 22; Lennox, No. 26 at p. 7)

⁴² (ACCA, No. 38 at p. 2; AHRI, No. 28 at pp. 4, 7; EEI, No. 35 at p. 2; Joint Gas Associations, No.

analysis⁴³ and full-fuel-cycle energy metrics;⁴⁴ (5) the monetization of emissions analysis;⁴⁵ (6) the utility impact analysis;⁴⁶ and (7) the manufacturer impact analysis.⁴⁷

DOE further received additional comments specific to the following topics: (1) the approach to evaluate hard-to-quantify effects⁴⁸ and evaluate market failures;⁴⁹ (2) the cumulative regulatory burden analysis;⁵⁰ (3) considerations of any potential supply chain constraints;⁵¹ (4) fuel neutrality and analysis of fuel switching;⁵² and (5) the need for retrospective review and validation of existing standards prior to initiating new rulemakings.⁵³

Given the significant volume and range of comments which require careful consideration, DOE has tentatively determined that the most appropriate path forward is to propose minor amendments to these methodology sections (e.g., sections 12 through 16) of the Process Rule, but to address the detailed topics raised in these comments as part of a separate process. DOE intends to separately undertake an analytic framework RFI in which DOE will conduct a review of its analytical methods, with the goal of ensuring that rulemaking analyses incorporate best practices and address topics raised during peer review⁵⁴ of DOE's rulemaking process.

²⁵ at pp. 22–24; Joint Advocates, No. 31 at p. 3; Lennox, No. 26 at p. 7; NAHB, No. 19 at p. 4; NMHC and NAA, No. 29 at pp. 2–5; ONE Gas, No. 37 at pp. 2–3; ONE Gas, No. 37 at pp. 2–3; Rinnai, No. 11 at pp. 3, 6–8)

⁴³ (APPA, No. 20 at p. 5; Ceres, No. 22 at p. 5; NEEA, No. 36 at p. 3; EEL, No. 35 at p. 5)

⁴⁴ (Joint Gas Associations, No. 25 at pp. 18–19; ONE Gas, No. 37 at pp. 4–5; Rinnai, No. 11 at pp. 3, 7–8)

⁴⁵ (AHRI, No. 28 at p. 10; BWC, No. 34 at p. 5; Ceres, No. 22 at p. 4; State Agencies, No. 33 at p. 2; Strauch, No. 18 at p. 2; NAHB, No. 19 at p. 5; NAFEM, No. 13 at p. 7; Zero Zone, No. 15 at p. 5)

⁴⁶ (ONE Gas, No. 37 at p. 4)

⁴⁷ (ACCA, No. 38 at p. 2; NAFEM, No. 13 at pp. 2–3; Rinnai, No. 11 at pp. 3, 6)

⁴⁸ (Heidi King Consulting, No. 30 at p. 5; Lennox, No. 26 at p. 5; NEMA, No. 23 at p. 6–7; NRECA, No. 17 at p. 2)

⁴⁹ (Joint Gas Associations, No. 25 at pp. 21, 22; Heidi King Consulting, No. 30 at p. 3; Rinnai, No. 11 at p. 9)

⁵⁰ (AHRI, No. 28 at p. 4; Lennox, No. 26 at p. 6; PHTA, No. 27 at pp. 1–2)

⁵¹ (APPA, No. 20 at pp. 2–3; EEL, No. 35 at pp. 2–3)

⁵² (Joint Gas Associations, No. 25 at pp. 11–15, 17; Rinnai, No. 11 at pp. 9, 12)

⁵³ (ACCA, No. 38 at p. 2; Joint Gas Associations, No. 25 at pp. 26–28; NAHB, No. 19 at p. 4; Rinnai, No. 11 at p. 10)

⁵⁴ The National Academies of Sciences, Engineering, and Medicine completed the peer review and transmitted to DOE its report, “Review of Methods Used by the U.S. Department of Energy in Setting Appliance and Equipment Standards,” (“NAS Report”) on January 7, 2022. The report is available at <https://www.nap.edu/catalog/25992/>

2. Product-Specific Comments

Solaray commented that DOE should consider including solar thermal water heating systems within the scope of its prioritization process for energy conservation standards and consider solar water heaters alongside conventional and hybrid technologies in future water heating rulemakings, or as a standalone or primary heating source for water. (Solaray, No. 8 at pp. 2–4)

In response, DOE plans to address the appropriate scope for water heaters as part of any future rulemakings on water heaters.

O. Severability

These procedures, interpretations, and policies for consideration of new or revised energy conservation standards and test procedures are separate and severable from one another and capable of operating independently. If any section or portion therein is stayed or determined to be invalid, or the applicability of any section to any person or entity is held invalid, it is DOE's intention that the validity of the remainder of these procedures will not be affected and will continue in effect, along with all applications thereof.

V. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

Section 6(a) of Executive Order (“E.O.”) 12866, “Regulatory Planning and Review,” 58 FR 51735 (Oct. 4, 1993), requires agencies to submit “significant regulatory actions” to the Office of Information and Regulatory Affairs (“OIRA”) in the Office of Management and Budget (“OMB”) for review. OIRA has determined that this proposed regulatory action constitutes a “significant regulatory action” under section 3(f) of E.O. 12866. Accordingly, this proposed regulatory action was submitted to OIRA for review under E.O. 12866.

B. Review Under Additional Executive Orders and Presidential Memoranda

DOE has examined this proposed rule and has tentatively determined that it is consistent with the policies and directives outlined in E.O. 14154, “Unleashing American Energy,” 90 FR 8353 (Jan. 29, 2025); E.O. 14192, “Unleashing Prosperity Through Deregulation,” 90 FR 9065 (Feb. 6, 2025); and Presidential Memorandum, “Delivering Emergency Price Relief for American Families and Defeating the

review-of-methods-used-by-the-us-department-of-energy-in-setting-appliance-and-equipment-standards.

Cost-of-Living Crisis,” 90 FR 8245 (Jan. 28, 2025).

Preliminarily, this proposed rulemaking has also been determined to be an “E.O. 14192 deregulatory action” because, within the requirements of EPCA, it intends to reduce unnecessary burdens to society by streamlining the regulatory framework and improving efficiency for regulated entities and the interested public. The primary impacts are from the proposal to make the Process Rule binding for actions that would increase stringency, so that manufacturers and other stakeholders have more certainty with respect to how individual rulemakings will proceed in the future, within laid out boundaries. In addition, the proposal re-instates a threshold for significant conservation of energy, again giving manufacturers and other stakeholders more certainty with respect to how rulemakings will proceed in the future in terms of new or amended standards while continuing to meet DOE's responsibilities under EPCA. The proposal to re-instate a comparative analysis among all analyzed TSLs would also allow DOE to best determine economic justification, consistent with statutory requirements, while promoting consumer choice and lowering first cost of appliances. In addition, the proposal related to ASHRAE equipment gives more certainty to manufacturers that DOE will only adopt standard levels above ASHRAE in very specific circumstances, allowing them to focus resources on adjusting to any revisions in ASHRAE. These benefits are difficult to quantify due to the breadth of products, and that most benefits will accrue in individual future rulemakings. Nevertheless, DOE believes these benefits would be substantial.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996) requires preparation of an initial regulatory flexibility analysis (“IRFA”) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by E.O. 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE

has made its procedures and policies available on the Office of the General Counsel's website (www.energy.gov/gc/office-general-counsel).

This proposed rule would impose no regulatory obligations on the public, including small entities, and it would not affect the ability of any interested person, including small entities, to participate in DOE's rulemaking process. Because this proposed rule to revise DOE's Process Rule instead would only impose procedural requirements on the Department itself, DOE certifies that this proposed rule would not have a "significant economic impact on a substantial number of small entities," and, therefore, the preparation of an IRFA is not warranted. Accordingly, DOE will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration ("SBA") for review under 5 U.S.C. 605(b).

D. Review Under the Paperwork Reduction Act of 1995

DOE is not amending its existing information collections through this proposed rule. Under existing provisions, manufacturers of covered products/equipment must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for such products/equipment, including any amendments adopted for those test procedures, on the date that compliance is required. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment (*see generally* 10 CFR part 429). The collection-of-information requirement for certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act ("PRA"). This requirement has been approved by OMB under OMB control number 1910-1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the 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 PRA, unless that collection of information displays a currently valid OMB Control Number.

Specifically, this proposed rule, addressing clarifications to the Process Rule itself, does not contain any collection of information requirement that would trigger the PRA.

E. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), DOE has analyzed this action in accordance with NEPA, as amended, DOE's NEPA implementing regulations (set forth in 10 CFR part 1021), and DOE's NEPA implementing procedures (published outside the Code of Federal Regulations on June 30, 2025 (Available at: www.energy.gov/nepa/articles/doe-nepa-implementing-procedures-june-2025)). The actions formally identified in appendix A of subpart D to part 1021 represent administrative and routine actions that are excepted from NEPA based on the definition of "major Federal action" in section 111(10) of NEPA. DOE has tentatively determined that the proposed amendments to the Process rule are administrative and routine. DOE has tentatively determined that as an administrative and routine action, this proposal is not a major Federal action significantly affecting the quality of the human environment within the meaning of NEPA and no further environmental review is needed.

F. Review Under Executive Order 13132

E.O. 13132, "Federalism," 64 FR 43255 (August 10, 1999), imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735.

DOE has examined this proposed rule and has tentatively determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the

various levels of government. It will primarily affect the procedures by which DOE develops proposed rules to revise energy conservation standards and test procedures for covered consumer products and commercial/industrial equipment. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

G. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of E.O. 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Regarding the review required by section 3(a), section 3(b) of E.O. 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and tentatively determined that, to the extent permitted by law, this proposed rule meets the relevant standards of E.O. 12988.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 ("UMRA") requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104-4, section 201 (codified at 2 U.S.C. 1531).

For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE’s policy statement is also available at www.energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.

DOE examined this proposed rule according to UMRA and its statement of policy and has tentatively determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year. Accordingly, no further assessment or analysis is required under UMRA.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule or policy that may affect family well-being. When developing a Family Policymaking Assessment, agencies must assess whether: (1) the action strengthens or erodes the stability or safety of the family and, particularly, the marital commitment; (2) the action strengthens or erodes the authority and rights of parents in the education, nurture, and supervision of their children; (3) the action helps the family perform its functions, or substitutes governmental activity for the function; (4) the action increases or decreases disposable income or poverty of families and children; (5) the proposed benefits of the action justify the financial impact on the family; (6) the action may be carried out by State or local government

or by the family; and whether (7) the action establishes an implicit or explicit policy concerning the relationship between the behavior and personal responsibility of youth, and the norms of society.

This proposed rule, which would amend the procedures DOE will follow in conducting rulemakings for new or amended energy conservation standards and test procedures, would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 12630

Pursuant to E.O. 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights,” 53 FR 8859 (March 18, 1988), DOE has determined that this proposed rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

K. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.

DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Review Under Executive Order 13211

E.O. 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A “significant energy action” is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that:

(1) is a significant regulatory action under Executive Order 12866, or any successor order, and is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the regulation be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has tentatively concluded that the regulatory action in this document, which proposes clarifications to the Process Rule that guides the Department in establishing and amending energy conservation standards and test procedures, is not a significant energy action because it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects for this proposed rule.

M. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (“OSTP”), issued its Final Information Quality Bulletin for Peer Review (“the Bulletin”). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government’s scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are “influential scientific information,” which the Bulletin defines as “scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions.” *Id.* at 70 FR 2667.

In response to OMB’s Bulletin, DOE conducted formal peer reviews of the energy conservation standards development process and the analyses that are typically used and has prepared a Peer Review report pertaining to the energy conservation standards rulemaking analyses.⁵⁵ Generation of

⁵⁵ The 2007 “Energy Conservation Standards Rulemaking Peer Review Report” is available at www.energy.gov/cmei/articles/building-

this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. Because available data, models, and technological understanding have changed since 2007, DOE has engaged with the National Academy of Sciences to review DOE's analytical methodologies to ascertain whether modifications are needed to improve DOE's analyses. DOE is in the process of evaluating the resulting report⁵⁶ and plans to consider any corresponding updates needed to its analytical framework in a separate proceeding, as discussed earlier in this document. Specifically, DOE plans to publish a separate analytic framework RFI to seek public input and peer review on any necessary updates to its rulemaking analytical methodologies.

VI. Public Participation

A. Participation in the Webinar

The time and date of the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website at: www.energy.gov/eere/buildings/public-meetings-and-comment-deadlines. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this document, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the webinar. Such persons may submit such request to make a prepared general statement to ApplianceStandardsQuestions@ee.doe.gov. Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this proposed rule and the topics they wish to discuss. Such

persons should also provide a daytime telephone number where they can be reached to enable DOE staff to make follow-up contact, if needed.

DOE requests persons seeking to make an oral presentation to submit an advance copy of their statements at least one week before the webinar. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral presentation should ask for such alternative arrangements.

C. Conduct of the Webinar

DOE will designate a DOE official to preside at the webinar and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the webinar. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the webinar, interested parties may submit further comments on the proceedings, as well as on any aspect of the proposed rulemaking, until the end of the comment period.

The webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this proposed rule, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this proposed rule. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this proposed rule. The official conducting the webinar will accept additional comments or questions from those

attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the webinar.

A transcript of the webinar will be included in the docket, which can be viewed as described in the Docket section at the beginning of this document and will be accessible on the DOE website. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the webinar, but no later than the date provided in the **DATES** section at the beginning of this document. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The www.regulations.gov web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Otherwise, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to www.regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information ("CBI")). Comments submitted through www.regulations.gov cannot be claimed as CBI. Comments received through the website will waive any CBI claims for

technologies-office-bto-peer-review-2007 (Last accessed May 11, 2026).

⁵⁶ The report is available at www.nationalacademies.org/our-work/review-of-methods-for-setting-building-and-equipment-performance-standards (Last accessed Oct. 6, 2025).

the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through www.regulations.gov before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that www.regulations.gov provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery/courier, or postal mail. Comments and documents submitted via email, hand delivery/courier, or postal mail also will be posted to www.regulations.gov. If you do not want your personal contact information to be publicly viewable, do not include it in your comments or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery/courier, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (“faxes”) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters’ names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery/courier two well-marked

copies: one copy of the document marked “confidential” including all the information believed to be confidential, and one copy of the document marked “non-confidential” with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE’s policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of proposed rulemaking and announcement of webinar.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

Signing Authority

This document of the Department of Energy was signed on June 30, 2026, by Audrey Robertson, Assistant Secretary (EERE) for Critical Minerals and Energy Innovation, 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 July 2, 2026.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons set forth in the preamble, DOE is proposing to amend part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Appendix A to subpart C of part 430 is revised to read as follows:

Appendix A to Subpart C of Part 430—Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment

1. Objectives
2. Scope
3. Mandatory Application of the Process Rule
4. Setting Priorities for Rulemaking Activity
5. Coverage Determination Rulemakings
6. Process for Developing Energy Conservation Standards
7. Policies on Selection of Standards
8. Test Procedures
9. ASHRAE Equipment
10. Direct Final Rules
11. Negotiated Rulemaking Process
12. Principles for Distinguishing Between Effective and Compliance Dates
13. Principles for the Conduct of the Engineering Analysis
14. Principles for the Analysis of Impacts on Manufacturers
15. Principles for the Analysis of Impacts on Consumers
16. Consideration of Non-Regulatory Approaches
17. Cross-cutting Analytical Assumptions

1. Objectives

This appendix establishes procedures, interpretations, and policies that DOE will follow in the consideration and promulgation of new or revised appliance energy conservation standards and test procedures under the Energy Policy and Conservation Act (EPCA). This appendix applies to both covered consumer products and covered commercial/industrial equipment. The Department’s objectives in establishing these procedures include:

(a) *Provide for early input from stakeholders.* The Department seeks to provide opportunities for public input early in the rulemaking process so that the initiation and direction of rulemakings is informed by comment from interested parties. Under the procedures established by this appendix, DOE will seek early input from interested parties in determining whether establishing new or amending existing energy conservation standards will result in significant savings of energy and is economically justified and technologically feasible. In the context of test procedure rulemakings, DOE will seek early input from interested parties in determining whether—

(1) Establishing a new or amending an existing test procedure will better measure the energy efficiency, energy use, water use (as specified in EPCA), or estimated annual

operating cost of a covered product/ equipment during a representative average use cycle or period of use (for consumer products); and

(2) Will not be unduly burdensome to conduct.

(b) *Increase predictability of the rulemaking timetable.* The Department seeks to make informed, strategic decisions about how to deploy its resources on the range of possible standards and test procedure development activities, and to announce these prioritization decisions so that all interested parties have a common expectation about the timing of different rulemaking activities. Further, when circumstances weigh towards doing so, DOE will offer the opportunity to provide input on the prioritization of rulemakings through a request for comment as DOE begins preparation of its Regulatory Agenda each spring.

(c) *Eliminate problematic design options early in the process.* The Department seeks to eliminate from consideration, early in the process, any design options that present unacceptable problems with respect to manufacturability, consumer utility, or safety, so that the detailed analysis can focus only on viable design options. Under the procedures in this appendix, DOE will eliminate from consideration design options if it concludes that manufacture, installation, or service of the design will be impractical, or that the design option will have a material adverse impact on the utility of the product, or if the design option will have a material adverse impact on safety or health. DOE will also eliminate from consideration proprietary design options that represent a unique pathway to achieving a given efficiency level. This screening will be done at the outset of a rulemaking.

(d) *Fully consider non-regulatory approaches.* The Department seeks to understand the effects of market forces and voluntary programs on encouraging the purchase of energy efficient products so that the incremental impacts of a new or revised standard can be accurately assessed and the Department can make informed decisions about where standards and voluntary programs can be used most effectively. DOE will continue to support voluntary efforts by manufacturers, retailers, utilities, and others to increase product/equipment efficiency.

(e) *Conduct thorough analysis of impacts.* In addition to understanding the aggregate social and private costs and benefits of standards, the Department seeks to understand the distribution of those costs and benefits among consumers, manufacturers, and others, as well as the uncertainty associated with these analyses of costs and benefits, so that any adverse impacts on subgroups and uncertainty concerning any adverse impacts can be fully considered in selecting a standard. Pursuant to this appendix, the analyses will consider the variability of impacts on significant groups of manufacturers and consumers in addition to aggregate social and private costs and benefits, report the range of uncertainty associated with these impacts, and take into account cumulative impacts of regulation on manufacturers. The Department will also

conduct appropriate analyses to assess the impact that new or amended test procedures will have on manufacturers and consumers.

(f) *Use transparent and robust analytical methods.* The Department seeks to use qualitative and quantitative analytical methods that are fully documented for the public and that produce results that can be explained and reproduced, so that the analytical underpinnings for policy decisions on standards are as sound and well-accepted as possible.

(g) *Support efforts to build consensus on standards.* The Department seeks to encourage development of consensus proposals. In certain circumstances proposals may also be developed in accordance with the Negotiated Rulemaking Act (5 U.S.C. 561 *et seq.*) and as outlined in section 11 of this appendix, for new or revised standards because standards with representative, broad-based support are likely to balance effectively the various interests affected by such standards. These proposals may result in a direct final rule in appropriate cases. DOE notes that the procedural requirements of section 6 of this appendix do not apply to direct final rules. The procedural requirements for direct final rules are specified in EPCA. (42 U.S.C. 6295(p)(4)).

(h) *Department policies.* In accordance with EPCA, it is the goal of the Department to preserve the availability in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding, and in doing so to safeguard the American people's freedom to choose from a variety of goods and appliances (including but not limited to lightbulbs, dishwashers, washing machines, gas stoves, water heaters, toilets, and shower heads); to promote market competition and innovation within the manufacturing and appliance industries; to ensure that the global effects of a rule, regulation, or action shall, whenever evaluated, be reported separately from its domestic costs and benefits (energy savings and efficiency), in order to promote sound regulatory decision making and prioritize the interests of the American people; and to guarantee opportunities for public comment and rigorous, peer-reviewed scientific analysis. (42 U.S.C. 6295(o)–(p)). The Department additionally has the goal of eliminating counterproductive requirements that raise the costs of home appliances in a manner consistent with the requirements of EPCA, which includes the consideration of energy savings relative to costs to consumers and manufacturers and impacts to markets for covered products. *Id.*

2. Scope

The procedures, interpretations, and policies described in this appendix apply to rulemakings concerning new or revised Federal energy conservation standards and test procedures, and related rule documents (*i.e.*, coverage determinations) for consumer products in Part A and commercial and industrial equipment under Part A–1 of the Energy Policy and Conservation Act (EPCA), as amended, except covered ASHRAE

equipment in Part A–1 are governed separately under section 9 of this appendix.

3. Mandatory Application of the Process Rule

The rulemaking procedures established in this appendix are binding on DOE for actions that are anticipated to increase the stringency of a standard or increase the scope of products subject to compliance with a standard. With respect to other actions, DOE will satisfy the requirements in EPCA and may choose to apply additional provisions in this appendix as may be appropriate so as to maintain flexibility and to provide relief without undue delay in appropriate cases. Certain actions as indicated may be exempt from the rulemaking procedures established by this appendix and may follow such expedited process as DOE may specify.

4. Setting Priorities for Rulemaking Activity

(a) In establishing its priorities for undertaking energy conservation standards and test procedure rulemakings, DOE will consider the following factors, consistent with applicable legal obligations:

- (1) Potential energy savings;
- (2) Potential social and private costs and benefits;
- (3) Applicable deadlines for rulemakings;
- (4) Incremental DOE resources required to complete the rulemaking process;
- (5) Other relevant regulatory actions affecting the products/equipment;
- (6) Stakeholder recommendations;
- (7) Evidence of energy efficiency gains in the market absent new or revised standards;
- (8) Status of required changes to test procedures;
- (9) Potential to protect consumer choice in covered products and equipment;
- (10) Potential to eliminate counterproductive requirements that increase the costs of appliances; and
- (11) Other relevant factors.

(b) When circumstances weigh towards doing so, DOE will offer the opportunity to provide input on prioritization of rulemakings through a request for comment as DOE begins preparation of its Regulatory Agenda each spring.

5. Coverage Determination Rulemakings

(a) DOE has discretion to conduct proceedings to determine whether additional consumer products and commercial/ industrial equipment should be covered under EPCA if certain statutory criteria are met. (42 U.S.C. 6292 and 42 U.S.C. 6295(l) for consumer products; 42 U.S.C. 6312 for commercial/industrial equipment)

(b) If DOE determines to initiate the coverage determination process, it will first publish a notice of proposed determination, providing an opportunity for public comment of not less than 60 days, in which DOE will explain how such products/equipment that it seeks to designate as “covered” meet the statutory criteria for coverage and why such coverage is “necessary or appropriate” to carry out the purposes of EPCA. In the case of commercial equipment, DOE will follow the same process, except that the Department must demonstrate that coverage of the equipment type is “necessary” to carry out the purposes of EPCA.

(c) DOE will publish its final decision on coverage as a separate notice, an action that will be completed prior to the initiation of any test procedure or energy conservation standards rulemaking (*i.e.*, DOE will not issue any Requests for Information (RFIs), Notices of Data Availability (NODAs), or any other mechanism to gather information for the purpose of initiating a rulemaking to establish a test procedure or energy conservation standard for the proposed covered product/equipment prior to finalization of the coverage determination). If DOE determines that coverage is warranted, DOE will proceed with its typical rulemaking process for both test procedures and standards. Specifically, DOE will finalize coverage for a product/equipment presumptively at least 180 days prior to publication of a proposed rule to establish a test procedure, such as where an increase of stringency is contemplated and to provide notice as contemplated under EPCA. And, DOE will complete the test procedure rulemaking at least 180 days prior to publication of a proposed energy conservation standard.

(d) If, during the substantive rulemaking proceedings to establish test procedures or energy conservation standards after completing a coverage determination, DOE finds it necessary and appropriate to expand or reduce the scope of coverage, a new coverage determination process will be initiated and finalized prior to moving forward with the test procedure or standards rulemaking.

6. Process for Developing Energy Conservation Standards

This section describes the process to be used in developing energy conservation standards for covered products and equipment other than those covered equipment subject to ASHRAE/IES Standard 90.1.

(a) *Early assessment.* (1) As the first step in any proceeding to consider establishing or amending any energy conservation standard, DOE will publish a document in the **Federal Register** announcing that DOE is considering initiating a rulemaking proceeding. As part of that document, DOE will solicit submission of related comments, including data and information on whether DOE should proceed with the rulemaking, including whether any new or amended rule would be cost-effective, economically justified, technologically feasible, or would result in a significant savings of energy. Based on the information received in response to the notice and its own analysis, DOE will determine whether to proceed with a rulemaking for a new or amended energy conservation standard or an amended test procedure.

(i) If DOE determines that a new or amended standard would not satisfy applicable statutory criteria, DOE would engage in notice and comment rulemaking to issue a determination that a new or amended standard is not warranted.

(ii) If DOE receives sufficient information suggesting it could justify a new or amended standard or the information received is inconclusive with regard to the statutory criteria, DOE would undertake the

preliminary stages of a rulemaking to issue or amend an energy conservation standard, as discussed further in paragraph (a)(2) of this section.

(2) If the Department determines it is appropriate to proceed with a rulemaking, the preliminary stages of a rulemaking to issue or amend an energy conservation standard that DOE will undertake will be a Framework Document and Preliminary Analysis, or an Advance Notice of Proposed Rulemaking (ANOPR). Requests for Information (RFI) and Notices of Data Availability (NODA) could be issued, as appropriate, in addition to these preliminary-stage documents.

(3) In those instances where the early assessment either suggested that a new or amended energy conservation standard might be justified or in which the information was inconclusive on this point, and DOE undertakes the preliminary stages of a rulemaking to establish or amend an energy conservation standard, DOE may still ultimately determine that such a standard is not economically justified, technologically feasible or would not result in a significant savings of energy. Therefore, DOE will examine the potential costs and benefits and energy savings potential of a new or amended energy conservation standard at the preliminary stage of the rulemaking. DOE notes that it will, consistent with its statutory obligations, consider both cost-effectiveness and economic justification when issuing a determination not to amend a standard.

(b) *Significant savings of energy.* (1) In evaluating the prospects of proposing a new or amended standard—or in determining that no new or amended standard is needed—DOE will first look to the projected energy savings that are likely to result. DOE will determine as a preliminary matter whether the rulemaking has the potential to result in “significant energy savings.” If the rulemaking passes the significant energy savings threshold, DOE will then compare these projected savings against the technological feasibility of and likely costs necessary to meet the new or amended standards needed to achieve these energy savings.

(2) Under its significant energy savings analysis, DOE will examine both the total amount of projected energy savings and the relative percentage decrease in energy usage that could be obtained from establishing or amending energy conservation standards for a given covered product or equipment. This examination will be based on the applicable product or equipment type as appropriate and will not be used to selectively examine classes or sub-classes of products and equipment solely for the purposes of projecting whether potential energy savings would satisfy (or not satisfy) the applicable thresholds detailed in this rule. Under the first step of this approach, the projected energy savings from a potential maximum technologically feasible (“max-tech”) standard will be evaluated against a threshold of 2.0 quads of FFC energy saved over a 30-year period.

(3) If the projected max-tech energy savings does not meet or exceed this threshold, those max-tech savings would then be compared to

the total energy usage of the covered product or equipment to calculate a potential percentage reduction in energy usage.

(4) If this comparison does not yield a reduction in FFC energy use of at least 10 percent over a 30-year period, the analysis will end, and DOE will propose to determine that no significant energy savings would likely result from setting new or amended standards.

(5) If either one of the thresholds described in paragraphs (b)(2) or (b)(4) of this section is reached, DOE will conduct analyses to ascertain whether a standard can be prescribed that produces the maximum improvement in energy efficiency that is both technologically feasible and economically justified and still constitutes significant energy savings (using the same criteria of either 2.0 quad of aggregate FFC energy savings or a 10-percent decrease in FFC energy use, as measured in quads—both over a 30-year period) at the level determined to be economically justified.

(6) In the case of ASHRAE equipment, DOE will examine the potential energy savings involved across the equipment category at issue.

(c) *Design options*—(1) *General.* Once the Department has initiated a rulemaking for a specific product/equipment but before publishing a proposed rule to establish or amend standards, DOE will identify the product/equipment categories and design options to be analyzed in detail, as well as those design options to be eliminated from further consideration. During the pre-proposal stages of the rulemaking, interested parties may be consulted to provide information on key issues through a variety of rulemaking documents. The preliminary stages of a rulemaking to issue or amend an energy conservation standard that DOE will undertake will be a framework document and preliminary analysis, or an advance notice of proposed rulemaking (ANOPR). Requests for Information (RFI) and Notice of Data Availability (NODA) could also be issued, as appropriate.

(2) *Identification and screening of design options.* During the pre-NOPR phase of the rulemaking process, the Department will develop a list of design options for consideration. Initially, the candidate design options will encompass all those technologies considered to be technologically feasible. Following the development of this initial list of design options, DOE will review each design option based on the factors described in paragraph (c)(3) of this section and the policies stated in section 7 of this appendix (*i.e.*, “Policies on Selection of Standards”). The reasons for eliminating or retaining any design option at this stage of the process will be fully documented and published as part of the NOPR and as appropriate for a given rule, in the pre-NOPR documents. The technologically feasible design options that are not eliminated in this screening will be considered further in the Engineering Analysis described in paragraph (d) of this section.

(3) *Factors for screening of design options.* The factors for screening design options include:

(i) *Technological feasibility.* Technologies incorporated in commercial products or in

working prototypes will be considered technologically feasible.

(ii) *Practicability to manufacture, install and service.* If mass production of a technology under consideration for use in commercially-available products (or equipment) and reliable installation and servicing of the technology could be achieved on the scale necessary to serve the relevant market at the time of the compliance date of the standard, then that technology will be considered practicable to manufacture, install and service.

(iii) *Adverse impacts on product utility or product availability.*

(iv) *Adverse impacts on health or safety.*

(v) *Unique-pathway proprietary technologies.* If a design option utilizes proprietary technology that represents a unique pathway to achieving a given efficiency level, that technology will not be considered further.

(d) *Engineering analysis of design options and selection of candidate standard levels.* After design options are identified and screened, DOE will perform the engineering analysis and the benefit/cost analysis and select the candidate standard levels based on these analyses. The results of the analyses will be published in a Technical Support Document (TSD) to accompany the appropriate rulemaking documents.

(1) *Identification of engineering analytical methods and tools.* DOE will select the specific engineering analysis tools (or multiple tools, if necessary to address uncertainty) to be used in the analysis of the design options identified as a result of the screening analysis.

(2) *Engineering and life-cycle cost analysis of design options.* DOE and its contractor will perform engineering and initial life-cycle cost analyses of the design options.

(3) *Review by stakeholders.* Interested parties will have the opportunity to review the results of the engineering and life-cycle cost analyses. If appropriate, a public workshop will be conducted to review these results. The analyses will be revised as appropriate on the basis of this input.

(4) *New information relating to the factors used for screening design options.* If further information or analysis leads to a determination that a design option, or a combination of design options, has unacceptable impacts, that design option or combination of design options will not be included in a candidate standard level.

(5) *Selection of candidate standard levels.* Based on the results of the engineering and initial life-cycle cost analysis of design options and the policies stated in paragraph (c) of this section, DOE will select the candidate standard levels for further analysis.

(e) *Pre-NOPR stage—(1) Documentation of decisions on candidate standard selection.*

(i) If the early assessment and screening analysis indicates that continued development of a standard is appropriate, the Department will publish either:

(A) A notice accompanying a framework document and, subsequently, a preliminary analysis or;

(B) An ANOPR.

The notice document will be published in the **Federal Register**, with accompanying

documents referenced and posted in the appropriate docket.

(ii) If DOE determines at any point in the pre-NOPR stage that no candidate standard level is likely to produce the maximum improvement in energy efficiency that is both technologically feasible and economically justified or constitute significant energy savings, that conclusion will be announced in the **Federal Register** with an opportunity for public comment provided to stakeholders. In such cases, the Department will proceed with a rulemaking that proposes not to adopt new or amended standards.

(2) *Public comment and hearing.* The length of the public comment period for pre-NOPR rulemaking documents will vary depending upon the circumstances of the particular rulemaking but will not be less than 75 calendar days. For such documents, DOE will determine whether a public hearing is appropriate. (Where DOE does publish a pre-NOPR document for a deregulatory action, it may reduce the comment period from the presumptive 75 days or required 60 days to something less.)

(3) *Revisions based on comments.* Based on consideration of the comments received, any necessary changes to the engineering analysis or the candidate standard levels will be made.

(f) *Analysis of impacts and selection of proposed standard level.* After the pre-NOPR stage, if DOE has determined preliminarily that a candidate standard level is likely to produce the maximum improvement in energy efficiency that is both technologically feasible and economically justified or constitute significant energy savings, further economic analyses of the impacts of the candidate standard levels will be conducted. The Department will propose new or amended standards based on the results of the impact analysis.

(1) *Identification of issues for analysis.* The Department, in consideration of comments received, will identify issues that will be examined in the impacts analysis.

(2) *Identification of analytical methods and tools.* DOE will select the specific economic analysis tools (or multiple tools if necessary to address uncertainty) to be used in the analysis of the candidate standard levels.

(3) *Analysis of impacts.* DOE will conduct the analysis of the impacts of candidate standard levels.

(4) *Factors to be considered in selecting a proposed standard.* The factors to be considered in selection of a proposed standard include:

(i) Impacts on manufacturers. The analysis of private manufacturer impacts will include: estimated impacts on cash flow, production, and inventory; assessment of impacts on manufacturers of specific categories of products/equipment and small manufacturers; assessment of impacts on manufacturers of multiple product-specific Federal regulatory requirements, including efficiency standards for other products and regulations of other agencies; and impacts on manufacturing capacity, plant closures, and loss of capital investment.

(ii) Private impacts on consumers. The analysis of consumer impacts will include: estimated private energy savings impacts on

consumers based on national average energy prices and energy usage; assessments of impacts on subgroups of consumers based on major regional differences in usage or energy prices and significant variations in installation costs or performance; sensitivity analyses using high and low discount rates reflecting both private transactions and social discount rates and high and low energy price forecasts; behavioral changes in response to changes in product utility, changes in covered product price, utility, performance, feature, and product availability, such as changes to purchase rate of products, substitution of other products, increases or decreases in usage, and other impacts of likely concern to all or some consumers, based to the extent practicable on direct input from consumers; economically based estimates of life-cycle costs or savings with sensitivity analysis; consideration of the increased initial and operating costs to consumers and the time required for energy cost savings to pay back these costs; and loss of utility and consumer welfare. Specifically, DOE will consider: the incremental installed cost as a percentage of the baseline total installed cost, the simple payback period as a percentage of the average lifetime, and the percentage of consumers for whom a standard level is expected to result in net cost. DOE will also consider the protection of consumer choice when analyzing the private impacts on consumers.

(iii) Impacts on competition, including industry concentration analysis.

(iv) Impacts on utilities. The analysis of utility impacts will include estimated marginal impacts on electric and gas utility costs and revenues.

(v) National energy, economic, and employment impacts. The analysis of national energy, economic, and employment impacts will include: estimated energy savings by fuel type; estimated net present value of benefits to all consumers; and estimates of the direct and indirect impacts on employment by appliance manufacturers, relevant service industries, energy suppliers, suppliers of complementary and substitution products, and the economy in general.

(vi) Other factors the Secretary considers relevant.

(vii) Impacts of non-regulatory approaches. The analysis of energy savings and consumer impacts will incorporate an assessment of the impacts of market forces and existing voluntary programs in promoting product/equipment efficiency, usage, and related characteristics in the absence of updated efficiency standards.

(viii) New information relating to the factors used for screening design options.

(g) *Notice of proposed rulemaking—(1) Documentation of decisions on proposed standard selection.* The Department will publish a NOPR in the **Federal Register** that proposes standard levels and explains the basis for the selection of those proposed levels and will post on its website a draft TSD documenting the analysis of impacts. The draft TSD will also be posted in the appropriate docket on www.regulations.gov. As required by 42 U.S.C. 6295(p)(1) of EPCA, the NOPR also will describe the maximum improvement in energy efficiency or

maximum reduction in energy use that is technologically feasible and, if the proposed standards would not achieve these levels, the reasons for proposing different standards.

(2) *Public comment and hearing.* There will be not less than 75 days for public comment on the NOPR, with at least one public hearing or workshop. (42 U.S.C. 6295(p)(2) and 42 U.S.C. 6306).

(3) *Revisions to impact analyses and selection of final standard.* Based on the public comments received, DOE will review the proposed standard and impact analyses and make modifications as necessary. If major changes to the analyses are required at this stage, DOE will publish a Supplemental Notice of Proposed Rulemaking (SNOPR), when required. DOE may also publish a NODA or RFI, where appropriate.

(h) *Final rule.* The Department will publish a Final Rule in the **Federal Register** that promulgates standard levels, responds to public comments received on the NOPR, and explains how the selection of those standards meets the statutory requirement that any new or amended energy conservation standard produces the maximum improvement in energy efficiency that is both technologically feasible and economically justified and constitutes significant energy savings, accompanied by a final TSD.

7. Policies on Selection of Standards

(a) *Purpose.* (1) Section 6 of this appendix describes the process that will be used to consider new or revised energy efficiency standards and lists a number of factors and analyses that will be considered at specified points in the process. The Department policies concerning the selection of new or revised standards, and decisions preliminary thereto, are described in this section. These policies are intended to elaborate on the statutory criteria provided in 42 U.S.C. 6295 of EPCA.

(2) The procedures described in this section are intended to assist the Department in making the determinations required by EPCA and do not preclude DOE's consideration of any other information consistent with the relevant statutory criteria. The Department will consider pertinent information in determining whether a new or revised standard is consistent with the statutory criteria.

(b) *Screening design options.* These factors will be considered as follows in determining whether a design option will receive any further consideration:

(1) *Technological feasibility.* Technologies that are not incorporated in commercial products or in commercially-viable, existing prototypes will not be considered further.

(2) *Practicability to manufacture, install and service.* If it is determined that mass production of a technology in commercial products and reliable installation and servicing of the technology could not be achieved on the scale necessary to serve the relevant market at the time of the compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility.* If a technology is determined to have significant adverse impact on the utility of the product/equipment to subgroups of consumers, or

result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the U.S. at the time, it will not be considered further.

(4) *Safety of technologies.* If it is determined that a technology will have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-pathway proprietary technologies.* If a technology has proprietary protection and represents a unique pathway to achieving a given efficiency level, it will not be considered further, due to the potential for monopolistic concerns.

(c) *Identification of candidate standard levels.* Based on the results of the engineering and cost/benefit analyses of design options, DOE will identify the candidate standard levels for further analysis. Candidate standard levels will be selected as follows:

(1) *Costs and savings of design options.* Design options will not be used as the basis for candidate standard levels if the design options result in:

(i) Life-cycle cost increases relative to the base case, using typical fuel costs, usage, and private discount rates;

(ii) More than a 10 percent increase in installed cost relative to the baseline total installed cost;

(iii) More than 20 percent of consumers projected to incur net costs; or

(iv) A simple payback period as a percentage of average lifetime of more than 50 percent.

(2) *Further information on factors used for screening design options.* If further information or analysis leads to a determination that a design option, or a combination of design options, has unacceptable impacts under the policies stated in this appendix, that design option or combination of design options will not be included in a candidate standard level.

(3) *Selection of candidate standard levels.* Candidate standard levels, which will be identified in the pre-NOPR documents and on which impact analyses will be conducted, will be based on the remaining design options.

(i) The range of candidate standard levels will typically include:

(A) The most energy-efficient combination of design options;

(B) The combination of design options with the lowest initial life-cycle cost estimate; and

(C) A combination of design options with an initial payback period of not more than three years.

(ii) Candidate standard levels that incorporate noteworthy technologies or fill in large gaps between efficiency levels of other candidate standard levels also may be selected.

(d) *Pre-NOPR stage.* New information provided in public comments on any pre-NOPR documents will be considered to determine whether any changes to the candidate standard levels are needed before proceeding to the analysis of impacts.

(e) *Selection of proposed standard.* Based on the results of the analysis of impacts, DOE will select a standard level to be proposed for

public comment in the NOPR. As required under 42 U.S.C. 6295(o)(2)(A), any new or revised standard must be designed to achieve the maximum improvement in energy efficiency that is determined to be both technologically feasible and economically justified.

(1) *Statutory policies.* The fundamental policies concerning the selection of standards include:

(i) A trial standard level will not be proposed or promulgated if the Department determines that it is not both technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) and 42 U.S.C. 6295(o)(3)(B)). For a trial standard level to be economically justified, the Secretary must determine that the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the factors listed in 42 U.S.C. 6295(o)(2)(B)(i). In making such a determination, the Secretary shall compare the benefits and burdens of the standard against the benefits and burdens of the baseline case ("no new standards" case) and in incremental progression for all other trial standard levels under consideration. This comparative ("walk up") analysis includes assessing the incremental changes in costs and benefits for each TSL's benefits and burdens relative to other TSLs and as part of a holistic analysis across all TSLs. (42 U.S.C. 6295(o)(2)(B)). The Secretary will also consider, consistent with the statute, other economic measures such as the life-cycle cost analysis, manufacturer impact analysis, and other relevant measures.

(ii) If the Department determines that interested persons have established by a preponderance of the evidence that a standard level is likely to result in the unavailability in the United States of any covered product/equipment type (or class) with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the U.S. at the time of the determination, then that standard level will not be proposed. (42 U.S.C. 6295(o)(4)).

(iii) If the Department determines that a standard level would not result in significant conservation of energy, that standard level will not be proposed. (42 U.S.C. 6295(o)(3)(B)).

(2) *Considerations in assessing economic justification.*

(i) The following considerations will guide the application of the economic justification criterion in selecting a proposed standard:

(A) If the Department determines that a candidate/trial standard level would result in a negative return on investment for the industry, would significantly reduce the value of the industry, or would cause significant adverse impacts to a significant subgroup of manufacturers (including small manufacturing businesses), that standard level will be presumed not to be economically justified unless the Department determines that specifically identified expected benefits of the standard would outweigh this and any other expected adverse effects.

(B) If the Department determines that a candidate/trial standard level would be the

direct cause of plant closures, significant losses in domestic manufacturer employment, or significant losses of capital investment by domestic manufacturers, that standard level will be presumed not to be economically justified unless the Department determines that specifically identified expected benefits of the standard would outweigh this and any other expected adverse effects.

(C) If the Department determines that a candidate/trial standard level would not result in significant energy conservation, that standard level will be presumed not to be economically justified.

(D) If the Department determines that a candidate/trial standard level is not practicable to manufacture or has a negative impact on consumer utility or safety, that standard level will be presumed not to be economically justified unless the Department determines that specifically identified expected benefits of the standard would outweigh this and any other expected adverse effects.

(E) If the Department determines that a candidate/trial standard level is not consistent with the policies relating to consumer costs in paragraph (c)(1) of this section, that standard level will be presumed not to be economically justified unless the Department determines that specifically identified expected benefits of the standard would outweigh this and any other expected adverse effects.

(F) If the Department determines that a candidate/trial standard level will have significant adverse impacts on a significant subgroup of consumers (including low-income consumers), that standard level will be presumed not to be economically justified unless the Department determines that specifically identified expected benefits of the standard would outweigh this and any other expected adverse effects.

(G) If the Department of Energy and the Department of Justice determine that a candidate/trial standard level would have significant anticompetitive effects, that standard level will be presumed not to be economically justified unless the Department of Energy determines that specifically identified expected benefits of the standard would outweigh this and any other expected adverse effects.

(ii) DOE will, consistent with paragraph (f) of this section, account for the views expressed by the Department of Justice regarding a given proposal's effects on competition.

(iii) The basis for a determination that triggers any presumption in paragraph (e)(2)(i) of this section and the basis for a determination that an applicable presumption has been rebutted will be supported by substantial evidence in the record and the evidence and rationale for making these determinations will be explained in the NOPR.

(iv) If none of the policies in paragraph (e)(2)(i) of this section is found to be dispositive, the Department will determine whether the benefits of a candidate standard level exceed the burdens considering all the pertinent information in the record.

(f) *Selection of a final standard.* New information provided in the public

comments on the NOPR and any analysis by the Department of Justice concerning impacts on competition of the proposed standard will be considered to determine whether issuance of a new or amended energy conservation standard produces the maximum improvement in energy efficiency that is both technologically feasible and economically justified and still constitutes significant energy savings or whether any change to the proposed standard level is needed before proceeding to the final rule. The same policies used to select the proposed standard level, as described in this section, will be used to guide the selection of the final standard level or a determination that no new or amended standard is justified.

8. Test Procedures

(a) *General.* As with the early assessment process for energy conservation standards, DOE believes that early stakeholder input is also very important during test procedure rulemakings. DOE will follow an early assessment process similar to that described in the preceding sections discussing DOE's consideration of amended energy conservation standards. (An early assessment stage may not be warranted for deregulatory actions.) Consequently, DOE will publish a notice in the **Federal Register** whenever DOE is considering initiation of a rulemaking to amend a test procedure. In that notice, DOE will request submission of comments, including data and information on whether an amended test procedure rule would:

(1) More accurately measure energy efficiency, energy use, water use (as specified in EPCA), or estimated annual operating cost of a covered product during a representative average use cycle or period of use without being unduly burdensome to conduct; or

(2) Reduce testing burden. DOE will review comments submitted and, subject to statutory obligations, determine whether it agrees with the submitted information. If DOE determines that an amended test procedure is not justified at that time, it will not pursue the rulemaking and will publish a notice in the **Federal Register** to that effect. If DOE receives sufficient information suggesting an amended test procedure could more accurately measure energy efficiency, energy use, water use (as specified in EPCA), or estimated annual operating cost of a covered product during a representative average use cycle or period of use and not be unduly burdensome to conduct, reduce testing burden, or the information received is inconclusive with regard to these points, DOE would undertake the preliminary stages of a rulemaking to amend the test procedure, as discussed further in the paragraphs that follow in this section.

(b) *Identifying the need to modify test procedures.* DOE will identify any necessary modifications to established test procedures prior to initiating the standards development process. It will consider all stakeholder comments with respect to needed test procedure modifications. If DOE determines that it is appropriate to continue the test procedure rulemaking after the early assessment process, it would provide further opportunities for early public input through **Federal Register** documents, including NODAs and/or RFIs.

(c) *Adoption of industry test methods.* DOE will adopt industry test standards as DOE test procedures for covered products and equipment, unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA) or estimated operating costs of that equipment during a representative average use cycle.

(d) *Issuing final test procedure modification.* Test procedure rulemakings establishing methodologies used to evaluate proposed energy conservation standards will be finalized at least 180 days prior to publication of a NOPR proposing new or amended energy conservation standards, with the following exceptions:

(1) Test procedure amendments limited to calculation changes (e.g., use factor or adder); or

(2) Test procedures developed in accordance with the Negotiated Rulemaking Act or by interested persons that are fairly representative of relevant points of view (including representatives of manufacturers of covered products, States, and efficiency advocates), as determined by the Secretary. Parties submitting a consensus recommendation may specify a time period between finalization of the test procedure and publication of a NOPR proposing new or amended energy conservation standards or a notice of proposed determination that standards do not need to be amended.

(e) *Compliance date of test procedures.* If required only for the evaluation and issuance of updated efficiency standards, use of the modified test procedures typically will not be required until the implementation date of updated standards.

9. ASHRAE Equipment

(a) EPCA provides that ASHRAE equipment is subject to unique statutory requirements and their own set of timelines. More specifically, pursuant to EPCA's statutory scheme for covered ASHRAE equipment, DOE is required to consider amending the existing Federal energy conservation standards and test procedures for certain enumerated types of commercial and industrial equipment (generally, commercial water heaters, commercial packaged boilers, commercial air-conditioning and heating equipment, and packaged terminal air conditioners and heat pumps) when ASHRAE Standard 90.1 is amended with respect to standards and test procedures applicable to such equipment. Not later than 180 days after the amendment of the Standard, the Secretary will publish in the **Federal Register** for public comment an analysis of the energy savings potential of amended energy efficiency standards. For each type of equipment, EPCA directs that if ASHRAE Standard 90.1 is amended, not later than 18 months after the date of publication of the amendment to ASHRAE Standard 90.1, DOE must adopt amended energy conservation standards at the new efficiency level in ASHRAE Standard 90.1 as the uniform national standard for such equipment, or amend the test procedure referenced in ASHRAE Standard 90.1 for the equipment at issue to be consistent with the

applicable industry test procedure, respectively, unless DOE determines by rule, and supported by clear and convincing evidence, that—

(1) A more-stringent standard would result in significant additional conservation of energy and is technologically feasible and economically justified; or (2) The test procedure would not meet the requirements for such test procedures specified in EPCA. In such standards case, DOE must adopt the more stringent standard not later than 30 months after the date of publication of the amendment to ASHRAE/IES Standard 90.1 for the affected equipment.

(b) For ASHRAE equipment, DOE will adopt the revised ASHRAE levels or the industry test procedure, as contemplated by EPCA, except in very limited circumstances.

With respect to DOE's consideration of standards more stringent than the ASHRAE levels or changes to the industry test procedure, DOE will do so only if it can meet a very high bar to demonstrate the "clear and convincing evidence" threshold. Clear and convincing evidence would exist only where the specific facts and data made available to DOE regarding a particular ASHRAE amendment demonstrates that there is no substantial doubt that a standard more stringent than that contained in the ASHRAE Standard 90.1 amendment is permitted because it would result in a significant additional amount of energy savings, is technologically feasible and economically justified, or, in the case of test procedures, that the industry test procedure does not meet the EPCA requirements. DOE will make this determination only after seeking data and information from interested parties and the public to help inform the Agency's views. DOE will seek from interested stakeholders and the public data and information to assist in making this determination, prior to publishing a proposed rule to adopt more-stringent standards or a different test procedure.

(c) DOE's review in adopting amendments based on an action by ASHRAE to amend Standard 90.1 is strictly limited to the specific standards or test procedure amendment for the specific equipment for which ASHRAE has made a change (*i.e.*, determined down to the equipment class level). DOE believes that ASHRAE not acting to amend Standard 90.1 is tantamount to a decision that the existing standard remains in place. Thus, when undertaking a review as required by 42 U.S.C. 6313(a)(6)(C), DOE would need to find clear and convincing evidence, as defined in this section, to issue a standard more stringent than the existing standard for the equipment at issue.

(d) For ASHRAE equipment, when determining whether a more stringent standard for the equipment category at issue would result in significant additional conservation of energy pursuant to 42 U.S.C. 6313(a)(6)(A)–(C), DOE will follow the process and thresholds described in section 6(b) of this appendix, "Significant Savings of Energy."

10. Direct Final Rules

(a) A direct final rule (DFR), as contemplated in 42 U.S.C. 6295(p)(4), is a

procedural mechanism separate from the negotiated rulemaking process outlined under the Negotiated Rulemaking Act (5 U.S.C. 563). DOE may issue a DFR adopting energy conservation standards for a covered product provided that:

(1) DOE receives a joint proposal from a group of "interested persons that are fairly representative of relevant points of view," including a consensus recommendation developed in accordance with the Negotiated Rulemaking Act (5 U.S.C. 561 *et seq.*). At a minimum, to be "fairly representative of relevant points of view" the group submitting a joint statement must include larger concerns and small businesses in the regulated industry/manufacturing community, energy advocates, energy utilities, as appropriate, consumers, and States. However, it will be necessary to evaluate the meaning of "fairly representative" on a case-by-case basis, subject to the circumstances of a particular rulemaking, to determine whether additional parties must be part of a joint statement in order to be "fairly representative of relevant points of view."

(2) This paragraph (a)(2) describes the steps DOE will follow with respect to a DFR.

(i) DOE must determine whether the energy conservation standard recommended in the joint proposal is in accordance with the requirements of 42 U.S.C. 6295(o) or 42 U.S.C. 6313(a)(6)(B) as applicable. Because the DFR provision is procedural, and not a separate grant of rulemaking authority, any standard issued under the DFR process must comply fully with the provisions of the EPCA subsection under which the rule is authorized. DOE will not accept or issue as a DFR a submitted joint proposal that does not comply with all applicable EPCA requirements.

(ii) Upon receipt of a joint statement recommending energy conservation standards, DOE will publish in the **Federal Register** that statement, as submitted to DOE, in order to obtain feedback as to whether the joint statement was submitted by a group that is fairly representative of relevant points of view. If DOE determines that the DFR was not submitted by a group that is fairly representative of relevant points of view, DOE will not move forward with a DFR and will consider whether any further rulemaking activity is appropriate. If the Secretary determines that a DFR cannot be issued based on the statement, the Secretary shall publish a notice of the determination, together with an explanation of the reasons for the determination.

(iii) Simultaneous with the issuance of a DFR, DOE must also publish a NOPR containing the same energy conservation standards as in the DFR. When publishing the DFR, DOE must solicit public comment for a period of at least 110 days; then, not later than 120 days after issuance of the DFR, the Secretary must determine whether any adverse comments "may provide a reasonable basis for withdrawing the direct final rule," based on the rulemaking record. If DOE determines that one or more substantive comments objecting to the DFR provides a sufficient reason to withdraw the DFR, DOE will do so and will instead proceed with the published NOPR (unless

the information provided suggests that withdrawal of that NOPR would likewise be appropriate). In making this determination, DOE may consider comments as adverse, even if the issue was brought up previously during DOE-initiated discussions (*e.g.*, publication of a framework or RFI document), if the Department concludes that the comments merit further consideration.

11. Negotiated Rulemaking Process

(a)(1) In those instances where negotiated rulemaking is determined to be appropriate, DOE will comply with the requirements of the Negotiated Rulemaking Act (NRA) (5 U.S.C. 561–570) and the requirements of the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). To facilitate potential negotiated rulemakings, and to comply with the requirements of the NRA and the FACA, DOE established the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC). Working groups can be established as subcommittees of ASRAC, from time to time, and for specific products/equipment, with one member representative from the ASRAC committee attending and participating in the meetings of a specific working group. (Consistent with 5 U.S.C. 565(b), committee membership is limited to 25 members, unless the agency determines that more members are necessary for the functioning of the committee or to achieve balanced membership.) Ultimately, the working group reports to ASRAC, and ASRAC itself votes on whether to make a recommendation to DOE to adopt a consensus agreement developed through the negotiated rulemaking.

(2) DOE will use the negotiated rulemaking process on a case-by-case basis and, in appropriate circumstances, in an attempt to develop a consensus proposal before issuing a proposed rule. When approached by one or more stakeholders or on its own initiative, DOE will use a convener to ascertain, in consultation with relevant stakeholders, whether the development of the subject matter of a potential rulemaking proceeding would be conducive to negotiated rulemaking, with the agency evaluating the convener's recommendation before reaching a decision on such matter. A neutral, independent convener will identify issues that any negotiation would need to address, assess the full breadth of interested parties who should be included in any negotiated rulemaking to address those issues, and make a judgment as to whether there is the potential for a group of individuals negotiating in good faith to reach a consensus agreement given the issues presented. DOE will have a neutral and independent facilitator, who is not a DOE employee or consultant, present at all ASRAC working group meetings.

(3) DOE will base its decision to proceed with a potential negotiated rulemaking on the report of the convener. The following additional factors militate in favor of a negotiated rulemaking:

(i) Stakeholders commented in favor of negotiated rulemaking in response to the initial rulemaking notice;

(ii) The rulemaking analysis or underlying technologies in question are complex, and

DOE can benefit from external expertise and/or real-time changes to the analysis based on stakeholder feedback, information, and data;

- (iii) The current standards have already been amended one or more times;
- (iv) Stakeholders from differing points of view are willing to participate; and
- (v) DOE determines that the parties may be able to reach an agreement.

(4) DOE will provide notice in the **Federal Register** of its intent to form an ASRAC working group (including a request for nominations to serve on the committee), announcement of the selection of working group members (including their affiliation), and announcement of public meetings and the subject matter to be addressed.

(b) DOE's role in the negotiated rulemaking process is to participate as a member of a group attempting to develop a consensus proposal for energy conservation standards for a particular product/equipment and to provide technical/analytical advice to the negotiating parties and legal input where needed to support the development of a potential consensus recommendation in the form of a term sheet.

(c) A negotiated rulemaking may be used to develop energy conservation standards, test procedures, product coverage, and other categories of rulemaking activities.

(d) A dedicated portion of each ASRAC working group meeting will be set aside to receive input and data from non-members of the ASRAC working group. This additional opportunity for input does nothing to diminish stakeholders' ability to provide comments and ask relevant questions during the course of the working group's ongoing deliberations at the public meeting.

(e) If DOE determines to proceed with a rulemaking at the conclusion of negotiations, DOE will publish a proposed rule or a Direct Final Rule. DOE will consider the approved term sheet in developing such proposed rule or Direct Final Rule. Further, any potential term sheet upon which an ASRAC working group reaches consensus must comply with all of the provisions of EPCA under which the rule is authorized. DOE cannot accept recommendations or issue a NOPR based upon a negotiated rulemaking that does not comply with all applicable EPCA requirements, including those product- or equipment-specific requirements included in the provision that authorizes issuance of the standard.

12. Principles for Distinguishing Between Prescribed, Effective, and Compliance Dates

(a) *Dates, generally.* The prescribed, effective, and compliance dates for either DOE test procedures or DOE energy conservation standards are typically not identical, and these terms should not be used interchangeably.

(b) *Prescribed date.* The prescribed date is the date a rule, including a direct final rule, is published in the **Federal Register**.

(c) *Effective date.* The effective date is the date a rule is legally operative after being published in the **Federal Register**.

(d) *Compliance date.* (1) For test procedures, the compliance date is the specific date when manufacturers are required to use the new or amended test

procedure requirements to make representations concerning the energy efficiency or use of a product, including certification that the covered product/equipment meets an applicable energy conservation standard.

(2) For energy conservation standards, the compliance date is the specific date upon which manufacturers are required to meet the new or amended standards for applicable covered products/equipment that are distributed in interstate commerce.

13. Principles for the Conduct of the Engineering Analysis

(a) The purpose of the engineering analysis is to develop the relationship between efficiency and cost of the subject product/equipment. The Department will use the most appropriate means available to determine the efficiency/cost relationship, including an overall system approach or engineering modeling to predict the reduction in energy use or improvement in energy efficiency that can be expected from individual design options as discussed in paragraphs (b) and (c) of this section. From this efficiency/cost relationship, measures such as payback, life-cycle cost, and energy savings can be developed and further expanded to consider economic concepts and impacts. The Department will identify issues that will be examined in the engineering analysis and the types of specialized expertise that may be required. DOE will select appropriate contractors, subcontractors, and expert consultants, as necessary, to perform the engineering analysis and the impact analysis. Also, the Department will consider data, information, and analyses received from interested parties for use in the analysis wherever feasible.

(b) The engineering analysis begins with the list of design options developed in consultation with the interested parties as a result of the screening process. The Department will establish the likely cost and performance improvement of each design option. Ranges and uncertainties of cost and performance will be established, although efforts will be made to minimize uncertainties by using measures such as test data or component or material supplier information where available. Estimated uncertainties will be carried forward in subsequent analyses. The use of quantitative models will be supplemented by qualitative assessments as appropriate.

(c) The next step includes identifying, modifying, or developing any engineering models necessary to predict the efficiency impact of any one or combination of design options on the product/equipment. A base case configuration or starting point will be established, as well as the order and combination/blending of the design options to be evaluated. DOE will then perform the engineering analysis and develop the cost-efficiency curve for the product/equipment. The cost-efficiency curve and any necessary models will be available to stakeholders during the pre-NOPR stage of the rulemaking.

14. Principles for the Analysis of Impacts on Manufacturers

(a) *Purpose.* The purpose of the manufacturer analysis is to identify the likely

private impacts of efficiency standards on manufacturers. The Department will analyze the impact of standards on manufacturers with substantial input from manufacturers and other interested parties. This section describes the principles that will be used in conducting future manufacturing impact analyses.

(b) *Issue identification.* In the impact analysis stage (section 6(f) of this appendix), the Department will identify issues that will require greater consideration in the detailed manufacturer impact analysis. Possible issues may include identification of specific types or groups of manufacturers and concerns over access to technology. Specialized contractor expertise, empirical data requirements, and analytical tools required to perform the manufacturer impact analysis also would be identified at this stage.

(c) *Industry characterization.* Prior to initiating detailed impact studies, the Department will seek input on the present and past industry structure and market characteristics. Input on the following issues will be sought:

- (1) Manufacturers and their current and historical relative market shares;
 - (2) Manufacturer characteristics, such as whether manufacturers make a full line of models or serve a niche market;
 - (3) Trends in the number of manufacturers;
 - (4) Financial situation of manufacturers;
 - (5) Trends in product/equipment characteristics and retail markets including manufacturer market shares and market concentration; and
 - (6) Identification of other relevant regulatory actions and a description of the nature and timing of any likely impacts.
- (d) *Cost impacts on manufacturers.* The costs of labor, material, engineering, tooling, and capital are difficult to estimate, manufacturer-specific, and usually proprietary. The Department will seek input from interested parties on the treatment of cost issues. Manufacturers will be encouraged to offer suggestions as to possible sources of data and appropriate data collection methodologies. Costing issues to be addressed include:

- (1) Estimates of total private cost impacts, including product/equipment-specific costs (based on cost impacts estimated for the engineering analysis) and front-end investment/conversion costs for the full range of product/equipment models.
- (2) Range of uncertainties in estimates of average cost, considering alternative designs and technologies which may vary cost impacts and changes in costs of material, labor, and other inputs which may vary costs.
- (3) Variable cost impacts on particular types of manufacturers, considering factors such as atypical sunk costs or characteristics of specific models which may increase or decrease costs.

(e) *Impacts on product/equipment sales, features, prices, and cost recovery.* In order to make manufacturer cash-flow calculations, it is necessary to predict the number of products/equipment sold and their sale price. This requires an assessment of the likely impacts of price changes on the number of products/equipment sold and on typical features of models sold. Past analyses have

relied on price and shipment data generated by economic models. The Department will develop additional estimates of prices and shipments by drawing on multiple sources of data and experience including: actual shipment and pricing experience; data from manufacturers, retailers, and other market experts; financial models, and sensitivity analyses. The possible impacts of candidate/trial standard levels on consumer choices among competing fuels will be explicitly considered where relevant.

(f) *Measures of impact.* The manufacturer impact analysis will estimate the impacts of candidate/trial standard levels on the net cash flow of manufacturers and model anticipated manufacturer behavior in response to such standards, such as modeling considerations of cost in compliance choices. Computations will be performed for the industry as a whole and for typical and atypical manufacturers. The exact nature and the process by which the analysis will be conducted will be determined by DOE, with input from interested parties, as appropriate. Impacts to be analyzed include:

(1) Industry net present value, with sensitivity analyses based on uncertainty of costs, sales prices, and sales volumes;

(2) Cash flows, by year; and

(3) Other measures of impact, such as revenue, net income, and return on equity, as appropriate. DOE also notes that the characteristics of a typical manufacturers worthy of special consideration will be determined in consultation with manufacturers and other interested parties and may include: manufacturers incurring higher or lower than average costs; and manufacturers experiencing greater or fewer adverse impacts on sales. Alternative scenarios based on other methods of estimating cost or sales impacts also will be performed, as needed.

(g) *Cumulative impacts of other federal regulatory actions.* (1) The Department will recognize and seek to mitigate the overlapping effects on manufacturers of new or revised DOE standards and other regulatory actions affecting the same products or equipment. DOE will analyze and consider the impact on manufacturers of multiple product/equipment-specific regulatory actions. These factors will be considered in setting rulemaking priorities, conducting the early assessment as to whether DOE should proceed with a standards rulemaking, assessing manufacturer impacts of a particular standard, and establishing compliance dates for a new or revised standard that, consistent with any statutory requirements, are appropriately coordinated with other regulatory actions to mitigate any cumulative burden.

(2) If the Department determines that a proposed standard would impose a significant impact on product or equipment manufacturers within approximately three years of the compliance date of another DOE standard that imposes significant impacts on the same manufacturers (or divisions thereof, as appropriate), the Department will, in addition to evaluating the impact on manufacturers of the proposed standard, assess the joint impacts of both standards on manufacturers.

(3) If the Department is directed to establish or revise standards for products/equipment that are components of other products/equipment subject to standards, the Department will consider the interaction between such standards in setting rulemaking priorities and assessing manufacturer impacts of a particular standard. The Department will assess, as part of the engineering and impact analyses, the cost of components subject to efficiency standards.

(h) *Summary of quantitative and qualitative assessments.* The summary of quantitative and qualitative assessments will contain a description and discussion of uncertainties. Alternative estimates of impacts, resulting from the different potential scenarios developed throughout the analysis, will be explicitly presented in the final analysis results.

(1) *Key modeling and analytical tools.* In its assessment of the likely impacts of standards on manufacturers, the Department will use models that are clear and understandable, feature accessible calculations, and have clearly explained assumptions. The Department will also support the development of economic models for price and volume forecasting. Research required to update key economic data will be considered.

(2) [Reserved]

15. Principles for the Analysis of Impacts on Consumers

(a) *Early consideration of impacts on consumer utility.* The Department will consider at the earliest stages of the development of a standard whether particular design options will lessen the utility of the covered products/equipment to the consumer. In analyzing the impacts of candidate/proposed trial standard levels, the Department will model consumer behavior and welfare impacts arising out of these trial standard levels. See also paragraph (c) of section 6 of this appendix.

(b) *Impacts on product/equipment availability.* The Department will determine, based on consideration of information submitted during the standard development process, whether a proposed standard is likely to result in the unavailability of any covered product/equipment type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products/equipment generally available in the U.S. at the time. DOE will not promulgate a standard if it concludes that it would result in such unavailability. In conjunction with the modeling of manufacturer and consumer behavior as a result of proposed standard levels, the Department will endeavor to estimate losses to society as a result of foregone production or unavailability.

(c) *Department of Justice review.* As required by law, the Department will solicit the views of the Department of Justice on any lessening of competition likely to result from the imposition of a proposed standard and will give the views provided full consideration in assessing economic justification of a proposed standard. In addition, DOE may consult with the

Department of Justice at earlier stages in the standards development process to seek its preliminary views on competitive impacts.

(d) *Variation in consumer impacts.* The Department will use regional analysis and sensitivity analysis tools, as appropriate, to evaluate the potential distribution of impacts of candidate/trial standard levels among different subgroups of consumers. The Department will consider impacts on significant segments of consumers in determining standards levels. Where there are significant negative impacts on identifiable subgroups, DOE will consider the efficacy of voluntary approaches as a means to achieve potential energy savings.

(e) *Payback period and first cost.* (1) In the assessment of consumer impacts of standards, the Department will consider life-cycle cost, payback period, and cost of conserved energy among other variables to evaluate the savings in operating expenses relative to increases in purchase price. The Department also performs sensitivity and scenario analyses when appropriate. The results of these analyses will be carried throughout the analysis and the ensuing uncertainty described.

(2) If, in the analysis of consumer impacts, the Department determines that a candidate/trial standard level would result in a substantial increase in product/equipment first costs to consumers or would not pay back such additional first costs through energy cost savings in less than three years, the Department will assess the likely impacts of such a standard on low-income households, product/equipment sales and fuel switching, as appropriate.

16. Consideration of Non-Regulatory Approaches

The Department recognizes that non-regulatory efforts by manufacturers, utilities, and other interested parties can result in substantial efficiency improvements. The Department intends to consider the likely effects of non-regulatory initiatives on product/equipment energy use, consumer utility and life-cycle costs, manufacturers, competition, and utilities, as well as the distribution of these impacts among different regions, consumers, manufacturers, and utilities. DOE will attempt to base its assessment on the actual impacts of such initiatives to date, but also will consider information presented regarding the impacts that any existing initiative might have in the future. Such information is likely to include a demonstration of the strong commitment of manufacturers, distribution channels, utilities, or others to such non-regulatory efficiency improvements. This information will be used in assessing the likely incremental impacts of establishing or revising standards, in assessing—where possible—appropriate compliance dates for new or revised standards, and in considering DOE support of non-regulatory initiatives.

17. Cross-Cutting Analytical Assumptions

In selecting values for certain cross-cutting analytical assumptions, DOE expects to continue relying upon the following sources and general principles:

(a) *Underlying economic assumptions.* The appliance standards analyses will generally

use the same economic growth and development assumptions that underlie the most current Annual Energy Outlook (AEO) published by the Energy Information Administration (EIA).

(b) *Analytic time length.* The appliance standards analyses will use two time lengths—30 years and another time length that is specific to the standard being considered such as the useful lifetime of the product under consideration. As a sensitivity case, the analyses will also use a 9-year regulatory timeline in analyzing the effects of the standard.

(c) *Energy price and demand trends.* Analyses of the likely impact of appliance standards on typical users will generally adopt the mid-range energy price and demand scenario of the EIA's most current AEO. The sensitivity of such estimated impacts to possible variations in future energy prices are likely to be examined using the EIA's high and low energy price scenarios.

(d) *Product/equipment-specific energy-efficiency trends, without updated standards.* DOE will model product/equipment-specific energy-efficiency trends under no standard scenarios.

(e) *Price forecasting.* DOE will endeavor to use robust price forecasting techniques in projecting future prices of products.

(f) *Private discount rates.* For residential and commercial consumers, ranges of three different real discount rates will be used. For residential consumers, the mid-range discount rate will represent DOE's approximation of the average financing cost (or opportunity costs of reduced savings) experienced by typical consumers. Sensitivity analyses will be performed using discount rates reflecting the costs more likely to be experienced by residential consumers with little or no savings and credit card financing and consumers with substantial savings. For commercial users, a mid-range discount rate reflecting DOE's approximation of the average real rate of return on commercial investment will be used, with

sensitivity analyses being performed using values indicative of the range of real rates of return likely to be experienced by typical commercial businesses. For national net present value calculations, DOE would use the Administration's approximation of the average real rate of return on private investment in the U.S. economy. For manufacturer impacts, DOE typically uses a range of real discount rates which are representative of the real rates of return experienced by typical U.S. manufacturers affected by the program.

(g) *Social discount rates.* Social discount rates as specified in OMB Circular A-4 will be used in assessing social effects such as costs and benefits.

(h) *Direct and indirect impacts.* DOE will endeavor to model and estimate both direct and indirect costs and impacts resulting from candidate and proposed trial standard levels.

[FR Doc. 2026-13674 Filed 7-6-26; 8:45 am]

BILLING CODE 6450-01-P



FEDERAL REGISTER

Vol. 91

Tuesday,

No. 128

July 7, 2026

Part IV

Nuclear Regulatory Commission

10 CFR Parts 2, 30, et al.

Implementation of the National Environmental Policy Act; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 30, 40, 50, 51, 52, 53, 54, 61, 70, 72, 76, and 110

[NRC–2025–0478]

RIN 3150–AL38

Implementation of the National Environmental Policy Act

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to revise the NRC's regulations to streamline and modernize its implementation of the National Environmental Policy Act of 1969, as amended (NEPA). These proposed revisions address Presidential directives in Executive Order (E.O.) 14300, "Ordering the Reform of the Nuclear Regulatory Commission," E.O. 14154, "Unleashing American Energy," Executive Order 14192, "Unleashing Prosperity Through Deregulation," Executive Order 14270, "Zero-Based Regulatory Budgeting to Unleash American Energy;" recent amendments to NEPA; and relevant NEPA case law. In addition, these proposed revisions aim to reduce regulatory burden while complying with NEPA requirements. The proposed rule would narrow the scope of NEPA reviews to effects (or impacts) within the NRC's substantive statutory authority; revise definitions; update procedures for determining the level of NEPA review; establish new categorical exclusions; provide new flexibility for licensees, applicants, and petitioners for rulemaking to submit environmental information; and remove outdated requirements and consolidate content provisions to improve clarity and efficiency. Consistent with section 102(2)(B) of NEPA and E.O. 14300, the NRC consulted with the Council on Environmental Quality (CEQ) during the development of this proposed rule. The NRC is issuing new draft guidance NUREG–2270, "Environmental Review Guidance for U.S. Nuclear Regulatory Commission Actions," for the implementation of the proposed requirements in this rulemaking. The NRC staff will carry out its NEPA responsibilities consistent with the proposed requirements in this rulemaking and the guidance in NUREG–2270.

DATES: Comments must be submitted electronically using <https://www.regulations.gov> by 11:59 p.m. eastern time on August 21, 2026.

Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration of only comments received before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2025–0478, at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

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.

Follow the search instructions on <https://www.regulations.gov> to view public comments.

You can read a plain language description of this proposed rule at <https://www.regulations.gov/docket/NRC-2025-0478>. For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Rome, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–0492, email: michelle.rome@nrc.gov and Andrew Carrera, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–1078, email: andrew.carrera@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents:

- I. Obtaining Information and Submitting Comments
 - A. Obtaining Information
 - B. Submitting Comments
- II. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission
- III. Background
- IV. Discussion
- V. Specific Request for Comment
- VI. Regulatory Flexibility Certification
- VII. Regulatory Analysis
- VIII. Backfitting and Issue Finality
- IX. Plain Writing
- X. National Environmental Policy Act
- XI. Paperwork Reduction Act
- XII. Executive Orders
- XIII. Availability of Guidance
- XIV. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–0478 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC–2025–0478.
- **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 "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, Monday through Friday, except Federal holidays.

- **Public Meeting:** The NRC may conduct a public meeting to describe the proposed amendments and answer questions from the public on the proposed rule. If the NRC determines it will hold a public meeting, NRC will publish a notice of the location, time, and agenda of the meeting on the NRC's public meeting website within 10 calendar days of the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: <https://www.nrc.gov/public-involve/public-meetings/index.cfm>.

B. Submitting Comments

Comments must be submitted using <https://www.regulations.gov> by 11:59 p.m. eastern time on August 21, 2026. Please include Docket ID NRC–2025–0478 in your comment submission.

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

comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

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

II. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission

On May 23, 2025, President Donald J. Trump signed E.O. 14300, “Ordering the Reform of the Nuclear Regulatory Commission.” Section 5, “Reforming and Modernizing the NRC’s Regulations,” requires the NRC to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking significantly streamlines NEPA review requirements, reduces unnecessary regulatory burden, and expands licensing efficiencies and flexibilities in accordance with section 5(c), which requires the NRC to “[r]evis[e], in consultation with the Council on Environmental Quality, NRC regulations governing NRC’s compliance with NEPA to reflect the Congress’s 2023 amendments to that statute and the policies articulated in sections 2 and 5 of Executive Order 14154 of January 20, 2025 (Unleashing American Energy).”

III. Background

NEPA sets forth a national policy for promoting environmental stewardship and ensuring that humans and nature can coexist in productive harmony. It requires Federal agencies to prepare detailed statements for major Federal actions significantly affecting the quality of the human environment, aiming to inform both agency decision-making and the public. NEPA emphasizes process over outcomes, focusing on informed decisions rather than mandating specific results. The proposed revisions to the NRC’s regulations in title 10 of the *Code of Federal Regulations* (10 CFR) part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” implement NEPA in a manner which is consistent with the NRC’s domestic licensing and related regulatory authority under the

Atomic Energy Act of 1954, as amended (AEA), the Energy Reorganization Act of 1974, as amended, and the Uranium Mill Tailings Radiation Control Act of 1978.

These proposed updates to streamline NEPA reviews would reduce regulatory burden and retain and expand licensing efficiencies within 10 CFR part 51 as required by Presidential directives in E.O.s, in consideration of amendments made to NEPA by the Fiscal Responsibility Act of 2023 (FRA) and the One Big Beautiful Bill Act, Public Law 119–21, 139 Stat. 72 (2025) (OBBBA), and the U.S. Supreme Court’s recent decision in *Seven County Infrastructure Coalition v. Eagle County, Colorado*, 605 U.S. 168 (2025), which has clarified the law governing NEPA analysis in multiple significant respects. In addition, the proposed revisions address Commission direction in Staff Requirements Memorandum (SRM)-SECY-24–0046, “Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments,” and SRM-SECY-25–0007, “Withdrawing the Environmental Justice Policy Statement and Environmental Justice Strategy.” These directives are discussed below.

1. Executive Orders

E.O. 14300 section 5(c) directs the NRC to revise its regulations consistent with “the policies articulated in sections 2 and 5 of Executive Order 14154.” E.O. 14154 rescinded E.O. 11991, “Relating to Protection and Enhancement of Environmental Quality,” issued by President Carter and previously cited by CEQ as the basis for its authority to engage in rulemaking under NEPA. Shortly thereafter, the CEQ rescinded its NEPA implementing regulations (40 CFR parts 1500–1508), effective April 11, 2025, “Removal of National Environmental Policy Act Implementing Regulations.” The CEQ subsequently issued guidance on September 29, 2025, with its “Memorandum for Heads of Federal Departments and Agencies: Implementation of the National Environmental Policy Act,” and its associated “Agency NEPA Procedures Template” (“CEQ Guidance”).

E.O. 14154 instructs agencies, consistent with applicable law, to “prioritize efficiency and certainty over any other objectives . . . that do not align with the policy goals set forth in section 2 of this order or that could otherwise add delays and ambiguity to the permitting process.” The NRC is revising its NEPA implementing regulations in 10 CFR part 51 to be consistent with these E.O.s and to

enhance the efficiency, clarity, and predictability of its environmental review process. The NRC developed this proposed rule consistent with the CEQ Guidance.

2. Fiscal Responsibility Act of 2023, National Environmental Policy Act Amendments

Congress passed the FRA, Public Law 118–5, signed into law on June 3, 2023, to add substantial details to streamline NEPA and codify procedural requirements, with modifications, including procedures that the NRC had previously addressed in its own regulations in 10 CFR part 51. The NEPA amendments became immediately applicable to the NRC (and other agencies subject to NEPA) upon FRA’s enactment.

On May 30, 2024, the NRC staff provided SECY-24–0046, “Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments,” to the Commission for consideration. In SECY-24–0046, the NRC staff included recommendations to streamline the NRC’s regulations in 10 CFR part 51 to enhance the efficiency and effectiveness of the NRC’s environmental reviews in light of the FRA. On July 28, 2025, the Commission issued SRM-SECY-24–0046, in which it approved the NRC staff’s recommendations. In the SRM to SECY-24–0046, among other things, the Commission directed the NRC staff to conduct rulemaking for 10 CFR part 51 to make NRC’s environmental reviews more efficient. The Commission directed the staff to examine narrowing the scope of the NRC’s NEPA reviews to only those environmental effects with a direct connection to radiological impacts (see SRM-SECY-24–0046). The Commission also directed the staff to consider establishing categorical exclusions for actions beyond those currently listed in § 51.22, including but not limited to subsequent license renewals, power uprate license amendments, microreactor licensing, advanced demonstration projects, site envelopes for specific reactor technologies, and site decommissioning.

Additionally, the Commission approved the NRC staff’s recommendations to modify the purpose and need statements in NEPA reviews to focus on the agency action, typically issuance of a license; authorize project sponsor preparation of environmental assessments (EA) or environmental impact statements (EIS); consider additional options in rulemaking to streamline and enhance NEPA review efficiencies related to deadlines and

extensions, bifurcated application submittals, detailed acceptance criteria for environmental information, and opportunities for preapplication interactions; and update guidance to include reevaluations of generic analyses without rulemaking.

3. Executive Order 14173: Ending Illegal Discrimination and Restoring Merit-Based Opportunity

E.O. 14173, “Ending Illegal Discrimination and Restoring Merit-Based Opportunity,” issued on January 21, 2025, revoked E.O. 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,” issued on February 11, 1994, among other things. In response to E.O. 14173, the Commission directed the staff, in SRM-COMSECY-25-0007, “Withdrawing the Environmental Justice Policy Statement and Environmental Justice Strategy,” to undertake a comprehensive review of the NRC’s environmental regulations, guidance, and training materials to remove references to environmental justice (EJ). The Commission also directed the staff to refrain from explicitly addressing EJ in its reviews under NEPA and ensure that those reviews fully comply with the requirements of NEPA. On April 30, 2025, the NRC withdrew its Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions (Environmental Justice Policy Statement) and its Environmental Justice Strategy.

4. *Seven County Infrastructure Coalition v. Eagle County, Colorado*

On May 29, 2025, the U.S. Supreme Court issued a decision in *Seven County Infrastructure Coalition v. Eagle County, Colorado*, 605 U.S. 168 (2025). The Court emphasized that NEPA does not require agencies to evaluate potential environmental effects arising from “future or geographically separate projects,” “particularly” those over which the agencies do not “exercise regulatory authority.” *Id.* at 186–190; *see also id.* at 186–87 (“[T]he textually mandated focus of NEPA is the . . . project at hand.”). More directly relevant to the NRC’s activities and this proposed rule, the Court also reaffirmed the holding of *Department of Transportation v. Public Citizen*, 541 U.S. 752 (2004), reiterating that “agencies are not required to analyze the effects of projects over which they do not exercise regulatory authority.” *Seven Cnty. Infra. Coal. v. Eagle Cnty.*, 605 U.S. at 188–189.

5. One Big Beautiful Bill Act of 2025, Sponsor Opt-In Fees

Congress again amended NEPA in 2025 through section 60026 of the OBBBA, adding section 112 of NEPA, titled “Project Sponsor Opt-in Fees for Environmental Reviews.” This provision allows project sponsors to pay a fee to obtain shortened NEPA review deadlines.

6. Council on Environmental Quality Consultation

Consistent with section 102(2)(B) of NEPA and E.O. 14300, the NRC consulted with the CEQ during the development of this proposed rule to ensure consistency with Federal government-wide policies and practices.

The changes in this rulemaking would address recently issued E.O.s and the Commission’s direction in SRM-COMSECY-25-0007 and SRM-SECY-24-0046. Details of the proposed revisions are provided in the “Discussion” section.

IV. Discussion

A. What action is the NRC taking?

In this rulemaking, the NRC is proposing to streamline and modernize 10 CFR part 51 regulations and associated guidance to alleviate unnecessary regulatory burden, expand licensing efficiencies and flexibilities, address executive actions, and ensure compliance with NEPA. The NRC is proposing to remove portions of 10 CFR part 51 that are not required to be in regulation because they are codified in NEPA or established in caselaw, and thus can instead be addressed in guidance, allowing for greater flexibility without reducing efficient resolution of procedural issues in hearings.

The elements proposed to be revised in 10 CFR part 51 would include:

1. Definitions (§ 51.4):

The NRC is proposing to revise the definition of effects in 10 CFR part 51 (or impacts, which are used interchangeably for the purposes of 10 CFR part 51 consistent with general NEPA practice) to align with the definition of effects in the CEQ Guidance and in response to recent efforts to streamline NEPA and the NRC’s permitting processes (e.g., the FRA amendments to NEPA, the Accelerating Deployment of Versatile, Advanced Nuclear For Clean Energy Act of 2024, and recent executive orders). Specifically, the NRC is redefining the scope of the environmental effects to those effects from the proposed agency action that are within the agency’s substantive authority to take action to

address (e.g., by denying or conditioning a license).

The CEQ’s recommended definition of “effects” explains that a “but for” causal relationship is insufficient to make an agency responsible for a particular effect under NEPA as recently interpreted by the U.S. Supreme Court in *Seven County*. The definition also excludes “effects that the agency has no ability to prevent due to the limits of its regulatory authority,” consistent with the U.S. Supreme Court’s holding in *Public Citizen* and reaffirmed in *Seven County*. This proposed definition is also consistent with the Commission’s consideration in 2022 that “[u]nder NEPA, ‘[a]n agency has no obligation to gather or consider environmental information if it has no statutory authority to act on that information.’” *NextEra Energy Point Beach, LLC* (Point Beach Nuclear Plant Units 1 and 2), CLI-22-5, 95 NRC 97, 104-05 (2022) (quoting *Sierra Club v. FERC* (Sabal Trail), 867 F.3d 1357, 1371-73 (D.C. Cir. 2017)).

The NRC’s regulatory authority is generally limited to matters with a reasonable nexus to radiological health and safety or the common defense and security, except concerning AEA § 11e.(2) byproduct material (72 FR 57416; Oct. 9, 2007, and 76 FR 56961; Sept. 15, 2011). This interpretation has been reviewed and upheld repeatedly by the courts. In 1969, the U.S. Court of Appeals for the First Circuit reviewed this issue in *New Hampshire v. the Atomic Energy Commission [AEC]*, 406 F.2d 170 (1st Cir. 1969), cert. denied, 395 U.S. 962 (1969). The First Circuit, after noting that the scope of the terms “public health and safety” were not specifically defined in the statute, reviewed the legislative history. *Id.* at 173-75 (citing as examples “[AEA] Sections 53(b), 63(b), 69, 81, 103(d), 104(d), 161(b), and 161(i)”). Based upon its review, the First Circuit concluded that the AEC’s (the NRC’s predecessor agency) regulatory authority was limited to the scrutiny of and protection against radiation hazards. The U.S. Court of Appeals for the District of Columbia Circuit similarly agreed that the AEA limits the NRC’s consideration of health and safety to the special hazards of radioactivity. *People Against Nuclear Energy v. Nuclear Regulatory Commission*, 678 F.2d 222 (D.C. Cir. 1982), rev’d on other grounds, *Metropolitan Edison Company v. People Against Nuclear Energy*, 460 U.S. 766 (1983). It is important to note that while the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA) amended the AEA to give the NRC the authority “to protect the public health

and safety and the environment from radiological and nonradiological hazards associated with the processing and with the possession of such material” with respect to certain byproduct material (§ 84.a.(1) of the AEA), the NRC’s authority over nonradiological hazards is limited to those hazards specifically associated with the processing and possession of byproduct material. The NRC’s authorizing statutes and other legislation express a Federal policy to restore, protect, or enhance environmental quality (e.g., Energy Reorganization Act of 1974 § 2(a), ADVANCE Act § 501). This policy direction is reflected in the NRC’s mission statement, “The NRC protects public health and safety and advances the nation’s common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment.” However, the NRC’s ability to take action to meet these policy directives is limited by the scope of its statutory authority to implement these goals; this proposed rule would ensure that the NRC’s NEPA activities align the scope of its reviews with the scope of its authority to carry out its environmental protection mission.

Therefore, under this proposed rule, the NRC’s evaluation of reasonably foreseeable effects of the proposed agency action and reasonable range of action alternatives (e.g., the no-action alternative) would focus on those radiological effects that the NRC has the substantive statutory authority to regulate (e.g., radiological impacts and, in some cases, the impact of chemical hazards of radiological materials), as described in the definition of “effects” in § 51.4. This means that while certain activities and their associated effects may have a close-causal relationship with the proposed agency action, the NRC may not have legal authority to prevent or mitigate the effects and therefore, will not consider those effects in its NEPA reviews. *See Seven County*, 605 U.S. at 199–200 (Sotomayor, J., concurring) (“NEPA requires consideration of environmental impacts only if such consideration would result in information on which the agency could act.”) For example, although the NRC has the statutory authority to issue a construction permit, it does not have the authority to condition or deny the permit to mitigate the non-radiological impacts—such as dust, noise, non-radiological water and air quality

impacts, non-radiological ecological impacts, etc., during construction. *See* 72 FR 57416. The exception to this narrowed NEPA scope would be NEPA reviews for actions related to AEA § 11e.(2) byproduct materials (e.g., mill tailings), for which the NRC has additional regulatory authority to protect the public health and safety and the environment from radiological and nonradiological hazards associated with the processing and the possession of such material. *See* 76 FR 56961. In practice, this change would mean that contested hearings adjudicating NEPA contentions would focus solely on those radiological effects that the NRC has the substantive statutory authority to regulate. Finally, the proposed definition of effects would not preclude appropriate consideration of environmental effects for activities for which the NRC has discretion to consider broader environmental effects, such as when issuing grants or procuring research.

The NRC is also proposing a number of changes to certain terms and definitions to provide clarity. The NRC is proposing to revise the definition of construction in 10 CFR part 51 to reference the definitions in other parts of the chapter to avoid inconsistencies if the NRC considers changes to the definitions in those parts (e.g., 10 CFR part 53, “Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants”). The term “construction” in NRC regulations is generally used to separate activities that require NRC authorization (i.e., construction that could affect radiological health and safety) from those that do not, which are often described as “pre-construction” activities.

In response to revisions to NEPA regarding the uses of the terms “head of agency” and “responsible official,” the NRC is defining both “head of agency” and “responsible official” to mean the NRC’s Executive Director for Operations. The Executive Director for Operations may also delegate its authority under 10 CFR part 51 to any appropriate NRC staff director.

Finally, the NRC is updating its definitions in § 51.4 for consistency with the terms and definitions in the CEQ Guidance. In addition, the NRC is removing the terms defined in NEPA section 111 and, instead, referring directly to that NEPA section (e.g., categorical exclusion, cooperating agency, EA, environmental document, EIS, finding of no significant impact).

2. Determining When NEPA Applies (§ 51.19):

As a first step in the NEPA review process, the NRC must determine whether NEPA applies to a proposed agency action. The NRC is proposing to revise 10 CFR part 51 to codify in new § 51.19 criteria for determining when NEPA does not apply or when NEPA review is not required in accordance with NEPA sections 106(a) and 111, consistent with CEQ Guidance. For example, NEPA would not apply when the proposed agency action does not result in final agency action under the Administrative Procedure Act (5 U.S.C. 704), and NEPA review is not required in circumstances where Congress, by statute, has prescribed decisional criteria with sufficient completeness and precision such that the NRC retains no residual discretion to alter its action based on the consideration of environmental factors, that is, the action is considered nondiscretionary within the meaning of NEPA sections 106(a)(4) or 111(10)(B)(vii), respectively. Additionally, NEPA does not apply when the proposed agency action is not a “major Federal action” as defined in NEPA section 111. The NRC is proposing to include in § 51.19 an illustrative list of the types of actions that are generally considered “major,” such as an application for a new license or permit and application for renewal of a license or permit, to help clarify when an action is a “major Federal action.” Furthermore, NEPA does not apply to “non-Federal actions,” that is, those actions with no or minimal Federal funding, or no or minimal Federal involvement whereby a Federal agency cannot control the outcome of the project (NEPA section 111(10)(B)(i)). The proposed new regulation at § 51.19 also identifies actions that do not meet the definition of a “major Federal action” such as actions initiating or relating to administrative or judicial civil or criminal enforcement actions or proceedings.

3. Purpose and Need of the Proposed Agency Action:

In alignment with the FRA’s amendments to NEPA, SRM–SECY–24–0046, and recent case law, the NRC’s proposed revisions to 10 CFR part 51 would significantly streamline NEPA reviews by (1) redefining the scope of the proposed agency action, (e.g., to approve an applicant’s request) and (2) narrowing the scope of the purpose and need and, thus, reducing the number of alternatives to those within the NRC’s substantive authority.

Modifying the purpose and need to focus on the agency action is based on amendments to NEPA in the FRA, which inserted the word “agency” into the phrase “proposed agency action.” In

SRM-SECY-24-0046, in which the Commission approved the NRC staff's recommendation to pursue this change through rulemaking, the Commission further clarified that the "staff should limit the alternative analysis to avoid analysis of forms of generation outside the NRC's regulatory and licensing authority." Consistent with this Commission direction and FRA amendments, the proposed rule would add the word "agency" to the phrase "proposed action" throughout NEPA. As a result, the agency action at the NRC will typically be the regulatory or licensing decision (*e.g.*, whether to issue an operating license) for the purposes of NEPA and 10 CFR part 51. The proposed agency action drives the scope of the purpose and need, and thus, the alternatives to the proposed agency action. Therefore, in most cases, the reasonable range of alternatives to the NRC regulatory or licensing decision would be defined as and limited to the no-action alternative (*e.g.*, not issuing the license) because not engaging in regulatory or licensing decisions is the only reasonable alternative to the agency action. That is, the NRC would not consider alternatives to the proposed agency action that the agency does not have the authority to implement (*e.g.*, facility siting and other technology or energy alternatives). The reasonably foreseeable effects of the no-action alternative would continue to include the negative environmental impacts of not implementing the proposed agency action.

4. Level of NEPA Review (§ 51.20):

The NRC is proposing to revise 10 CFR part 51 to provide more flexibilities in determining whether to prepare an EA or EIS, which will help streamline the NEPA review process. This change would incorporate NEPA section 106(b), added by the FRA, which establishes threshold determinations for when a Federal agency should prepare an EA or EIS and is based on a determination of the significance of the reasonably foreseeable effect of the proposed agency action on the quality of the human environment. As such, the NRC is proposing to revise 10 CFR part 51 to eliminate the list of specific agency actions requiring the preparation of an EIS in § 51.20 and reflect NEPA section 106(b), except where an EIS is required by statute, and add procedures for determining the appropriate level of NEPA review. Removing the list of actions in § 51.20(b) that automatically require an EIS would provide greater flexibility to consider and implement streamlined environmental review approaches, where appropriate, and would eliminate the need for

exemptions to allow the preparation of an EA where an EIS is currently required by NRC regulations. The exception is the issuance of a license for construction and operation of a uranium enrichment facility, for which section 193 of the AEA requires preparation of an EIS.

Therefore, after determining that NEPA applies, the NRC would analyze and determine whether to apply an established categorical exclusion to the proposed agency action pursuant to § 51.22. If the NRC cannot apply a categorical exclusion, the NRC will consider the proposed agency action's reasonably foreseeable effects to determine whether to prepare an EA or EIS. The NRC has historically used the term "special circumstances" to describe situations in which information is present that indicates an activity that would normally be categorically excluded could have significant environmental effects. In this rulemaking, the NRC is proposing to adopt the term "extraordinary circumstances," which is identical in meaning. This change in terminology would bring the NRC's NEPA regulations and procedures more in line with the rest of the Federal government but does not reflect a substantive change. In addition, NRC may apply a categorical exclusion to a proposed agency action when extraordinary circumstances are present when the NRC determines that despite the extraordinary circumstance, the proposed agency action is not likely to result in reasonably foreseeable adverse significant effects or the proposed agency action is modified to avoid adverse effects.

Once the NRC determines the level of NEPA review required for a proposed agency action, the NRC will provide a unique identification number for tracking purposes on all associated environmental review documents prepared for the proposed agency action. The NRC will coordinate with CEQ and other Federal agencies to ensure uniformity of such identification numbers across Federal agencies.

5. Establish new categorical exclusions (§ 51.22):

Categorical exclusions are an essential tool for reducing the regulatory burden for categories of actions that can be shown to have no significant effect on the quality of the human environment. As previously discussed, the NRC is proposing to revise § 51.20 to use the CEQ Guidance for determining the appropriate level of NEPA review. The first step in determining the level of NEPA review is consideration of whether to apply a categorical

exclusion. The NRC is proposing four enhancements to its use of categorical exclusions.

First, the NRC is proposing to increase the number and types of categorical exclusions listed in § 51.22. Second, the NRC is proposing to revise its regulations to allow for adoption of categorical exclusions established by other federal agencies in accordance with NEPA section 109. While this process has been available since prior to the FRA, the NRC is now proposing to explicitly incorporate this pathway within its regulations and guidance. Third, the NRC is proposing a process to establish new categorical exclusions by listing them on the NRC's website at <https://www.nrc.gov/NEPAcatex>. Last, the NRC is proposing to expressly use the petition for rulemaking process in § 2.802 to allow any interested party, including licensees and prospective or current applicants, to propose a new categorical exclusion for the NRC to consider. This expanded framework for categorical exclusions is consistent with the direction in E.O. 14154 to streamline the permitting process and addresses the direction in SRM-SECY-24-0046 to consider establishing categorical exclusions for actions beyond those currently listed in § 51.22, including but not limited to subsequent license renewals, power uprate license amendments, microreactor licensing, advanced demonstration projects, site envelopes for specific reactor technologies, and site decommissioning. The following discussion provides additional information under each pathway.

Enhancement 1. Establishing New Categorical Exclusions Under § 51.22: During the NRC's evaluation to identify and establish new categorical exclusions beyond those listed in § 51.22, the NRC, (i) consistent with SRM-SECY-24-0046, defined parameters for the categories of actions to clarify limiting characteristics for each categorical exclusion; (ii) considered the proposed new definition of "effects," which limits the scope of the effects the NRC would consider under NEPA to those effects that the NRC has the substantive statutory authority to mitigate; and (iii) considered the new definition of "categorical exclusion" in NEPA section 111(1). The NRC is proposing to expand the categories of actions that normally do not significantly affect the quality of the human environment to the list of categorical exclusions in § 51.22, such as categorical exclusions related to license renewal, construction permits, early site permits, and other common licensing activities. The bases for the new categorical exclusions and revised

existing categorical exclusions can be found in “U.S. Nuclear Regulatory Commission Written Record of Support of Proposed Amendments to 10 CFR 51.22 in Accordance with Executive Order 14300 and SRM–SECY–24–0046,” which is available as indicated in the “Availability of Documents” section of this document. Additionally, in a separate proposed rulemaking for 10 CFR part 57, “Licensing Requirements for Microreactors and Other Low Consequence Reactors,” the NRC is considering a new categorical exclusion, one related to general licenses for the construction of certain structures, systems related to the construction and operation of low-consequence reactors, respectively; while this rule proposes a new categorical exclusion, it has a separate basis and purpose that the NRC has determined do not need to be combined with this rulemaking.

Enhancement 2. Adopting a Categorical Exclusion from Another Agency. In accordance with NEPA section 109, the NRC may adopt a categorical exclusion established by another federal agency. While adopting a categorical exclusion from another agency has been available to Federal agencies previously, the NRC’s current regulations and guidance do not consider or address the possibility of adoption. Therefore, the NRC is proposing to revise § 51.22 to allow for the adoption of categorical exclusions listed in another agency’s NEPA procedures. The process for adopting another Federal agency’s categorical exclusion is described in NRC staff’s draft guidance, which aligns with the NEPA section 109 and the CEQ Guidance. Under NEPA section 109, the NRC may rely on categorical exclusions adopted from other agencies prior to incorporating them into § 51.22; however, § 2.335, “Consideration of Commission rules and regulations in adjudicatory proceedings,” which requires a waiver to challenge NRC regulations in an individual adjudicatory proceeding, would not apply until the categorical exclusion is added to the NRC’s regulations in § 51.22.

Enhancement 3. Establishing New Categorical Exclusions Outside of Rulemaking: The NRC recognizes that the current process for establishing categorical exclusions by regulation might pose some challenges in establishing new categorical exclusions in the future, including those that the NRC could adopt from other agencies. Therefore, the NRC is also revising § 51.22 to add another option for publishing categorical exclusions established or adopted by the NRC to

provide greater flexibility and increase efficiency. Specifically, the NRC is proposing to establish categorical exclusions outside of the rulemaking process via public notification on the NRC’s website at <http://www.nrc.gov/NEPACatex>. Categorical exclusions noticed and published on NRC’s website will be incorporated via rulemaking at appropriate intervals. As with categorical exclusions adopted from other agencies, § 2.335, “Consideration of Commission rules and regulations in adjudicatory proceedings,” would not apply until the categorical exclusion is added to the NRC’s regulations in § 51.22. The NRC has developed corresponding guidance in NUREG–2270 outlining the process for establishing categorical exclusions outside of rulemaking on its website, which includes consultation with CEQ and notice to the public.

Enhancement 4. Prospective Applicant or Interested Party-Proposed Categorical Exclusions: Prospective applicants or any interested party would also be able to propose a new categorical exclusion for a category of actions that normally does not significantly affect the quality of the human environment by submitting a petition for rulemaking in accordance with § 2.802. Using the existing petition for rulemaking process provides clarity to the submission process and ensures the requestor is entitled to updates and a formal response. To avoid undue delay in establishing a new categorical exclusion, if requested by the petition, the NRC will consider using the process for establishing categorical exclusions via publication on NRC’s website. To ensure that the NRC is able to conduct an efficient and timely review, and that the categorical exclusion is established, if appropriate, and available when the application is submitted, prospective applicants and interested parties should submit proposed categorical exclusions, along with the supporting rationale and bases, to the NRC at least six months in advance of the expected application submittal or authorization request.

Finally, the NRC is proposing to revise the definition of categorical exclusion in 10 CFR part 51 to align with the definition in NEPA section 111(1) and the definition of previously disturbed areas in 10 CFR part 51 to clarify its meaning is within the context of categorical exclusions in § 51.22.

6. Application framework: Expand from one to two environmental information preparation approaches for applicants (§ 51.46):

In alignment with the FRA’s amendments to NEPA and SRM–SECY–24–0046, the NRC’s proposed revisions

to 10 CFR part 51 expand the options that applicants and petitioners for rulemaking would have for providing environmental information that the NRC requires to comply with NEPA. If an action does not fall under an established categorical exclusion, the proposed revisions to 10 CFR part 51 will allow applicants and petitioners (in case of a petitioner for rulemaking) to either submit an environmental report for the NRC to use in developing an environmental document, or alternatively, applicants and petitioners for rulemaking can prepare a draft environmental document under NRC’s supervision in accordance with NEPA section 107(f). The latter approach increases licensing flexibility for applicants and petitioners.

The NRC proposes to add new § 51.46 to establish the procedures for applicant-prepared or petitioner-prepared draft environmental documents in accordance with NEPA section 107(f), which requires Federal agencies to prescribe procedures to allow a project sponsor to prepare an EA or an EIS under the supervision of the Federal agency. The proposed procedures in § 51.46 would establish the roles and responsibilities of applicants and petitioners and the NRC. A prospective applicant or petitioner for rulemaking would opt-in by submitting a written request to the NRC prior to beginning preparation of the draft environmental document or environmental report. The NRC would in turn evaluate the request and, at its discretion, authorize an applicant-hired or petitioner-hired contractor to prepare the draft environmental document. Because the NRC will be responsible for the contents and findings of the environmental document including any final determinations and findings, the NRC has defined the term “draft environmental document” in § 51.4 to mean an applicant-prepared EA or applicant-prepared EIS that does not include an agency-prepared final impact finding, determination, or other agency decision document, to distinguish it from the term “environmental document,” which is defined in section 111(5) of NEPA and the NRC is reserving for NRC-prepared EAs, EISs, and findings of no significant impacts, consistent with the statutory definition.

Paragraph (a) of § 51.46 would establish the commitments that a prospective applicant or petitioner must commit to in its request, including providing the contractor(s) qualifications to the NRC and ensuring that the contractor(s) will have no financial or other interest in the outcome of the proposed agency action

by providing a disclosure statement. To avoid a potential conflict of interest, the proposed regulations would establish that if a prospective applicant or petitioner wants to use this process, the prospective applicant will not be able to prepare the draft environmental document itself but will need to hire a qualified contractor because the prospective applicant does have a vested interest, including a financial interest, in the proposed agency action. The proposed commitments would also require that the relevant procurement documents specify that the draft environmental document must meet the requirements of 10 CFR part 51 and to authorize the NRC to conduct oversight of the draft environmental document preparation process. Similarly, a prospective applicant or petitioner and its contractor must commit to cooperate with the NRC's supervision of the draft environmental document preparation process and meet the set schedule. The schedule will be established by the NRC, in accordance with NEPA deadlines, as proposed in § 51.15, and E.O. 14300 deadlines, which the NRC intends to codify in a separate rulemaking. The NRC will consult with any cooperating agencies and the applicant when setting the schedule, as the lead agency determines appropriate.

The NRC, however, would be responsible for determining the level of NEPA review, providing supervision of and guidance for the prospective applicant or petitioner and applicant-hired contractor. While an applicant-hired contractor would prepare a draft environmental document under this process, the NRC would be responsible for conducting all consultations required by other environmental statutes unless the NRC authorizes the prospective applicant or petitioner (or applicant- or petitioner-hired contractor) to do so, as appropriate, and the prospective applicant or petitioner (and applicant- or petitioner-hired contractor, if it is the case) accepts such responsibility. Finally, the NRC will independently evaluate and take responsibility for the content, accuracy, and scope of the final environmental document, including by issuing any final determinations and the final agency decision on the application.

In addition to being a voluntary process, the NRC is proposing that participation in the applicant-prepared draft environmental document process under § 51.46 would occur prior to the submittal of the application and, specifically, prior to beginning preparation of the applicant-prepared draft environmental document or environmental report. The NRC staff

believes this timeframe supports an efficient, timely, and predictable review and decisionmaking by avoiding or mitigating potential challenges to the NEPA statutory deadlines in NEPA section 107(g)(1) and, consequently, the milestones called for in Section 5(a) of E.O. 14300. A prospective applicant or petitioner opt-in request submitted at the same time as an application could impact the NRC's review schedule considering the steps the applicant and the NRC have to take, including hiring and authorizing a qualified contractor(s), respectively. While the NRC will be supervising the applicant-hired contractor, the NRC is ultimately responsible for the contents and findings in the environmental document and would thus need to independently evaluate the applicant-prepared draft environmental document. Additionally, consistent with proposed § 51.46(e), the NRC may terminate the applicant-prepared draft environmental document at any time and would, thus, have to complete or fully prepare the environmental document itself. In these instances, the likelihood of challenging the NEPA statutory deadlines is high, thus, requiring the need to evaluate an extension of the NEPA deadlines. Extending the NEPA deadlines, however, would increase the likelihood of challenging the milestones in Section 5(a) of E.O. 14300. Accordingly, the NRC is proposing that a prospective applicant's request to participate in the applicant-prepared draft environmental document process proposed § 51.46 be submitted prior to beginning preparation of an applicant-prepared draft environmental document or environmental report.

7. Deadlines (§ 51.15):

In accordance with NEPA section 107(g), which establishes the deadlines for the publication of EAs and EISs and the process for extending those deadlines, the NRC is proposing to revise § 51.15 to codify the EA and EIS statutory deadlines, the start date and completion date for calculating these deadlines, and the process to extend those deadlines. Accordingly, proposed §§ 51.15(a)(1) and 51.15(a)(2) provide that the NRC must publish EAs no later than one year, and EISs no later than two years, after the sooner of when the NRC determines that NEPA requires the preparation of an EA or EIS or the date the NRC issues a notice of intent to prepare an EA or EIS (*i.e.*, start date), respectively. The proposed regulations also establish that for applications and petitions for rulemaking, the NRC's determination that an EA or EIS is required coincides with the docketing of a complete application or petition, or

with the publication of an EA determining that an EIS is required as proposed in § 51.15(a)(2)(iii). If, after initially beginning with preparation of an EA, the NRC determines that a finding of no significant impact cannot be reached, the NRC may publish either a notice of intent to prepare an EIS, an EA determining that an EIS is required, or both. Publication of an EIS in this case would be no later than two years following publication of the notice of intent to prepare an EIS or the EA determining that an EIS is required.

The proposed § 51.15(a)(3) provides that the completion date of an EA or EIS will be the date the NRC publishes the EA or EIS in ADAMS or the **Federal Register**. In accordance with NEPA section 107(g), if the NRC determines it is not able to meet the deadlines in § 51.15(a), the NRC will consult with the applicant, if any, prior to establishing a new deadline, as indicated in proposed § 51.15(a)(5).

Lastly, in accordance with NEPA section 112, the NRC proposes to add new paragraph (b) in § 51.15 to describe the process that should be used when licensees or applicants opt to pay a fee for an expedited EA or EIS deadline.

8. Requirements for Environmental Information Supporting Environmental Documents and Categorical Exclusions (§ 51.45):

The NRC would retain the general requirement for an applicant or petitioner for rulemaking to submit an environmental report in § 51.45. However, to support the NRC's enhanced approach to the use of categorical exclusions, the NRC would allow applicants and petitioners for rulemaking to provide the bases and rationale to justify the applicability of a categorical exclusion listed in § 51.22 or on the NRC website, including supporting analyses (see § 51.45(b)) in lieu of an environmental report. The level of evidence and supporting analyses to justify the applicability of an established categorical exclusion will vary depending on the proposed agency action. For example, certain categorical exclusions (§§ 51.22(a)(1) through (a)(16)) do not have threshold criteria that have to be met for the categorical exclusion to apply and may not need a justification based on the type of license requested. For example, nuclear laundries, which collect and launder items such as coveralls contaminated with radioactive materials, are a specific type of license at the NRC (*e.g.*, nuclear laundries have a specific fee category under 10 CFR part 170, "Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954,

As Amended”) that is categorically excluded under § 51.22(a)(10)(xiv) without additional criteria. If an applicant submits a request for a license to operate a nuclear laundry, no additional information is needed to determine that the categorical exclusion applies, unless extraordinary circumstances are present (e.g., the applicant is proposing to use novel technologies or to accept items for laundering that have substantially higher levels of contamination than nuclear laundries have previously handled).

Those categorical exclusions that do require additional or more complex criteria to be met, such as §§ 51.22(d) through 51.22(l), require information to be submitted as part of the application to justify the applicability of the categorical exclusion. For example, new reactor applications may meet the proposed new categorical exclusion in § 51.22(i), but only if the application meets the plant parameter and site parameter envelopes in Table C–1 of appendix C to 10 CFR part 51 and no new and significant information has been identified that would change the conclusions listed in the appendix. Demonstrating that those criteria are met requires substantial supporting information that may not otherwise be included in the application.

The NRC is also proposing to incorporate in the regulations at § 51.45(a) for environmental reports and in § 51.45(b) for information justifying the applicability of a categorical exclusion, a provision consistent with its longstanding practice of requiring an applicant or petitioner for rulemaking to submit information to the Commission relevant to NRC’s compliance with other statutes, including but not limited to, the Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, National Historic Preservation Act, Clean Air Act, Clean Water Act, National Marine Sanctuaries Act, and Marine Mammal Protection Act. The purpose of these provisions is to maintain the NRC’s ability to collect information relevant to compliance with these other statutes, which has historically been integrated with the NRC’s NEPA procedures; however, the NRC is not revising procedures for or otherwise addressing any compliance obligations it may have with respect to statutes other than NEPA as part of this rulemaking.

While the NRC is proposing to remove the regulations at §§ 51.54 and 51.55, which describe the information applicants must include in an environmental report for a manufacturing license and a standard

design certification, respectively, such information would continue to be required in new paragraphs § 51.45(c), for standard design certifications, and § 51.45(d), for manufacturing licenses. These proposed new regulations also address the requirement to provide information to justify the applicability of a categorical exclusion for an application for a standard design certification and manufacturing license, respectively. The NRC is also proposing to incorporate the environmental report requirements in § 51.56 for non-power production or utilization facilities into § 51.45.

The NRC is proposing to retain § 51.60 as modified to conform with the proposed revisions to § 51.45(a) and to incorporate the requirements in § 51.68, which address the environmental information that petitioners for rulemaking must submit to the NRC when requesting amendments of 10 CFR parts 30, 31, 32, 33, 34, 35, 36, 39, 40 or 70 of this chapter. This would ensure that references in existing categorical exclusions, which are not being changed, to the list of materials actions listed in § 51.60 are not affected. The NRC is proposing to retain the environmental report requirements in § 51.62 for land disposal of radioactive waste licensed under 10 CFR part 61, “Licensing Requirements for Land Disposal of Radioactive Waste,” as modified to conform with the proposed revisions to § 51.45(a). While the NRC is proposing to remove § 51.61 regarding environmental reports for independent spent fuel storage installation and monitored retrievable storage installation licenses, such required information would now be included in § 51.60(d).

Lastly, information regarding environmental considerations and environmental analysis in § 51.45 would be removed as part of this rulemaking because the information is addressed in other sections of 10 CFR part 51 (e.g., requirements that the environmental report includes a description of the proposed agency action, purpose and need, affected environment, and environmental impacts) or in guidance (e.g., how the environmental impacts should be presented in the environmental report); or the information is no longer required consistent with the definition of “effects” in § 51.4 (e.g., impacts of preconstruction activities or other impacts without a reasonable nexus to radiological health and safety or the common defense and security).

9. Preparation Requirements for Environmental Documents (§§ 51.30,

51.31, 51.32, 51.70, 51.71, 51.75, 51.76, 51.92, and 51.95).

In SRM–SECY–24–0046, the Commission directed the staff to focus on standardization of the environmental document preparation process and agency interactions with the applicant to enable consistent and efficient completion of environmental reviews and approval of the underlying agency action. Consistent with this direction, the NRC staff is proposing to retain most of the procedures in §§ 51.30, 51.31, and 51.32 related to the preparation of EAs and findings of no significant impact, and most of the procedures in §§ 51.70 and 51.71 related to the preparation of EISs. The proposed revisions to the regulations for preparing EAs and EISs align with the applicable procedures established by CEQ in the CEQ Guidance. The NRC is also proposing to incorporate language from the CEQ Guidance to add new paragraph § 51.32(a)(8) to codify the option of a finding of no significant impact based on mitigation. While the NRC has historically had the option to reach a finding of no significant impact based on mitigation, the option has not previously been codified in the NRC’s NEPA procedures. The NRC does not consider this proposal to be a change in its NEPA practice.

In addition to containing the regulations for preparing EAs and findings of no significant impact, the NRC would retain §§ 51.30, 51.31, and 51.32 regarding when to prepare an EA for a standard design certification or a manufacturing license under 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” and 10 CFR part 53, “Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants,” the scope of these EAs, and the findings of no significant impact associated with these EAs. Although the proposed regulations would eliminate references to the specific option of publishing a draft finding of no significant impact for public comment, the NRC would continue to have the option of requesting public comment, in certain circumstances, to assist in preparation of an EA under proposed § 51.30(f).

Under this proposed rule, the NRC would discontinue preparation and publication of draft EISs as currently outlined in 10 CFR part 51, including the routine solicitation of public comments on draft EISs under § 51.73 because NEPA does not require the preparation and publication of draft EISs. Therefore, the proposed regulations at §§ 51.70 and 51.71 solely focus on the preparation of and general

content requirements for EISs, respectively, rather than on the preparation and general content requirements of draft EISs as the regulations currently provide. In accordance with NEPA section 107(c), the NRC will continue to include a request for public comment in each notice of intent to prepare an EIS. Although the proposed regulations would eliminate § 51.73, the NRC would have the option of additional requests for public comment, in certain circumstances, to assist in preparation of an EIS, under proposed § 51.70(a).

The NRC is proposing to retain the provisions regarding the preparation of a concise public decision document for proposed agency actions for which the NRC has prepared an environmental impact statement. In accordance with proposed § 51.102(a), the NRC will prepare and timely publish a concise public decision document or joint decision document notifying the public that the decisionmaker has certified that the NRC has considered all relevant information raised in the NEPA process and that the NEPA process has closed. This publication allows the NRC to comply with its obligations under NEPA and its decision-making process under the AEA. The required contents of this concise public record of decision in § 51.103 have been integrated into proposed § 51.102(b), as applicable. Alternatively, the NRC may integrate its considerations under NEPA into another decision-making document without meeting the formal requirements for a record of decision under § 51.102(b). This integrated consideration would perform the same function as a formal record of decision.

To further streamline and standardize the requirements addressing the contents of environmental reports and environmental documents, the NRC is proposing to combine, as appropriate, the environmental report requirements in §§ 51.49, 51.50, and 51.53 regarding limited work authorizations (LWAs); construction permits (CPs), early site permits (ESPs), and combined licenses (COLs); operating licenses, operating license renewals, and postoperating licenses; respectively, with the applicable environmental document content requirements in §§ 51.71, 51.75, 51.76, and 51.95. The resulting new regulations would be housed under §§ 51.75, 51.76, and 51.95 for LWAs; CPs, ESPs, and COLs; operating licenses, operating license renewals, and postoperating licenses; respectively. These regulations would apply to the preparation of both EAs and EISs. Accordingly, the regulations at § 51.96 addressing the requirements for

environmental documents relying on a generic environmental impact statement (GEIS) for licensing new nuclear reactors would also be incorporated into § 51.75. These proposed regulations also address the environmental information that NRC and licensees and applicants need to use when relying on the codified environmental impact findings in §§ 51.51, 51.52, appendix B, or appendix C of 10 CFR part 51.

Lastly, the proposed environmental report requirements in § 51.45(a) would also require that applicants address the matters specified in the proposed § 51.75, § 51.76, or § 51.95, as applicable.

In combining the requirements addressing the contents of environmental reports in §§ 51.49, 51.50, and 51.53 and contents of environmental documents in §§ 51.71, 51.75, 51.76, and 51.95 for LWAs, CPs, ESPs, and COLs, operating licenses, operating license renewals, and postoperating licenses, the NRC is also proposing to remove some of the environmental information requirements in consideration of the proposed revision to the definition of “effects” in § 51.4. For example, the requirement at § 51.53(c)(3)(ii)(G) to provide an assessment of the impact of the proposed action on public health from thermophilic organisms would be removed because nonradiological human health impacts are not within the NRC’s substantive regulatory authority (*i.e.*, the NRC could not impose or enforce mitigation for human health impacts from thermophilic organisms). The conditions and considerations listed in § 51.53(c)(3)(ii) with continuing relevance would be incorporated into the proposed new paragraph (5) in § 51.95(c). Paragraphs 51.53(c)(3)(ii)(A)–(C), (E)–(K), (M)–(O), and (Q) would be eliminated because they are outside the scope of the NRC’s statutory authority relating to renewing operating licenses for utilization facilities.

Additionally, the NRC is proposing to revise § 51.76(a) for LWA requests submitted as part of complete CP or COL applications to remove the option of preparing a partial environmental document in light of the statutory NEPA deadlines because it is not feasible for the NRC to prepare two environmental documents, one for the LWA and another for the CP or COL application in the same timeframe (*e.g.*, one year for an EA). Therefore, the NRC is proposing to only keep the option of preparing one environmental document for complete applications submitted in accordance with § 51.75(a) (for CPs) or § 51.75 (c) (for COLs) that include a request for a

LWA. Paragraph 51.76(b) addresses phased applications for LWAs under § 2.101(a)(9), in which an applicant for a CP or a COL submits a partial application requesting an LWA. To ensure alignment with the statutory NEPA deadlines defined in § 51.15, in the case of a partial application including a request for an LWA, the NRC is proposing to prepare an environmental document for the LWA only for which the statutory deadline will start upon acceptance for docketing of part one of the application. The statutory deadline for part two of the application (*i.e.*, the full CP or COL), would begin upon NRC acceptance for docketing of part two of the application. Finally, the NRC is proposing to remove the requirement for preparation of a single environmental document to address both the LWA and CP or COL in cases where the applicant submits an environmental report that contains complete information for both phases. This would ensure the NRC has the flexibility to develop the appropriate environmental documents based on the circumstances for each application.

10. Effects on existing GEISs and codified environmental information:

The proposed 10 CFR part 51 would retain codified environmental impact conclusions within the scope of the NRC’s regulatory authority in the following sections: § 51.23, “Environmental impacts of continued storage of spent nuclear fuel beyond the licensed life for operation of a reactor,” § 51.51, “Uranium fuel cycle environmental data—Table S–3,” § 51.52, “Environmental effects of transportation of fuel and waste—Table S–4,” appendix B of 10 CFR part 51, “Environmental Effect of Renewing the Operating License of a Nuclear Power Plant,” and appendix C of 10 CFR part 51, “Environmental Effect of Issuing a Permit or License for a New Nuclear Reactor.” Retaining the codified conclusions on effects within the NRC’s substantive statutory authority (*i.e.*, radiological impacts on health and safety and the common defense and security) would allow NRC staff, and licensees, applicants, and petitioners, to cite and incorporate the codified conclusions in environmental review documents, which would avoid duplication of these analyses and requires contentions to meet a heightened standard under § 2.335, “Consideration of Commission rules and regulations in adjudicatory proceedings,” to be admitted on these items. In consideration of the proposed new definition of “effects” in § 51.4, the NRC is proposing to remove codified conclusions for environmental effects

that are beyond the NRC's substantive statutory authority from these sections and tables. For the purposes of § 51.23, only the effects of continued storage within the scope of the NRC's regulatory authority will be deemed incorporated into future environmental documents, if applicable. The original analysis of the effects of continued storage included analysis of environmental effects beyond the scope of the NRC's statutory authority to regulate. The NRC's proposed definition of effects would apply to that term as used in § 51.23; however, the NRC is not proposing to make changes to the Continued Storage Generic Environmental Impact Statement as part of this proposed rule. In a separate rulemaking, the NRC is considering updates to the values in Table S-3 and Table S-4 to address effects related to fuels with increased enrichment; while these rules both propose changes to the tables, they have separate bases and purposes that the NRC has determined do not need to be combined.

Additionally, the NRC's EISs have used significance levels of SMALL, MODERATE, or LARGE for environmental effects or impacts, but have not indicated whether the impact would necessarily be considered significant for the purposes of an EA. Rather, these significance levels for environmental impacts generally consider the potentially affected environment (previously referred to as "context") and degree (previously referred to as "intensity") in determining if the environmental effect is noticeable and destabilizing:

- SMALL is defined as environmental effects that are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource.
- MODERATE is defined as environmental effects are sufficient to alter noticeably, but not destabilize, important attributes of the resource.
- LARGE is defined as environmental effects that are clearly noticeable and are sufficient to destabilize important attributes of the resource.

The NRC originally established the three levels of significance as part of the amendments to its regulation in 10 CFR part 51 for the NEPA review of applications for renewal of nuclear power plant operating licenses (61 FR 28467) and codified in them Table B-1 of appendix B to 10 CFR part 51. These definitions were adapted to accommodate the environmental resource attributes of importance. Significance impact levels have been applied across the NRC's EISs since they were established in 1996 to help readers

compare impacts across multiple environmental issue areas. Historically, the NRC has not defined a SMALL impact as significant or not significant. As part of this rulemaking, the NRC has reviewed the technical basis documents and codified conclusions in § 51.23 and Tables B-1 and C-1 of 10 CFR part 51 and determined that a SMALL conclusion in these documents means that there is no significant impact. For instance, for the purposes of assessing radiological impacts, the Commission has concluded that impacts are of small significance if doses to individuals and releases do not exceed the permissible levels in the Commission's regulations (61 FR 66543). The AEA requires the NRC to promulgate, inspect, and enforce standards that provide an adequate level of protection of the public health and safety. Health impacts on individual humans are the focus of NRC regulations limiting radiological doses. Numerous EAs developed by the NRC have concluded a no significant impact with respect to radiological human health if doses to individuals and releases do not exceed the permissible levels in the Commission's regulations. Therefore, if doses to individuals and releases do not exceed the permissible levels in the Commission's regulations, the impacts are not significant.

For those environmental impacts outside of human health (e.g., exposure of radionuclides to nonhuman biota), when a SMALL impact is concluded, the NRC has determined that the environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource and this is comparable to a no significant impact determination. This is demonstrated in the evaluations presented in the license renewal GEIS (NUREG-1437, Rev 2, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants—Final Report"). NUREG-1437 divides environmental issues into generic issues (termed Category 1 issues) and nuclear power plant- or site-specific issues (termed Category 2 issues). The findings for the Category 1 issues resulting in a SMALL impact identified that impacts from license renewal were insignificant, not expected to be significant, or would not be affected. Therefore, the Commission has determined that a SMALL impact means no significant impact for these areas.

The practical effect of this determination is that in the proposed revisions to §§ 51.22 and 51.23, Table B-1, and Table C-1 of 10 CFR part 51, actions that fall within the bounds of those generic analyses would meet the

criteria for a categorical exclusion, or the basis for a finding of no significant impact if the NRC prepares an EA.

The proposed § 51.51 would also remove the caveat that only environmental reports submitted "on or after September 4, 1979" must use Table S-3, Table of Uranium Fuel Cycle Environmental Data within environmental reports for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor. The NRC has removed the caveat regarding "on or after September 4, 1979," since it is no longer relevant and all specified environmental reports would be required to use of Table S-3, Table of Uranium Fuel Cycle Environmental Data.

The NRC recognizes that, following these revisions, there would no longer be any Category 2 issues in Appendix C. Nonetheless, the NRC proposes to retain references to Category 2 issues in Appendix C within the rule text to account for the possibility that future updates may identify Category 2 issues.

11. Removing references to environmental justice (§ 51.53 and Table B-1 of 10 CFR part 51):

In SRM-COMSECY-25-0007, the Commission directed the NRC to remove environmental justice (EJ) references in regulations, guidance and training materials. Thus, the scope of rulemaking with respect to EJ would be limited to amending NRC's regulations at § 51.53, "Postconstruction environmental reports," which identifies EJ information to be included in license renewal applicant's environmental reports, and 10 CFR part 51, subpart A, appendix B, Table B-1 which require license renewal environmental reviews to include an EJ analysis for the Category 2 issue.

12. Other changes to conform with the FRA Amendments to NEPA and the CEQ Guidance:

The NRC is proposing revisions in 10 CFR part 51 to update the regulations for consistency with the FRA NEPA amendments, such as inserting the word "Federal" before "resources" in the phrase "irreversible and irretrievable commitment of resources," incorporating terms like "technically and economically feasible" when addressing reasonable alternatives, and the requirement to evaluate negative environmental impacts from the no action alternative. With respect to the evaluation of negative impacts from the no-action alternative, the NRC has, in general, considered such impacts; however, this consideration would now be explicitly codified in the regulations.

The NRC is also proposing to codify the page limits for EISs and EAs in accordance with NEPA section 107(e). Paragraph 51.30(e) would establish that an EA must not exceed 75 pages, not including any citations or appendices. Paragraph 51.70(b) would establish that except for an EIS for a proposed agency action of extraordinary complexity, EISs must not exceed 150 pages, not including any citations or appendices. Proposed § 51.70(c) also explains that an EIS for a proposed agency action of extraordinary complexity must not exceed 300 pages, not including any citations or appendices. The NRC will determine at the earliest possible stage of preparation of an EIS whether the conditions for exceeding the 150-page limit are present.

The NRC is also proposing to remove its procedures for scoping in §§ 51.26–51.29 and appendix B and appendix C of 10 CFR part 51. Instead, the NRC is proposing to incorporate the relevant procedures into the NRC's draft guidance. Removing the scoping procedures from 10 CFR part 51 does not eliminate the requirement to publish a notice of intent to prepare an EIS and include in this notice a request for public comment on alternatives or effects and on relevant information, studies, or analyses with respect to the proposed agency action pursuant to NEPA section 107(c). The NRC is proposing that as soon as practicable after determining that an EIS will be prepared by the NRC in connection with a proposed agency action, the NRC will publish a notice of intent to prepare an EIS in the **Federal Register** and include a request for public comment on this notice. This requirement is reflected in proposed § 51.70. The NRC may consider, in certain circumstances, requesting comments on additional topics in the notice of intent or otherwise if it determines that scoping would assist in the preparation of an EIS. The NRC would address any substantive comments that are within the scope of the proposed agency action, as appropriate, in the development of the EIS. The NRC would continue to describe appropriate methods to collect comments in the notice of intent. The NRC may consider publishing a notice of intent to prepare an EA or conducting scoping for an EIS or EA if it determines that issuing a notice of intent to prepare an EA or conducting scoping for an EA or EIS would assist in the preparation of these documents.

To streamline and enhance environmental review efficiency, the NRC will, to the fullest extent possible and when it would be most efficient to do so, continue to prepare EAs and EISs

concurrently and integrated with analyses and related surveys and studies required by other environmental Federal statutes. The NRC will also continue to coordinate, to the fullest extent possible, the preparation of EAs and EISs with any other agency document to streamline those reviews.

Additionally, to reduce duplication and increase efficiency between NEPA and State, Tribal, and local requirements, the NRC is proposing to add §§ 51.30(g) and 51.70(d) providing for the NRC to cooperate with State, Tribal, and local agencies that are responsible for preparing environmental documents.

13. Public hearings

The NRC is proposing to remove the regulations in 10 CFR part 51 related to public hearings, mainly §§ 51.104 through 51.108, except for the regulations addressing public hearings in proceedings for issuance of materials license with respect to a geologic repository at § 51.109. The procedures governing public hearings are included in 10 CFR part 2, “Agency Rules Practice and Procedures,” and do not need to be repeated in 10 CFR part 51.

Additionally, participation in the NEPA process, for example, as part of a scoping process for an EIS, does not entitle the participant to become a party to the proceeding to which the environmental document relates. Participation in an adjudicatory proceeding is governed by the procedures in §§ 2.309 and 2.315 of this chapter. Participation in a rulemaking proceeding in which the Commission has decided to have a hearing is governed by the provisions in the notice of hearing.

14. Lead Agencies, Participating Federal Agencies, and Cooperating Agencies

The FRA amendments to NEPA revised or created the definitions and requirements for “lead agency,” “joint lead agency,” “cooperating agency,” and “participating Federal agency.” These amendments require that agencies identify in writing the lead agency when there are two or more participating Federal agencies and require that the head of the lead agency lead the consultation process. In many instances, a proposed agency action or decision is undertaken that may include other actions or decisions undertaken by other Federal agencies. These actions and decisions are “related actions,” in that they are each the responsibility of a particular agency, but they are all interdependent parts of a larger action and depend on the larger action for their justification. In such instances, NEPA section 107(a)(1)(A) requires that the

multiple agencies involved determine which of them will be the lead agency based on consideration of the magnitude of agency's involvement; project approval or disapproval authority; expertise concerning the action's environmental effects; duration of agency's involvement; and sequence of agency's involvement. When serving as the lead agency, the NRC is ultimately responsible for completing the NEPA process and will determine and document the scope of the proposed agency action. When a joint lead relationship is established pursuant to NEPA section 107(a)(1)(B), the NRC and the other joint lead agency or agencies are collectively responsible for completing the NEPA process. These agreements should be documented in memoranda of understanding or other means of documentation and should be signed by representatives of each agency. If the NRC and another Federal agency are unable to agree on which agency will be the lead agency, the affected agency may request that CEQ designate a lead agency pursuant to NEPA section 107(a)(5). In accordance with NEPA section 102(2)(C), during the preparation of an environmental impact statement, the NRC is required to consult with and obtain comments of any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact of the action or is authorized to develop and enforce environmental standards that govern proposed agency action. The NRC will conduct this consultation during the comment period opened for the notice of intent to prepare an environmental impact statement. The NRC will address any substantive comments that are within the scope of the proposed agency action, as appropriate.

15. Conforming Changes and Editorial Corrections

The NRC is proposing to make conforming changes to 10 CFR parts 2, 30, 40, 50, 52, 53, 54, 61, 70, 72, 76, and 110 to ensure that the environmental requirements discussion in those sections reflected the revised requirements in 10 CFR part 51 and to make editorial corrections to citations.

B. Why do the requirements need to be revised?

The NRC must revise its requirements in 10 CFR part 51 to comply with Presidential directives in E.O. 14300 to (1) streamline implementation of NEPA, (2) alleviate unnecessary regulatory burden, and (3) expand flexibilities for applicants and licensees while complying with environmental requirements. The proposed rulemaking

also addresses amendments to NEPA made by the FRA and OBBBA, recent case law relevant to the interpretation of NEPA, and Commission direction in SRM-SECY-24-0046 and SRM-COMSECY-25-0007.

C. Whom would this action affect?

The regulatory changes proposed in this rule would affect all persons and entities conducting activities subject to regulation by the NRC or potentially affected by NRC regulated activities. This includes, but is not limited to, applicants for permits, licenses, license amendments, license renewals, certifications, and other forms of regulatory approval; petitioners for rulemaking; and recipients of NRC grants, cooperative agreements, or other financial assistance.

D. When would this action take effect?

The requirements proposed in this rule would take effect 30 days from the date of publication of the final rule. New applications submitted to the NRC must comply with the requirements within six months from the effective date of the final rule. No environmental report or any supplement to an environmental report filed with the NRC, and no EA, or EIS or finding of no significant impact or any supplement to any of the foregoing issued prior to the effective date of the final rule, need be redone and no notice of intent to prepare an EIS or notice of availability of these environmental documents need be republished solely by reason of the promulgation of these revisions to 10 CFR part 51.

V. Specific Request for Comment

The NRC is seeking advice and recommendations from the public on the proposed rule. The NRC is particularly interested in comments with clear justifications and supporting rationale from the public on the following:

1. Considering the NRC's substantive statutory authority and the NRC's obligations under NEPA as amended by the FRA and OBBBA and as shaped by recent case law and E.O.s, has the NRC proposed removing the assessment of any environmental impacts from the scope of its NEPA reviews that should continue to be addressed (in Table S-3, Table S-4, appendix B, or appendix C to 10 CFR part 51; or as discussed in the associated draft staff guidance, NUREG-2270, "Environmental Review Guidance for U.S. Nuclear Regulatory Commission Licensing Actions")? Beyond radiological impacts, are there other environmental effects that have a close causal relationship to an NRC licensing

decision and that are not remote in time, geographically separate, or the result of an attenuated causal chain that the NRC should consider in its environmental reviews? Please provide detailed rationales.

2. E.O. 14154 directs all agencies, consistent with applicable law, to "prioritize efficiency and certainty over any other objectives." Does the proposed rule prioritize efficiency and certainty over other objectives in a manner consistent with applicable law? Are there potential unintended consequences or increases in regulatory uncertainty that could result from the proposed changes in this rule, such as the need for additional NEPA reviews by other agencies? Please identify the regulatory requirement with your response and be as specific as possible regarding potential unintended consequences or increases in uncertainty.

3. Are there NEPA procedures that the NRC proposes to eliminate from the regulations—either by deletion or by moving them into guidance—that should be retained in the regulations? If so, why? Please identify the specific procedures, regulatory requirement, or other related items with your response.

4. What additional specific licensing or regulatory actions should the NRC consider for categorical exclusion from further NEPA review and why? Please describe actions you believe normally result in no significant environmental impacts and explain the basis for your recommendation. Furthermore, please provide any parameters that clarify limiting characteristics for each categorical exclusion. Please also provide comments on the newly proposed categorical exclusions in terms of whether the actions would normally result in no significant environmental impacts.

5. What additional NRC actions should the NRC consider developing generic environmental documents for (e.g., technology- or application-specific) that could further streamline future environmental reviews?

6. Considering the NRC's obligations under NEPA as amended by FRA and OBBBA and as shaped by recent case law and E.O.s, are there additional approaches that the NRC should consider to preserve meaningful public engagement in the NRC's environmental review process—either within the context of NEPA or at other stages during review of an application (e.g., pre-application engagement, ad hoc public briefings, listening sessions, etc.)? If so, what are they?

7. What additional information on the procedures for applicant-prepared EAs

and EISs can the NRC provide to inform prospective applicants' decision on whether to pursue that process? Should the NRC consider moving more information on applicant-prepared EAs and EISs from the regulation to the guidance document to allow for greater flexibility in the program? What changes, if any, should the NRC consider to make the process for applicant-prepared NEPA documentation clearer or more efficient? Do the requirements in § 51.46 appropriately balance agency compliance with NEPA with the goal of realizing efficiencies for applicants?

8. How can interagency coordination on environmental matters be improved to foster more effective and efficient environmental reviews that meet statutory requirements under NEPA and other environmental statutes such as the National Historic Preservation Act (NHPA), Coastal Zone Management Act, and Endangered Species Act, consistent with the NRC's statutory authority? What effect, if any, does the NRC's proposal to narrow the scope of its environmental reviews have on interagency coordination? How might the proposed changes affect NHPA section 106 consultations with State Historic Preservation Officers, Indian Tribes, and interested parties including the public? The NRC is particularly interested in feedback from Tribes and state agencies on these matters.

9. Can the NRC improve the organization, accessibility, or usability of its draft consolidated NEPA guidance document, NUREG-2270, issued with this rule? Should additional information be provided as to how an applicant would use the guidance document for common licensing actions?

10. What environmental topics or issues are missing from the NRC's draft NEPA guidance document, NUREG-2270?

11. Given the new draft consolidated environmental review guidance, NUREG-2270, should the NRC sunset or retain existing NEPA guidance (e.g., NUREG-1555, "Environmental Standard Review Plan," NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs", Regulatory Guide 4.2, "DG-4037 (RG 4.2 Rev 5) Preparation of Environmental Reports for Nuclear Power Stations")?

12. It is not feasible for the NRC to prepare separate environmental documents for both actions in response to a complete application requesting both an LWA and a CP or COL in the same timeframe (e.g., one year for EAs) as currently provided in § 51.76(a). Therefore, the NRC is proposing that it

would prepare a single environmental document to address the full CP or COL requested, which would also provide the required NEPA review of actions under an LWA. What other feasible alternatives or procedural changes could address these timeframes to ensure efficient, timely, and predictable decisionmaking for LWAs requested as part of a complete application for a CP or COL?

VI. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. Therefore, in accordance with section 605(b), the NRC is not preparing a regulatory flexibility certification analysis. The rule will in fact apply to some small entities that are among the NRC licensees, applicants, and petitioners for rulemaking. The rule will revise the existing NEPA regulations, however, it will impose no new burden on those small entities.

VII. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. This proposed rule is considered to be a deregulatory action that would alleviate unnecessary regulatory burden and expand flexibilities for applicants and licensees, while maintaining compliance with environmental requirements. Over a 10-year analysis period (fiscal year 2027–2036), the proposed revisions to NEPA requirements are projected to generate cumulative, undiscounted cost savings of \$134.8 million. Using 2024 as the base year, the net present value of these savings is estimated at \$108.4 million when discounted at 3 percent, or \$82.7 million when discounted at 7 percent. The annualized cost savings would be \$7.9 million discounted at 3 percent, or \$7.3 million discounted at 7 percent. These figures represent net savings, as the one-time implementation costs are expected to be minimal.

In addition, the NRC estimates cost savings in 2024 dollars to be \$8.10 million discounted at 7 percent in perpetuity.

The NRC requests public comment on the draft regulatory analysis, including the assumptions in the uncertainty analysis and the numbers presented in Appendix A. The regulatory analysis is available as indicated in the “Availability of Documents” section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

VIII. Backfitting and Issue Finality

The NRC has determined that the proposed changes to 10 CFR part 51 do not meet the definition of “backfitting” in § 50.109, § 53.1390, § 70.76, or § 72.62, all entitled “Backfitting,” or affect the issue finality provisions in 10 CFR parts 52 or part 53 because the proposed changes relate to procedures for future NRC activities and do not involve changes to existing requirements or impose new requirements on current applicants or licensees.

IX. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

X. National Environmental Policy Act

NEPA does not require agencies to prepare a NEPA analysis before establishing or updating agency procedures for implementing NEPA. Agency NEPA implementing procedures are not themselves subject to NEPA (*Heartwood v. U.S. Forest Serv.*, 230 F.3d 947, 954–955 (7th Cir. 2000)). Therefore, the NRC did not further conduct a NEPA analysis of this proposed rule.

XI. Paperwork Reduction Act

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections.

Type of submission: New.

The title of the information collection: Implementation of the National Environmental Policy Act Proposed Rule.

OMB Approval Number(s): (3150–0021).

The form number if applicable: N/A.

How often the collection is required or requested: Justification for categorical exclusions, environmental report, or applicant- or petitioner-prepared EAs or EISs are required upon submittal of an application for a combined license, construction permit, operating license, operating license renewal, early site permit, design certification, decommissioning or license termination

review, or manufacturing license, or upon submittal of a petition for rulemaking.

Who will be required or asked to respond: All persons and entities seeking action from the NRC. This includes, but is not limited to, applicants for permits, licenses, license amendments, license renewals, certifications, and other forms of regulatory approval; petitioners for rulemaking; and recipients of NRC grants, cooperative agreements, or other financial assistance.

An estimate of the number of annual responses: 21.

The estimated number of annual respondents: 21.

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 44,016.

Abstract: The NRC is proposing to amend its regulations in 10 CFR part 51 to: (1) streamline implementation of the National Environmental Policy Act of 1969, as amended (NEPA), (2) alleviate unnecessary regulatory burden, and (3) expand flexibilities for applicants and licensees while complying with environmental requirements. The revisions are necessitated by and consistent with Executive Order (E.O.) 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” E.O. 14154, “Unleashing American Energy,” and Commission direction in SRM–SECY–25–0007, “Withdrawing the Environmental Justice Policy Statement and Environmental Justice Strategy,” dated April 10, 2025, and SRM–SECY–24–0046, “Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments,” dated July 28, 2025. During its comprehensive review and revision of the 10 CFR part 51 regulations, the NRC identified certain information collection requirements that should be amended under this proposed rule to streamline the regulations and improve efficiency.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your response.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.

3. Is there a way to enhance the quality, utility, and clarity of the

information to be collected? Please explain your response.

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the Office of Management and Budget (OMB) clearance package and proposed rule are available in the “Availability of Documents” section of this document or may be viewed free of charge by contacting the NRC’s Public Document Room reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. You may obtain information and comment on submissions related to the OMB clearance package by searching on <https://www.regulations.gov> under Docket ID NRC–2025–0478.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the above issues, by the following method:

Federal rulemaking website: Go to <https://www.regulations.gov> and search for Docket ID NRC–2025–0478. Submit comments by August 6, 2026.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XII. Executive Orders

The following are Executive orders that are related to this proposed rule:

A. Executive Order 12866: Regulatory Planning and Review (as amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is a

significant regulatory action. Accordingly, NRC submitted this proposed rule to OIRA for review. The NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(B) of E.O. 12866. More can be found in Section VII, of this document, “Regulatory Analysis.”

B. Executive Order 14154: Unleashing American Energy

The NRC has examined this proposed rule and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is a deregulatory action as defined by E.O. 14192. Details on the estimated costs of this proposed rule can be found in Section VII, of this document, “Regulatory Analysis.”

D. Executive Order 14270: Zero-Based Regulatory Budgeting To Unleash American Energy

E.O. 14270, “Zero-Based Regulatory Budgeting to Unleash American Energy,” requires the NRC to insert a conditional sunset date into all new or amended NRC regulations provided the regulations are (1) promulgated under the Atomic Energy Act of 1954, as amended (AEA), the Energy Reorganization Act of 1974, as amended, or the Nuclear Waste Policy Act of 1982, as amended (NWP); (2) not statutorily required; and (3) not part of the NRC’s permitting regime. The NRC determined that the regulatory changes proposed in this rule are necessary for compliance with NEPA. Therefore, the NRC views this rulemaking to be outside the scope of Executive Order 14270 and did not insert conditional sunset dates for the regulatory changes in this proposed rule.

XIII. Availability of Guidance

The NRC is issuing new draft guidance NUREG–2270, “Environmental Review Guidance for U.S. Nuclear Regulatory Commission Licensing Actions,” for the implementation of the proposed requirements in this rulemaking. The draft guidance is available as indicated in the “Availability of Documents” section of this document. You may obtain information and comment submissions related to the draft guidance by searching on <https://www.regulations.gov> under Docket ID NRC–2025–0478.

The draft guidance document provides general procedures for determining the level of environmental review and documentation required for NRC actions. The draft guidance document is written in general terms to accommodate the NRC’s broad variety of regulatory actions and regulated facilities. The draft guidance document provides staff, licensees, prospective applicants, and petitioners for rulemaking with methods to meet the requirements established by legislation and the 10 CFR part 51 regulations. The guidance will not be a substitute for legislation and regulations, and compliance with the guidance document is not required. Methods different from those set out in the guidance document will be acceptable if they provide a basis for concluding that the NRC’s regulations have been met.

You may submit comments on this draft regulatory guidance by the methods outlined in the **ADDRESSES** section of this document.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./web link/ Federal Register citation
SECY–24–0046, “Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments,” dated March 30, 2024.	ML24078A013 (Package).
SRM–SECY–25–0007, “Withdrawing the Environmental Justice Policy Statement and Environmental Justice Strategy,” dated April 10, 2025.	ML25100A106.
SRM–SECY–24–0046, “Implementation of the Fiscal Responsibility Act of 2023 National Environmental Policy Act Amendments,” dated July 28, 2025.	ML25209A050.
Draft Regulatory Analysis for Implementation of the National Environmental Policy Act Proposed Rule, June 2026.	ML26176A426.
NUREG–2270, “Environmental Review Guidance for U.S. Nuclear Regulatory Commission Licensing Actions,” Draft for Comment, June 2026.	ML25269A176.
OMB Supporting Statement Package for the Implementation of the National Environmental Policy Act Requirements Proposed Rule (OMB Clearance No. 3150–0021).	ML25272A091 (Package).
U.S. Nuclear Regulatory Commission Written Record of Support of Proposed Amendments to 10 CFR 51.22 in Accordance with Executive Order 14300 and SRM–SECY–24–0046.	ML26176A427.
Final rule, “Environmental Review for Renewal of Nuclear Power Plant Operating Licenses,” dated June 5, 1996.	61 FR 28467.

Document	ADAMS accession No./web link/ Federal Register citation
Final rule, "Environmental Review for Renewal of Nuclear Power Plant Operating Licenses," dated December 18, 1996.	61 FR 66543.
Final rule, "Limited Work Authorizations for Nuclear Power Plants," dated October 9, 2007	72 FR 57416.
Final rule, "Licenses, Certifications, and Approvals for Materials Licensees," dated September 15, 2011.	76 FR 56961.
Proposed rule, "Licensing Requirements for Microreactors and Other Reactors with Comparable Risk Profiles," dated May 1, 2026.	91 FR 23628.
Proposed rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," dated October 31, 2024.	89 FR 86918.
Final rule, "Categorical Exclusions from Environmental Review," dated March 30, 2026	91 FR 155519.
Final rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," dated March 30, 2026.	91 FR 15696.
Correction notice, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors; Correction," dated April 13, 2026.	91 FR 18772.
Final rule, "Generic Environmental Impact Statement for Licensing of New Nuclear Reactors," dated April 24, 2026.	91 FR 2239.
NUREG-1437, Volume 1, Rev 2, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants—Final Report," dated August 31, 2024.	ML24086A526.
NUREG-2249, "Generic Environmental Impact Statement for Licensing of New Nuclear Reactors" dated April 2026.	ML25324A130.
Policy statement withdrawal, "Policy Statement on the Treatment of Environmental Justice Matters in NRC Regulatory and Licensing Actions; Environmental Justice Strategy," dated April 30, 2025.	90 FR 17887.
Interim final rule, "Removal of National Environmental Policy Act Implementing Regulations," dated February 25, 2025.	90 FR 10610.
"Memorandum for Heads of Departments and Agencies: Implementation of the National Environmental Policy Act, Appendix 1—Agency NEPA Procedures Template," dated September 29, 2025.	https://ceq.doe.gov/docs/ceq-regulations-and-guidance/Appendix-1-Agency-NEPA-Procedures-Template.pdf .
Executive Order 14154, "Unleashing American Energy," dated January 29, 2025	90 FR 8353.
Executive Order 14173, "Ending Illegal Discrimination and Restoring Merit-Based Opportunity," dated January 31, 2025.	90 FR 8633.
Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," dated May 29, 2025.	90 FR 22587.
Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 16, 1994.	59 FR 7629.
Executive Order 11991, "Relating to Protection and Enhancement of Environmental Quality," dated May 25, 1977.	42 FR 26967.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at <https://www.regulations.gov> under Docket ID NRC-2025-0478. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC-2025-0478); (2) click the "Subscribe" link; and (3) enter an email address and click on the "Subscribe" link.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Confidential business information, Environmental protection, Freedom of information, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalties, Fusion, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 40

Criminal penalties, Exports, Government contracts, Hazardous materials transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Inspection, Issue finality, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 53

Administrative practice and procedure, Antitrust, Backfitting, Construction permit, Combined license, Classified information, Criminal penalties, Early site permit, Emergency planning, Fees, Fire prevention, Fire protection, Inspection, Intergovernmental relations, Limited

work authorization, Manufacturing license, Nuclear power plants and reactors, Operating license, Penalties, Prototype, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Standard design, Standard design certification, Training programs.

10 CFR Part 54

Administrative practice and procedure, Age-related degradation, Backfitting, Classified information, Criminal penalties, Environmental protection, Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 61

Criminal penalties, Hazardous waste, Indians, Intergovernmental relations, Low-level waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Waste treatment and disposal, Whistleblowing.

10 CFR Part 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 76

Certification, Criminal penalties, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Special nuclear material, Uranium, Uranium enrichment by gaseous diffusion.

10 CFR Part 110

Administrative practice and procedure, Classified information, Criminal penalties, Exports, Imports, Intergovernmental relations, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Scientific equipment.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended;

the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to amend 10 CFR parts 2, 30, 40, 50, 51, 52, 53, 54, 61, 70, 72, 76, and 110.

PART 2—AGENCY RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 2 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 29, 53, 62, 63, 81, 102, 103, 104, 105, 161, 181, 182, 183, 184, 186, 189, 191, 234 (42 U.S.C. 2039, 2073, 2092, 2093, 2111, 2132, 2133, 2134, 2135, 2201, 2231, 2232, 2233, 2234, 2236, 2239, 2241, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 114(f), 134, 135, 141 (42 U.S.C. 10134(f), 10154, 10155, 10161); Administrative Procedure Act (5 U.S.C. 552, 553, 554, 557, 558); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note. Section 2.205(j) also issued under Sec. 31001(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note).

■ 2. In § 2.101:

■ a. Revise paragraphs (a)(3)(ii), (a)(4), and (b);

■ b. In paragraphs (a)(3)(i), (e)(1), (e)(5), remove the phrase “subpart A of”;

■ c. In paragraphs (a)(3)(iii), (f), (f)(1), (f)(2)(i)(D), and (f)(4), remove the phrase “environmental report” and add in its place the phrase “information required under part 51 of this chapter”;

■ d. In paragraph (a)(9)(ii)(a–1), remove the phrase “§ 51.20(b)” and add in its place the phrase “part 51”;

The revisions read as follows:

§ 2.101 Filing of application.

(a) * * *

(3) * * *

(ii) Serve a copy on the chief executive of the municipality in which the facility or site which is the subject of an early site permit is to be located or, if the facility or site which is the subject of an early site permit is not to be located within a municipality, on the chief executive of the county, containing as applicable, the docket number of the application; a brief description of the proposed site and facility; the location of the site and facility; the name, address, telephone number, and email address (if available) of the applicant’s representative who may be contacted for further information; notification if an environmental document will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, the applicant will transmit a copy of the application and environmental information required

under part 51 of this chapter, to the executive who makes the request. In complying with the requirements of this paragraph, the applicant should not make public distribution of those parts of the application subject to § 2.390(d). The applicant shall submit to the Director, Office of Nuclear Reactor Regulation, an affidavit that service of the notice of availability of the application has been completed along with a list of names and addresses of those executives upon whom the notice was served; and

* * * * *

(4) The tendered application for a construction permit, operating license, early site permit, standard design approval, combined license, or manufacturing license will be formally docketed upon receipt by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, of the required additional copies. Distribution of the additional copies shall be deemed to be complete as of the time the copies are deposited in the mail or with a carrier prepaid for delivery to the designated addresses. The date of docketing shall be the date when the required copies are received by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate. Within 10 days after docketing, the applicant shall submit to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, an affidavit that distribution of the additional copies to Federal, State, and local officials has been completed in accordance with requirements of this chapter and written instructions furnished to the applicant by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate. Amendments to the application and environmental information required under part 51 of this chapter shall be filed and distributed and an affidavit shall be furnished to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, in the same manner as for the initial application. If it is determined that all or any part of the tendered application and/or environmental information required under part 51 of this chapter is incomplete and therefore not acceptable for processing, the applicant will be informed of this determination, and the

respects in which the document is deficient.

* * * * *

(b) After the application has been docketed, each applicant for a license for receipt of waste radioactive material from other persons for the purpose of commercial disposal by the waste disposal licensee, except applicants under part 61 of this chapter, which must comply with paragraph (f) of this section, shall serve a copy of the application and environmental information required under part 51 of this chapter, as appropriate, on the chief executive of the municipality in which the activity is to be conducted or, if the activity is not to be conducted within a municipality on the chief executive of the county, containing the docket number of the application; a brief description of the proposed site and facility; the location of the site and facility as primarily proposed and alternatively listed; the name, address, telephone number, and email address (if available) of the applicant's representative who may be contacted for further information; notification if an environmental document will be issued by the Commission and will be made available upon request to the Commission; and notification that if a request is received from the appropriate chief executive, and the applicant will transmit a copy of the application and environmental report or draft environmental document, to the executive who makes the request. In complying with the requirements of this paragraph the applicant should not make public distribution of those parts of the application subject to § 2.390(d). The applicant shall submit to the Director, Office of Nuclear Material Safety and Safeguards, an affidavit that service of the notice of availability of the application or environmental information required under part 51 of this chapter has been completed along with a list of names and addresses of those executives upon whom the notice was served.

* * * * *

■ 3. In § 2.309, revise paragraphs (f)(1)(vi) and (f)(2) to read as follows:

§ 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

* * * * *

(f) * * *

(1) * * *

(vi) In a proceeding other than one under § 52.103 or § 53.1452 of this chapter provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact. This

information must include references to specific portions of the application (including any requirements pursuant to 10 CFR part 51 and the safety report) that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief. This information also must clearly indicate whether the petitioner is disputing the adequacy of the information in the application, is asserting that the application fails to contain information on a relevant matter as required by law, or both; and

* * * * *

(2) Contentions must be based on documents or other information available at the time the petition is to be filed, such as the application, supporting safety analysis report, environmental report, draft environmental document, or other supporting document filed by an applicant or licensee, or otherwise available to a petitioner. On issues arising under the National Environmental Policy Act, participants shall file contentions based on the applicant's environmental report or draft environmental document. Participants may file new or amended environmental contentions after the deadline in paragraph (b) of this section (e.g., based on the NRC environmental document) if the associated motion for leave to file complies with the requirements in paragraph (c) of this section.

* * * * *

■ 4. In § 2.332, revise paragraph (d) to read as follows:

§ 2.332 General case scheduling and management.

* * * * *

(d) Effect of NRC staff's schedule on scheduling order. In establishing a schedule, the presiding officer shall take into consideration the NRC staff's projected schedule for completion of its safety and environmental requirements under 10 CFR part 51 to ensure that the hearing schedule does not adversely impact the staff's ability to complete its reviews in a timely manner. Hearings on safety issues may be commenced before publication of the NRC staff's safety evaluation upon a finding by the presiding officer that commencing the hearings at that time would expedite the proceeding. Where an environmental impact statement (EIS) is involved, hearings on environmental issues addressed in the EIS may not commence before the issuance of the final EIS. In

addition, discovery against the NRC staff on safety or environmental issues, respectively, should be suspended until the staff has issued the SER or EIS, unless the presiding officer finds that the commencement of discovery against the NRC staff (as otherwise permitted by the provisions of this part) before the publication of the pertinent document will not adversely affect completion of the document and will expedite the hearing.

■ 5. In § 2.337, revise paragraphs (g)(1), (g)(2)(iv) and (g)(3)(iv) to read as follows:

§ 2.337 Evidence at a hearing.

* * * * *

(g) * * *

(1) *Facility construction permits.* In a proceeding involving an application for construction permit for a production or utilization facility, the NRC staff shall offer into evidence any report submitted by the ACRS in the proceeding in compliance with section 182(b) of the Act, any safety evaluation prepared by the NRC staff, and any categorical exclusion documentation or environmental document prepared in the proceeding under part 51 of this chapter by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, or their designee.

(2) * * *

(iv) Any categorical exclusion documentation or environmental document prepared in the proceeding under part 51 of this chapter by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, or their designee if there is any, but only if there are admitted contentions or contested matters with respect to the adequacy of the categorical exclusion, environmental impact statement, or environmental assessment.

* * * * *

(3) * * *

(iv) Any categorical exclusion documentation or environmental document in the proceeding under part 51 of this chapter by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, or their designee if there is any, but only if there are admitted contentions or contested matters with respect to the adequacy or applicability of the categorical exclusion or adequacy of the environmental document.

§ 2.605 [Amended]

■ 6. In § 2.605, remove paragraph (b)(1) and redesignate paragraph (b)(2) as paragraph (b)(1) and remove and reserve (b)(2).

§ 2.606 [Amended]

■ 7. In § 2.606, wherever it may appear, remove the phrase “subpart A”.

§ 2.625 [Amended]

■ 8. In § 2.625, remove paragraph (b)(1) and redesignate paragraph (b)(2) as paragraph (b)(1) and remove and reserve (b)(2).

§ 2.627 [Amended]

■ 9. In § 2.627, wherever it may appear, remove the phrase “subpart A”.

§ 2.649 [Amended]

■ 10. In § 2.649, remove the phrase “subpart A of”.

■ 11. In § 2.802, revise paragraph (c)(1)(viii) to read as follows:

§ 2.802 Petition for rulemaking—requirements for filing.

* * * * *

(c) * * *

(1) * * *

(viii) Provide any environmental information required under part 51 of this chapter.

* * * * *

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

■ 12. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

§ 30.32 [Amended]

■ 13. In § 30.32, in paragraph (f) wherever it may appear, remove the phrase “subpart A”.

§ 30.33 [Amended]

■ 14. In § 30.33, in paragraph (a)(5) remove the phrase “subpart A of”.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

■ 15. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act secs. 11(e)(2), 62, 63, 64, 65, 81, 161, 181, 182, 183, 186, 193, 223, 234, 274, 275 (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2231, 2232, 2233, 2236, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act secs. 201, 202, 206 (42

U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, Pub. L. 109–59, 119 Stat. 594 (2005).

Section 40.7 also issued under Energy Reorganization Act sec. 211, Pub. L. 95–601, sec. 10, as amended by Pub. L. 102–486, sec. 2902 (42 U.S.C. 5851). Section 40.31(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152). Section 40.46 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234). Section 40.71 also issued under Atomic Energy Act sec. 187 (42 U.S.C. 2237).

■ 16. In § 40.31, in paragraph (f), wherever it may appear, remove the phrase “subpart A” and revise paragraph (k) to read as follows:

§ 40.31 Application for specific licenses.

* * * * *

(k) A license application for a uranium enrichment facility must be accompanied by the environmental information required under part 51 of this chapter.

* * * * *

§ 40.32 [Amended]

■ 17. In § 40.32, in paragraph (e) remove the phrase “subpart A of”.

■ 18. In appendix A to part 40, in Criterion 3 remove the phrase “reports” and add in its place the phrase “information required by part 51 of this chapter”; and revise Criterion 9(c) to read as follows:

Appendix A to Part 40—Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores Processed Primarily for Their Source Material Content

* * * * *

Criterion 9: * * *

(c) The licensee shall submit this plan in conjunction with the environmental information required by part 51 of this chapter. The plan must include a signed original of the financial instrument obtained to satisfy the surety arrangement requirements of this criterion (unless a previously submitted and approved financial instrument continues to cover the cost estimate for decommissioning). The surety arrangement must also cover the cost estimate and the payment of the charge for long-term surveillance and control required by Criterion 10 of this section.

* * * * *

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131,

2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note.

■ 20. In § 50.10, revise paragraphs (d)(3)(ii), (e)(1)(i), (e)(1)(ii) and (f) to read as follows:

§ 50.10 License required; limited work authorization.

* * * * *

(d) * * *

(3) * * *

(iii) Environmental information required by part 51 of this chapter.

* * * * *

(e) * * *

(1) * * *

(i) The NRC staff issues the final documentation required under NEPA and all applicable Federal environmental consultations have been complete, in accordance with part 51 of this chapter;

(ii) The presiding officer makes the finding in part 51 of this chapter, as applicable;

* * * * *

(f) Effect of limited work authorization. Any activities undertaken under a limited work authorization are entirely at the risk of the applicant and, except as to the matters determined under paragraph (e)(1) of this section, the issuance of the limited work authorization has no bearing on the issuance of a construction permit or combined license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act. The categorical exclusions, environmental assessment, or environmental impact statement for a construction permit or combined license application for which a limited work authorization was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of limited work authorization in determining the proposed action (*i.e.*, issuance of the construction permit or combined license).

* * * * *

■ 21. In § 50.30, revise paragraph (f) to read as follows:

§ 50.30 Filing of application; oath or affirmation.

* * * * *

(f) Environmental information. An application for a construction permit, operating license, early site permit, combined license, or manufacturing

license for a nuclear power reactor, testing facility, fuel reprocessing plant, or other production or utilization facility whose construction or operation may be determined by the Commission to have a significant impact in the environment, shall be accompanied by an environmental information required under part 51 of this chapter.

* * * * *

■ 22. Revise and republish § 50.36b to read as follows:

§ 50.36b Environmental conditions.

(a) Each construction permit under this part, each early site permit under part 52 of this chapter, and each combined license under part 52 of this chapter may include conditions to protect the environment during construction. These conditions are to be set out in an attachment to the permit or license, which is incorporated in and made a part of the permit or license. These conditions will be derived from information contained in the environmental information submitted pursuant to part 51 this chapter as analyzed and evaluated by the NRC, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a production or utilization facility, including a combined license under part 52 of this chapter, and each license for a nuclear power reactor facility that no longer authorizes operation of the reactor under § 50.82(a)(1) or § 52.110(a) of this chapter has been submitted, which is of a type described in § 50.21(b)(2) or (3) or § 50.22 or is a testing facility, may include conditions to protect the environment during operation and decommissioning. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental information submitted pursuant to part 51 of this chapter as analyzed and evaluated by the NRC, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

§ 50.40 [Amended]

■ 23. In § 50.40, in paragraph (d) remove the phrase “subpart A of”.

■ 24. In § 50.82:

■ a. In paragraph (a)(4)(i), remove the phrase “environmental impact statements” and add in its place the phrase “environmental documents or categorical exclusions”; and

■ b. Revise paragraph (a)(9)(ii)(G).

The revision reads as follows:

§ 50.82 Termination of license.

(a) * * *

(9) * * *

(ii) * * *

(G) A supplement to the environmental information required under part 51 of this chapter, describing any new information or significant environmental change associated with the licensee’s proposed termination activities.

* * * * *

■ 25. In § 50.83, revise paragraph (d)(3) to read as follows:

§ 50.83 Release of part of a power reactor facility or site for unrestricted use.

* * * * *

(d) * * *

(3) A supplement to the environmental information required under part 51 of this chapter, describing any new information or significant environmental change associated with the licensee’s proposed release activities.

* * * * *

■ 26. In § 50.135, revise paragraph (d)(3) to read as follows:

§ 50.135 Renewal of non-power production or utilization facility licenses issued under § 50.22 and testing facility licenses.

* * * * *

(d) * * *

(3) Each application must include the environmental information required by part 51 of this chapter.

* * * * *

Appendix N to Part 50 [Amended]

■ 27. In Appendix N to part 50, in paragraph 2., remove the phrase “§ 51.50” and add in its place the phrase “part 51” and in paragraph 3., remove the phrase “§ 51.53” and add in its place the phrase “part 51”.

Appendix Q to Part 50 [Amended]

■ 28. Amend appendix Q to part 50 by:

■ a. Wherever it may appear, remove the phrase “§ 51.20b” and add in its place the phrase “part 51”;

■ b. In paragraph 7., remove the phrase “subpart A of”; and

■ c. Remove paragraph 7.(a) and redesignate paragraph 7.(b) as paragraph 7.(a) and remove and reserve 7.(b).

■ 29. Revise and republish part 51 to read as follows:

PART 51—IMPLEMENTATION OF THE NATIONAL ENVIRONMENTAL POLICY ACT

Sec.

51.1 Scope.

51.4 Definitions.

51.6 Specific exemptions.

Subpart A—[Reserved]

51.13 Emergencies.

51.15 Deadlines.

51.17 Information collection requirements; OMB approval.

51.19 Determination of when NEPA applies.

51.20 Determination of the appropriate level of NEPA review.

51.22 Establishing categorical exclusions.

51.23 Environmental impacts of continued storage of spent nuclear fuel beyond the licensed life for operation of a reactor.

51.30 Environmental assessment.

51.31 Determinations based on environmental assessment.

51.32 Finding of no significant impact.

51.41 Requirement to submit environmental information.

51.45 Environmental report and information.

51.46 Applicant-prepared draft environmental documents.

51.51 Uranium fuel cycle environmental data—Table S-3.

51.52 Environmental effects of transportation of fuel and waste—Table S-4.

51.60 Environmental report—materials licenses.

51.62 Environmental report—land disposal of radioactive waste licensed under 10 CFR part 61.

51.67 Environmental information concerning geologic repositories.

51.70 Environmental impact statement—general.

51.71 Environmental impact statements—contents.

51.75 Environmental documents—construction permit, early site permit, or combined license.

51.76 Environmental documents—limited work authorization.

51.92 Supplement to the final environmental document.

51.95 Postconstruction environmental document.

51.101 Limitations on actions.

51.102 Documentation of decision.

51.109 Public hearings in proceedings for issuance of materials license with respect to a geologic repository.

Appendix A—[Reserved]**Appendix B 10 CFR Part 51—
Environmental Effect of Renewing the
Operating License of a Nuclear Power
Plant****Appendix C of Part 51—Environmental
Effect of Issuing a Permit or License for
a New Nuclear Reactor****Subpart B—[Reserved]**

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National Environmental Policy Act of 1969 (42 U.S.C. 4321–4336c, 4336e); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note. 51.30, 51.60, 51.80, and 51.97 also issued under Nuclear Waste Policy Act secs. 135, 141, 148 (42 U.S.C. 10155, 10161, 10168). Section 51.22 also issued under Atomic Energy Act sec. 274 (42 U.S.C. 2021) and under Nuclear Waste Policy Act sec. 121 (42 U.S.C. 10141). Sections 51.67, and 51.109 also issued under Nuclear Waste Policy Act sec. 114(f) (42 U.S.C. 10134(f)).

§ 51.1 Scope.

This part establishes procedures that the NRC will use to comply with the National Environmental Policy Act (NEPA) of 1969, as amended, in the conduct of its domestic licensing and related regulatory functions. These regulations do not apply to export licensing matters within the scope of part 110 of this chapter, or to any environmental effects which NRC's domestic licensing and related regulatory functions may have upon the environment of foreign nations. Subject to these limitations, the regulations in this part implement the National Environmental Policy Act of 1969, as amended.

§ 51.4 Definitions.

(a) As used in this part and for the purposes of compliance with NEPA: *Act* means the Atomic Energy Act of 1954 (Pub. L. 83–703, 68 Stat. 919) including any amendments thereto.

Authorization means any license, permit, approval, finding, determination, or other administrative decision issued by an agency that is required or authorized under Federal law in order to implement a proposed agency action.

Commission means the Nuclear Regulatory Commission or its authorized representatives.

Connected action means a separate Federal action within the authority of NRC that is closely related to the proposed agency action and should be addressed in a single environmental

document because the proposed agency action:

(1) Automatically triggers the separate Federal action, which independently would require the preparation of additional environmental documents;

(2) Cannot proceed unless the separate Federal action is taken previously or simultaneously; or

(3) Is an interdependent part of a larger Federal action that includes a separate Federal action, which mutually depend on the larger Federal action for their justification.

Construction has the meaning assigned in the part of this chapter that governs the authorized activity. For example, for an activity licensed under part 50 of this chapter, construction has the meaning provided in § 50.4 of this part.

DOE or Department of Energy means the U.S. Department of Energy or its duly authorized representatives.

Draft environmental document means an applicant-prepared environmental assessment or environmental impact statement that does not include an agency-prepared final impact finding, agency-prepared impact determination, or any other agency decision-making document.

Effects or impacts for the purposes of NEPA means changes to the human environment from the proposed agency action or alternatives that are reasonably foreseeable and have a reasonably close causal relationship to the proposed agency action or alternatives.

(1) Effects can include ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic (such as the effects on employment), social, or health effects. Effects appropriate for analysis under NEPA may be either beneficial or adverse, or both, with respect to these values.

(2) A “but for” causal relationship is insufficient to make an agency responsible for a particular effect under NEPA. Effects should generally not be considered if they are remote in time, geographically remote, or the product of a lengthy causal chain. Effects do not include those effects that the agency has no ability to prevent due to the limits of its regulatory authority, or that would occur regardless of the proposed agency action, or that would need to be initiated by a third party.

(3) The NRC's regulatory authority for production and utilization facilities and source, special, and byproduct materials is limited to effects or impacts with a reasonable nexus to radiological health and safety or the common defense and security. The NRC has additional

regulatory authority concerning certain byproduct material defined in § 11e.(2) of the Atomic Energy Act, typically licensed under part 40 of this chapter, to protect the public health and safety and the environment from radiological and nonradiological hazards associated with the processing and possession of such material.

Environmental report means a document submitted to the Commission by an applicant for a permit, license, or other form of permission, or an amendment to or renewal of a permit, license or other form of permission, or by a petitioner for rulemaking, to aid the Commission in complying with NEPA, and other environmental statutes, including but not limited to the Endangered Species Act, National Historic Preservation Act, Clean Air Act, Clean Water Act, Magnuson-Stevens Fishery Conservation and Management Act, National Marine Sanctuaries Act, and Marine Mammal Protection Act.

Head of the agency means the NRC's Executive Director for Operations.

Human environment means comprehensively the natural and physical environment and the relationship of Americans with that environment. (See also the definition of “effects” in this section.)

Mitigation means measures that avoid, minimize, or compensate for effects caused by a proposed agency action or alternatives as described in an environmental document or record of decision or another decision document and that have a nexus to those effects. While NEPA requires consideration of mitigation, it does not mandate the form or adoption of any mitigation. NEPA also does not provide authority to impose mitigation. Mitigation includes:

(1) Avoiding the impact altogether by not taking a certain action or parts of an action.

(2) Minimizing effects by limiting the degree or magnitude of the action and its implementation.

(3) Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.

(4) Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.

(5) Compensating for the impact by replacing or providing substitute resources or environments.

NEPA means the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321, *et seq.*).

NEPA process means all measures necessary for compliance with the requirements of section 2 and title I of NEPA § 102(2), 42 U.S.C. 4332(2).

Notice of Intent means a public notice that the NRC will prepare and consider an environmental document.

NRC means the Nuclear Regulatory Commission, the agency established by Title II of the Energy Reorganization Act of 1974, as amended.

NRC staff director means the Executive Director for Operations; the Director, Office of Nuclear Reactor Regulation; the Director, Office of Nuclear Material Safety and Safeguards; the Director, Office of Nuclear Regulatory Research; the Director, Office of Public Affairs; and the designee of any NRC staff director.

Publish and publication mean methods found by the agency to efficiently and effectively make environmental documents and information available for review by interested persons, including electronic publication.

Previously disturbed areas as used in § 51.22 of this part means areas that have been changed by development of the facility and remain altered by human activity such that they do not support important habitat or habitat to important species and no longer have the potential to yield historic and cultural resources. This includes the lateral and vertical extent of alteration from natural cover to a managed state.

Reasonable alternatives means a reasonable range of alternatives that are technically and economically feasible, within the scope of the NRC's statutory authority, and meet the purpose and need for the proposed agency action.

Reasonably foreseeable means sufficiently likely to occur such that a person of ordinary prudence would take it into account in reaching a decision.

Related action means an action undertaken by an agency, e.g., a permitting action, some other type of authorization action, an analysis required by statute, or the like, that bears a relationship to other actions undertaken by other agencies relevant to NEPA, e.g., that is an interdependent part of a larger action and depends on the larger action for its justification.

Responsible federal official means the NRC's Executive Director for Operations or their designee.

Scope consists of the range of actions, alternatives, and effects to be considered in an environmental document. The scope of an individual environmental document may depend on the document's relationships to other environmental documents.

Uranium enrichment facility means:

(1) Any facility used for separating the isotopes for uranium or enriching uranium in the isotope 235, except laboratory scale facilities designed or

used for experimental or analytical purposes only; or

(2) Any equipment or device, or important component part especially designed for such equipment or device, capable of separating the isotopes of uranium or enriching uranium in the isotope 235.

(b) Unless specifically defined in this section, the terms defined in NEPA § 111 as used in this part have the meaning assigned in NEPA § 111.

§ 51.6 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and are otherwise in the public interest.

Subpart A [Reserved]

§ 51.13 Emergencies.

Whenever emergency circumstances make it necessary and whenever, in other situations, the health and safety of the public may be adversely affected if mitigative or remedial actions are delayed, the Commission may take an action with significant environmental impact without observing the provisions of these regulations. In taking an action covered by this section, the Commission will consult with the Council on Environmental Quality as soon as feasible concerning appropriate alternative NEPA arrangements.

§ 51.15 Deadlines.

(a) Absent a project sponsor's payment of a fee for an expedited deadline pursuant to NEPA § 112:

(1) The NRC will complete an environmental assessment no later than one year after the sooner of:

(i) When the NRC determines that NEPA requires the preparation of an environmental assessment, or

(ii) The date the NRC issues a notice of intent to prepare an environmental assessment.

(iii) For applications and petitions for rulemaking, the NRC's determination that NEPA requires the preparation of an environmental assessment is made when a complete application or petition is docketed.

(2) The NRC will complete an environmental impact statement no later than two years after the sooner of:

(i) When the NRC determines that NEPA requires the preparation of an environmental impact statement, or

(ii) The date the NRC issues a notice of intent to prepare an environmental assessment or environmental impact statement.

(iii) For applications and petitions for rulemaking, the NRC's determination that NEPA requires the preparation of an environmental impact statement is made when a complete application or petition is docketed or when an environmental assessment resulting in a determination that an environmental impact statement is required is published.

(3) The completion date of an environmental assessment or environmental impact statement will be the date the NRC publishes the environmental document in the NRC's Agencywide Documents Access and Management System or the **Federal Register**.

(4) The environmental assessment and environmental impact statement will be published (unless the deadline is extended pursuant to the provision below), at the latest, on the day the deadline elapses, in as substantially complete form as is possible.

(5) If the NRC determines it is not able to meet the deadline prescribed by NEPA § 107(g)(1), the NRC will consult with the applicant, if any, pursuant to NEPA § 107(g)(2). After such consultation, if needed, it may establish a new deadline. The new deadline will provide only so much additional time as is necessary to complete such environmental assessment or environmental impact statement.

(b) Project sponsors intending to pay a fee for an expedited environmental impact statement or environmental assessment deadline pursuant to NEPA § 112 for which the NRC would be the lead agency should consult with the NRC before submitting a request to the Council on Environmental Quality. The NRC will use such consultation to assist the project sponsor in providing an accurate description of the project as it relates to the anticipated environmental impact statement or environmental assessment-associated costs.

§ 51.17 Information collection requirements; OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC 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. OMB has approved the information collection requirements contained in this part under control number 3150-0021.

(b) The approved information collection requirements in this part appear in §§ 51.6, 51.41, 51.45, 51.46, 51.51, 51.52, 51.60, 51.60(c), 51.62 and 51.62(d) of this part.

Preliminary Procedures

Classification of Licensing and Regulatory Actions

§ 51.19 Determination of when NEPA applies.

(a) The NRC will determine that NEPA does not apply to a proposed agency action when:

(1) The actions or decision do not result in final agency action under the Administrative Procedure Act, or other relevant statute that also includes a finality requirement;

(2) The proposed agency action or decision is exempted from NEPA by law;

(3) Compliance with NEPA would clearly and fundamentally conflict with the requirements of another provision of law;

(4) In circumstances where Congress by statute has prescribed decisional criteria with sufficient completeness and precision such that the NRC retains no residual discretion to alter its action based on the consideration of environmental factors, then that function of the NRC is nondiscretionary within the meaning of NEPA § 106(a)(4) or § 111(10)(B)(vii), and NEPA does not apply to the action in question;

(5) The proposed agency action is an action for which another statute's requirements serve the function of agency compliance with NEPA; or

(6) The proposed agency action is not a "major Federal action." The terms "major" and "Federal action," each have independent force. NEPA applies only when both of these two criteria are met. While such a determination is inherently bound up in the facts and circumstances of each individual situation, and is thus reserved to the judgment of the NRC in each instance, the NRC provides its officers and employees and the public at large with the following interpretive guidance:

(i) The NRC anticipates, on the basis of its experience, that the following types of actions are generally "major:" an application for a new license or permit; an application for renewal of a license or permit; significant amendments to licenses or permits; some exemption requests; rulemaking; decommissioning actions; license termination; and limited work authorizations.

(ii) NEPA does not apply to "non-Federal actions." Therefore, under NEPA § 111(10)(B)(i), NEPA does not

apply to actions with no or minimal Federal funding, or with no or minimal Federal involvement where a Federal agency cannot control the outcome of the project. A "but for" causal relationship is insufficient to make an agency responsible for a particular effect under NEPA. By the same token, minimal Federal funding or involvement does not by itself convert that action into a Federal action within the meaning of the language of the statute.

(7) In addition to the illustrative general categories set forth in NEPA § 111(10), the NRC has determined that the following non-exhaustive list of NRC actions are not subject to NEPA because NRC anticipates they do not meet the definition of a "major Federal action:" NRC actions initiating or relating to administrative or judicial civil or criminal enforcement actions or proceedings including issuance of notices of violation, orders, and denials of requests for action pursuant to subpart B of part 2 of this chapter; matters covered by parts 15 and part 160 of this chapter; and issuance of confirmatory action letters, bulletins, generic letters, notices of deviation, and notices of nonconformance.

(8) The issuance or update of the NRC's NEPA procedures is not subject to NEPA review.

(b) In determining whether NEPA applies to a proposed agency action, the NRC will consider only the action or project at hand.

§ 51.20 Determination of the appropriate level of NEPA review.

(a) If the NRC determines under § 51.19 of this part that NEPA applies to a proposed licensing or regulatory action or decision, the NRC will then determine the appropriate level of NEPA review in the following sequence and manner. At all steps in the following process, the NRC will consider the proposed agency action and its effects.

(1) If the NRC has established pursuant to § 51.22 of this part a categorical exclusion that covers the proposed agency action, the NRC will analyze whether to apply the categorical exclusion to the proposed agency action and apply the categorical exclusion, if appropriate.

(2) [Reserved]

(b) Except as provided in paragraph (d) of this section, if the NRC cannot apply a categorical exclusion to the proposed agency action, the NRC will consider the proposed agency action's reasonably foreseeable effects consistent with paragraph (c) of this section, and then will prepare, as appropriate, an

environmental assessment or environmental impact statement in accordance with paragraphs (b)(1) or (b)(2), respectively, of this section.

(1) The NRC will prepare an environmental assessment, consistent with §§ 51.30, 51.31, and 51.32 of this part, if the proposed agency action is not likely to have reasonably foreseeable significant effects or the significance of the effects is unknown; or

(2) The NRC will prepare an environmental impact statement, consistent with §§ 51.70 and 51.71 of this part, if the proposed agency action is likely to have reasonably foreseeable significant effects.

(c) When considering whether the reasonably foreseeable effects of the proposed agency action are significant, the NRC will analyze the potentially affected environment and degree of the effects of the action. The NRC may use any reliable data source and will not undertake new research unless it is essential to evaluating alternatives and the cost and time of obtaining it are not unreasonable.

(d) Issuance of a license for a uranium enrichment facility requires preparation of an environmental impact statement pursuant to Atomic Energy Act § 193(a)(1).

§ 51.22 Establishing categorical exclusions.

The NRC may establish categories of licensing, regulatory, and administrative actions eligible for categorical exclusion that the NRC finds are within a category of actions that normally does not significantly affect the quality of the human environment within the meaning of NEPA § 102(2)(C). The NRC may establish these categorical exclusions by rule or public notification on the NRC's website, <http://www.nrc.gov/NEPACatex>, or by adopting pursuant to NEPA § 109 categorical exclusions established by other Federal agencies into regulation or on the NRC's website, <http://www.nrc.gov/NEPACatex>. A prospective applicant or any other interested party may also propose a new categorical exclusion for a category of actions that normally does not significantly affect the quality of the human environment for NRC consideration by submitting a petition for rulemaking in accordance with § 2.802 of this chapter. If appropriate, the NRC may establish a new categorical exclusion on its website, <http://www.nrc.gov/NEPACatex>, while a decision on whether to pursue rulemaking is pending.

(a) The following categories of NRC actions are excluded from the requirement to prepare an

environmental assessment or environmental impact statement:

(1) Actions that are administrative, procedural, or solely financial in nature, including, for example:

(i) Issuance of or changes to procedures for filing and reviewing applications;

(ii) Issuance of or changes to recordkeeping or reporting requirements;

(iii) Issuance of or changes to surety, insurance, or indemnity requirements;

(iv) Issuance of or changes to administrative procedures or requirements;

(v) Actions on petitions for rulemaking, but not including rulemakings in response to a petition for rulemaking;

(vi) Amendments to the regulations in this chapter that are corrective or of a minor or nonpolicy nature and do not substantially modify existing regulations;

(vii) Issuance of or changes to guidance for the implementation of regulations in this chapter and other informational and procedural documents that do not impose any legal requirements;

(viii) Changes to a person or organization's name, position, or title;

(ix) Revisions that are editorial, corrective, or otherwise minor, including the updating of NRC-approved references, or changes to formatting of a document;

(x) Changes to contact information;

(xi) Personnel or managerial actions;

(xii) Actions on or changes to requirements for decommissioning funding under parts 30, 40, 50, 53, 70, or 72 of this chapter; or

(xiii) Termination of licenses that were issued but for which no construction activities have begun or where all decommissioning activities have been completed and approved and license termination is a final administrative step.

(2) Issuance of or changes to education, training, experience, qualification, or other employment suitability requirements.

(3) Amendments to parts 1, 2, 4, 5, 7, 8, 9, 10, 11, 12, 13, 15, 16, 19, 21, 25, 26, 55, 75, 95, 110, 140, 150, 160, 170, or 171 of this chapter.

(4) Procurement of general equipment and supplies, and procurement of technical assistance and personal services relating to the safe operation and protection of commercial reactors, other facilities, and materials subject to NRC licensing and regulation.

(5) Entrance into or amendment, suspension, or termination of all or part of an agreement with a State under

section 274 of the Atomic Energy Act of 1954, as amended, providing for assumption by the State and discontinuance by the Commission of certain regulatory authority of the Commission.

(6) Approvals of direct or indirect transfers of any license issued by the NRC (any associated amendments of a license required to reflect the approval of a direct or indirect transfer of an NRC license are included in paragraph (a)(1) of this section).

(7) The import of nuclear facilities and materials under part 110 of this chapter, but not including the import of spent power reactor fuel.

(8) Approvals of or changes to operators' licenses under part 55 or part 53 of this chapter.

(9) Approvals of package designs for packages to be used for the transportation of licensed materials.

(10) Actions under parts 30, 31, 32, 33, 34, 35, 36, 39, 40 or 70 of this chapter authorizing the following:

(i) Distribution of radioactive material and devices or products containing radioactive material to general licensees and to persons exempt from licensing;

(ii) Distribution of radiopharmaceuticals, generators, reagent kits and/or sealed sources to persons licensed under § 35.18 of this chapter;

(iii) Nuclear pharmacies;

(iv) Use of radioactive materials for medical and veterinary purposes;

(v) Use of radioactive materials for research and development and for educational purposes;

(vi) Industrial radiography;

(vii) Irradiators;

(viii) Use of sealed sources and use of gauging devices, analytical instruments and other devices containing sealed sources;

(ix) Use of uranium as shielding material in containers or devices;

(x) Possession of radioactive material incident to performing services such as installation, maintenance, leak tests and calibration;

(xi) Use of sealed sources and/or radioactive tracers in well-logging procedures;

(xii) Acceptance of packaged radioactive wastes from others for transfer to licensed land burial facilities provided the interim storage period for any package does not exceed 180 days and the total possession limit for all packages held in interim storage at the same time does not exceed 50 curies;

(xiii) Manufacturing or processing of source, byproduct, or special nuclear materials for distribution to other licensees, except processing of source material for extraction of rare earth and other metals;

(xiv) Nuclear laundries;

(xv) Possession, manufacturing, processing, shipment, testing, or other use of depleted uranium military munitions; or

(xvi) Any use of source, byproduct, or special nuclear material not listed above which involves quantities and forms of source, byproduct, or special nuclear material similar to those listed in paragraphs (a)(10)(i) through (xv) of this section.

(11) Standard design approvals under part 52 or 53 of this chapter.

(12) Issuance of amendments to § 72.214 of this chapter for new, amended, revised, or renewed certificates of compliance for cask designs used for spent fuel storage.

(13) Issuance, amendment, modification, or renewal of a certificate of compliance of gaseous diffusion enrichment plants under part 76 of this chapter.

(14) The decommissioning of sites where licensed operations have been limited to the use of—

(i) Small quantities of short-lived radioactive materials;

(ii) Radioactive materials in sealed sources, provided there is no evidence of leakage of radioactive material from these sealed sources; or

(iii) Radioactive materials in such a manner that a decommissioning plan is not required by §§ 30.36(g)(1), 40.42(g)(1), or 70.38(g)(1) of this chapter, and the NRC has determined that the facility meets the radiological criteria for unrestricted use in § 20.1402 of this chapter without further remediation or analysis.

(15) The Commission finding for a combined license under § 52.103(g) or § 53.1452(g) of this chapter.

(16) Actions under § 50.55a of this chapter.

(b) The following categories of NRC actions are excluded from the requirement to prepare an environmental assessment or environmental impact statement, provided that any ground disturbance is limited to previously disturbed areas:

(1) Procurement of confirmatory research.

(2) Review and approval of transportation routes under § 73.37 of this chapter.

(c) The following categories of NRC actions are excluded from the requirement to prepare an environmental assessment or environmental impact statement except to the extent they include activities directly affecting the environment, such as the construction of facilities; a major disturbance brought about by blasting, drilling, excavating or other means; field

work, except that which only involves noninvasive or non-harmful techniques such as taking water or soil samples or collecting non-protected species of flora and fauna; or the release of radioactive material:

(1) Grants to institutions of higher education in the United States, to fund scholarships, fellowships, and stipends for the study of science, engineering, or another field of study that the NRC determines is in a critical skill area related to its regulatory mission, to support faculty and curricular development in such fields, and to support other domestic educational, technical assistance, or training programs (including those of trade schools) in such fields.

(2) [Reserved]

(d) The following categories of NRC actions are excluded from the requirement to prepare an environmental assessment or environmental impact statement provided that any ground disturbance is limited to previously disturbed areas and there is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite, no significant increase in individual or cumulative public or occupational radiation exposure, and no significant increase in the potential for or consequences from radiological accidents.

(1) Changes to inspection or surveillance requirements.

(2) Changes to equipment servicing or maintenance requirements.

(3) Changes to safeguard plans or materials control and accounting inventory requirements, including modifications to systems used for security and/or materials accountability.

(4) Changes to requirements for fire protection, emergency planning, physical security, cybersecurity, or quality assurance.

(5) Changes to scheduling requirements.

(6) Changes to extend implementation dates for activities previously found to not have a significant environmental impact.

(7) Actions that result in a change in process operations or equipment under licenses for fuel cycle facilities or radioactive waste disposal sites, or under the materials licenses identified in § 51.60(b)(1) of this part.

(8) Authorizations under, or changes to requirements in part 50, 52, or part 53 of this chapter with respect to installation or use of a facility component.

(e) In accordance with section 121 of the Nuclear Waste Policy Act of 1982 (42 U.S.C. 10141), the promulgation of

technical requirements and criteria that the Commission will apply in approving or disapproving applications under part 60 or part 63 of this chapter shall not require an environmental impact statement, an environmental assessment, or any environmental review under subparagraph (H) or (I) of NEPA § 102(2).

(f) The following categories of NRC actions normally do not significantly affect the quality of the human environment:

(1) Approvals related to long term surveillance plans provided that criteria in appendix A in part 40 of this chapter for Title II site or 40 CFR 192 for Title I sites are met.

(2) Approvals of partial site releases or license termination plans, except for facilities or sites that possess Atomic Energy Act § 11e.(2) byproduct material, provided that the NRC has determined that the radiological criteria for unrestricted use in § 20.1402 of this chapter are met.

(3) Issuance of standard design certifications and manufacturing licenses under part 52 or part 53 of this chapter provided that the severe accident mitigation design alternatives do not provide cost beneficial risk improvements.

(4) Changes to standard design certifications and manufacturing licenses under part 52 or part 53 of this chapter provided that no new severe accident mitigation design alternatives to reasonably incorporate into the design are identified and previously considered severe accident mitigation design alternatives remain rejected.

(g) Approvals under § 20.2002 of this chapter normally do not significantly affect the quality of the human environment provided that there is no significant change in the types or significant increase in the amounts of any radiological effluents that may be released offsite, no significant increase in public or occupational radiation exposure, and no significant increase in the potential for or consequences from radiological accidents.

(h) Actions related to changes to reactor power levels normally do not significantly affect the quality of the human environment provided that there is no significant change in the types or significant increase in the amounts of any radiological effluents that may be released offsite, no significant increase in public or occupational radiation exposure, no significant increase in the potential for or consequences from radiological accidents, and no significant increase in radioactive solid waste.

(i) Actions under part 50, part 52, or part 53 of this chapter related to a limited work authorization, construction permit, operating license, early site permit, or combined license for nuclear power or non-power reactors normally do not significantly affect the quality of the human environment provided that the facility and site meet or are bounded by and will continue to meet or be bounded by the environmental plant parameter and site parameter envelopes in Table C-1 of appendix C of this part, and no new and significant information has been identified for any of the issues identified as Category 1 and listed in Table C-1, such that it would change the conclusions listed in the table and further described in NUREG-2249.

(j) Actions related to renewed licenses under part 54 of this chapter normally do not significantly affect the quality of the human environment provided that:

(1) No substantial new circumstances or information has been identified for any of the issues identified as Category 1 and listed in Table B-1 of appendix B of this part, such that it would change the conclusions listed in the table and further described in NUREG-1437, Revision 2;

(2) Inadvertent radionuclide releases to groundwater have not resulted in radionuclide concentrations onsite or offsite that exceed drinking water maximum contaminant levels and there are no current or ongoing inadvertent releases under investigation, and;

(3) For plants with cooling ponds, cooling pond water quality is maintained such that the maximum contaminant levels for radionuclides in drinking water have not been exceeded.

(k) Actions related to the possession of special nuclear material for an activity at a permanent site that normally do not significantly affect the quality of the human environment provided that (i) there are no associated effluents that may be released offsite, or there is no significant change in the types of or significant increase in the amounts of effluents that may be released offsite, (ii) occupational and public dose meets part 20 of this chapter limits, and (iii) any new or increased possession limit for licensed material is of a physical form that is not readily dispersible. This categorical exclusion would not apply to actions related to enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, or scrap recovery of special nuclear material.

(l) Actions under part 72 of this chapter, except decommissioning actions under § 72.54 of this chapter, related to the storage of undamaged spent fuel or reactor related greater-than-class-C waste in a dry cask independent spent fuel storage installation located within the site boundary of an operating nuclear power plant or located at an away-from-reactor decommissioned reactor site normally do not significantly affect the quality of the human environment provided that occupational and public dose meets part 20 of this chapter limits, real individual dose meets § 72.104 of this chapter limit, and postulated accident dose meets § 72.106 of this chapter limit.

§ 51.23 Environmental impacts of continued storage of spent nuclear fuel beyond the licensed life for operation of a reactor.

(a) The Commission has generically determined that the environmental impacts of continued storage of spent nuclear fuel beyond the licensed life for operation of a reactor are those impacts identified in NUREG-2157, "Generic Environmental Impact Statement for Continued Storage of Spent Nuclear Fuel."

(b) Environmental reports or applicant-prepared draft environmental documents are not required to discuss the environmental impacts of spent nuclear fuel storage in a reactor facility storage pool or an ISFSI for the period following the term of the reactor operating license, reactor combined license, or ISFSI license. If the impacts of continued storage of spent fuel are relevant to the proposed agency action, then the impact determinations in NUREG-2157 regarding continued storage shall be deemed incorporated into the environmental documents. For the purposes of an environment assessment that relies on the impact determinations in NUREG-2157, a SMALL impact determination means that the impacts are not significant.

(c) This section does not alter any requirements to consider the environmental impacts of spent fuel storage during the term of a reactor operating license or combined license, or a license for an ISFSI in a licensing proceeding.

Environmental Assessment

§ 51.30 Environmental assessment.

(a) The NRC will prepare an environmental assessment as soon as practicable after determining that an environmental assessment is required under § 51.20 of this part.

(b) Other than an environmental assessment for a standard design

certification or a manufacturing license under part 52 or part 53 of this chapter, as appropriate and to the extent required by the scope, an environmental assessment will address the matters described in §§ 51.45, 51.51, 51.52, 51.60, 51.62, 51.75, 51.76, and 51.95 of this part, as applicable. For the purpose of providing evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact, an environmental assessment for proposed agency actions must identify the proposed agency action and include:

- (1) A brief discussion of:
 - (i) The purpose and need for the proposed agency action;
 - (ii) Alternatives to the extent required by NEPA; and
 - (iii) The reasonably foreseeable effects of the proposed agency action and alternatives, as appropriate.

(c) An environmental assessment for a standard design certification under subpart B of part 52 or part 53 of this chapter must identify the proposed agency action, and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the design certification. An environmental assessment for an amendment to a design certification will be limited to the consideration of whether the design change which is the subject of the proposed amendment renders a severe accident mitigation design alternative previously rejected in the earlier environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the design certification must be addressed.

(d) An environmental assessment for a manufacturing license under subpart F of part 52 or part 53 of this chapter must identify the proposed agency action, and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the manufacturing license. An environmental assessment for an amendment to a manufacturing license will be limited to consideration of whether the design change which is the subject of the proposed amendment either renders a severe accident mitigation design alternative previously rejected in an environmental assessment

to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the manufacturing license must be addressed. In either case, the environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

(e) An environmental assessment must not exceed 75 pages, not including any citations or appendices.

(f) The NRC may, in certain circumstances (e.g., uncertain effects or effects involving unique or unknown risks), issue a notice of intent to prepare an environmental assessment and request public comment to assist in preparation of an environmental assessment.

(g) The NRC may cooperate with State, Tribal, and local agencies that are responsible for preparing environmental documents.

§ 51.31 Determinations based on environmental assessment.

(a) *General.* Upon completion of an environmental assessment for proposed agency actions other than those involving a standard design certification or a manufacturing license under part 52 or part 53 of this chapter, the appropriate NRC staff director authorized to take the action will determine whether to prepare an environmental impact statement or a finding of no significant impact on the proposed agency action.

(b) *Standard design certification.*

(1) The proposed rule involving the issuance or amendment of a standard design certification must state that:

(i) The Commission has determined in § 51.32 of this part that there is no significant environmental impact associated with the issuance of the standard design certification or its amendment, as applicable; and

(ii) Comments on the environmental assessment will be limited to the consideration of severe accident mitigation design alternative as required by § 51.30(c) of this part.

(2) The Commission will prepare a environmental assessment following the close of the public comment period for the proposed standard design certification.

(c) *Manufacturing license.* Upon completion of the environmental assessment for actions involving issuance or amendment of a manufacturing license (manufacturing license environmental assessment) in

accordance with § 51.30(d) of this part, the appropriate NRC staff director will determine the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the design of the reactor to be manufactured under the manufacturing license.

Finding of No Significant Impact

§ 51.32 Finding of no significant impact.

(a) A finding of no significant impact will:

- (1) Identify the proposed agency action;
- (2) Describe the purpose and need for the proposed agency action based on the NRC's substantive statutory authority;
- (3) State that the Commission has determined not to prepare an environmental impact statement for the proposed agency action;
- (4) Document the reasons why the proposed agency action will not have a significant effect on the quality of the human environment;
- (5) Include the environmental assessment or a summary of the environmental assessment in the finding of no significant impact. If the assessment is included, the finding need not repeat any of the discussion in the assessment but may incorporate it by reference;
- (6) Identify any other related environmental documents;
- (7) State that the finding and any related environmental documents are available for public inspection and where the documents may be inspected; and
- (8) If applicable, state the authority for any mitigation that NRC has adopted and any applicable monitoring or enforcement provisions. If NRC finds no significant effects based on mitigation, the mitigated finding of no significant impact will state any mitigation requirements enforceable by the agency or voluntary mitigation commitments that will be undertaken to avoid significant effects.

(b) The Commission finds that there is no significant environmental impact associated with the issuance of:

- (1) A standard design certification under subpart B of part 52 or part 53 of this chapter;
 - (2) An amendment to a design certification;
 - (3) A manufacturing license under subpart F of part 52 or part 53 of this chapter; or
 - (4) An amendment to a manufacturing license.
- (c) The finding of no significant impact will be prepared by the NRC

staff director authorized to take the action. Whenever the NRC makes a finding of no significant impact on a proposed agency action, the finding or a notice of availability of the finding will be published in the **Federal Register**.

Environmental Reports and Information, and Applicant-Prepared Draft Environmental Documents—Requirements Applicable to Applicants and Petitioners for Rulemaking General

§ 51.41 Requirement to submit environmental information.

The NRC may require an applicant for a permit, license, or other form of permission, or amendment to or renewal of a permit, license or other form of permission, or a petitioner for rulemaking to submit such information to the NRC as may be useful in aiding the NRC in complying with NEPA and with any other environmental statutory compliance obligations it may have, under statutes, including but not limited to, the Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, National Historic Preservation Act, Clean Air Act, Clean Water Act, National Marine Sanctuaries Act, and Marine Mammal Protection Act. The Commission will independently evaluate and be responsible for the reliability of any information which it uses.

Environmental Reports—General Requirements

§ 51.45 Environmental report and information.

(a) Unless the applicant or petitioner for rulemaking believes its application or petition is subject to a categorical exclusion, each applicant or petitioner for rulemaking must submit with its application or petition for rulemaking one signed original of a separate document entitled "Applicant's" or "Petitioner's Environmental Report," as appropriate. An applicant or petitioner for rulemaking may submit a supplement to an environmental report at any time. Submittal of a supplement to an environmental report would be grounds for extending the NEPA deadlines in accordance with § 51.15(a)(5) of this part.

(1) If the application is for an amendment to or a renewal of a license or other form of permission for which the applicant has previously submitted an environmental report, the supplement to the applicant's environmental report may be limited to incorporating by reference and updating

or supplementing the information previously submitted to reflect any significant new information, including any significant environmental change resulting from operational experience or a change in operations or proposed decommissioning activities. If the applicant is a Federal agency, the environmental report may be in the form of either an environmental impact statement or an environmental assessment, as appropriate, provided that the submittal includes all the information required for an environmental report.

(2) An environmental report or supplement to an environmental report must contain environmental information necessary for the NRC to prepare an environmental assessment in accordance with the procedures in §§ 51.30, 51.31, and 51.32 of this part, or an environmental impact statement in accordance with the procedures in §§ 51.70 and 51.71 of this part. An environmental report for a production and utilization facility, other than environmental reports for standard design certifications or manufacturing licenses under part 52 or part 53 of this chapter, must also address the matters specified in §§ 51.51, 51.52, 51.75, 51.76, and 51.95 of this part, as applicable. An environmental report must also include information relevant to NRC's statutory compliance obligations under statutes, including but not limited to the Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, National Historic Preservation Act, Clean Air Act, Clean Water Act, National Marine Sanctuaries Act, and Marine Mammal Protection Act.

(b) Applicants and petitioners for rulemaking who believe that a categorical exclusion applies to their application or petition must include in their application or petition a justification for the application of a categorical exclusion. For categorical exclusions the applicant or petitioner for rulemaking must provide the rationale and bases for applying a categorical exclusion, including any supporting analyses. A categorical exclusion under NEPA does not excuse the NRC from other statutory consultations and responsibilities. Therefore, the Commission may require an applicant for a permit, license, or other form of permission, or amendment to or renewal of a permit, license, or other form of permission, or a petitioner for rulemaking to submit such information to the Commission as may be useful in aiding the Commission in complying with other environmental statutes, including but not limited to,

the Endangered Species Act, National Historic Preservation Act, Clean Air Act, Clean Water Act, Magnuson-Stevens Fishery Conservation and Management Act, National Marine Sanctuaries Act, and Marine Mammal Protection Act.

(c) Each applicant for a standard design certification under subpart B of part 52 or part 53 of this chapter must submit with its application information that either justifies the categorical exclusion in § 51.22(f)(3) of this part by providing the rationale and bases for concluding that the severe accident mitigation design alternatives do not provide cost beneficial risk improvements, or addresses, in an environmental report, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives. If the application is for an amendment to a design certification, the applicant must submit information that either justifies the categorical exclusion in § 51.22(f)(4) of this part by providing the rationale and bases for concluding that no new severe accident mitigation design alternatives to reasonably incorporate into the design are identified and previously considered severe accident mitigation alternatives remain rejected, or addresses, in a supplemental environmental report, whether the design change which is the subject of the proposed amendment either renders a severe accident mitigation design alternative previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives that may be reasonably incorporated into the design certification.

(d) Each applicant for a manufacturing license under subpart F of part 52 or part 53 of this chapter must submit with its application information that either justifies the categorical exclusion in § 51.22(f)(3) of this part by providing the rationale and bases for concluding that the severe accident mitigation design alternatives do not provide cost beneficial risk improvements, or addresses, in an environmental report, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives into the design of the reactor to be manufactured. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license, the benefits and impacts of utilizing the reactor in a nuclear power plant, or an evaluation of alternative energy sources. If the

application is for an amendment to a manufacturing license, the applicant must submit information that either justifies the categorical exclusion in § 51.22(f)(4) of this part by providing the rationale and bases for concluding that no new severe accident mitigation design alternatives to reasonably incorporate into the design are identified and previously considered severe accident mitigation alternatives remain rejected, or addresses, in a supplemental environmental report, whether the design change which is the subject of the proposed amendment either renders a severe accident mitigation design alternative previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives that may be reasonably incorporated into the design of the manufactured reactor. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

(e) Each applicant for a non-power production or utilization construction permit or facility license, or renewal of a non-power production or utilization facility license issued pursuant to § 50.21(a) or (c) or § 50.22 of this chapter must submit with its application an environmental report in accordance with paragraph (a) of this section. If the application is for a renewal of a license for which the applicant has previously submitted an environmental report, the supplement, to the extent applicable, must include an analysis of any environmental impacts resulting from operational experience or a change in operations, and an analysis of any environmental impacts that may result from proposed decommissioning activities.

(f) The analyses for environmental reports submitted in accordance with paragraph (a) of this section and the rationale and bases for application of a categorical exclusion submitted in accordance with paragraph (b) of this section for limited work authorizations, construction permits, early site permits, operating licenses, combined licenses, and materials licenses listed in § 51.60(b) of this part must, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, those considerations or factors must be discussed in qualitative terms. The environmental report should contain sufficient data to aid the Commission in its development of an independent analysis.

(g) The submittals referenced in paragraph (a) of this section must list all Federal permits, licenses, approvals and other entitlements which must be obtained in connection with the proposed agency action, and must describe the status of compliance with these requirements. The environmental report must also include a discussion of the status of compliance with applicable environmental quality standards and requirements including, but not limited to, applicable zoning and land-use regulations, and thermal and other water pollution limitations or requirements which have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection.

(h) The information submitted pursuant to this section should not be confined to information supporting the proposed agency action or application of a categorical exclusion but should also include adverse information.

Applicant-Prepared Draft Environmental Documents—General Requirements

§ 51.46 Applicant-prepared draft environmental documents.

(a) In lieu of the environmental report required under §§ 51.45(a), 51.60, and 51.62 of this part, in accordance with NEPA section 107(f), the NRC may, at its discretion, authorize an applicant-hired or petitioner-hired contractor to prepare a draft environmental document, in whole or in part, under NRC supervision. A prospective applicant or petitioner for rulemaking must submit a written notice requesting participation in this process prior to beginning preparation of an applicant-prepared draft environmental document or environmental report.

The request must include the following commitments:

(1) The prospective applicant will hire a contractor, or contractors, with qualifications or experience to prepare draft environmental documents that meet the requirements of this part.

(2) The prospective applicant will ensure that the relevant procurement documents specify that the draft environmental document will meet the requirements of part 51 of this chapter and authorize the NRC to conduct oversight of the preparation process.

(3) The prospective applicant will ensure the contractor, or contractors, have no financial or other interest in the outcome of the proposed agency action. A disclosure statement for the NRC-supervised applicant-hired contractor's execution specifying that the contractor has no financial or other interest in the

outcome of the action. Such statements need not include privileged or confidential trade secrets or other confidential business information.

(4) The prospective applicant and their contractor(s) will cooperate with the NRC's supervision of the preparation of the draft environmental document and in meeting the schedule established by NRC, including through timely submittal of information requested by the NRC.

(5) The prospective applicant and their contractor(s) will meet the requirements of this part and comply with all other applicable environmental laws, regulations, or executive orders under the NRC's purview.

(b) The NRC will be responsible for the following:

(1) Determining the appropriate level of NEPA review.

(2) Providing supervision and guidance to the prospective applicant and applicant-hired contractor.

(3) Conducting all consultations required under other environmental statutes unless the NRC is authorized by law to permit the prospective applicant or applicant-hired contractor to conduct all or part of a required consultation, as appropriate, and the applicant accepts that responsibility.

(4) Independently evaluating and taking responsibility for the content, accuracy, and scope of the environmental document, including by issuing any final determinations and the final agency decision on the application.

(c) An applicant-prepared draft environmental document for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, must use Table S-3, Table of Uranium Fuel Cycle Environmental Data, in § 51.51 of this part as the basis

for evaluating the contribution of the environmental effects of uranium mining and milling, the production of uranium hexafluoride, isotopic enrichment, fuel fabrication, reprocessing of irradiated fuel, transportation of radioactive materials and management of low-level wastes and high-level wastes related to uranium fuel cycle activities to the environmental costs of licensing the nuclear power reactor. Table S-3 must be included in the applicant-prepared draft document and may be supplemented by a discussion of the environmental effects of the data set forth in the table as weighed in the analysis for the proposed facility.

(d) An applicant-prepared draft environmental document prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, and submitted after February 4, 1975, must contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. That statement must indicate that the reactor and this transportation meet either all of the conditions in § 51.52(a) of this part or all of the conditions in § 51.52(b) of this part.

(e) The NRC may terminate the process described in this section at any time if it determines that the applicant or applicant-hired contractor is failing to meet commitments. The NRC will provide notice at least 30 days in advance of any reasons for the potential termination of this process and opportunities for the applicant to resolve the matter that will allow the NRC to meet its obligations (e.g., proposing an appropriate schedule extension, providing needed

information, requesting that NRC staff complete the environmental document).

(f) The NRC will independently evaluate the draft environmental document, take responsibility for its contents and findings, and decide whether to issue the environmental document as final. The NRC may choose in its discretion to accept, edit, revise, or independently author sections of the environmental document or the whole document.

Environmental Reports—Production And Utilization Facilities

§ 51.51 Uranium fuel cycle environmental data—Table S-3.

(a) Every environmental report submitted in accordance with § 51.45(a) of this part for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, must take Table S-3, Table of Uranium Fuel Cycle Environmental Data, as the basis for evaluating the contribution of the environmental effects of uranium mining and milling, the production of uranium hexafluoride, isotopic enrichment, fuel fabrication, reprocessing of irradiated fuel, transportation of radioactive materials and management of low-level wastes and high-level wastes related to uranium fuel cycle activities to the environmental costs of licensing the nuclear power reactor. Table S-3 must be included in the environmental report submitted in accordance with § 51.45(a) of this part and may be supplemented by a discussion of the environmental effects of the data set forth in the table as weighed in the analysis for the proposed facility.

(b) Table S-3.

TABLE S-3—TABLE OF URANIUM FUEL CYCLE ENVIRONMENTAL DATA ¹

[Normalized to model LWR annual fuel requirement [WASH-1248] or reference reactor year [NUREG-0116]]

Environmental considerations	Total	Maximum effect per annual fuel requirement or reference reactor year of model 1,000 MWe LWR
Effluents—Chemical (MT)		
Other gases:		
F	.67	Principally from UF ₆ , production, enrichment, and reprocessing. Concentration within range of state standards—below level that has effects on human health.
HCl	.014	
Liquids:		
SO ₄	9.9	From enrichment, fuel fabrication, and reprocessing steps. Components that constitute a potential for adverse environmental effect are present in dilute concentrations and receive additional dilution by receiving bodies of water to levels below permissible standards. The constituents that require dilution and the flow of dilution water are: NH ₃ —600 cfs., NO ₃ —20 cfs., Fluoride—70 cfs.
NO ₃	25.8	
Fluoride	12.9	
CA ⁺	5.4	
C1 [−]	8.5	
Na ⁺	12.1	

TABLE S-3—TABLE OF URANIUM FUEL CYCLE ENVIRONMENTAL DATA ¹—Continued
 [Normalized to model LWR annual fuel requirement [WASH-1248] or reference reactor year [NUREG-0116]]

Environmental considerations	Total	Maximum effect per annual fuel requirement or reference reactor year of model 1,000 MWe LWR
NH ₃	10.0	
Fe	.4	
Tailings Solutions (thousands of MT).	240	From mills only—no significant effluents to environment.
Solids	91,000	Principally from mills—no significant effluents to environment.
Effluents—Radiological (curies)		
Gases (including entrainment):		
Rn-222		Presently under reconsideration by the Commission.
Ra-226	.02	
Th-230	.02	
Uranium	.034	
Tritium (thousands)	18.1	
C-14	24	
Kr-85 (thousands)	400	
Ru-106	.14	Principally from fuel reprocessing plants.
I-129	1.3	
I-131	.83	
Tc-99		Presently under consideration by the Commission.
Fission products and transuranics ...	.203	
Liquids:		
Uranium and daughters	2.1	Principally from milling—included tailings liquor and returned to ground—no effluents; therefore, no effect on environment.
Ra-226	.0034	From UF6 production.
Th-230	.0015	
Th-234	.01	From fuel fabrication plants—concentration 10 percent of 10 CFR part 20 for total processing 26 annual fuel requirements for model LWR.
Fission and activation product	5.9 x 10 ⁻⁶	
Solids (buried on site):		
Other than high level (shallow)	11,300	9,100 Ci comes from low level reactor wastes and 1,500 Ci comes from reactor decontamination and decommissioning—buried at land burial facilities. 600 Ci comes from mills—included in tailings returned to ground. Approximately 60 Ci comes from conversion and spent fuel storage. No significant effluent to the environment.
TRU and HLW (deep)	1.1 x 10 ⁷	Buried at Federal Repository.
Transportation (person-rem):		
Exposure of workers and general public.	2.5	
Occupational exposure (person-rem).	22.6	From reprocessing and waste management.

¹ Table S-3 does not include health effects from the effluents described in the Table, or estimates of releases of Radon-222 from the uranium fuel cycle or estimates of Technetium-99 released from waste management or reprocessing activities. These issues may be the subject of litigation in the individual licensing proceedings.

Data supporting this table are given in the "Environmental Survey of the Uranium Fuel Cycle," WASH-1248, April 1974; the "Environmental Survey of the Reprocessing and Waste Management Portion of the LWR Fuel Cycle," NUREG-0116 (Supp.1 to WASH-1248); the "Public Comments and Task Force Responses Regarding the Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle," NUREG-0216 (Supp. 2 to WASH-1248); and in the record of the final rulemaking pertaining to Uranium Fuel Cycle Impacts from Spent Fuel Reprocessing and Radioactive Waste Management, Docket RM-50-3. The contributions from reprocessing, waste management and transportation of wastes are maximized for either of the two fuel cycles (uranium only and no recycle). The contribution from transportation excludes transportation of cold fuel to a reactor and of irradiated fuel and radioactive wastes from a reactor which are considered in Table S-4 of § 51.20(g) of this part. The contributions from the other steps of the fuel cycle are given in columns A-E of Table S-3A of WASH-1248.

§ 51.52 Environmental effects of transportation of fuel and waste—Table S-4.

Every environmental report submitted in accordance with § 51.45(a) of this part prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled nuclear power reactor, and submitted after February 4, 1975, must contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. That statement must indicate that the reactor and this transportation meet either all of

the conditions in paragraph (a) of this section or all of the conditions of paragraph (b) of this section.

(a)(1) The reactor has a core thermal power level not exceeding 3,800 megawatts;

(2) The reactor fuel is in the form of sintered uranium dioxide pellets having a uranium-235 enrichment not exceeding 4% by weight, and the pellets are encapsulated in zircaloy rods;

(3) The average level of irradiation of the irradiated fuel from the reactor does not exceed 33,000 megawatt-days per metric ton, and no irradiated fuel

assembly is shipped until at least 90 days after it is discharged from the reactor;

(4) With the exception of irradiated fuel, all radioactive waste shipped from the reactor is packaged and in a solid form;

(5) Unirradiated fuel is shipped to the reactor by truck; irradiated fuel is shipped from the reactor by truck, rail, or barge; and radioactive waste other than irradiated fuel is shipped from the reactor by truck or rail; and

(6) The environmental impacts of transportation of fuel and waste to and

from the reactor, with respect to normal conditions of transport and possible accidents in transport, are as set forth in Summary Table S-4 in paragraph (c) of this section; and the values in the table represent the contribution of the transportation to the environmental costs of licensing the reactor.

(b) For reactors not meeting the conditions of paragraph (a) of this section, the statement must contain a full description and detailed analysis of the environmental effects of transportation of fuel and wastes to and from the reactor, including values for the environmental impact under normal

conditions of transport and for the environmental risk from accidents in transport. The statement must indicate that the values determined by the analysis represent the contribution of such effects to the environmental costs of licensing the reactor.

(c) Table S-4.

SUMMARY TABLE S-4—ENVIRONMENTAL IMPACT OF TRANSPORTATION OF FUEL AND WASTE TO AND FROM ONE LIGHT-WATER-COOLED NUCLEAR POWER REACTOR ¹

[Normal Conditions of Transport]

Exposed population	Estimated number of persons exposed	Range of doses to exposed individuals ² (per reactor year)	Cumulative dose to Exposed population (per reactor year) ³
Transportation workers	200	0.01 to 300 millirem	4 man-rem.
General public:			
Onlookers	1,100	0.003 to 1.3 millirem	3 man-rem.
Along Route	600,000	0.0001 to 0.06 millirem.	

Types of Effects: Radiological Effects

Environmental Risk: Small⁴

¹ Data supporting this table are given in the Commission's "Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants," WASH-1238, December 1972; and Supp. 1 of NUREG-75/038, April 1975. Both documents are available for electronic access at the NRC's Publicly Available Records System Library at <https://www.nrc.gov/reading-rm/adams>.

² The Federal Radiation Council has recommended that the radiation doses from all sources of radiation other than natural background and medical exposures should be limited to 5,000 millirem per year for individuals as a result of occupational exposure and should be limited to 500 millirem per year for individuals in the general population. The dose to individuals due to average natural background radiation is about 130 millirem per year.

³ Man-rem is an expression for the summation of whole body doses to individuals in a group. Thus, if each member of a population group of 1,000 people were to receive a dose of 0.001 rem (1 millirem), or if 2 people were to receive a dose of 0.5 rem (500 millirem) each, the total man-rem dose in each case would be 1 man-rem.

⁴ Although the environmental risk of radiological effects stemming from transportation accidents is currently incapable of being numerically quantified, the risk remains small regardless of whether it is being applied to a single reactor or a multireactor site.

Environmental Reports—Materials Licenses

§ 51.60 Environmental report—materials licenses.

(a) Each applicant for a license or other form of permission, or an amendment to or renewal of a license or other form of permission issued pursuant to parts 30, 32, 33, 34, 35, 36, 39, 40, 61, 70 and/or 72 of this chapter, and covered by paragraphs (b)(1) through (b)(5) of this section, must submit with its application an environmental report in accordance with the procedures in § 51.45(a) of this part, unless a categorical exclusion is applicable. Information to justify the applicability of a categorical exclusion must be submitted to the NRC in accordance with § 51.45(b) of this part.

(b) As required by paragraph (a) of this section, each applicant must prepare an environmental report for the following types of actions, unless the action qualifies for a categorical exclusion:

(1) Issuance or renewal of a license or other form of permission for:

(i) Possession and use of special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride pursuant to part 70 of this chapter.

(ii) Possession and use of source material for uranium milling or production of uranium hexafluoride pursuant to part 40 of this chapter.

(iii) Storage of spent fuel in an independent spent fuel storage installation (ISFSI) or the storage of spent fuel or high-level radioactive waste in a monitored retrievable storage installation (MRS) pursuant to part 72 of this chapter.

(iv) Receipt and disposal of radioactive waste from other persons pursuant to part 61 of this chapter.

(v) Processing of source material for extraction of rare earth and other metals.

(vi) Use of radioactive tracers in field flood studies involving secondary and tertiary oil and gas recovery.

(vii) Construction and operation of a uranium enrichment facility.

(2) Issuance of an amendment that would authorize or result in

(i) A significant expansion of a site,

(ii) A significant change in the types of effluents,

(iii) A significant increase in the amounts of effluents,

(iv) A significant increase in individual or cumulative occupational radiation exposure,

(v) A significant increase in the potential for or consequences from radiological accidents, or

(vi) A significant increase in spent fuel storage capacity, in a license or other form of permission to conduct an activity listed in paragraph (b)(1) of this section.

(3) Amendment of a license to authorize the decommissioning of an independent spent fuel storage installation (ISFSI) or a monitored retrievable storage installation (MRS) pursuant to part 72 of this chapter.

(4) Issuance of a license amendment pursuant to part 61 of this chapter authorizing

(i) Closure of a land disposal site,

(ii) Transfer of the license to the disposal site owner for the purpose of institutional control, or

(iii) Termination of the license at the end of the institutional control period.

(5) Any other licensing action for which the Commission determines an environmental report is necessary.

(c) Petitioners for rulemaking requesting amendments of parts 30, 31, 32, 33, 34, 35, 36, 39, 40 or part 70 of this chapter concerning the exemption from licensing and regulatory requirements of or authorizing general licenses for any equipment, device,

commodity or other product containing byproduct material, source material or special nuclear material must submit with the petition a separate document entitled "Petitioner's Environmental Report," in accordance with § 51.45(a) of this part, unless a categorical exclusion is applicable. Information to justify the applicability of a categorical exclusion must be submitted to the NRC in accordance with § 51.45(b) of this part.

(d) The environmental report for an application for a license for storage of spent fuel in an ISFSI or for the storage of spent fuel and high-level radioactive waste in an MRS pursuant to part 72 of this chapter must contain the information specified in § 51.45(a) of this part and must address the siting evaluation factors contained in subpart E of part 72 of this chapter.

§ 51.62 Environmental report—land disposal of radioactive waste licensed under 10 CFR part 61.

(a) Each applicant for issuance of a license for land disposal of radioactive waste pursuant to part 61 of this chapter must submit with its application an environmental report in accordance with § 51.45(a) of this part. The environmental report and any supplement to the environmental report may incorporate by reference information contained in the application or in any previous application, statement or report filed with the Commission provided that such references are clear and specific and that copies of the information so incorporated are available at the NRC website, <http://www.nrc.gov>, and/or at the NRC Public Document Room.

(b) The environmental report must contain the information specified in § 51.45(a) of this part, must address the applicant's environmental monitoring program required by §§ 61.12(l), 61.53 and 61.59(b) of this chapter, and must be as complete as possible in the light of information that is available at the time the environmental report is submitted.

(c) The applicant must supplement the environmental report in a timely manner as necessary to permit the Commission to review, prior to issuance, amendment or renewal of a license, new information regarding the environmental impact of previously proposed activities, information regarding the environmental impact of any changes in previously proposed activities, or any significant new information regarding the environmental impact of closure activities and long-term performance of the disposal site.

§ 51.67 Environmental information concerning geologic repositories.

(a) In lieu of an environmental report, the Department of Energy, as an applicant for a license or license amendment pursuant to part 60 or part 63 of this chapter, shall submit to the Commission any final environmental impact statement which the Department of Energy prepares in connection with any geologic repository developed under Subtitle A of Title I, or under Title IV, of the Nuclear Waste Policy Act of 1982, as amended. (See § 60.22 or § 63.22 of this chapter as to the required time and manner of submission.) The statement shall include, among the alternatives under consideration, denial of a license or construction authorization by the Commission.

(b) Under applicable provisions of law, the Department of Energy may be required to supplement its final environmental impact statement if it makes a substantial change in its proposed action that is relevant to environmental concerns or determines that there are substantial new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts. The Department shall submit any supplement to its final environmental impact statement to the Commission. (See § 60.22 or § 63.22 of this chapter as to the required time and manner of submission.)

(c) Whenever the Department of Energy submits a final environmental impact statement, or a final supplement to an environmental impact statement, to the Commission pursuant to this section, it shall also inform the Commission of the status of any civil action for judicial review initiated pursuant to § 119 of the Nuclear Waste Policy Act of 1982. This status report, which the Department shall update from time to time to reflect changes in status, shall:

(1) State whether the environmental impact statement has been found by the courts of the United States to be adequate or inadequate; and

(2) Identify any issues relating to the adequacy of the environmental impact statement that may remain subject to judicial review.

Environmental Impact Statements—General Requirements

§ 51.70 Environmental impact statements—general.

(a) The NRC will publish a notice of intent to prepare an environmental impact statement in the **Federal Register** as soon as practicable after determining that preparation of an

environmental impact statement is required under § 51.20 of this part. The notice of intent will include a request for public comment on alternatives or impacts and on relevant information, studies, or analyses with respect to the proposed agency action. The NRC will prepare an environmental impact statement as soon as practicable after publication of the notice of intent to prepare an environmental impact statement. The NRC may, in certain circumstances (e.g., uncertain effects or effects involving unique or unknown risks), request additional public comment to assist in preparation of an environmental impact statement.

(b) Except as provided in paragraph (c) of this section, an environmental impact statement must not exceed 150 pages, not including citations or appendices.

(c) An environmental impact statement for a proposed agency action of extraordinary complexity must not exceed 300 pages, not including any citations or appendices.

(d) The NRC may cooperate with State, Tribal, and local agencies that are responsible for preparing environmental impact statements.

§ 51.71 Environmental impact statements—contents.

(a) As appropriate, the environmental impact statement will address the topics in paragraphs (b), (c), (d), (e) and (f) of this section and the matters specified in §§ 51.45, 51.51, 51.52, 51.60, 51.62, 51.75, 51.76, and 51.95, as applicable.

(b) The environmental impact statement will include a description of the proposed agency action and a discussion of the purpose and need for the proposed agency action. The statement will also include a description of the environment affected and discuss:

(1) Reasonably foreseeable environmental effects of the proposed agency action. Effects will be discussed in proportion to their significance;

(2) Any reasonably foreseeable adverse environmental effects which cannot be avoided should the proposal be implemented;

(3) A reasonable range of alternatives to the proposed agency action, including an analysis of any adverse environmental impacts of not implementing the proposed agency action in the case of a no action alternative, that are technically and economically feasible and meet the purpose and need of the proposed agency action;

(4) The relationship between local short-term uses of man's environment

and the maintenance and enhancement of long-term productivity;

(5) Any irreversible and irretrievable commitments of Federal resources which would be involved in the proposed agency action should it be implemented; and

(6) Any means identified to mitigate adverse environmental effects of the proposed agency action.

(c) While satisfaction of Commission standards and criteria pertaining to radiological effects will be necessary to meet the licensing requirements of the Atomic Energy Act, the analysis will, for the purposes of NEPA, consider the radiological effects of the proposed agency action and alternatives.

(d) Environmental impact statements will be analytic, concise, and no longer than necessary to comply with NEPA in light of the page limits under § 51.70 of this part and deadlines under § 51.15 of this part. With respect to issues that are not of a significant nature and do not meaningfully inform the consideration of environmental effects and the resulting decision on how to proceed, there will be no more than a brief discussion to explain why those issues are not significant and therefore not analyzed further.

(e) The analysis for all environmental impact statements will, to the fullest extent practicable, quantify the various factors considered. To the extent that there are important qualitative considerations or factors that cannot be quantified, these considerations or factors will be discussed in qualitative terms.

(f) To the extent sufficient information is available, the environmental impact statement will include consideration of major points of view concerning the reasonably foreseeable environmental effects of the proposed agency action and the alternatives, and contain an analysis of substantive issues and objections raised by other Federal, State, Tribal, and local agencies and interested persons.

Environmental Documents—
Production and Utilization Facilities

**§ 51.75 Environmental Documents—
construction permit, early site permit, or
combined license.**

(a) *Construction permit stage.* If an environmental document is required under § 51.20 of this part in connection with issuance of a construction permit for a production or utilization facility, the environmental document must meet the requirements of this paragraph. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 of this part must be evaluated on the basis of impact

values set forth in Table S–3, Table of Uranium Fuel Cycle Environmental Data, which must be set out in the environmental document. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the table shall be required.¹ The environmental document must take account of dose commitments and health effects from fuel cycle effluents set forth in Table S–3 and other fuel cycle impacts within the NRC's statutory authority as may reasonably appear significant. The environmental document will also consider the applicant's procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, that will be included in the license as environmental conditions in accordance with § 50.36b of this chapter. For non-light-water reactors as defined in § 50.2 of this chapter, the environmental document must contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear reactor.

(b) *Early site permit stage.* If an environmental document is required under § 51.20 of this part in connection with issuance of an early site permit for a production or utilization facility, the environmental document must meet the requirements of this paragraph. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 of this part must be evaluated on the basis of impact values set forth in Table S–3, Table of Uranium Fuel Cycle Environmental Data, which must be set out in the environmental document. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the table must be required.¹ The environmental document must take account of dose commitments and health effects from fuel cycle effluents set forth in Table S–3 and other fuel cycle impacts within the NRC's statutory authority as may reasonably appear significant. The environmental document must also include an evaluation of the environmental effects of construction and operation of a reactor, or reactors, which have design characteristics that fall within the site characteristics and design parameters for the early site permit application, but only to the extent addressed in the early site permit environmental report. For other than light-water-cooled nuclear power reactors, the environmental document

will address the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor. The environmental document will also consider the applicant's procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, that will be included in the license as environmental conditions in accordance with § 50.36b of this chapter.

(c) *Combined license stage.* If an environmental document is required under § 51.20 of this part in connection with issuance of a combined license that does not reference an early site permit, the environmental document must meet the requirements of this paragraph. The contribution of the environmental effects of the uranium fuel cycle activities specified in § 51.51 of this part must be evaluated on the basis of impact values set forth in Table S–3, Table of Uranium Fuel Cycle Environmental Data, which shall be set out in the environmental document. With the exception of radon-222 and technetium-99 releases, no further discussion of fuel cycle release values and other numerical data that appear explicitly in the table must be required.¹ The environmental document must take account of dose commitments and health effects from fuel cycle effluents set forth in Table S–3 and other fuel cycle impacts within the NRC's statutory authority as may reasonably appear significant.

(1) *Combined license application referencing an early site permit.* If the combined license application references an early site permit, then the environmental document must be prepared as a supplement to the early site permit environmental document. The supplement must be prepared in accordance with § 51.92 of this part. The environmental document need not address information or analyses contained in the environmental report the applicant submitted to the NRC for the early site permit stage or resolved in the Commission's early site permit environmental document, but will address, in addition to the environmental information and analyses otherwise required in this part:

(i) Information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit;

(ii) Information to resolve any significant environmental issue that was not resolved in the early site permit proceeding;

(iii) Any new and significant information for issues related to the impacts of construction and operation of

the facility that were resolved in the early site permit proceeding;

(iv) The process used to identify new and significant information regarding the conclusions in the early site permit environmental document. The process must use a reasonable methodology for identifying such new and significant information; and

(v) Whether all environmental terms and conditions that have been included in the early site permit will be satisfied by the applicant by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the applicant by the time of issuance of the combined license must be set forth as terms or conditions of the combined license.

(2) *Combined license application referencing a standard design certification.* If the combined license application references a standard design certification and the site characteristics of the combined license's site fall within the site parameters specified in the design certification environmental assessment or a standard design certification that was categorically excluded in accordance with § 51.22 of this part, then the combined license environmental document must incorporate by reference the design certification environmental assessment, and summarize the findings and conclusions of the environmental assessment with respect to severe accident mitigation design alternatives, or must incorporate by reference the categorically excluded standard design certification, respectively.

(3) *Combined license application referencing a manufactured reactor.* If the combined license application proposes to use a manufactured reactor and the site characteristics of the combined license's site fall within the site parameters specified in the manufacturing license environmental assessment or a manufactured reactor that was categorically excluded in accordance with § 51.22 of this part, then the combined license environmental document must incorporate by reference the manufacturing license environmental assessment, and summarize the findings and conclusions of the environmental assessment with respect to severe accident mitigation design alternatives, or must incorporate by reference the categorically excluded manufacturing license, respectively. The combined license environmental document will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

(d) *Construction permit, early site permit, or combined license for a*

nuclear reactor. If an environmental document being prepared in accordance with paragraph (a), (b), or (c) of this section relies upon, or if the applicant's environmental report relied upon the findings of one or more of the issues identified as Category 1 issues in appendix C of this part, the environmental document must be prepared as a supplement to NUREG-2249, "Generic Environmental Impact Statement for Licensing of New Nuclear Reactors." The supplemental environmental document will incorporate the conclusions in NUREG-2249 for issues identified as Category 1 for which the applicant has demonstrated that the applicable values and assumptions have been met and for which neither the applicant nor the NRC identified any new and significant information. The supplemental environmental document must contain an analysis for those issues identified as Category 1 for which the applicant could not demonstrate that the applicable values and assumptions were met or for which any new and significant information was identified by the applicant or the NRC, and for any issues identified as Category 2. The supplemental environmental document will consider alternatives for reducing adverse environmental impacts for all issues identified as Category 1 issues in appendix C of this part for which the applicant does not provide the information specified in this paragraph, and for any issues identified as Category 2 issues in appendix C of this part. No such consideration is required for Category 1 issues in appendix C of this part that meet the applicable values and assumptions as specified in this paragraph. The supplemental environmental document will describe the process used to identify new and significant information regarding the issues identified as Category 1 issues in appendix C of this part for which the applicant relied on the findings for those issues.

(e) *Construction permit, early site permit, or combined license for a nuclear reactor.* In connection with:

(1) A construction permit, an early site permit, or a combined license that does not reference an early site permit for a nuclear reactor, as defined in § 50.2 of this chapter, and for which the NRC relied on any of the findings in appendix C of this part in preparing a supplemental environmental document in accordance with § 51.75(d) of this section, the supplemental environmental document must include a recommendation regarding the environmental acceptability of approving the construction permit, the

early site permit, or the combined license. Recommendations and the final decision on the proposed agency action must integrate:

(i) The conclusions in NUREG-2249 for issues designated as Category 1 for which the applicant has demonstrated that the applicable values and assumptions have been met and for which neither the applicant nor the NRC identified any new and significant information.

(ii) Information developed for those Category 1 issues for which the applicant could not demonstrate that the applicable values and assumptions were met and those Category 2 issues applicable to the plant and any new and significant information.

(2) A combined license that references an early site permit for which the environmental document for that early site permit relied on any of the findings in appendix C of this part, the environmental document must be prepared as a supplement to the environmental document for the early site permit. The supplement for the combined license must meet the requirements of § 51.92 of this part and must be considered a supplement to NUREG-2249.

(3) The issuance of an operating license for which the NRC relied on any of the findings in appendix C of this part in preparing the supplemental environmental document for the construction permit for that nuclear reactor, the environmental document must be prepared as a supplement to the environmental document for the construction permit. The supplement must meet the requirements of § 51.95(b) of this part and must be considered a supplement to NUREG-2249.

¹ Values for releases of Rn-222 and Tc-99 are not given in the table. The amount and significance of Rn-222 releases from the fuel cycle and Tc-99 releases from waste management or reprocessing activities shall be considered in the environmental document and may be the subject of litigation in individual licensing proceedings.

§ 51.76 Environmental documents—limited work authorization.

An environmental document prepared in connection with issuance of a limited work authorization must meet the requirements in the following paragraphs.

(a) *Limited work authorization submitted as part of complete construction permit or combined license application.* If the application for a limited work authorization is submitted as part of a complete construction permit or combined license application,

then the NRC will prepare a single environmental document addressing both the limited work authorization and the construction permit or combined license application in accordance with § 51.75(a) or (c) of this part, as applicable. The environmental document will also address the activities the applicant proposes to be conducted under the limited work authorization.

(b) *Phased application for limited work authorization under § 2.101(a)(9) of this chapter.* If the application for a limited work authorization is submitted in accordance with § 2.101(a)(9) of this chapter, then the environmental document for part one of the application may be limited to consideration of the activities proposed to be conducted under the limited work authorization and the proposed redress plan. If either part of the application relies on any of the findings in appendix C of this part in its environmental report, then the environmental document for part one may implement the process in § 51.75(d) of this part to determine whether it can rely on any of the findings in appendix C of this part. Siting issues, including issues related to operation of the proposed nuclear power plant at the site, may not be considered unless included as part of the application in accordance with § 2.101(a)(9)(ii)(a–1) of this chapter. After part two of the application is docketed, the NRC will prepare an environmental document for part two of the application in accordance with § 51.75(a) or (c) of this part, as applicable. No updating of the information contained in the environmental document prepared for part one is necessary in preparation of the environmental document prepared for part two.

(1) For part one of the application, the statutory deadline provided in § 51.15 of this part will start upon NRC acceptance for docketing of part one of the application.

(2) For part two of the application, the statutory deadline provided in § 51.15 of this part will start upon NRC acceptance for docketing of part two of the application.

(c) *Limited work authorization submitted as part of an early site permit application.* If the application for a limited work authorization is submitted as part of an application for an early site permit, then the NRC will prepare an environmental document in accordance with § 51.75(b) of this part. However, the analysis must also address the activities proposed to be conducted under the limited work authorization.

(d) *Limited work authorization request submitted by an early site*

permit holder. If the application for a limited work authorization is submitted by a holder of an early site permit, then the NRC will prepare a supplement to the environmental document for the early site permit, if appropriate.

(e) *Limited work authorization for a site where an environmental document was prepared, but the facility construction was not completed.* If the limited work authorization is for activities to be conducted at a site for which the NRC has previously prepared an environmental document for the construction and operation of a nuclear power plant, and a construction permit was issued but construction of the plant was not completed, then the environmental document must incorporate by reference the earlier environmental document. The environmental document must be limited to a consideration of whether there is significant new information with respect to the environmental impacts of construction, relevant to the activities to be conducted under the limited work authority, so that the conclusion of the referenced environmental document on the impacts of construction would, when analyzed in accordance with § 51.71 of this part, lead to the conclusion that the limited work authorization should not be issued or should be issued with appropriate conditions.

(f) *Environmental document.* An environmental document prepared under this section must separately evaluate the environmental impacts and proposed alternatives attributable to the activities proposed to be conducted under the limited work authorization. However, if the “Applicant’s Environmental Report—Limited Work Authorization Stage” or “Applicant-prepared Draft Environmental Document—Limited Work Authorization Stage,” also contains the information described in § 51.75 of this part, then the environmental document may also address the impacts of construction and operation for the proposed facility (including the environmental impacts attributable to the limited work authorization) in accordance with § 51.71, and § 51.75(a) or (c) of this part, as applicable. For any environmental document prepared under this section, if the applicant’s environmental report or applicant-prepared draft environmental document relied upon the findings of one or more of the issues identified as Category 1 issues in appendix C of this part, the environmental document must be prepared as a supplement to NUREG–2249, “Generic Environmental Impact Statement for Licensing of New Nuclear

Reactors.” The supplemental environmental document will incorporate the conclusions in NUREG–2249 for issues identified as Category 1 for which the applicant has demonstrated that the applicable values and assumptions have been met and for which neither the applicant nor the NRC identified any new and significant information. The supplemental document must contain an analysis for those issues identified as Category 1 for which the applicant could not demonstrate that the applicable values and assumptions were met or for which any new and significant information was identified by the applicant or the NRC, and for any issues identified as Category 2.

§ 51.92 Supplement to the environmental document.

If the proposed agency action has not been taken, a supplement to an environmental document is required if:

- (a) There are substantial changes in the proposed agency action that are relevant to environmental effects; or
- (b) The NRC decides, in its discretion, that there are substantial new circumstances or information about the significance of the adverse effects that bear on the proposed agency action or its effects.

§ 51.95 Postconstruction environmental document.

(a) *General.* An environmental document prepared under the provisions of this section may incorporate by reference any information contained in a previous environmental document that relates to the same production or utilization facility. Documents that may be referenced include, but are not limited to, the final environmental impact statement; supplements to the final environmental impact statement, including supplements prepared at the operating license stage; final generic environmental impact statements; environmental assessments and records of decision prepared in connection with the construction permit, the operating license, the early site permit, or the combined license and any license amendment for that facility.

(b) *Initial operating license stage.* In connection with the issuance of an operating license for a production or utilization facility, the environmental document must be a supplement to the final environmental document on the construction permit for that facility, which will update the prior environmental review. The supplement will only cover matters that differ from the final environmental document or

that reflect significant new information concerning matters discussed in the final environmental document.

(c) *Operating license renewal stage.* In connection with the renewal of an operating license or combined license for a nuclear power plant, the environmental document must be a supplement to the Commission's NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," which is available in the NRC's Publicly Available Records System Library at www.nrc.gov/reading-rm/adams.

(1) The supplemental environmental document for the operating license renewal stage need not discuss other issues not related to the environmental effects of the proposed agency action and associated alternatives. The supplemental environmental document will rely on conclusions as amplified by the supporting information in the license renewal generic environmental impact statement for issues designated as Category 1 in Table B-1 of appendix B of this part. The supplemental environmental document must contain an analysis of those issues identified as Category 2 in Table B-1 of appendix B of this part for the proposed agency action in accordance with the considerations in paragraph (5) of this section.

(2) The supplemental environmental document must also consider the impacts from the applicant's plans to modify the facility or its administrative control procedures as described in accordance with § 54.21 of this chapter.

(3) The supplemental environmental document must be issued as a final environmental document after considering any significant new information relevant to the proposed agency action contained in the supplement or incorporated by reference.

(4) The supplemental environmental document must contain a recommendation regarding the environmental acceptability of the license renewal action. To make recommendations and reach a final decision on the proposed agency action, the environmental document must integrate the conclusions in the license renewal generic environmental impact statement for issues designated as Category 1 with information developed for those Category 2 issues applicable to the nuclear power plant under paragraph (5) of this section and any new and significant information.

(5) For license renewal applications covered by Table B-1 for a nuclear power plant for which an operating license, construction permit, or

combined license was issued as of June 30, 1995, the supplemental environmental document must address the information required in paragraphs (c)(1) and (c)(2) of this section subject to the following considerations:

(i) For those issues identified as Category 2 issues in Table B-1 of appendix B of this part, the analyses of the environmental impacts of the proposed agency action, including the impacts of continued operations and any planned refurbishment activities, if any, during the renewal term must address:

(A) The impact of radionuclides discharged in plant effluents and other wastewater to the ponds and the impact on groundwater quality and beneficial use, if the applicant's plant utilizes cooling ponds.

(B) If the NRC has not previously considered severe accident mitigation alternatives for the applicant's plant in an environmental impact statement or related supplement or in an environmental assessment, consideration of alternatives to mitigate severe accidents.

(C) The impact of any documented inadvertent releases of radionuclides into groundwater. The analyses must include a description of any groundwater protection program used by the applicant for the surveillance of piping and components containing radioactive liquids for which a pathway to groundwater may exist. The analysis must also include a description of any past inadvertent releases and the projected impact to the environment (e.g., aquifers, rivers, lakes, ponds, ocean) during the license renewal term.

(ii) The analyses must consider alternatives for reducing adverse impacts for all Category 2 license renewal issues in appendix B of this part.

(iii) The analyses must consider any new and significant information regarding the environmental impacts of license renewal of which the applicant or NRC is aware.

(d) *Postoperating license stage.* In connection with the amendment of certain licensing actions, the environmental document will be prepared as a supplemental environmental document if an environmental document is required by § 51.20 of this part. These actions include the amendment of an operating or combined license authorizing decommissioning activities at a production or utilization facility, either for unrestricted use or based on continuing use restrictions applicable to the site. They also include the amendment of a license to approve a

license termination plan or decommissioning plan under §§ 50.82, 52.110, and part 53 of this chapter, either for unrestricted use or based on continuing use restrictions applicable to the site. Additionally, this applies to the issuance, amendment or renewal of a license to store spent fuel at a nuclear power reactor after expiration of the operating or combined license for the nuclear power reactor. In each of these cases, the environmental document will be prepared as an update to the prior environmental document with any new information or significant environmental change associated with the applicant's proposed decommissioning activities or with the applicant's proposed activities with respect to the planned storage of spent fuel. The supplement or assessment may incorporate by reference any information contained in the final environmental document—for the operating or combined license stage, as appropriate, or in the records of decision prepared in connection with the early site permit, construction permit, operating license, or combined license for that facility.

NEPA Procedure and Administrative Action—General

§ 51.101 Limitations on actions.

(a) Except as provided in § 51.13 of this part and paragraph (c) of this section, until the NRC publishes a record of decision or other decision document integrating the NRC's considerations under NEPA in connection with a proposed agency action for which an environmental impact statement is prepared, or a finding of no significant impact or notice of a finding of no significant impact in the **Federal Register**, or makes a categorical exclusion determination, as applicable, the NRC staff will take no action concerning a proposal that would:

(i) Have an adverse environmental effect, or

(ii) Limit the choice of reasonable alternatives.

(b) If NRC is considering an application and becomes aware that the applicant is about to take an action within the NRC's jurisdiction that would meet either of the criteria in paragraph (a) of this section, the NRC should promptly notify the applicant that the NRC will take appropriate action to ensure that the objectives and procedures of NEPA are achieved.

(c) This section does not preclude any applicant for an NRC permit, license, or other form of permission, or amendment to or renewal of an NRC permit, license,

or other form of permission, from developing any plans or designs or performance of other activities necessary to support an application for Federal, State, Tribal, or local permits or assistance.

§ 51.102 Documentation of Decision.

(a) At the time of the NRC's decision on the proposed agency action for which an environmental impact statement was prepared, the NRC will prepare and timely publish a concise public record of decision document or joint decision document notifying the public that the decisionmaker has certified that the NRC has considered all relevant information raised in the NEPA process and that the NEPA process has closed. Alternatively, the NRC may integrate its considerations under NEPA into any other decision-making document, with documentation appropriate for the proposal under consideration.

(b) The record of decision, or other decision document, will be clearly identified and will:

(1) State the decision.

(2) Identify all alternatives considered by the NRC in reaching the decision and state that the reasonable range of alternatives is discussed in the environmental impact statement.

(3) Discuss preferences among alternatives based on relevant factors, including the NRC's statutory mission and any essential considerations of national policy, which were evaluated by the NRC in making the decision and state how these considerations entered into the decision.

(4) State whether the NRC has taken all practicable measures within its jurisdiction to avoid or minimize environmental harm from the alternative selected, and if not, explain why those measures were not adopted. Summarize any license conditions and monitoring programs adopted in connection with mitigation measures.

(c) The record of decision may be integrated into any other record prepared by the NRC in connection with the action.

(d) The record of decision may incorporate by reference material contained in an environmental impact statement.

Geologic Repositories

§ 51.109 Public hearings in proceedings for issuance of materials license with respect to a geologic repository.

(a)(1) In a proceeding for issuance of a construction authorization for a high-level radioactive waste repository at a geologic repository operations area under parts 60 and 63 of this chapter,

and in a proceeding for issuance of a license to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area under parts 60 and 63 of this chapter, the NRC staff shall, upon the publication of the notice of hearing in the **Federal Register**, present its position on whether it is practicable to adopt, without further supplementation, the environmental impact statement (including any supplement thereto) prepared by the Secretary of Energy. If the position of the staff is that supplementation of the environmental impact statement by NRC is required, it shall file its final supplemental environmental impact statement with the Environmental Protection Agency, furnish that statement to commenting agencies, and make it available to the public, before presenting its position, or as soon thereafter as may be practicable. In discharging its responsibilities under this paragraph, the staff shall be guided by the principles set forth in paragraphs (c) and (d) of this section.

(2) Any other party to the proceeding who contends that it is not practicable to adopt the DOE environmental impact statement, as it may have been supplemented, shall file a contention to that effect within thirty (30) days after the publication of the notice of hearing in the **Federal Register**. Such contention must be accompanied by one or more affidavits which set forth factual and/or technical bases for the claim that, under the principles set forth in paragraphs (c) and (d) of this section, it is not practicable to adopt the DOE environmental impact statement, as it may have been supplemented. The presiding officer shall resolve disputes concerning adoption of the DOE environmental impact statement by using, to the extent possible, the criteria and procedures that are followed in ruling on motions to reopen under § 2.326 of this chapter.

(b) In any such proceeding, the presiding officer will determine those matters in controversy among the parties within the scope of NEPA and this subpart, specifically including whether, and to what extent, it is practicable to adopt the environmental impact statement prepared by the Secretary of Energy in connection with the issuance of a construction authorization and license for such repository.

(c) The presiding officer will find that it is practicable to adopt any environmental impact statement prepared by the Secretary of Energy in connection with a geologic repository proposed to be constructed under Title

I of the Nuclear Waste Policy Act of 1982, as amended, unless:

(1)(i) The action proposed to be taken by the Commission differs from the action proposed in the license application submitted by the Secretary of Energy; and

(ii) The difference may significantly affect the quality of the human environment; or

(2) Significant and substantial new information or new considerations render such environmental impact statement inadequate.

(d) To the extent that the presiding officer determines it to be practicable, in accordance with paragraph (c) of this section, to adopt the environmental impact statement prepared by the Secretary of Energy, such adoption shall be deemed to satisfy all responsibilities of the Commission under NEPA and no further consideration under NEPA or this subpart shall be required.

(e) To the extent that it is not practicable, in accordance with paragraph (c) of this section, to adopt the environmental impact statement prepared by the Secretary of Energy, the presiding officer will:

(1) Determine whether the requirements of section 102(2) (A), (C), and (H) of NEPA and the regulations in this subpart have been met;

(2) Independently consider the final balance among conflicting factors contained in the record of the proceeding with a view to determining the appropriate action to be taken;

(3) Determine, after weighing the environmental, economic, technical and other benefits against environmental and other costs, whether the construction authorization or license should be issued, denied, or appropriately conditioned to protect environmental values;

(4) Determine, in an uncontested proceeding, whether the NEPA review conducted by the NRC staff has been adequate; and

(5) Determine, in a contested proceeding, whether in accordance with the regulations in this subpart, the construction authorization or license should be issued as proposed.

(f) In making the determinations described in paragraph (e) of this section, the environmental impact statement will be deemed modified to the extent that findings and conclusions differ from those in the final statement prepared by the Secretary of Energy, as it may have been supplemented. The initial decision will be distributed to any persons not otherwise entitled to receive it who responded to the request in the notice of docketing. If the Commission reaches conclusions

different from those of the presiding officer with respect to such matters, the final environmental impact statement will be deemed modified to that extent and the decision will be similarly distributed.

(g) The provisions of this section shall be followed in any proceedings for the issuance of a license to receive and possess source, special nuclear, and byproduct material at a geologic repository operations area.

Appendix A [Reserved]

Appendix B 10 CFR Part 51— Environmental Effect of Renewing the Operating License of a Nuclear Power Plant

The Commission has assessed the environmental impacts associated with granting a renewed operating license for a nuclear power plant for which an operating license, construction permit, or combined license was issued as of June 30, 1995. This assessment applies to applications for initial or a first (*i.e.*, one term) subsequent license renewal. Table B–1 summarizes the

Commission's findings on the scope and magnitude of environmental impacts of renewing the operating license for a nuclear power plant as required by the National Environmental Policy Act of 1969, as amended. Table B–1, subject to an evaluation of those issues identified in Category 2 as requiring further analysis and possible significant new information, represents the analysis of the environmental impacts associated with renewal of any operating license. On a 10-year cycle, the Commission intends to review the material in this appendix and update it if necessary.

TABLE B–1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR INITIAL AND ONE TERM OF SUBSEQUENT LICENSE RENEWAL OF NUCLEAR POWER PLANTS ¹

Issue	Category ²	Finding ³
Surface Water Resources		
Surface water use and quality (non-cooling system impacts).	1	SMALL. Impacts are expected to be small if best management practices are employed to control soil erosion and spills. Surface water use associated with continued operations and refurbishment associated with license renewal would not increase significantly or would be reduced if refurbishment occurs during a plant outage.
Discharge of metals in cooling system effluent.	1	SMALL. Discharges of metals have not been found to be a problem at operating nuclear power plants with cooling-tower-based heat dissipation systems and have been satisfactorily mitigated at other plants. Discharges are monitored and controlled as part of the National Pollutant Discharge Elimination System (NPDES) permit process.
Discharge of biocides, sanitary wastes, and minor chemical spills.	1	SMALL. The effects of these discharges are regulated by Federal and State environmental agencies. Discharges are monitored and controlled as part of the NPDES permit process. These impacts have been small at operating nuclear power plants.
Effects of dredging on surface water quality.	1	SMALL. Dredging to remove accumulated sediments in the vicinity of intake and discharge structures and to maintain barge shipping has not been found to be a problem for surface water quality. Dredging is performed under permit from the U.S. Army Corps of Engineers, and possibly, from other State or local agencies.
Groundwater Resources		
Groundwater quality degradation (plants with cooling ponds).	2	SMALL or MODERATE. Sites with cooling ponds could degrade groundwater quality. The significance of the impact would depend on site-specific conditions including cooling pond water quality, site hydrogeologic conditions (including the interaction of surface water and groundwater), and the location, depth, and pump rate of water wells.
Radionuclides released to groundwater.	2	SMALL or MODERATE. Leaks of radioactive liquids from plant components and pipes have occurred at numerous plants. Groundwater protection programs have been established at all operating nuclear power plants to minimize the potential impact from any inadvertent releases. The magnitude of impacts would depend on site-specific characteristics.
Terrestrial Resources		
Exposure of terrestrial organisms to radionuclides.	1	SMALL. Doses to terrestrial organisms from continued nuclear power plant operation and refurbishment during the license renewal term would be expected to remain well below U.S. Department of Energy exposure guidelines developed to protect these organisms.
Aquatic Resources		
Exposure of aquatic organisms to radionuclides.	1	SMALL. Doses to aquatic organisms from continued nuclear power plant operation and refurbishment during the license renewal term would be expected to remain well below U.S. Department of Energy exposure guidelines developed to protect these organisms.
Human Health		
Radiation exposures to plant workers.	1	SMALL. Occupational doses from continued operations and refurbishment associated with license renewal are expected to be within the range of doses experienced during the current license term and would continue to be well below regulatory limits.
Radiation exposures to the public ...	1	SMALL. Radiation doses to the public from continued operations and refurbishment associated with license renewal are expected to continue at current levels and would be well below regulatory limits.

TABLE B-1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR INITIAL AND ONE TERM OF SUBSEQUENT LICENSE RENEWAL OF NUCLEAR POWER PLANTS ¹—Continued

Issue	Category ²	Finding ³
Postulated Accidents		
Design-basis accidents	1	SMALL. The NRC staff has concluded that the environmental impacts of design-basis accidents are of small significance for all plants.
Severe accidents ⁴	1	SMALL. The probability-weighted consequences of atmospheric releases, fallout onto open bodies of water, releases to groundwater, and societal and economic impacts from severe accidents are small for all plants. Severe accident mitigation alternatives do not warrant further plant-specific analysis because the demonstrated reductions in population dose risk and continued severe accident regulatory improvements substantially reduce the likelihood of finding cost-effective significant plant improvements.
Waste Management		
Low-level waste storage and disposal.	1	SMALL. The comprehensive regulatory controls that are in place and the low public doses being achieved at reactors ensure that the radiological impacts on the environment would remain small during the license renewal term.
Onsite storage of spent nuclear fuel	1	During the license renewal term, SMALL. The expected increase in the volume of spent fuel from an additional 20 years of operation can be safely accommodated onsite during the license renewal term with small environmental impacts through dry or pool storage at all plants. For the period after the licensed life for reactor operations, the impacts of onsite storage of spent nuclear fuel during the continued storage period are discussed in NUREG-2157 and as stated in § 51.23(b), shall be deemed incorporated into this issue.
Offsite radiological impacts of spent nuclear fuel and high-level waste disposal.	1	For the high-level waste and spent-fuel disposal component of the fuel cycle, the EPA established a dose limit of 0.15 mSv (15 millirem) per year for the first 10,000 years and 1.0 mSv (100 millirem) per year between 10,000 years and 1 million years for off-site releases of radionuclides at the proposed repository at Yucca Mountain, Nevada. The Commission concludes that the impacts would not be sufficiently large to require the NEPA conclusion, for any plant, that the option of extended operation under 10 CFR part 54 should be eliminated. Accordingly, while the Commission has not assigned a single level of significance for the impacts of spent fuel and high-level waste disposal, this issue is considered Category 1.
Mixed-waste storage and disposal ..	1	SMALL. The comprehensive regulatory controls and the facilities and procedures that are in place ensure proper handling and storage, as well as negligible doses and exposure to toxic materials for the public and the environment at all plants. License renewal would not increase the small, continuing risk to human health and the environment posed by mixed waste at all plants. The radiological and nonradiological environmental impacts of long-term disposal of mixed waste from any individual plant at licensed sites are small.
Uranium Fuel Cycle		
Offsite radiological impacts—individual impacts from other than the disposal of spent fuel and high-level waste.	1	SMALL. The impacts to the public from radiological exposures have been considered by the Commission in Table S-3 of this part. Based on information in the GEIS, impacts to individuals from radioactive gaseous and liquid releases, including radon-222, would remain at or below the NRC's regulatory limits.
Offsite radiological impacts—collective impacts from other than the disposal of spent fuel and high-level waste.	1	There are no regulatory limits applicable to collective doses to the general public from fuel-cycle facilities. The practice of estimating health effects on the basis of collective doses may not be meaningful. All fuel-cycle facilities are designed and operated to meet the applicable regulatory limits and standards. The Commission concludes that the collective impacts are acceptable. The Commission concludes that the impacts would not be sufficiently large to require the NEPA conclusion, for any plant, that the option of extended operation under 10 CFR part 54 should be eliminated. Accordingly, while the Commission has not assigned a single level of significance for the collective impacts of the uranium fuel cycle, this issue is considered Category 1.
Transportation	1	SMALL. The impacts of transporting materials to and from uranium-fuel-cycle facilities on workers, the public, and the environment are expected to be small.
Termination of Nuclear Power Plant Operations and Decommissioning		
Termination of plant operations and decommissioning.	1	SMALL. License renewal is expected to have a negligible effect on the impacts of terminating operations and decommissioning on all resources.

¹ Data supporting this table are contained in NUREG-1437, Revision 2, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants," August 2024.

² The numerical entries in this column are based on the following category definitions:

Category 1: For the issue, the analysis reported in the Generic Environmental Impact Statement has shown:

(1) The environmental impacts associated with the issue have been determined to apply to all nuclear plants;

(2) A single significance level (*i.e.*, SMALL, MODERATE, or LARGE) has been assigned to the impacts (except for offsite radiological impacts of spent nuclear fuel and high-level waste disposal and offsite radiological impacts—collective impacts from other than the disposal of spent fuel and high-level waste); and

(3) Mitigation of adverse impacts associated with the issue has been considered in the analysis, and it has been determined that additional plant-specific mitigation measures are not likely to be sufficiently beneficial to warrant implementation.

The generic analysis of the issue may be adopted in each plant-specific review.

Category 2: For the issue, the analysis reported in the Generic Environmental Impact Statement has shown that one or more of the criteria of Category 1 cannot be met, and therefore additional plant-specific review is required.

³ The impact findings in this column are based on the definitions of three significance levels. Unless the significance level is identified as beneficial, the impact is adverse, or in the case of “SMALL,” may be negligible. The definitions of significance follow:

SMALL—For the issue, environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource. For the purposes of assessing radiological impacts, the Commission has concluded that those impacts that do not exceed permissible levels in the Commission’s regulations are considered SMALL as the term is used in this table.

MODERATE—For the issue, environmental effects are sufficient to alter noticeably, but not to destabilize, important attributes of the resource.

LARGE—For the issue, environmental effects are clearly noticeable and are sufficient to destabilize important attributes of the resource.

These levels are used for describing the environmental impacts of the proposed agency action (license renewal), as well as for the impacts of a range of reasonable alternatives to the proposed agency action.

For issues where probability is a key consideration (*i.e.*, accident consequences), probability was a factor in determining significance.

For the purpose of assessing impacts when preparing a categorical exclusion or environmental assessment, the Commission has concluded that a SMALL significance level is the equivalent of concluding no significant impact.

⁴ Although the NRC does not anticipate any license renewal applications for nuclear power plants for which a previous severe accident mitigation design alternative (SAMDA) or severe accident mitigation alternative (SAMA) analysis has not been performed, alternatives to mitigate severe accidents must be considered for all plants that have not considered such alternatives and would be the functional equivalent of a Category 2 issue requiring plant-specific analysis.

Appendix C of Part 51—Environmental Effect of Issuing a Permit or License for a New Nuclear Reactor

The Commission has assessed the environmental impacts associated with authorizing the construction, operation, and decommissioning of a nuclear reactor. Table C–1 summarizes the

Commission’s generic findings on the scope and magnitude of environmental impacts of such an authorization as required by section 102(2) of the National Environmental Policy Act of 1969, as amended. Table C–1 presents the results of the generic analysis of those environmental impacts associated with building,¹ operating, and

decommissioning a nuclear reactor that the NRC has designated as Category 1, as well as listing the issues that could not be resolved generically, designated as Category 2.² On a 10-year cycle, the Commission intends to review the material in this appendix and update it if necessary.

TABLE C–1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR ISSUING A PERMIT OR LICENSE FOR A NEW NUCLEAR REACTOR ¹

Issue	Category ²	Finding ³	Plant parameter envelope/site parameter envelope values and assumptions ⁴
Water Resources			
Groundwater Quality Degradation Due to Plant Discharges.	1	SMALL	The plant is outside the recharge area for any EPA-designated SSA, or any aquifer designated to have special protections by a State, Tribal, or regional authority. The plant is outside the wellhead protection area or designated contributing area for any public water supply well. There are no planned discharges to the subsurface (by infiltration or injection).
Water Quality Degradation due to Inadvertent Spills and Leaks during Operation.	1	SMALL	Applicable requirements and guidance on spill prevention and control are followed, including relevant BMPs and IPPPs. There are no planned discharges to the subsurface (by infiltration or injection), including stormwater discharge. A groundwater protection program conforming to currently applicable industry guidance is established and followed. Adherence to requirements in NPDES permits issued by the EPA or a given State, and any other applicable permits.
Degradation of Water Quality from Plant Effluent Discharges to Municipal Systems.	1	SMALL	Municipal Systems’ Available Capacity to Receive and Treat Plant Effluent accounts for all existing and reasonably foreseeable future discharges. Agreement to discharge to a municipal treatment system is obtainable.
Terrestrial Ecology			
Exposure of Terrestrial Organisms to Radionuclides.	1	SMALL	Applicants would demonstrate in their application that any radiological nonhuman biota doses would be below International Atomic Energy Agency (IAEA) and National Council on Radiation Protection and Measurements (NCRP) guidelines.

¹ The term “building,” as used in the NR GEIS, includes the full range of preconstruction (building activities not within the NRC’s regulatory authority), and construction and installation

activities (building activities within the NRC’s regulatory authority).

² For the purpose of assessing impacts when preparing a categorical exclusion or environmental

assessment, the Commission has concluded that a SMALL significance level is the equivalent of concluding no significant impact.

TABLE C-1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR ISSUING A PERMIT OR LICENSE FOR A NEW NUCLEAR REACTOR ¹—Continued

Issue	Category ²	Finding ³	Plant parameter envelope/site parameter envelope values and assumptions ⁴
Aquatic Ecology			
Exposure of aquatic organisms to radionuclides.	1	SMALL	Applicants would demonstrate in their application that any radiological nonhuman biota doses would be below IAEA and NCRP guidelines.
Environmental Hazards—Radiological Environment			
Radiological dose to construction workers.	1	SMALL	For protection against radiation, the applicant must meet the regulatory requirements of: —10 CFR 20.1101 Radiation Protection Programs if issued a license. —10 CFR 20.1201 Occupational dose limits for adults 10 CFR 20.1301 Dose limits for individual members of the public. —Appendix B to 10 CFR part 20 Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage. —10 CFR 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors. —10 CFR 50.36a. Technical specifications on effluents from nuclear power reactors. Application contains sufficient technical information for the staff to complete the detailed technical safety review. Application will be found to be in compliance by the NRC with the above regulations through a radiation protection program and an effluent release monitoring program.
Occupational doses to workers	1	SMALL	For protection against radiation, the applicant must meet the regulatory requirements of: —10 CFR 20.1101 Radiation Protection Programs if issued a license. —10 CFR 20.1201 Occupational dose limits for adults. —Appendix B of 10 CFR part 20 Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage. —10 CFR 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors. —10 CFR 50.36a Technical specifications on effluents from nuclear power reactors. Application contains sufficient technical information for the staff to complete the detailed technical safety review. Application will be found to be in compliance by the NRC with the above regulations through a radiation protection program and an effluent release monitoring program.
Maximally exposed individual annual doses.	1	SMALL	For protection against radiation, the applicant must meet the regulatory requirements of: —10 CFR 20.1101 Radiation Protection Programs if issued a license. —10 CFR 20.1301 Dose limits for individual members of the public. —Appendix B of 10 CFR part 20 ALIs and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage. —10 CFR 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors. —10 CFR 50.36a Technical specifications on effluents from nuclear power reactors. Application contains sufficient technical information for the staff to complete the detailed technical safety review. Application will be found to be in compliance by the NRC with the above regulations through a radiation protection program and an effluent release monitoring program.

TABLE C-1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR ISSUING A PERMIT OR LICENSE FOR A NEW NUCLEAR REACTOR¹—Continued

Issue	Category ²	Finding ³	Plant parameter envelope/site parameter envelope values and assumptions ⁴
Total population annual doses	1	SMALL	For protection against radiation, the applicant must meet the regulatory requirements of: —10 CFR 20.1101 Radiation Protection Programs if issued a license. —10 CFR 20.1301 Dose limits for individual members of the public. —Appendix B of 10 CFR part 20 ALIs and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage. —10 CFR 50.34a Design objectives for equipment to control releases of radioactive material in effluents—nuclear power reactors. —10 CFR 50.36a Technical specifications on effluents from nuclear power reactors. Application contains sufficient technical information for the staff to complete the detailed technical safety review. Application will be found to be in compliance by the NRC with the above regulations through a radiation protection program and an effluent release monitoring program.
Nonhuman biota doses	1	SMALL	Applicants would demonstrate in their application that any radiological nonhuman biota doses would be below IAEA and NCRP guidelines.

Waste Management—Radiological Waste Management

Low-level radioactive waste (LLRW).	1	SMALL	Applicants must meet the regulatory requirements of 10 CFR part 20 (e.g., 10 CFR 20.1406 and subpart K), 10 CFR part 61, 10 CFR part 71, and 10 CFR part 72. Quantities of LLRW generated at a new nuclear reactor would be less than the quantities of LLRW generated at existing nuclear power plants, which generate an average of 21,200 cubic feet [ft ³] (600 cubic meters [m ³]) and 2,000 curies [Ci] (7.4×10^{13} becquerels [Bq]) per year for boiling water reactors and half that amount for pressurized water reactors.
Onsite spent nuclear fuel management.	1	SMALL	Compliance with 10 CFR part 72.
Mixed waste	1	SMALL	RCRA Small Quantity Generator for Mixed Waste.

Postulated Accidents

Design Basis Accidents Involving Radiological Releases.	1	SMALL	For the exclusion area boundary, the maximum total effective dose equivalent for any 2-hour period during the radioactivity release should be calculated. For the low-population zone, the total effective dose equivalent should be calculated for the duration of the accident release (i.e., 30 days, or other duration as justified). The above calculations would compare the design basis accident doses with the dose criteria given in regulations related to the application (e.g., 10 CFR 50.34(a)(1), 10 CFR 52.17(a)(1), and 10 CFR 52.79(a)(1)), standard review plans (e.g., standard review plan criteria, table 1 in standard review plan section 15.0.3 of NUREG-0800), and regulatory guides, (e.g., RG 1.183), as applicable.
Accidents Involving Releases of Hazardous Chemicals.	1	SMALL	Reactor inventory of a regulated substance is less than its Threshold Quantity (TQ). TQs are found in 40 CFR 68.130, tables 1, 2, 3, and 4; and Reactor inventory of an extremely hazardous substance is less than its Threshold Planning Quantity (TPQ). TPQs are found in 40 CFR part 355, appendices A and B.

TABLE C-1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR ISSUING A PERMIT OR LICENSE FOR A NEW NUCLEAR REACTOR¹—Continued

Issue	Category ²	Finding ³	Plant parameter envelope/site parameter envelope values and assumptions ⁴
Severe Accidents	1	SMALL	Within the maximum population dose risk 95th confidence bounding value of 9.727×10^3 person-rem per reactor year (<i>i.e.</i>, Indian Point Energy Center Units 2 and 3) specified in the 1996 LR GEIS and demonstrating the utilization of 10 CFR 50.155 or diverse and flexible coping strategies (FLEX) to address mitigation of beyond-design-basis events; or Within the maximum 10- and 150-mile Exposure Index at the 95th confidence bounds value of 1.896×10^4 and 2.864×10^6, respectively (<i>i.e.</i>, Indian Point Energy Center Units 2 and 3) specified in the 1996 LR GEIS and demonstrating the utilization of 10 CFR 50.155 or FLEX to address mitigation of beyond-design-basis events; or Utilizing the source term from 10 CFR 50.34(a)(1)(ii)(D), or the equivalent 10 CFR part 52 regulation, with a non-intact containment or confinement for population density assessments under 10 CFR 100.21(h) to demonstrate a calculated total effective dose equivalent (TEDE) of no greater than 1 rem over a period of 30 days and that no further mitigation is necessary because health effects are shown not to be significant or a new reactor that is co-located with an existing LWR may compare its source terms to demonstrate that the LWR's severe accident risks bounds the new reactor's risks; or Utilizing 10 CFR 50.33(g)(2) to demonstrate there is no plume exposure pathway emergency planning zone where the projected total effective dose equivalent exceeds 1 rem over 96 hours (<i>i.e.</i>, 10 CFR 50.33(g)(2)(i)(A)) and no further mitigation is necessary because health effects are shown not to be significant.
Acts of Terrorism	1	SMALL	The environmental impacts of acts of terrorism and sabotage only need to be addressed if a reactor facility is subject to the jurisdiction of the U.S. Court of Appeals for the Ninth Circuit.
Fuel Cycle			
Uranium Recovery	1	SMALL	Table S-3 of 10 CFR 51.51 is expected to bound the radiological impacts for new reactor fuels, because of uranium fuel cycle changes since WASH-1248, including: —Increasing use of in situ leach uranium mining has lower radiological environmental impacts than traditional mining and milling methods. —Current light-water reactors (LWRs) are using nuclear fuel more efficiently due to higher levels of fuel burnup resulting in less demand for mining and milling activities. Must satisfy the regulatory requirements of 10 CFR part 40, "Domestic Licensing of Source Material," and 10 CFR part 71, "Packaging and Transportation of Radioactive Material."
Uranium Conversion	1	SMALL	Table S-3 of 10 CFR 51.51 is expected to bound the radiological impacts for new reactor fuels because of uranium fuel cycle changes since WASH-1248, including: Current LWRs are using nuclear fuel more efficiently due to higher levels of fuel burnup resulting in less demand for conversion activities. Must satisfy the regulatory requirements of 10 CFR part 40, "Domestic Licensing of Source Material," 10 CFR part 71, "Packaging and Transportation of Radioactive Material," and 10 CFR part 73, "Physical Protection of Plants and Materials."
Enrichment	1	SMALL	Table S-3 is expected to bound the radiological impacts for new nuclear reactor fuels, because of uranium fuel cycle changes since WASH-1248, including: Current LWRs are using nuclear fuel more efficiently due to higher levels of fuel burnup resulting in less demand for enrichment activities. Must satisfy the regulatory requirements of 10 CFR part 40, "Domestic Licensing of Source Material;" 10 CFR part 70, "Domestic Licensing of Special Nuclear Material;" 10 CFR part 71, "Packaging and Transportation of Radioactive Material;" and 10 CFR part 73, "Physical Protection of Plants and Materials."

TABLE C-1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR ISSUING A PERMIT OR LICENSE FOR A NEW NUCLEAR REACTOR¹—Continued

Issue	Category ²	Finding ³	Plant parameter envelope/site parameter envelope values and assumptions ⁴
Fuel Fabrication (excluding metal fuel and liquid-fueled molten salt).	1	SMALL	Table S-3 is expected to bound the radiological impacts for new nuclear reactor fuels, because of uranium fuel cycle changes since WASH-1248, including: Current LWRs are using nuclear fuel more efficiently due to higher levels of fuel burnup resulting in fewer discharged fuel assemblies to be fabricated each year and due to longer time periods between refueling. Must satisfy the regulatory requirements of 10 CFR part 40, "Domestic Licensing of Source Material;" 10 CFR part 70, "Domestic Licensing of Special Nuclear Material;" 10 CFR part 71, "Packaging and Transportation of Radioactive Material;" and 10 CFR part 73, "Physical Protection of Plants and Materials."
Reprocessing	1	SMALL	Table S-3 is expected to bound the radiological impacts for new nuclear reactor fuels, because of uranium fuel cycle changes since WASH-1248, including: Current LWRs are using nuclear fuel more efficiently due to higher levels of fuel burnup resulting in fewer discharged fuel assemblies to be reprocessed each year. Reprocessing capacity up to 900 metric tons of uranium [MTU]/yr. Must satisfy the regulatory requirements of 10 CFR part 40, "Domestic Licensing of Source Material;" 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities;" 10 CFR part 70, "Domestic Licensing of Special Nuclear Material;" 10 CFR part 71, "Packaging and Transportation of Radioactive Material;" 10 CFR part 72, "Licensing Requirements for the Independent Storage of Spent Fuel, High-Level Radioactive Waste, and Reactor-related Greater Than Class C Waste;" and 10 CFR part 73, "Physical Protection of Plants and Materials."
Storage and Disposal of Radiological Wastes.	1	SMALL	Table S-3 is expected to bound the radiological impacts for new nuclear reactor fuels, because of uranium fuel cycle changes since WASH-1248, including: Current LWRs are using nuclear fuel more efficiently due to higher levels of fuel burnup resulting in fewer discharged fuel assemblies to be stored and disposed. Waste and spent fuel inventories, as well as their associated certified spent fuel shipping and storage containers, are not significantly different from what has been considered for LWR evaluations in NUREG-2157. Must satisfy the regulatory requirements of 10 CFR part 40, "Domestic Licensing of Source Material;" 10 CFR part 70, "Domestic Licensing of Special Nuclear Material;" 10 CFR part 71, "Packaging and Transportation of Radioactive Material;" 10 CFR part 72, "Licensing Requirements for the Independent Storage of Spent Fuel, High-Level Radioactive Waste, and Reactor-related Greater Than Class C Waste;" and 10 CFR part 73, "Physical Protection of Plants and Materials."
Transportation of Fuel and Waste			
Transportation of Unirradiated Fuel.	1	SMALL	The maximum annual one-way shipment distance does not exceed 59,160 km (36,760 mi). The annual shipments associated with the one-way shipment distance have been normalized to a net electrical output of 880 megawatts electric [MW(e)], <i>i.e.</i> , 1,100 MW(e) with an 80 percent capacity factor from WASH-1238. The maximum annual round-trip shipment distance does not exceed 118,320 km (73,520 mi). The annual shipments associated with the round-trip shipment distance have been normalized to a net electrical output of 880 MW(e), <i>i.e.</i> , 1,100 MW(e) with an 80 percent capacity factor from WASH-1238.
Transportation of Radioactive Waste.	1	SMALL	The maximum annual round-trip shipment distance does not exceed 293,145 km (182,152 mi). The annual shipments associated with the round-trip shipment distance have been normalized to a net electrical output of 880 MW(e), <i>i.e.</i> , 1,100 MW(e) with an 80 percent capacity factor and a shipment volume of 2.34 m ³ /shipment from WASH-1238.

TABLE C-1—SUMMARY OF FINDINGS ON ENVIRONMENTAL ISSUES FOR ISSUING A PERMIT OR LICENSE FOR A NEW NUCLEAR REACTOR ¹—Continued

Issue	Category ²	Finding ³	Plant parameter envelope/site parameter envelope values and assumptions ⁴
Transportation of Irradiated Fuel.	1	SMALL	The maximum annual one-way shipment distance does not exceed 505,393 km (314,037 mi). The annual shipments associated with the one-way shipment distance have been normalized to a net electrical output of 880 MW(e), <i>i.e.</i> , 1,100 MW(e) with an 80 percent capacity factor and a shipment capacity of 0.5 MTU/shipment from WASH-1238. The maximum annual round-trip shipment distance does not exceed 1,010,786 km (628,073 mi). The annual shipments associated with the round-trip shipment distance have been normalized to a net electrical output of 880 MW(e), <i>i.e.</i> , 1,100 MW(e) with an 80 percent capacity factor and a shipment capacity of 0.5 MTU/shipment from WASH-1238. A maximum peak rod burnup of 80 gigawatt-days [GWd]/MTU for UO ₂ fuel and peak pellet burnup of 133 GWd/MTU for TRI-structural ISOTropic (TRISO) fuel.
Decommissioning			
Decommissioning	1	SMALL	The environmental impacts for the following resource areas were generically addressed in NUREG-0586, Supplement 1, would be limited to operational areas, would not be detectable or destabilizing and are expected to have a negligible effect on the impacts of terminating operations and decommissioning: —Radiological. —Radiological Accidents (non-spent-fuel-related). —Occupational Issues. —Transportation. —Irretrievable Resource.

¹Data supporting this table are contained in NUREG-2249, “Generic Environmental Impact Statement for Licensing of New Nuclear Reactors.”

²Category 1 issues—Radiological environmental issues for which the NRC has been able to make a generic finding of SMALL adverse environmental impacts, or beneficial impacts, provided that the applicant's proposed reactor facility and site meet or are bounded by relevant values and assumptions in the PPE and SPE that support the generic finding for that Category issue.

³A finding of SMALL impacts means that environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource. For the purposes of assessing radiological impacts, the Commission has concluded that those impacts that do not exceed permissible levels in the Commission's regulations are considered SMALL as the term is used in this table. For issues where probability is a key consideration (*i.e.*, accident consequences), probability was a factor in determining significance.

Subpart B [Reserved]

PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

■ 31. In § 52.17, revise paragraph (a)(2) to read as follows:

§ 52.17 Contents of applications; technical information.

(a) * * *

(2) A complete environmental report or draft environmental document as required by part 51 of this chapter.

* * * * *

§ 52.18 [Amended]

■ 32. In § 52.18, in the second sentence, remove the phrase “environmental impact statement during review of the application,” and add the phrase

“environmental document” and remove the phrase “during review of the application.”

■ 33. Revise and republish § 52.21 to read as follows:

§ 52.21 Administrative review of applications; hearings.

All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR part 2, as applicable.

§ 52.24 [Amended]

■ 34. In § 52.24, in paragraph (a)(8) remove the phrase “subpart A of 10 CFR part 51” and add in its place the phrase “part 51 of this chapter”.

■ 35. In § 52.47, revise paragraph (b)(2) to read as follows:

§ 52.47 Contents of application; technical information.

* * * * *

(b) * * *

(2) Environmental information as required by part 51 of this chapter.

* * * * *

§ 52.54 [Amended]

■ 36. In § 52.54, in paragraph (a)(7) remove the phrase “subpart A of”.

■ 37. In § 52.80, revise paragraph (b) to read as follows:

§ 52.80 Contents of applications; additional technical information.

* * * * *

(b) Environmental information as required by part 51 of this chapter.

* * * * *

§ 52.97 [Amended]

■ 38. In § 52.97, in paragraph (a)(1)(vi) remove the phrase “subpart A of”.

■ 39. In § 52.110, revise paragraphs (d)(1) and (i)(2)(vii) to read as follows:

§ 52.110 Termination of license.

* * * * *

(d) * * *

(1) Before or within two years following permanent cessation of operations, the licensee shall submit a post-shutdown decommissioning activities report (PSDAR) to the NRC, and a copy to the affected State(s). The report must include a description of the planned decommissioning activities along with a schedule for their accomplishment, an estimate of

expected costs, and a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued categorical exclusion or environmental document.

* * * * *

(i) * * *

(2) * * *

(vii) A supplement to the environmental information as required by part 51 of this chapter describing any substantial new circumstance or information associated with the licensee's proposed termination activities; and

* * * * *

■ 40. In § 52.158, revise paragraph (b)(1) to read as follows:

§ 52.158 Contents of application; additional technical information.

* * * * *

(b) * * *

(1) Environmental information as required by part 51 of this chapter.

* * * * *

■ 41. Revise and republish § 52.163 to read as follows:

§ 52.163 Administrative review of applications; hearings.

A proceeding on a manufacturing license is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of proposed action in § 2.105 of this chapter. All hearings on manufacturing licenses are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

§ 52.167 [Amended]

■ 42. In § 52.167, in paragraph (a)(7) remove the phrase “subpart A of”.

■ 43. In appendix N to part 52, revise paragraph 6. to read as follows:

Appendix N to Part 52—

Standardization of Nuclear Power Plant Designs: Combined Licenses To Construct and Operate Nuclear Power Reactors of Identical Design at Multiple Sites

* * * * *

6. If a categorical exclusion under part 51 of this chapter does not apply, the NRC staff shall issue environmental documents for each of the applications under part 51 of this chapter. If the applications reference a standard design certification, then the environmental document, if required under part 51 of this chapter, for each of the applications

must incorporate by reference the design certification environmental assessment. If the applications do not reference a standard design certification, then the NRC staff shall prepare supplemental environmental documents which address severe accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental document prepared for each application.

* * * * *

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

■ 44. The authority citation for part 53 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 103, 108, 122, 147, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Pub. L. 115–439, 132 Stat. 5571.

■ 45. In § 53.1070, revise paragraph (i)(2)(vii) to read as follows:

§ 53.1070 Termination of license.

* * * * *

(i) * * *

(2) * * *

(vii) Environmental information required by part 51 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

* * * * *

■ 46. In § 53.1080, revise paragraphs (b)(5) and (d)(3) to read as follows:

§ 53.1080 Release of part of a commercial nuclear plant or site for unrestricted use.

* * * * *

(b) * * *

(5) A discussion that provides the reasons for concluding that the environmental impacts associated with the licensee's proposed release of the property will be bounded by appropriate previously issued environmental impact statements, environmental assessments, or categorical exclusions.

* * * * *

(d) * * *

(3) Information required under part 51 of this chapter.

* * * * *

■ 47. In § 53.1100, revise paragraph (f) to read as follows:

§ 53.1100 Filing of application for licenses, certifications, or approvals; oath or affirmation.

* * * * *

(f) *Environmental requirements.* An application for a CP, OL, early site permit, design certification, COL, or ML for a commercial nuclear plant must address the environmental requirements under 10 CFR part 51.

■ 48. In § 53.1112:

■ a. In paragraph (a), remove the phrase “environmental report or draft document” and add in its place the phrases “environmental information” and remove the phrase “§ 51.50” and add in its place the phrase “part 51”; and

■ b. Revise paragraph (b).

The revision reads as follows:

§ 53.1112 Environmental conditions.

* * * * *

(b) Each license authorizing operation of a commercial nuclear plant under this part, and each license for a commercial nuclear plant for which the certification of permanent cessation of operations required under § 53.1070 has been submitted may include conditions to address environmental issues during operation and decommissioning. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from environmental information submitted under part 51 of this chapter as analyzed and evaluated by the NRC, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data and any conditions and monitoring requirement for the protection of the nonaquatic environment.

■ 49. In § 53.1130, revise paragraphs (a)(3)(ii), (b)(1)(i) and (c). The revisions read as follows:

§ 53.1130 Limited work authorizations.

* * * * *

(a) * * *

(3) * * *

(ii) Any required environmental information in accordance with part 51 of this chapter; and

* * * * *

(b) * * *

(1) * * *

(i) The NRC staff determines that a categorical exclusion applies to the LWA or issues the environmental document for the LWA under part 51 of this chapter;

* * * * *

(c) *Effect of limited work authorization.* Any activities undertaken under an LWA are entirely at the risk of the applicant and, except as to the matters determined under paragraph (b)(1) of this section, the issuance of the LWA has no bearing on the requirements of the Act and rules, regulations, or orders issued under the Act. The categorical exclusion or environmental document for a CP or COL application for which an LWA was previously issued will not address, and the presiding officer will not consider, the sunk costs of the holder of the LWA in determining the proposed action (*i.e.*, issuance of the CP or COL).

■ 50. In § 53.1146, revise paragraph (a)(2) to read as follows:

§ 53.1146 Contents of applications for early site permits; technical information.

(a) * * *

(2) Environmental information to justify a categorical exclusion under part 51 of this chapter as applicable, or other information to address the environmental requirements under part 51 of this chapter.

* * * * *

■ 51. In § 53.1149:

■ a. Revise paragraph (a); and

■ b. In paragraph (b) remove the phrase “impact statement” and add in its place the phrase “document”.

The revision reads as follows:

§ 53.1149 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the applicable standards set out in this part. In addition, if a categorical exclusion under part 51 of this chapter does not apply, the Commission must prepare an environmental document during review of the application, under the applicable provisions of 10 CFR part 51. The Commission must determine, after consultation with FEMA, as applicable, whether the information required of the applicant by § 53.1146(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 53.1146(b)(2)(i) are acceptable under either § 50.160 or appendix E to part 50 and § 50.47(b) of this chapter, and whether any emergency plans submitted by the applicant under § 53.1146(b)(2)(ii) provide reasonable assurance that adequate protective measures can and

will be taken in the event of a radiological emergency.

■ 52. In § 53.1241, revise paragraph (a)(1) to read as follows:

§ 53.1241 Contents of applications for standard design certifications; other application content.

(a) * * *

(1) *Environmental requirements.*

Environmental information as required by part 51 of this chapter.

* * * * *

■ 53. In § 53.1282, revise and republish paragraph (b) to read as follows:

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

* * * * *

(b) *Environmental requirements.*

(1) The application must contain environmental information as required by part 51 of this chapter.

(2) If the ML application references a standard design certification, the no environmental report or environmental document is required to contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant.

* * * * *

§ 53.1285 [Amended]

■ 54. In paragraph (b) remove the phrase “impact statement” and add in its place the phrase “document”.

■ 55. In § 53.1312, revise paragraph (a)(1) to read as follows:

§ 53.1312 Contents of applications for construction permits; other application content.

(a) * * *

(1) Environmental information as required under part 51 of this chapter; or

* * * * *

■ 56. In § 53.1372, revise paragraph (a) to read as follows:

§ 53.1372 Contents of applications for operating licenses; other application content.

* * * * *

(a) *Environmental requirements.*

Environmental information as required in accordance with part 51 of this chapter.

* * * * *

■ 57. In § 53.1419, revise paragraphs (a)(1) and (a)(1)(i) to read as follows:

§ 53.1419 Contents of applications for combined licenses; other application content.

(a) * * *

(1) *Environmental requirements.*

(i) Environmental information as required under part 51 of this chapter or

* * * * *

■ 58. In § 53.1470, revise paragraphs (d) and (f) to read as follows:

§ 53.1470 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

* * * * *

(d) Each application submitted pursuant to this section must contain environmental information to address the requirements under part 51 of this chapter, as applicable. The application may incorporate by reference a single document on the environmental impacts of the common design that are applicable to each site.

* * * * *

(f) The NRC must meet the requirements of 10 CFR part 51 for each of the applications. If a categorical exclusion does not apply, and the applications reference a standard design certification, then the environmental document for each of the applications must incorporate by reference the standard design certification environmental assessment. If a categorical exclusion does not apply, and the applications do not reference a standard design certification, then the NRC must prepare environmental documents which address severe accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental document prepared for each application.

* * * * *

PART 54—REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 102, 103, 104, 161, 181, 182, 183, 186, 189, 223, 234 (42 U.S.C. 2132, 2133, 2134, 2136, 2137, 2201, 2231, 2232, 2233, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); 44 U.S.C. 3504 note.

Section 54.17 also issued under E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391.

■ 60. Revise and republish § 54.23 to read as follows:

§ 54.23 Contents of application—environmental information.

Each application must include a supplement to the environmental information that complies with the requirements of part 51 of this chapter.

§ 54.29 [Amended]

■ 61. In § 54.29, in paragraph (b) remove the phrase “subpart A of”.

**PART 61—LICENSING
REQUIREMENTS FOR LAND
DISPOSAL OF RADIOACTIVE WASTE**

■ 62. The authority citation for part 61 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 65, 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 206, 211 (42 U.S.C. 5841, 5846, 5851); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

■ 63. Revise and republish § 61.10 to read as follows:

§ 61.10 Content of application.

An application to receive from others, possess and dispose of wastes containing or contaminated with source, byproduct or special nuclear material by land disposal must consist of general information, specific technical information, institutional information, and financial information as set forth in §§ 61.11 through 61.16. Environmental information required under part 51 of this chapter must accompany the application.

§ 61.23 [Amended]

■ 64. In § 61.23, in paragraph (l) remove the phrase “subpart A of”.

§ 61.28 [Amended]

■ 65. In § 61.28, revise paragraph (b) to read as follows:

§ 61.28 Contents of application for closure.

* * * * *

(b) Environmental information required under part 51 of this chapter.

**PART 70—DOMESTIC LICENSING OF
SPECIAL NUCLEAR MATERIAL**

■ 66. The authority citation for part 70 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Section 70.21(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

Section 70.31 also issued under Atomic Energy Act sec. 57(d) (42 U.S.C. 2077(d)).

Sections 70.36 and 70.44 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234).

Section 70.81 also issued under Atomic Energy Act secs. 186, 187 (42 U.S.C. 2236, 2237).

Section 70.82 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

■ 67. In § 70.21, revise paragraph (f) and (h) to read as follows:

§ 70.21 Filing.

* * * * *

(f) Any application for a license under this part shall include the environmental information required by part 51 of this chapter.

* * * * *

(h) A license application for a uranium enrichment facility must be accompanied by environmental information required under part 51 of this chapter.

* * * * *

§ 70.23 [Amended]

■ 68. In § 70.23, in paragraph (a)(7) remove the phrase “subpart A of”.

**PART 72—LICENSING
REQUIREMENTS FOR THE
INDEPENDENT STORAGE OF SPENT
NUCLEAR FUEL, HIGH-LEVEL
RADIOACTIVE WASTE, AND
REACTOR-RELATED GREATER THAN
CLASS C WASTE**

■ 69. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 70. Revise and republish § 72.34 to read as follows:

§ 72.34 Environmental information.

Each application for an ISFSI or MRS license under this part must be accompanied environmental information which meets the requirements of part 51 of this chapter.

§ 72.40 [Amended]

■ 71. In § 72.40, in paragraph (b) remove the phrase “subpart A of”.

■ 72. In § 72.90, revise paragraph (e) to read as follows:

§ 72.90 General considerations.

* * * * *

(e) Pursuant to part 51 of this chapter for each proposed site for an ISFSI and pursuant to sections 141 or 148 of NWP, as appropriate (96 Stat. 2241, 101 Stat. 1330–235, 42 U.S.C. 10161, 10168) for each proposed site for an MRS, the potential for radiological impacts on the region must be evaluated with due consideration of the characteristics of the population, including its distribution, and of the regional environs.

* * * * *

**PART 76—CERTIFICATION OF
GASEOUS DIFFUSION PLANTS**

■ 73. The authority citation for part 76 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 122, 161, 193(f), 223, 234, 1701 (42 U.S.C. 2152, 2201, 2243(f), 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 206, 211 (42 U.S.C. 5841, 5846, 5851); 44 U.S.C. 3504 note.

Section 76.22 is also issued under Atomic Energy Act sec. 193(f) (42 U.S.C. 2243(f)).

Section 76.35(j) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

■ 74. In § 76.35, revise paragraph (c) to read as follows:

§ 76.35 Contents of application.

* * * * *

(c) Any relevant information concerning deviations from the published environmental documents or environmental permits under which the plants currently operate from which the Commission can prepare an environmental document related to the compliance plan.

* * * * *

**PART 110—EXPORT AND IMPORT OF
NUCLEAR EQUIPMENT AND
MATERIAL**

■ 75. The authority citation for part 110 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 51, 53, 54, 57, 62, 63, 64, 65, 81, 82, 103, 104, 109, 111, 121, 122, 123, 124, 126, 127, 128, 129, 133, 134, 161, 170H, 181, 182, 183, 184, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2071, 2073, 2074, 2077, 2092, 2093, 2094, 2095, 2111, 2112, 2133, 2134, 2139, 2141, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2160c, 2160d, 2201, 2210h, 2231, 2232, 2233, 2234, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Administrative Procedure Act (5 U.S.C. 552, 553); 42 U.S.C. 2139a, 2155a; 44 U.S.C. 3504 note.

Section 110.1(b) also issued under 22 U.S.C. 2403; 22 U.S.C. 2778a; 50 App. U.S.C. 2401et seq.

§ 110.43 [Amended]

■ 76. In § 110.43, in paragraph (c) remove the phrase “subpart A of”.

§ 110.45 [Amended]

■ 77. In § 110.45, in paragraph (b)(3) remove the phrase “subpart A of”.

Dated: July 02, 2026.

For the Nuclear Regulatory Commission.

Tomas Herrera,

Acting Secretary of the Commission.

[FR Doc. 2026–13687 Filed 7–6–26; 8:45 am]

BILLING CODE 7590–01–P

Reader Aids

Federal Register

Vol. 91, No. 128

Tuesday, July 7, 2026

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000****Laws** **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000****The United States Government Manual** **741-6000**

Other Services

Electronic and on-line services (voice) **741-6020**Privacy Act Compilation **741-6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov**.Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov**.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.**PENS** (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html** and select *Join or leave the list (or change settings)*; then follow the instructions.**FEDREGTOC** and **PENS** are mailing lists only. We cannot respond to specific inquiries.**Reference questions.** Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, JULY

39843-40352	1
40353-40858	2
40859-41520	6
41521-42134	7

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
11038.....40855**Administrative Orders:**
Presidential
Determinations:
No. 2026-16 of June
26, 2026.....40351
No. 2026-17 of June
26, 2026.....41519

5 CFR

351.....41521
430.....41521
537.....41521
Proposed Rules:
250.....40435
412.....40444
432.....40444
715.....40444
752.....40444
1201.....40444

6 CFR

124.....40879

7 CFR

1b.....40353
1417.....40859
Proposed Rules:
3560.....40468

8 CFR

Proposed Rules:
204.....40676
205.....40676
216.....40676
235.....40676

10 CFR

72.....39843
1040.....39850, 39851
1042.....39851**Proposed Rules:**
2.....42086
20.....40290
30.....42086
40.....42086
50.....42086
51.....42086
52.....42086
53.....42086
54.....42086
61.....40290, 42086
70.....42086
72.....39900, 42086
73.....40290
76.....42086
110.....42086
150.....40290
430.....41578, 42034
431.....41578

14 CFR

25.....39852
39.....39854, 40353, 40356,
40360, 40363, 40865, 40867,
41539, 41542
71.....40366
73.....40870
259.....40368
260.....41556
399.....39872, 40368, 41556
1216.....39879
1250.....40872

Proposed Rules:

1.....40470
39.....39903, 40487, 40900
43.....39906
61.....39906
65.....39906
71.....39931
91.....39906, 40470
117.....40902
121.....40902
147.....39906
399.....39932

17 CFR

Proposed Rules:

15.....40102
16.....40102
17.....40102

18 CFR

Proposed Rules:

141.....41591
260.....41591
357.....41591
369.....41591

20 CFR

404.....40804
416.....40804

21 CFR

516.....41557
520.....41557
522.....41557
524.....41557
529.....41557
556.....41557
558.....41557

Proposed Rules:

1308.....39940, 40909, 40917

26 CFR

Proposed Rules:

1.....40490
31.....40490

27 CFR

478.....40879

Proposed Rules:

478.....40924

479.....40924, 40944	668.....40136	Proposed Rules:	45 CFR
28 CFR	685.....40136	51.....41591	1351.....40426
124.....41466	Proposed Rules:	52.....40491	
29 CFR	655.....39945	62.....40494	47 CFR
31.....40372	656.....39945	141.....39952	Proposed Rules:
1608.....40879	657.....39945	174.....40962	25.....40964
Proposed Rules:	658.....39945	180.....40962	
4022.....40954	660.....39945	42 CFR	48 CFR
33 CFR	661.....39945	Proposed Rules:	Proposed Rules:
100 40381, 40382, 40885	662.....39945	52d.....41604	212.....40508
165 39895, 39897, 40382,	663.....39945	405.....41216	225.....40508
40384, 40385, 40387, 40388,	664.....39945	410.....41216	252.....40508
40389, 40392, 40393, 40394,	669.....39945	413.....41734	
40395, 40396, 40397, 40398,	36 CFR	414.....41216	50 CFR
40400, 40401, 40402, 40403,	Proposed Rules:	416.....41734	216.....41566, 41570
40404, 40887, 40888, 40889,	200.....39948	419.....41734	300.....41570
40891, 40892, 40896, 41564	216.....39948	422.....41216	622.....39898
34 CFR	40 CFR	423.....41216	635.....40898
600.....40136	52.....40406, 40409	424.....41216	Proposed Rules:
	63.....41410	427.....41734	17.....41606
		484.....41216	622.....41611
		488.....41734	
		498.....41216	

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List July 1, 2026

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly

enacted public laws. To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html>

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.