determine ZIP Codes served by each ADC; labeling: * * *

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Colleen Hibbert-Kapler,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2025–08691 Filed 5–15–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 410, 411, 414, 423, 424, 425, 427, 428, and 491

[CMS–1807–F2 and CMS–4204–F3]

RINs 0938–AV33 and 0938–AV16

Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments; and Appeal Rights for Certain Changes in Patient Status; Corrections and Correcting Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rules; corrections and correcting amendment.

SUMMARY: This document corrects technical and typographical errors in the final rule that appeared in the December 9, 2024 **Federal Register** titled ''Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments'' (hereinafter referred to as the ''CY 2025 PFS final rule''). The effective date was January 1, 2025. It also corrects a technical error in the final rule correcting amendment that appeared in the December 30, 2024, **Federal Register** titled ''Medicare Program: Appeal Rights for Certain Changes in Patient Status and Changes to the Medicare Claims and Medicare Prescription Drug Coverage Determination Appeals Procedures; Correcting Amendment''.

DATES:

Effective date: The corrections and correcting amendment are effective May 16, 2025.

Applicability date: The CY 2025 PFS final rule corrections indicated in this document are applicable beginning January 1, 2025.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov,* for any issues not identified below. Please indicate the specific issue in the subject line of the email.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for the following issues: digital mental health treatment (DMHT), certification of therapy plans of care with a physician or NPP order, telehealth, continuous glucose monitoring, and estimated impacts by specialty.

Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov* for issues related to RHC payments.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program benchmarking methodology.

Rachel Radzyner, (410) 786–8215 for issues related to Part B for preventive services, including payment for COVID–19 vaccination.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Amy Gruber, (410) 786–1542, for issues related to low titer O+ whole blood transfusion therapy during ground ambulance transport.

Trevey Davis, (667) 290–8527, for issues related to Alternative Payment Models (APMs).

Aucha Prachanronarong, (410) 786–1879, for inquiries related to the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program.

Kristy Nishimoto, (206) 615–2367, for issues related to the Appeal Rights for Certain Changes in Patient Status.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2024–25382 of December 9, 2024, the CY 2025 PFS final rule (89 FR 97710), there were technical and typographical errors that are identified and corrected in this correcting amendment. These corrections are applicable as if they had been included in the CY 2025 PFS final rule, which was effective January 1, 2025.

In FR Doc. 2024–31146 of December 30, 2024 (89 FR 106362), in the final rule correcting amendment titled ''Medicare Program: Appeal Rights for Certain Changes in Patient Status and Changes to the Medicare Claims and Medicare Prescription Drug Coverage Determination Appeals Procedures; Correcting Amendment'' (hereinafter referred to as the Medicare Appeals Correcting Amendment) there is a technical error associated with the amendatory instructions for regulation text that is identified and corrected in this correcting amendment. The Medicare Appeals Correcting Amendment corrected errors in the October 15, 2024 final rule (89 FR 83240).

II. Summary of Errors

A. Summary of Errors in the CY 2025 Physician Fee Schedule Final Rule

1. Summary of Errors in the Preamble

On page 97767, we inadvertently made a typographical error in the 2025 Facility Fee for Q3014.

On page 97804, we inadvertently mischaracterized a public comment submitted in response to the CY 2025 PFS proposed rule (89 FR 61596).

On page 97913, we made a typographical error in the preamble in referring to a section of Pub. 100–02, chapter 15.

On page 97917, we inadvertently made a typographical error in response to a public comment.

On page 97925, we inadvertently included a reference to the ''FD&C Act''.

On page 97927, we inadvertently mischaracterized State authority as State ''prescriptive authority''.

On page 98078, we inadvertently provided an incomplete and incorrect description of the monthly dosing intervals for Sublocade® and Brixadi®.

On page 98103, we inadvertently included an incorrect description of the number of measures for performance year 2025 under our proposal to adopt the APP Plus quality measure set and after the CMS Web Interface sunsets, compared to the number of measures reported in performance year 2024.

On page 98113, we inadvertently made an error in the description of the heading in the final regulation text at 42 CFR 425.512(a)(7).

On page 98118, we inadvertently included an incorrect Quality # for the Controlling High Blood Pressure measure.

On pages, 98119, 98121, 98128, 98129, 98130, and 98131 we inadvertently included a former measure title for Quality #: 001.

On pages 98128 and 98164, we made typographical errors in table numbers.

On page 98217, we inadvertently made typographical errors.

On page 98229, we inadvertently made a typographical error in the discussion of the proposed policies for the Medicare Part B Drug Inflation Rebate Program.

On page 98244, we inadvertently stated the term for ''Billing and payment code FDA approval or licensure date'' is defined in the regulations text at § 427.302(c).

On page 98248, 98253, 98258, 98263, 98264, 98265, 98266, 98268, 98271, 98296, 98306, 98307, and 98308, we made technical errors in section references.

On page 98251, we inadvertently included language indicating we proposed to codify a policy at § 427.303(b)(4) and inadvertently made a typographical error.

On pages 98257, 98261, 98262, 98298, and 98301, we inadvertently made technical errors in table references.

On page 98262, we inadvertently omitted language from an explanation about ''Example 1'' in Table 59 due to a drafting error.

On page 98266, we inadvertently made technical errors in the discussion of the statutory preclusion of administrative or judicial review on the determination of units.

On page 98269, we inadvertently omitted a section reference and made a technical error in the discussion of the reconciliation process.

On page 98278, we inadvertently made a typographical error in our comment response regarding the definitions of ''line extension'' and ''new formulation''.

On page 98278, we inadvertently made technical errors in terminology in our discussion of the calculation of the total Part D drug rebate amount.

On page 98279, we inadvertently made a technical error in terminology to the section heading and text in our discussion of the calculation of the per unit Part D drug rebate amount.

On page 98284, we inadvertently made a typographical error in our comment response regarding how CMS will determine whether an NDC–9 represents a new NDC–9 of a Part D rebatable drug.

On page 98287, we inadvertently made a technical error in terminology in our discussion of the calculation of the inflation adjusted payment amount and situations in which manufacturers do not report units to the Medicaid Drug Rebate Program.

On page 98306, we inadvertently made a typographical error in our discussion of the Preliminary Rebate Report.

On page 98308, we inadvertently made a typographical error in our discussion of the multi-step process to provide each manufacturer of a Part D rebatable drug with a reconciled rebate amount on a regular basis.

On page 98310, we inadvertently made errors in several section references and a technical error in terminology used in our discussion of data elements included in Rebate Reports.

On page 98311, we inadvertently made a typographical error in our discussion of Rebate Reports for the applicable periods beginning October 1, 2022, and October 1, 2023.

On page 98312, we inadvertently made a typographical error in our discussion of severability.

On page 98332, we inadvertently made a typographical error.

On pages 98358, 98366, 98367, 98368, 98369, and 98370, we inadvertently included a former measure title for Quality #001.

On pages 98369, 98370, and 98371, we inadvertently omitted previously finalized and available measure collection types.

On page 98408, in Table 75, we inadvertently made a typographical error regarding the previously established and finalized Case Minima for the Total Per Capita Cost measure.

On page 98434, we inadvertently included a measure that was finalized for removal starting in the CY 2025 performance period.

On pages 98468 and 98469, we inadvertently made typographical errors in our discussion of the estimate of total annual burden for the ICR for rebate reduction requests and for rebate reduction extension requests.

On page 98474, we inadvertently reference a measure by its former title.

On page 98479, in Table 96, we inadvertently made typographical errors referencing MIPS quality measure counts and in a column header and in the number of MIPS CQMs specifications removed for CY 2025.

On page 98493, we inadvertently made several technical errors in the Quality Payment Program row (second row) and the TOTAL row (fourth row) of Table 107, which summarized the annual burden estimates of the finalized provisions subject to the Paperwork Reduction Act of 1995. While two figures are incorrect in the sixth and eighth columns in the second row, they were set forth correctly on pages 98470, 98472, and 98547 in the CY 2025 PFS final rule. The figures reflecting the totals of the third, fourth, sixth, and eighth columns of the fourth row are incorrect.

On page 98494, we inadvertently made a typographical error in our discussion of the inflation rebate provisions for purposes of the regulatory impact analysis.

On page 98495, we inadvertently made a typographical error in the summary discussion of the effective date of the removal of RHCs productivity standards.

On page 98508, we inadvertently neglected to update the expected percentage changes in total RVUs per practitioner to reflect the public use file published with the CY 2025 PFS final rule.

On page 98518, we inadvertently made a typographical error in our regulatory impact analysis discussion of the effective date of the removal of RHCs productivity standards.

On page 98528, we inadvertently made a typographical error in our discussion of the inflation rebate provisions for purposes of the regulatory impact analysis.

On pages 98547 and 98548, regarding incremental estimated burden from associated final policies set forth in Table 128, we inadvertently included duplicative rows containing incorrect section references (that is, rows 10 through 19). In section IV. of this correcting document, we provide a corrected Table 128.

On pages 98549 and 98550, we inadvertently made typographical errors in reference to the first MIPS performance period available for two measures in the APP Plus quality measure set, an error in reference to a MIPS collection type, and we inadvertently made a typographical error in a citation.

2. Summary of Errors in the Regulations Text

On page 98582 at § 427.302, there is a technical error in the regulation heading for Calculation of the per unit Part B drug rebate amount.

On page 98582 at § 427.302, we inadvertently omitted a word in the discussion of the identification of the payment amount benchmark quarter.

On page 98585 at § 427.401(b)(2)(iv), in the regulation text for ''Reducing the rebate amount for Part B rebatable drugs currently in shortage'', we inadvertently made a technical error.

On page 98587 at § 427.501(d)(1)(i), we inadvertently included one erroneous section reference and made a technical error in the discussion of the preliminary reconciliation.

On page 98590 at § 428.202, in the regulation heading for ''Calculation of

the per unit Part D drug rebate amount'' and in paragraph (a), we inadvertently made a technical error in terminology.

On page 98593 at § 428.204, in the introductory text for ''Treatment of new formulations of Part D rebatable drugs,'' we inadvertently made errors in section references.

On page 98593 in § 428.204(b), we inadvertently made a technical error in terminology.

On page 98594, in § 428.301(b)(2)(iv), in the regulation text for ''Reducing the rebate amount for Part D rebatable drugs currently in shortage'', we inadvertently made a technical error.

3. Summary and Corrections of Errors in the Addenda on the CMS Website

In Addendum B, due to a typographical error, the Global indicator for HCPCS code G0560 was incorrect. Therefore in Addendum B, column L, row 13679, the Global indicator for HCPCS code G0560 that reads ''ZZZ'' is corrected to read ''XXX.''

B. Summary of Errors in the December 30, 2024 Final Rule Correcting Amendment

In the amendatory instructions for § 405.1210, we made an error regarding paragraph (b)(3). The amendment instruction indicated that we were adding paragraph (b)(3) instead of revising paragraph (b)(3). Because of this error, OFR included an editorial note in the electronic Code of Federal Regulations (eCFR) for § 405.1210 stating that the paragraph could not be incorporated due to the inaccurate amendatory instruction. Therefore, we are correcting the amendatory instruction and providing the revised regulatory text.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (the APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements; in cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act as well. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and includes a statement of the finding and the reasons for it in the rule. In addition, section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

In our view, this correcting amendment does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical and typographical errors in the CY 2025 PFS final rule. The corrections contained in this document are consistent with, and do not make substantive changes to, the policies and payment methodologies that were proposed, subject to notice and comment procedures, and adopted in the CY 2025 PFS final rule. As a result, the corrections made through this correcting amendment are intended to resolve inadvertent errors so that the CY 2025 PFS final rule accurately reflects the policies adopted therein. It also merely corrects a technical error in the Medicare Appeals Correcting Amendment.

In addition, even if this were a rulemaking to which the notice and comment and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the CY 2025 PFS final rule and Medicare Appeals Correcting Amendment or delaying the effective date of the corrections would be contrary to the public interest because it is in the public's interest for physicians and practitioners to receive appropriate payments in as timely a manner as possible, and to ensure that the CY 2025 PFS final rule accurately reflects our policies as of the date they take effect. Further, such procedures would be unnecessary because we are not making any substantive revisions to the CY 2025 PFS final rule or the Medicare Appeals Correcting Amendment, but rather, we are simply correcting the **Federal Register** documents to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the CY 2025 PFS and Medicare Appeals (October 15, 2024) final rules. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

Moreover, even if these corrections were considered to be retroactive rulemaking, they would be authorized under section 1871(e)(1)(A)(ii) of the Act, which permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. As we have explained previously, we believe it would be contrary to the public interest not to implement these corrections because it is in the public's interest for physicians and practitioners to receive appropriate payments in as timely a manner as possible, and to ensure that the CY 2025 PFS final rule and Medicare Appeals (October 15, 2024) final rule (which was subsequently corrected by Medicare Appeals Correcting Amendment) accurately reflect our policies.

IV. Correction of Errors in the Preamble of the CY 2025 PFS Final Rule

In FR Doc. 2024–25382 of December 9, 2024 (89 FR 97710), make the following corrections:

1. On page 97767, top of the page, in the table titled ''Table 13: The Medicare Telehealth Originating Site Facility Fee'', third column (2025 Facility Fee for Q3014), last row, the figure ''$31.04'' is corrected to read ''$31.01''.

2. On page 97804, first column, first full and second full paragraphs, the paragraphs ''Interested parties submitted a public comment in response to the CY 2025 PFS proposed rule that asked CMS to establish coding and payment similar to CPT codes 0446T and 0448T for services related to a newly FDA approved implantable 365-day continuous glucose monitoring system. The commenter stated that creating new coding will allow for continuity of this service during the manufacturer's transition from the 180-day monitoring service as described by the current codes, to the new 365-day monitoring service.

''We agree with the commenters request and are establishing two new HCPCS codes to describe services related to the new 365-day monitoring service. Specifically, we are establishing HCPCS code G0564 (Creation of subcutaneous pocket with insertion of 365-day implantable interstitial glucose sensor, including system activation and patient training) and G0565 (removal of implantable interstitial glucose sensor

with creation of subcutaneous pocket at different anatomic site and insertion of new 365-day implantable sensor, including system activation). We believe it is important for beneficiaries to have continued access to this valuable service during the transition from a 180 to 365-day monitoring period. HCPCS codes G0564 and G0565 are contractor priced and effective January 1, 2025. CPT codes 0446T and 0448T should continue to be used to bill for the 180-day continuous glucose monitoring service.'' are corrected to read as follows:

''*Comment:* An interested party submitted a public comment in response to the CY 2025 PFS proposed rule requesting that CMS update the existing CPT codes 0446T and 0448T's direct practice expense inputs to replace a 180-day glucose sensor with an implantable 365-day continuous glucose monitoring system. The commenter indicated that it expected the 365-day continuous glucose monitoring system would receive FDA clearance in September 2024. The commenter stated that updating the direct practice expense inputs would allow for continuity of this service during the manufacturer's transition from the 180-day monitoring service as described by the current codes, to the new 365-day monitoring service.

''*Response:* While we understand that the commenter requested an update to the existing CPT codes' direct PE inputs, we note that we did not propose to modify these inputs in the proposed rule. We are establishing two new HCPCS codes to describe services related to the new 365-day monitoring service in anticipation of an expected transition from the 180- to 365-day device. Specifically, we are establishing HCPCS code G0564 (Creation of subcutaneous pocket with insertion of 365-day implantable interstitial glucose sensor, including system activation and patient training) and G0565 (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365-day implantable sensor, including system activation). We believe it is important for beneficiaries to have continued access to these valuable services during the expected transition from the 180 to 365-day monitoring service. HCPCS codes G0564 and G0565 are contractor priced and effective January 1, 2025. CPT codes 0446T and 0448T should continue to be used to bill for the 180-day continuous glucose monitoring service.''

3. On page 97913, third column, first partial paragraph, lines 3 and 4, the reference, ''Pub. 100–02, chapter 15, section 220.1.4.C'' is corrected to read ''Pub. 100–02, chapter 15, section 220.1.3.C''.

4. On page 97917, first column, third full paragraph, lines 22 and 23, the phrase ''applicable sections of the MBPM, chapter 5'' is corrected to read ''applicable sections of the MBPM, chapter 15''.

5. On page 97925, third column, fourth full paragraph, lines 3 and 4, the phrase ''pathways are inadequate FD&C Act because'' is corrected to read ''pathways are inadequate because''.

6. On page 97927, first column, first full paragraph, lines 7 and 8, the phrase ''in accordance with State prescriptive authority'' is corrected to read ''in accordance with State authority''.

7. On page 98078, third column, first partial paragraph, lines 19 through 24, the phrase ''differences in minimum time between monthly dosing (26 days for Sublocade® versus 28 days for monthly Brixadi®), and differences in buprenorphine half- lives (19–26 days for Sublocade® versus 43–60 days for Brixadi®)'' is corrected to read ''differences in monthly dosing intervals (26 to 44 days for Sublocade® versus 21 to 35 days for monthly Brixadi®), and differences in buprenorphine half- lives (43 to 60 days for Sublocade® versus 19 to 26 days for Brixadi®)''.

8. On page 98103, third column, first partial paragraph, lines 7 through 11, the phrase ''the number of measures reported from ten measures in performance year 2024 to eight measures in performance year 2025 after the CMS Web Interface sunsets.'' is corrected to read ''the number of measures reported from 11 measures in performance year 2024 to 6 measures in performance year 2025 after the CMS Web Interface sunsets.''.

9. On page 98113, third column, first bulleted paragraph,

a. Lines 1 through 5, the sentence ''We are finalizing to add a descriptive heading (''Facility-based scoring'') to § 425.512(a)(7) to more accurately describe the policy at paragraph (a)(7).'' is corrected to read ''We are not finalizing the addition of a descriptive heading (''Facility-based scoring'') to § 425.512(a)(7) to describe the policy at paragraph (a)(7).''.

b. Lines 9 through 13, the sentence ''We are finalizing the heading to read as follows: 'Shared Savings Program Scoring Policy for Excluded APP Measures and APP Measures That Lack a Benchmark.' '' is corrected by removing the sentence.

10. On page 98118, middle of the page, second column, second partial paragraph, lines 4 and 5, the phrase ''Quality #: 001 Controlling High Blood Pressure'' is corrected to read ''Quality #: 236 Controlling High Blood Pressure''.

11. On page 98119,

a. Top of the page, first column, first partial paragraph, lines 1 and 2, the phrase ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

b. Lower two-thirds of the page, first column, first full paragraph, lines 9 and 10, the phrase ''Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Glycemic Status Assessment Greater Than 9%''.

12. On page 98121, first column, first partial paragraph, lines 1 through 3, the phrase ''Quality #: 001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Quality #: 001 Diabetes: Glycemic Status Assessment Greater Than 9%''.

13. On page 98128,

a. Top of the page,

(1) First column, first paragraph, lines 10 and 11, the phrase ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (Quality #: 001)'' is corrected to read ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%) (renamed to Diabetes: Glycemic Status Assessment Greater Than 9% in this final rule) (Quality #: 001)''.

(2) Third column, first full paragraph, lines 9 through 10, the phrase that reads ''Tables 39 through B–42 of this final rule'' is corrected to read ''Tables 39 through 42 of this final rule.''.

b. Lower half of the page, in the table titled ''TABLE 39: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2025'', third row (Quality #001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

14. On page 98129, in the table titled ''TABLE 40: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2026'', fourth row (Quality #001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

15. On page 98130, in the table titled ''TABLE 41: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs for Performance Year 2027'', fourth row (Quality #001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

16. On page 98131, in the table titled ''TABLE 42: Measures Included in the APP Plus Quality Measure Set for Shared Savings Program ACOs Beginning with Performance Year 2028 or the Performance Year that is one year after the eCQM Specifications become available for Quality IDs: 487 and 493, whichever is later'', fourth row (Quality # 001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

17. On page 98164, first column, first partial paragraph, line 1, the table number ''Table D–B7'' is corrected to read ''Table 115''.

18. On page 98217, in the table titled ''TABLE 51: CY 2025 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID–19 Continues into CY 2025,'' fifth and sixth rows, the entries are corrected to read as follows:

Category of Part B product administration	Part B payment amount (unadjusted)	Amount update	Geographic adjustment
COVID–19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis): [3 4] Intravenous Infusion: Health Care Setting	$450	N/A	GAF

19. On page 98229, first column, second bulleted paragraph, line 9, the phrase ''date. Proposed § 427.302(c)(4)'' is corrected to read as follows:

''date.

• Proposed § 427.302(c)(4)''.

20. On page 98244, lower two-thirds of the page, first column, last paragraph, lines 33 and 34, the phrase ''By defining and referencing the billing and payment'' is corrected to read ''By referencing the billing and payment''.

21. On page 98248,

a. First column, first full paragraph, line 11, the reference ''§ 427.303'' is corrected to read ''§ 427.303(b)(1)''.

b. Second column, first full paragraph, line 31, the reference ''§ 427.303(b)(1)(iii)'' is corrected to read ''§ 427.303(b)(1)(iv)''.

22. On page 98251, third column, first partial paragraph,

a. Lines 23 through 28, the sentence ''We further proposed codifying policy that CMS may consult with the FDA for technical assistance in instances where there is ambiguity as to whether a new product is therapeutically equivalent'' is corrected by removing the sentence.

b. Line 29, the phrase ''on or'' is corrected to read ''on and''.

23. On page 98253, second column, third full paragraph, line 13, the reference ''§ 427.301'' is corrected to read ''§ 427.501(b)(1)''.

24. On page 98257, second column, second full paragraph, line 25, the reference ''Table 58'' is corrected to read ''Table 57''.

25. On page 98258, lower half of the page, third column, first full paragraph, line 4, the reference ''§ 427.402(a)'' is corrected to read ''§ 427.402(b)(1)''.

26. On page 98261, third column, first full paragraph, line 36, the reference ''Table 59'' is corrected to read ''Table 58''.

27. On page 98262, lower two-thirds of the page, second column, first partial paragraph,

a. Line 13, the reference ''Table 60'' is corrected to read ''Table 59''.

b. Lines 24 and 25, the phrase ''rebate reduction 60 calendar days'' is corrected to read ''rebate reduction was submitted less than 60 calendar days''.

28. On page 98263, top of the page, third column, first partial paragraph,

a. Line 10, the reference ''§ 427.401(b)(4)(iii)'' is corrected to read ''§ 427.401(b)(2)(iii)''.

b. Line 22, the reference ''(b)(4)(iv)'' is corrected to read ''(b)(2)(iv)''.

29. On page 98264, first column, third full paragraph, line 9, the reference ''§ 427.501(c)(1)'' is corrected to read ''§ 427.501(d)(1)''.

30. On page 98265, third column, first full paragraph, line 7, the reference ''§ 427.503(a)(1)'' is corrected to read ''§ 427.301(a)(1)''.

31. On page 98266,

a. First column, fourth full paragraph,

(1) Line 23, the reference ''§ 427.503'' is corrected to read ''§ 427.502(c)''.

(2) Line 24, the reference ''§ 428.403'' is corrected to read ''§ 428.402(c)''.

b. Second column, third full paragraph,

(1) Line 6, the phrase ''as determined under'' is corrected to read ''as set forth in''.

(2) Line 7, ''§ 427.503(a)(1)'' is corrected to read ''§ 427.301(a)(1)''.

32. On page 98268, first column, first full paragraph, line 27, the reference ''§ 427.301'' is corrected to read ''§ 427.501(b)(1)''.

33. On page 98269, third column, fourth full paragraph,

a. Lines 12 and 13, the reference ''the specified amount exceeds'' is corrected to read ''the specified amount as determined under § 427.302(b) exceeds''.

b. Line 15, the reference ''§ 427.301(g)'' is corrected to read ''§ 427.302(g)''.

34. On page 98271, first column,

a. First partial paragraph,

(1) Line 8, the reference ''§ 427.501(c)'' is corrected to read ''§ 427.501(d)(1)''.

(2) Line 11, the reference ''§ 427.501(d)(1)'' is corrected to read ''§ 427.501(d)(2)''.

b. Third full paragraph,

(1) Line 5, the reference ''§ 427.501(b)(iii)'' is corrected to read ''§ 427.501(b)(1)(iii)''.

(2) Line 6, the reference ''§ 427.501(d)(i)(B)'' is corrected to read ''§ 427.501(d)(1)(i)(B)''.

35. On page 98278, first column,

a. First full paragraph, lines 7 and 8, the phrase ''such as extended-release formulation reference'' is corrected to read ''such as an extended-release formulation''.

b. Third full paragraph, lines 26 and 27, the phrase ''per unit Part D drug inflation rebate amount'' is corrected to read ''per unit Part D rebate amount''.

36. On page 98279, second column,

a. Second full paragraph, the section heading ''iii. Calculation of the Per Unit Part D Drug Rebate Amount'' is corrected to read ''iii. Calculation of the Per Unit Part D Rebate Amount''.

b. Third full paragraph,

(1) Line 5, the phrase ''Part D drug rebate amount'' is corrected to read ''Part D rebate amount''.

(2) Lines 9 and 10, the phrase ''Part D drug inflation rebate amount'' is corrected to read ''Part D rebate amount''.

(3) Line 16, the phrase ''Part D drug inflation rebate amount'' is corrected to read ''Part D rebate amount''.

37. On page 98284, third column, first partial paragraph, line 18, the reference ''(c)(2)'' is corrected to read ''(2)''.

38. On page 98287, first column,

a. Second full paragraph, lines 3 and 4, the phrase ''Part D drug inflation rebate amount'' is corrected to read ''Part D rebate amount''.

b. Last paragraph, lines 3 and 4, the phrase ''Part D drug inflation rebate amount'' is corrected to read ''Part D rebate amount''.

39. On page 98296, top of the page, first column, first partial paragraph, line

1, the reference ''428.201(a)'' is corrected to read ''428.201(a)(1)(i)''.

40. On page 98298, third column, first partial paragraph, line 15, the reference ''Table 60'' is corrected to read ''Table 61''.

41. On page 98301, third column, first partial paragraph, line 23, the reference to ''Table 61'' is corrected to read ''Table 62''.

42. On page 98306, third column,

a. First partial paragraph, lines 18 and 19, the reference ''October 1, 2024, as determined under § 428.402'' is corrected to read ''October 1, 2024''.

b. First full paragraph, line 14, the word ''believes'' is corrected to read ''believe''.

43. On page 98307, second column, third paragraph, line 5, the reference ''§ 428.401(b)(iii) and § 428.401(d)(i)(B)'' is corrected to read ''§ 428.401(b)(1)(iii) and (d)(1)(i)(C)''.

44. On page 98308,

a. First column, second paragraph, line 25, the reference ''§ 428.405(a)(1)'' is corrected to read ''§ 428.401(d)(1)(i)(G)''.

b. Third column, first full paragraph, lines 15 and 16, the reference ''§ 428.401(d)(1)(i) and (d)(2)'' is corrected to read ''§ 428.401(d)(1)(i), and (2)''.

45. On page 98310, second column, second paragraph,

a. Lines 5 through 7, the phrase ''§ 428.401(d)(1)(i)(C) to specify that the reconciliation will include updated payment'' is corrected to read ''§ 428.401(b)(1)(iii) to specify that the Rebate Report will include the payment''.

b. Lines 16 and 17, the reference ''§ 428.401(b)(iii) and § 428.401(d)(1)(i)(B)'' is corrected to read ''§ 428.401(d)(1)(i)(C)''.

c. Lines 40 and 41, the phrase ''benchmark period manufacturer price'' is corrected to read ''payment amount benchmark period''.

d. Lines 43 and 44, the reference ''§ 428.401(b)(iii) and § 428.401(d)(1)(i)(B)'' is corrected to read ''§ 428.401(b)(1)(iii) and (d)(1)(i)(C)''.

46. On page 98311, first column, first partial paragraph, line 14, the phrase ''applicable periods'' is corrected to read ''applicable period''.

47. On page 98312, third column, first partial paragraph, line 6, the phrase ''Part D Rebatable drugs'' is corrected to read ''Part D rebatable drugs''.

48. On page 98332, third column, first partial paragraph, line 6, the phrase ''patients in hemorrhagic over traditional'' is corrected to read ''patients in hemorrhagic shock over traditional''.

49. On page 98358, second column, first full paragraph, lines 13 through 14, the title ''Quality ID #001 Diabetes: Hemoglobin A1c (HbA1c) Poor Control'' is corrected to read ''Quality ID #001 Diabetes: Glycemic Status Assessment Greater Than 9%''.

50. On page 98366, top of the page, in table titled ''TABLE 67: Alignment of the APP Plus Measure Set with the Adult Universal Foundation Measure Set'', first row (Quality #001), third column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

51. On page 98367, top of the page, in the table titled ''TABLE 68 APP Plus Quality Measure Set for the CY 2025 Performance Period'', first row (Quality #001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

52. On page 98368, in the table titled ''TABLE 69: APP Plus Quality Measure Set for the CY 2026 Performance Period'', first row (Quality #001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

53. On page 98369, in the table titled ''TABLE 70: APP Plus Quality Measure Set for the CY 2027 Performance Period'',

a. First row (Quality #001), second column (Measure Title), the entry is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

b. Last row (Quality #305), Third column (Collection Type), the entry ''eCQM (all APP reporters); Medicare CQM (SSP ACOs only)'' is corrected to read ''eCQM/MIPS CQM/Part B Claims (all APP reporters); Medicare CQM (SSP ACOs only)''.

54. On pages 98370 and 98371, in the table titled ''TABLE 71: APP Plus Quality Measure Set for the CY 2028 Performance Period and Subsequent Performance Periods'',

a. First row (Quality #001), second column (Measure Title), the entry ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control'' is corrected to read ''Diabetes: Glycemic Status Assessment Greater Than 9%''.

b. Ninth row (Quality #305), third column (Collection Type), the entry ''eCQM (all APP reporters); Medicare CQM (SSP ACOs only)'' is corrected to read ''eCQM/MIPS CQM/Part B Claims (all APP reporters); Medicare CQM (SSP ACOs only)''.

55. On pages 98406 through 98408, in the table titled ''Table 75: Summary Table of Previously Established and Finalized Cost Measures for the CY 2025 Performance Period/2027 MIPS Payment Year and Future Performance Periods'', last row (Total Per Capita Cost), third column (Case Minima), the entry ''20 beneficiary months'' is corrected to read ''20 beneficiaries''.

56. On page 98434, after the table titled ''TABLE 82: Proposed topped out measures impacted by limited measure choice and subject to defined topped out measure benchmark for the CY 2025 performance period/2027 MIPS Payment Year'' is corrected by adding a table note to read as follows:

''CMS included MIPS CQM 436 on the list in error. The removal of this measure was previously finalized.''

57. On page 98468,

a. First column, fourth full paragraph, lines 1 through 4, the sentence ''The following changes will be submitted to OMB for approval under control number 0938–INSERT (CMS–INSERT).'' is corrected by removing the sentence.

b. Second column, last paragraph, line 12, the mathematical phrase ''3,100 hours (310 hr per form * 10 forms)'' is corrected to read ''310 hours (31 hr per form * 10 forms)''.

c. Third column,

(1) First partial paragraph, line 22, the phrase ''the potential shortage T'' is corrected to read ''the potential shortage''.

(2) First full paragraph, lines 5 and 6, the mathematical phrase ''3,100 hours (310 hr per form * 10 forms)'' is corrected to read ''310 hours (31 hr per form * 10 forms)''.

58. On page 98469, first column, first partial paragraph, line 22, the mathematical expression ''(3)))].'' is corrected to read ''(3))].''

59. On page 98474, first column, second paragraph, lines 6 through 8, the phrase ''Quality #001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control'' is corrected to read ''Quality #001: Diabetes: Glycemic Status Assessment Greater Than 9%''.

60. On page 98479,

a. Top of the page, second column, second paragraph, lines 11 through 14, the phrase that reads ''one MIPS quality measure from the current MIPS quality measure inventory of 197 measures (198 current + 9 new measures'' is corrected to read ''three MIPS quality measures from the current MIPS quality measure inventory of 198 measures (198 current + 7 new measures''.

b. Middle of the page, in the table titled ''TABLE 96: Summary of Quality Measure Inventory Finalized for the CY

2025 Performance Period/2027 MIPS Payment Year'',

(1) Header row, second column, the heading ''# Measures Proposed as New*'' is corrected to read ''# Measures Finalized as New*''.

(2) Second row (MIPS CQMs Specifications), third column (# Measures Finalized for Removal*), the entry ''–11'' is corrected to read ''–10''.

61. On page 98493, top half of the page, in the table titled ''TABLE 107: Annual Requirements and Burden Estimates'', the listed entries (first and third rows) are corrected to read as follows:

Section(s) under Title 42 of the CFR	OMB control No. (CMS ID No.)	Number respondents	Total annual responses	Time per response (hours)	Total annual time (hours)	Labor cost ($/hr)	Total cost ($)
§§ 414.1325, 414.1335, 414.1365 Quality Payment Program.	0938–1314 (CMS–10621).	41,195 Clinicians; 10,765 Group TINs; 20 Sub-groups; 6 Virtual Groups; Total: 51,986.	68,954	Varies	(7,570)	Varies	(913,176)
Total	.....	52,006	68,974	Varies	(6,950)	Varies	(838,420)

62. On page 98494, second column, first partial paragraph, line 5 the word, ''established'' is corrected to read ''establishes''.

63. On page 98495, third column, first full paragraph, line 5 that reads, ''beginning on or after January 1, 2025'' is corrected to read ''ending after December 31, 2024.''

64. On page 98508, first column,

a. Line 11, the phrase ''80 percent'' is corrected to ''82 percent''.

b. Line 13, the phrase ''75 percent'' is corrected to ''76 percent''.

c. Line 31, the phrase ''1 percent'' is corrected to read ''0 percent''.

d. Line 34, the phrase ''24 percent'' is corrected to read ''23 percent''.

e. Line 39, the phrase ''13 percent'' is corrected to read ''14 percent''.

f. Lines 43 and 44, the phrase ''14 percent'' is corrected to read ''15 percent''.

65. On page 98518, second column, third full paragraph, line 7 the phrase, ''beginning on or after January 1, 2025,'' is corrected to read ''ending after December 31, 2024.''

66. On page 98528, second column, first full paragraph, lines 8 through 9, the phrase ''Part D drugs and biological products; covered under Part D'' is corrected to read ''drugs and biological products covered under Part D''.

67. On pages 98547 and 98548, in the table titled ''TABLE 128: Incremental Estimated Burden from Associated Finalized Policies'', the table is corrected to read as follows:

TABLE 128—INCREMENTAL ESTIMATED BURDEN FROM ASSOCIATED FINALIZED POLICIES

[Asterisks refer to paragraph directly following table]

Burden description and associated provisions	Burden hours	Burden dollars
Total burden associated with the provision to continue the policies and ICRs set forth in the CY 2024 PFS final rule into the CY 2025 performance period/2027 MIPS payment year with updated data and assumptions (outlined in section V.B.6.a.(1)(a) of this final rule).	594,447	$71,079,848
Burden change for MVP registration ICR due to the provision of additional MVPs (outlined in section V.B.6.c.(5).(a).(i) of this final rule).*	+626	+66,759
Burden change for Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(2) of this final rule).*	−7,697	−898,035
Burden change for Quality Data Submission by Clinicians: CQM/QCDR Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(3) of this final rule).*	−6,866	−823,269
Burden change for Quality Data Submission by Clinicians: eCQM Collection Type ICR for capturing reduced number of quality submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(4) of this final rule).*	−9,664	−$1,176,109
Burden change for MVP Quality Submission ICR submissions due to the provision of additional MVPs (outlined in section V.B.6.c.(5).(a).(iii) of this final rule).*	+16,031	+1,917,478
Total change in burden due to policy for CY 2025 performance period/2027 MIPS payment year	−7,570	−913,176
Total burden set forth in the CY 2025 PFS final rule	586,877	70,166,672

The total change in burden due to this policy provision includes an increase in burden due to an anticipated increase in the number of respondents that will participate in MVP reporting based on the addition of six new MVPs. Therefore, there is a decrease in burden in the MIPS CQM and QCDR, eCQM, and Medicare Part B ICRs due to respondents who previously submitted MIPS through those collection types submitting data with reduced quality submission requirements as an MVP Participant. Total change in burden also reflects an increase in submission burden due to the additional MVP registrants. See section V.B.6.c.(2) of this final rule for additional detail.

68. On page 98549, third column

a. First partial paragraph, lines 1 through 3 the phrase ''or the next performance period following the availability of the eCQM specifications'' is corrected to read ''or the performance period that is 1 year after the eCQM specifications become available for each respective measure''.

b. Second partial paragraph, lines 10 through 11, the phrase ''MIPS CQMQCDR'' is corrected to read ''MIPS CQM/QCDR''.

69. On page 98550, first column,

a. First partial paragraph, lines 15 through 17, the phrase ''or the next performance period following the availability of the eCQM specifications'' is corrected to read ''or the performance period that is 1 year after the eCQM specifications become available for each respective measure''.

b. First full paragraph, lines 10 through 11, the citation ''(88 FR 84862)'' is corrected to read ''(85 FR 84862)''.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

For the reasons set forth in the preamble, CMS corrects 42 CFR parts 405, 427, and 428 by making the following correcting amendments:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.1210 is amended by revising paragraph (b)(3) to read as follows:

§ 405.1210 Notifying eligible beneficiaries of appeal rights when a beneficiary is reclassified from an inpatient to an outpatient receiving observation services.

* * * * *

(b) * * *

(3) *When delivery of the notice is valid.* Delivery of the written notice of appeal rights described in this section is valid if—

(i) The eligible beneficiary (or the eligible beneficiary's representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents, except as provided in paragraph (b)(4) of this section; and

(ii) The notice is delivered in accordance with paragraph (b)(1) of this section and contains all the elements described in paragraph (b)(2) of this section.

* * * * *

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 3. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 4. Amend § 427.302 by revising the section heading and paragraph (c) introductory text to read as follows:

§ 427.302 Calculation of the per unit Part B rebate.

* * * * *

(c) *Identification of the payment amount benchmark quarter.* For each Part B rebatable drug, CMS will identify the applicable payment amount benchmark quarter as set forth in paragraphs (c)(1) through (3) of this section, as applicable, subject to paragraphs (c)(4) and (5) of this section, using the earliest first marketed date of any NDC ever marketed under any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed, and using the earliest approval or licensure date of any FDA application under which any NDCs that have ever been assigned to the billing and payment code as of the applicable calendar quarter have been marketed:

* * * * *

§ 427.401 [Amended]

■ 5. Amend § 427.401 in paragraph (b)(2)(iv) by removing the phrase ''set forth'' and adding in its place the word ''described''.

■ 6. Amend § 427.501 by revising paragraph (d)(1)(i) introductory text to read as follows:

§ 427.501 Rebate Reports and reconciliation.

* * * * *

(d) * * *

(1) * * *

(i) *Preliminary reconciliation.* At least 1 month prior to the issuance of a report with the reconciled rebate amount for an applicable calendar quarter as set forth in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the rebate amount for an applicable calendar quarter based on the information set forth in paragraphs (b)(1)(i) through (ix) of this section and provide the information set forth in paragraphs (b)(1) and (d)(1)(i)(A) through (F) of this section to the manufacturer of a Part B rebatable drug for the applicable calendar quarter, if applicable:

* * * * *

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

■ 7. The authority citation for part 428 continues to read as follows:

Authority: 42 U.S.C. 1395w–114b, 1302, and 1395hh.

■ 8. Amend § 428.202 by revising the section heading and paragraph (a) to read as follows:

§ 428.202 Calculation of the per unit Part D rebate amount.

(a) *Formula for calculating the per unit Part D rebate amount.* CMS will calculate the per unit Part D rebate amount for a Part D rebatable drug and applicable period by determining the amount by which the AnMP for the Part D rebatable drug, as calculated in accordance with paragraph (b) of this section, exceeds the inflation-adjusted payment amount, as calculated in accordance with paragraph (f) of this section.

* * * * *

■ 9. Amend § 428.204—

■ a. In the introductory text by removing the reference ''§ 428.201(a)'' and adding in its place the reference ''§ 428.201(a)(1)(i)''; and

■ b. By revising paragraph (b).

The revision reads as follows:

§ 428.204 Treatment of new formulations of Part D rebatable drugs.

* * * * *

(b) *Calculation of the inflation rebate amount ratio.* The inflation rebate amount ratio is equal to the per unit Part D rebate amount for the initial drug, as determined under § 428.202(a), divided by the AnMP for that initial drug for the applicable period.

* * * * *

§ 428.301 [Amended]

■ 10. Amend § 428.301 in paragraph (b)(2)(iv) by removing the phrase ''set forth'' and adding in its place the word ''described''.

Wilma Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 8

[Docket No. DOI–2024–0017; 256D0102DM, DS6CS00000, DLSN00000.000000, DX6CS25]

RIN 1093–AA29

Joint Policies of the Departments of the Interior and of the Army Relative to Reservoir Project Lands; Delay of Effective Date

AGENCY: Office of the Secretary, Interior.

ACTION: Direct final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2025, from President Donald J. Trump, entitled ''Regulatory Freeze Pending Review,'' this action delays the effective date of the direct final rule published on January 16, 2025, to June 16, 2025.

DATES: As of May 16, 2025, the effective date of the rule published on January 16, 2025 (90 FR 4669), delayed until May 16, 2025 (90 FR 15935), is further delayed until June 16, 2025.