including prior authorization of other DMEPOS items.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this regulatory document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this regulatory document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2021, that threshold is approximately $158 million. This regulatory document will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule or other regulatory document) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulatory document does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: January 10, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–00572 Filed 1–12–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 416, 419, and 512

Office of the Secretary

45 CFR Part 180

[CMS–1753–CN]

RIN 0938–AU43

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Correction

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

ACTION: Final rule with comment period; correction.

SUMMARY: This document corrects technical errors in the final rule with comment period that appeared in the **Federal Register** on November 16, 2021, titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model.''

DATES:

Effective date: Effective January 13, 2022.

Applicability date: The corrections in this correcting document are applicable beginning January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at (410) 786–4617.

SUPPLEMENTARY INFORMATION:

I. Background

In the final rule with comment period that appeared in the November 16, 2021, **Federal Register** (86 FR 63458) titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model'' (hereinafter referred to as the CY 2022 OPPS/ASC final rule with comment period), there were a number of technical and typographical errors that are identified and corrected in this correcting document. The provisions in this correction document are effective as if they had been included in the document that appeared in the November 16, 2021 **Federal Register**. Accordingly, the corrections are effective January 1, 2022.

II. Summary of Errors

A. Summary of Errors in the Preamble

1. Hospital Outpatient Prospective Payment System (OPPS) Corrections

On page 63463, use of incorrect wage index assignments for community mental health centers (CMHCs) resulted in an inaccurate payment impact estimate. We stated that ''we estimate a 1.1 percent increase in CY 2022 payments to CMHCs relative to their CY 2021 payments.'' We are correcting our estimate of the increase in payments for CMHCs from ''1.1 percent'' to ''1.6 percent''.

On page 63490, we noted that one commenter, a hospital association, supported CMS's proposal to continue to unpackage Omidria in the ASC setting. However, there were several commenters, including several hospital associations, that expressed broad support for CMS's proposal to unpackage and pay separately for non-opioid pain management drugs that function as surgical supplies, including the drug Omidria. We are correcting the text to acknowledge the additional commenters.

On page 63497, the table number for the table included on this page was inadvertently omitted from the table's title. Therefore, we are adding the number ''4'' to the table's title.

On page 63543 and 63544, we listed the incorrect APC assignment for CPT codes 66989 and 66991. We are correcting the APC assignment for these codes from APC 1526 to APC 1563.

On page 63548, second column, under section ''6. Calculus Aspiration With Lithotripsy Procedure (APC 5376)'' of the APC-Specific section, we are correcting the long descriptor for

HCPCS code C9761, to include the terms ''ureter,'' ''bladder,'' or ''steerable''. The correct long descriptor for HCPCS code C9761 is ''Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable''.

On page 63549, in Table 23: Final SI And APC Assignment For HCPCS Code C9761, we inadvertently used the incorrect long descriptor for HCPCS code C9761. We are correcting the long descriptor for HCPCS code C9761 from ''Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable)'' to ''Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable''.

On page 63565, we inadvertently omitted the HOP Panel recommendation related to CPT code 55880. Therefore, we are adding the language that describes the HOP Panel's recommendation for this code.

On page 63569, we inadvertently omitted a summary of several public comments and our responses related to the appropriate APC assignments for CPT codes 0652T, 0653T, and 0654T. Therefore, we are adding a new subsection titled ''38. Other Procedures/Services'' that includes the comments and our response.

On page 63633, Table 39, ''Drugs and Biologicals with Pass-Through Payment Status Expiring after CY 2022,'' we inadvertently used the wrong dosage unit in the long descriptor for HCPCS code J9272. The correct dosage unit is ''10 mg,'' not ''100 mg''. Therefore, we are changing the dosage unit in the long descriptor for HCPCS code J9272 from ''100 mg'' to ''10 mg.''

On page 63634, Table 39, ''Drugs and Biologicals with Pass-Through Payment Status Expiring after CY 2022,'' we inadvertently excluded HCPCS code J9021 (Injection, asparaginase, recombinant, (rylaze), 0.1 mg), even though it is a drug with pass-through status expiring after CY 2022. Therefore, we are adding an entry for HCPCS code J9021 that includes the long descriptor, status indicator, APC assignment, and the pass-through eligibility period for the drug described by HCPCS code J9021.

On pages 63812 and 63980, our revisions to the device offset percentages for certain device-intensive procedures results in a revised ASC weight scalar. Therefore, we are revising our ASC weight scalar from 0.8552 to 0.8546.

On pages 63978 and 63979, Table 84, ''Estimated Impact of the CY 2022 Changes for the Hospital Outpatient Prospective Payment System'', use of incorrect wage index assignments for CMHCs resulted in inaccurate payment impact estimates in the table. We are making changes in the descriptive text to accurately reflect those updates. In addition, the row for CMHCs of the Table 84 is being corrected to include payment impact estimates based on the correct CMHC wage index assignments.

2. Hospital Outpatient Quality Reporting (OQR) Program Corrections

On page 63845, the title of section ''b'' incorrectly states: ''Beginning With the CY 2023 Reporting Period/CY 2025 Payment Determination.'' We are correcting this from ''CY 2023 Reporting Period/CY 2025 Payment Determination'' to ''CY 2025 Reporting Period/CY 2027 Payment Determination.''

On page 63847, in the footnote for the OP–31 measure in table 63, we stated the incorrect timeline for mandatory reporting of the OP–31 measure. We are correcting this from ''CY 2023 reporting period/CY 2025 payment determination'' to ''CY 2025 reporting period/CY 2027 payment determination.''

On page 63849, in Table 65, we omitted a footnote for the OP–31 measure. We are adding the following footnote: ''OP–31 measure is voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).''

3. Ambulatory Surgical Center Quality Reporting Program (ASCQR) Corrections

On page 63892, in Table 69, the footnote for the ASC–20 measure is incorrect. We are removing this incorrect footnote from the table.

On page 63894, in Table 71, we omitted the ASC–15 measure from the table. We are adding the ASC–15 measure to the list of measures in Table 71 by adding the following to the list of measures in the table: ASC–15a—About Facilities and Staff, ASC–15b—Communication About Procedure, ASC–15c—Preparation for Discharge and Recovery, ASC–15d—Overall Rating of Facility, ASC–15e—Recommendation of Facility. We are also adding the following footnotes to the ASC–15 a–e measure: ''The ASC–15 measure is voluntarily collected effective beginning with the CY 2026 payment determination and mandatory beginning with the CY 2027 payment determination and subsequent years, as set forth in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63887 through 63892).''

4. Radiation Oncology Model Corrections

On page 63917, we inadvertently omitted the word ''be'' in a sentence. We are correcting that omission by inserting the word. In addition, we are revising a sentence to correct the word ''of'' to read ''at''.

On page 63937, we repeated the term ''RO''. We are removing one instance to correct this error.

On page 63940, we inadvertently omitted a period at the end of a sentence. We are correcting this omission by adding in the period.

On page 63987, in Table 91, ''Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting January 1, 2022),'' we are correcting the Part B Premium Revenue Offset total from ''50'' to ''40''.

B. Summary of Errors and Corrections to the OPPS and ASC Addenda Posted on the CMS Website

1. OPPS Addenda Posted on the CMS Website

a. Corrections to Addendum A

In Addendum A (OPPS APCs for CY 2022), we inadvertently assigned OPPS status indicator ''K'' rather than ''G'' to the drug APCs listed below, even though we used our equitable adjustment authority to mimic continued pass-through status through the end of CY 2022 for the drugs assigned to these APCs. Accordingly, we are correcting the OPPS status indicator from SI ''K'' to ''G'' in Addendum A for the drug APCs listed below.

- APC 9339 (Iodine i-131 iobenguane 1mci)
- APC 9180 (Inj., patisiran, 0.1 mg)
- APC 9183 (Inj., plazomicin, 5 mg)
- APC 9179 (Inj., aristada initio, 1 mg)
- APC 9182 (Inj mogamulizumab-kpkc, 1 mg)

We inadvertently assigned HCPCS code J2798 status indicator ''N'', meaning that payment for the item or service is packaged, even though this drug will receive continued separate payment to mimic pass-through status during CY 2022. Accordingly, we are assigning HCPCS code J2798 to APC 9181 (Inj., perseris, 0.5 mg) and adding this APC to Addendum A with an OPPS status indicator assignment of ''G'', a payment rate of $10.677, and a minimum unadjusted copayment of $2.14.

b. Corrections to Addendum B

In Addendum B (OPPS Payment by HCPCS Code for CY 2022), we inadvertently assigned OPPS status indicator ''K'' or ''N'' rather than ''G'' and assigned comment indicator ''CH'' to the HCPCS codes for the drugs listed below, even though we used our equitable adjustment authority to mimic continued pass-through status through the end of CY 2022 for these drugs and the OPPS status indicator and APC assignments for these drugs are not changing. Accordingly, we changed the status indicator from SI ''K'' or ''N'' to ''G'' for the drug HCPCS codes listed below. We also removed comment indicator ''CH'' from these HCPCS codes because there is no change to the SI or APC assignment from CY 2021.

- A9590 (Iodine i-131 iobenguane 1mci)
- J0222 (Inj., patisiran, 0.1 mg)
- J0291 (Inj., plazomicin, 5 mg)
- J1943 (Inj., aristada initio, 1 mg)
- J9204 (Inj mogamulizumab-kpkc, 1 mg)
- J2798 (Inj., perseris, 0.5 mg)

In Addendum B, we inadvertently assigned HCPCS code J2798 status indicator ''N'', meaning that payment for the item or service is packaged, even though this drug will receive continued separate payment to mimic pass-through status during CY 2022. We are correcting this error in Addendum B by indicating that this HCPCS code is assigned to APC 9181 (Inj., perseris, 0.5 mg) with a status indicator assignment of ''G'', a payment rate of $10.677, and a minimum unadjusted copayment of $2.14.

In Addendum B, we inadvertently assigned HCPCS codes 66989 and 66991 to APC 1526 and status indicator ''S''. We are correcting this error in Addendum B by indicating that HCPCS codes 66989 and 66991 are assigned to APC 1563 with a status indicator of ''T''.

In Addendum B, we inadvertently assigned new HCPCS code A2003 to status indicator ''A''. Since this code was created in error, we are deleting this code from Addendum B.

c. Corrections to Addendum C

In Addendum C, we inadvertently assigned CPT codes 66989 and 66991 to APC 1526 and status indicator ''S''. Accordingly, we are correcting the APC assignment from 1526 to 1563 and status indicator ''T''.

In Addendum C (HCPCS Codes Payable Under the 2022 OPPS by APC), we inadvertently assigned OPPS status indicator ''K'' rather than ''G'' to the drug APCs listed below, even though we used our equitable adjustment authority to mimic continued pass-through status through the end of CY 2022 for the drugs assigned to these APCs. Accordingly, we are correcting the OPPS status indicator from SI ''K'' to ''G'' in Addendum C for the HCPCS codes and drug APCs listed below.

- HCPCS code A9590; APC 9339 (Iodine i-131 iobenguane 1mci)
- HCPCS code J0222; APC 9180 (Inj., patisiran, 0.1 mg)
- HCPCS code J0291; APC 9183 (Inj., plazomicin, 5 mg)
- HCPCS code J1943; APC 9179 (Inj., aristada initio, 1 mg)
- HCPCS code J9204; APC 9182 (Inj mogamulizumab-kpkc, 1 mg)

We inadvertently assigned HCPCS code J2798 status indicator ''N'', meaning that payment for the item or service is packaged, even though this drug will receive continued separate payment to mimic pass-through status during CY 2022. We are correcting this error by assigning HCPCS code J2798 (Inj., perseris, 0.5 mg) to APC 9181 (Inj., perseris, 0.5 mg) and adding this APC to Addendum C with status indicator assignment of ''G'', a payment rate of $10.677, and the minimum unadjusted copayment of $2.14.

d. Corrections to Addendum P

In Addendum P of the OPPS/ASC proposed rule, we applied a 31 percent device offset percentage to CPT code 0618T and HCPCS code C9761. In Addendum P to the CY 2022 OPPS/ASC final rule with comment period, we assigned device offset percentages of 1.9 percent for CPT code 0618T and 5.15 percent for HCPCS code C9761. We are correcting the device offset percentages in Addendum P to display the 31 percent default device offset percentage as was displayed in the CY 2022 OPPS/ASC proposed rule Addendum P for the CPT/HCPCS codes below.

- CPT code 0618T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange);
- HCPCS code C9761 (Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable).

The impact file provided with the CY 2022 OPPS/ASC final rule with comment period at *https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientpps/cms-1753-fc* utilized the incorrect wage index values in Column F of ''2022 NFRM Impact File.11012021.xlsx'' for certain CMHCs, providers affected by the imputed rural floor, and providers affected by the cap on wage index decreases. These corrections to the wage index have effects on estimated CY 2022 OPPS and OPPS Outlier Payment, which were displayed in Columns M and N of that same file. As a result, we are updating the impact file to provide corrected numbers, which will have corrected values in those same columns in the updated impact file.

To view the corrected CY 2022 OPPS status indicators, APC assignments, relative weights, copayment rates, device-intensive status, and short descriptors for Addenda A, B, and C that resulted from these technical corrections, we refer readers to the Addenda and supporting files that are posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.* Select ''CMS–1753–CN'' from the list of regulations. All corrected Addenda for this correcting document are contained in the zipped folder titled ''2022 CN OPPS Addenda'' at the bottom of the page for CMS–1753–CN.

2. ASC Payment System Addenda Posted on the CMS Website

In ASC Addendum AA, we inadvertently assigned CPT codes 66989 and 66991 ''N'' (No) in column D (Subject to Multiple Procedure Discounting). We are correcting this error in Addendum AA by revising the procedure discounting status from ''N'' (No) to ''Y'' (Yes), indicating that the procedure is subject to multiple procedure discounting.

In ASC Addendum AA, we inadvertently assigned CPT codes C9779 and C9780 payment indicator ''J8'' (Device-intensive procedure; paid at adjusted rate) in column F (Final CY 2022 Payment Indicator) even though these procedures are not payable in the ASC setting. We are correcting this error in Addendum AA by removing these codes from Addendum AA.

In ASC Addendum AA, we inadvertently assigned CPT code 0414T payment indicator ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) in column F (Final CY 2022 Payment Indicator), but this procedure is designated as device-intensive under the OPPS. Therefore, we are correcting this error by assigning payment indicator ''J8'' to CPT code 0414T and correcting the ASC payment rate and ASC relative weight to reflect a 31 percent device offset percentage.

In Addendum AA of the OPPS/ASC proposed rule, we applied a 31 percent device offset percentage to CPT codes 66987 and 66988 and HCPCS code C9757 and assigned a ''J8'' payment indicator—Device-intensive procedure; paid at adjusted rate.—and a payment rate that reflected a 31 percent default device offset percentage. We changed the ASC payment rates in the CY 2022 OPPS/ASC final rule with comment period Addendum AA and device offset percentages in Addendum FF to reflect 11.27 percent for CPT code 66987, 12.35 percent for 66988, and 22.14 percent for HCPCS code C9757. In ASC Addendum AA, we are correcting the payment indicator for CPT codes 66987 and 66988 and HCPCS code C9757 to ''J8'' and revising the ASC payment rate and ASC relative weights to reflect a device offset percentage of 31 percent as was displayed in the CY 2022 OPPS/ASC proposed rule. In ASC Addendum FF, we are correcting the device offset percentages for CPT codes 66987 and 66988 and HCPCS code C9757 to reflect the device offset percentage of 31 percent as was displayed in the CY 2022 OPPS/ASC proposed rule.

In ASC addendum BB, we inadvertently assigned HCPCS code J2798 payment indicator ''N1'', meaning that payment for the item or service is packaged, even though this drug will receive continued separate payment to mimic pass-through status during CY 2022. We are correcting this error in Addendum BB by changing the payment indicator from ''N1'' to ''K2'' and adding a payment rate of $10.68.

In ASC Addendum FF, we inadvertently added CPT codes C9779 and C9780 but these procedures are not payable in the ASC setting. We are correcting this error by removing these codes from Addendum FF.

In ASC Addendum FF, we inadvertently assigned CPT code 0414T payment indicator ''G2'' (non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) under column D (Final CY 2022 Payment Indicator) and a device portion that reflects a device offset percentage of 27.06 percent but this procedure is designated as device-intensive under the OPPS. Therefore, we are correcting this error by assigning payment indicator ''J8'' (device-intensive procedure; paid at adjusted rate) to CPT code 0414T, assigning a 31 percent device offset percentage, and assigning a device portion of $7,233.62.

To view the corrected final CY 2022 ASC payment indicators, payment weights, payment rates, and multiple procedure discounting indicator for Addendum BB that resulted from this technical correction, we refer readers to the ASC Addenda and supporting files on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.* Select ''CMS–1753–CN'' from the list of regulations. The corrected ASC addenda for this correcting document are contained in the zipped folder titled ''2022 CN ASC Addenda'' at the bottom of the page for CMS–1753–CN.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (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 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) 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 notice and comment and delay in effective date of the APA 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 rulemaking requirements for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest. In addition, both 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 an agency includes a statement of support.

We believe that this correcting document does not constitute a rulemaking that would be subject to the notice and comment and delayed effective date requirements. This correcting document corrects technical and typographical errors in the preamble, addenda, payment rates, and tables included or referenced in the CY 2022 OPPS/ASC final rule with comment period but does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, the corrections made through this correcting document are intended to ensure that the information in the CY 2022 OPPS/ASC final rule with comment period accurately reflects the policies adopted in that rule.

In addition, even if this were a rule to which the notice and comment procedures 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 final rule or delaying the effective date would be contrary to the public interest because it is in the public's interest for providers to receive appropriate payments in as timely a manner as possible, and to ensure that the CY 2022 OPPS/ASC final rule with comment period reflects our policies as of the date they take effect and are applicable.

Furthermore, such procedures would be unnecessary, as we are not altering our payment methodologies or policies, but rather, we are simply correctly implementing the policies that we previously proposed, requested comment on, and subsequently finalized. This correcting document is intended solely to ensure that the CY 2022 OPPS/ASC final rule with comment period accurately reflects these payment methodologies and policies. For these reasons, we believe we have good cause to waive the notice and comment and delayed effective date requirements.

IV. Correction of Errors

In FR Doc. 2021–24011 of November 16, 2021 (86 FR 63458), we are making the following corrections:

1. On page 63463, second column, first full paragraph, line 9, ''1.1 percent'' is corrected to read ''1.6 percent''.

2. On page 63490, third column, third full paragraph, in lines 13 through 16, the text ''One commenter, a hospital association, also supported CMS's proposal to continue to unpackage Omidria in the ASC setting'' is corrected to read ''Several commenters, including several hospital associations and ophthalmology professional societies, also provided broad support for CMS's proposal to continue to unpackage Omidria in the ASC setting.''

3. On page 63497, the title of the table is corrected to read:

''**TABLE 4: SUMMARY OF PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY.**''

4. On page 63543, third column, second full paragraph, the text ''We believe that APC 1526 (New Technology—Level 26 ($4001–$4500)), with a payment rate of $4,250.50, most accurately accounts for the resources associated with furnishing MIGS'' is corrected to read ''We believe that APC 1563 (New Technology—Level 26 ($4001–$4500)), with a payment rate of $4,250.50, most accurately accounts for the resources associated with furnishing MIGS.''

5. On page 63544, first column, second paragraph, the sentence ''In summary, after consideration of the public comments, we are finalizing the reassignment of CPT codes 66989 and 66991 to APC 1526 and assignment of CPT code 0671T to APC 5491'' is corrected to read ''In summary, after consideration of the public comments, we are finalizing the reassignment of CPT codes 66989 and 66991 to APC 1563 and assignment of CPT code 0671T to APC 5491.''

6. On page 63548, second column, in the section titled ''6. Calculus Aspiration With Lithotripsy Procedure (APC 5376),'' the long descriptor for HCPCS code C9761, ''Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy (ureteral catheterization is included) and vacuum aspiration of the kidney, collecting system and urethra if applicable,'' is corrected to read ''Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable.''

7. On page 63549, in ''Table 23: Final SI And APC Assignment For HCPCS Code C9761,'' the long descriptor for HCPCS C9761 is corrected to read ''Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable''.

8. On page 63565, third column, before the first full paragraph that reads ''In summary, after careful consideration of the public comments'' add the following text:

''In addition, at the August 23, 2021 HOP Panel Meeting, a presenter requested that we reassign CPT code 55880 to APC 5376. Based on the information presented, the HOP Panel recommended that CMS reassign CPT code 55880 to APC 5376 for CY 2022. However, as stated above, based on our analysis of the claims for this CY 2022 OPPS/ASC final rule with comment period, our data shows a geometric mean cost of approximately $5,708 for predecessor HCPCS code C9747 based on 279 single claims, which is more comparable to the geometric mean cost of about $4,299 for APC 5375, rather than the geometric mean cost of approximately $8,042 for APC 5376. Consequently, we are not accepting the APC Panel's recommendation to reassign CPT code 55880 to APC 5376.''

9. On page 63569, second column, after the first partial paragraph and before ''IV. OPPS Payment for Devices,'' add the following text:

''38. Other Procedures/Services

For CY 2022, we proposed to continue to assign the transnasal esophagogastroduodenoscopy (EGD) CPT codes 0652T (Esophagogastroduodenoscopy, flexible, transnasal; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)) and 0653T (Esophagogastroduodenoscopy, flexible, transnasal; with biopsy, single or multiple) to APC 5301 (Level 1 Upper GI Procedures) with a payment rate of $830.39. In addition, we proposed to assign CPT code 0654T (Esophagogastroduodenoscopy, flexible, transnasal; with insertion of intraluminal tube or catheter) to APC 5302 (Level 2 Upper GI Procedures) with a payment rate of $1,666.59.

Comment: Some commenters requested the reassignment of the transnasal EGD procedures to the next higher-level APCs within the Upper GI series. They stated that the costs for the surgical procedures are significantly different than the costs associated with the analogous transoral EGD CPT codes 43235, 43239, and 43241, which are assigned to the same corresponding APCs. Specifically, the commenters requested the reassignment of CPT codes 0652T and 0653T to APC 5302 (Level 2 Upper GI Procedures) with a payment rate of $1,666.59, and CPT code 0654T to APC 5303 (Level 3 Upper GI Procedures), with a payment rate of $3,160.76. The commenters explained that the surgical procedure associated with CPT codes 0652T through 0654T utilize a new transnasal single-use endoscopy system known as EvoEndo Model LE Single-Use Gastroscope, which has an estimated cost of about $1,500. They stated that the EvoEndo device is not paid separately as a transitional pass-through device because it is not described by HCPCS C1748 (Endoscope, single-use (*i.e.,* disposable), upper gi, imaging/illumination device (insertable)). The commenters stated that HCPCS C1748 was created for the EXALT Model D Single-Use Duodenoscope, which is used during endoscopic retrograde cholangiopancreatography (ERCP) procedures.

In addition, based on the cost of the EvoEndo device that is used in the procedure, the commenters agreed with the device-intensive assignment for the codes under the ASC payment system.

Response: Because the codes are new for CY 2021 and we have no claims data available for OPPS ratesetting, we believe that we should maintain the APC assignments for CPT codes 0652T and 0653T to APC 5301, and 0654T to APC 5302. However, once we have claims data, we will review the APC assignments and determine whether a change is necessary. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS. In addition, we thank the commenters for their input on the device-intensive status for the codes under the ASC payment system.

In summary, after consideration of the public comments, we are finalizing our proposal, without modifications. Specifically, we are assigning CPT codes 0652T and 0653T to APC 5301, and CPT code 0654T to APC 5302 for CY 2022. In addition, we are finalizing the device-intensive status for the codes for CY 2022. The final CY 2022 payment rates for the codes can be found in Addendum B to the CY 2022 OPPS/ASC final rule with comment period. We refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website. Finally, for the final ASC Device Offset Percentages for CY 2022, we refer readers to ASC Addendum FF of this final rule with comment period.''

10. On page 63633, ''Table 39: Drugs and Biologicals with Pass-Through Payment Status Expiring after CY 2022,'' fourth row, third column titled ''Long Descriptor,'' the figure ''100 mg'' is corrected to read ''10 mg''.

11. On Page 63634, in ''Table 39: Drugs and Biologicals with Pass-Through Payment Status Expiring after CY 2022,'' at the end of the table, add the following row to read as follows:

N/A	J298	Injection, risperidone, (perseris), 0.5 mg	G	9181	10/01/2021	09/30/2024

12. On page 63812, the last sentence of the second column is corrected to read, ''Based on updated data for this final rule with comment period, the final CY 2022 ASC weight scalar is 0.8546.''

13. On page 63845, first column; under section ''b. OP–31: Cataracts,'' in lines 4–6, ''CY 2023 Reporting Period/CY 2025 Payment Determination'' is corrected to read ''CY 2025 Reporting Period/CY 2027 Payment Determination.''

14. On page 63847, Table 63, in the second footnote, the text ''CY 2023 reporting period/CY 2025 payment determination'' is corrected to read ''CY 2025 reporting period/CY 2027 payment determination''.

15. On page 63849, Table 65, add the footnote ''*** OP–31 measure is voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).''

16. On page 63892, Table 69, remove the footnote ''** We note that, if adoption finalized, an ASC/measure number will be assigned for this measure in the final rule.''

17. On page 63894, Table 71 is revised to read as follows:

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Table 71: ASCQR Program Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263±	Patient Burn
ASC-2	0266±	Patient Fall
ASC-3	0267±	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265±	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11*	1536±	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a**	None	About Facilities and Staff
ASC-15b**	None	Communication About Procedure
ASC-15c**	None	Preparation for Discharge and Recovery
ASC-15d**	None	Overall Rating of Facility
ASC-15e**	None	Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

± NQF endorsement was removed.

* The ASC-11 measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).

**The ASC-15 measure is voluntarily collected effective beginning with the CY 2026 payment determination and mandatory beginning with the CY 2027 payment determination and subsequent years, as set forth in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63887 through 63892).

17. On page 63917, second column, first full paragraph,

a. In lines 4–5, the word ''be'' is inserted between ''will'' and ''included''.

b. In line 18, the first instance of the word ''of'' is corrected to read ''at''.

18. On page 63937, first column, second partial paragraph, in line 23, remove the term ''RO'' between the words ''that'' and ''if''.

19. On page 63940, second column, first full paragraph, in line 12, insert a period between the words ''expires'' and ''CMS''.

20. On page 63978, in Table 84, ''Estimated Impact of the CY 2022 Changes for the Hospital Outpatient Prospective Payment System,'' the row for ''CMHCs'' is revised to read as follows:

CMHCs	39	0.4	-0.5	1.9	1.6

21. On page 63979,

a. First column,

1. First paragraph, in line 18, ''1.1 percent'' is corrected to read ''1.6 percent''.

2. Second paragraph,

a. In line 4, ''1.0 percent'' is corrected to read ''0.5 percent''.

b. In line 9, ''1.4 percent'' is corrected to read ''1.9 percent''.

c. In line 12, ''1.1 percent'' is corrected to read ''1.6 percent''.

22. On page 63980, first column, first paragraph, in line 10, ''0.8552'' is corrected to read ''0.8546''.

23. On page 63987, Table 91, ''Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting January 1, 2022),'' in the ''Total'' column, ''Part B Premium Revenue Offset'' line, the figure ''50'' is corrected to read ''40''.

Karuna Seshasai,

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

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NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

45 CFR Parts 1149 and 1158

RIN 3135–AA33

Civil Penalties Adjustment for 2022

AGENCY: National Endowment for the Arts, National Foundation on the Arts and the Humanities.

ACTION: Final rule.

SUMMARY: The National Endowment for the Arts (NEA) is adjusting the maximum civil monetary penalties (CMPs) that may be imposed for violations of the Program Fraud Civil Remedies Act (PFCRA) and the NEA's Restrictions on Lobbying to reflect the requirements of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act). The 2015 Act further amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. This final rule provides the 2022 annual inflation adjustments to the initial ''catch-up'' adjustments made on June 15, 2017, and reflects all other inflation adjustments made in the interim.

DATES: This rule is effective January 13, 2022.

FOR FURTHER INFORMATION CONTACT: Daniel Fishman, Assistant General Counsel, National Endowment for the Arts, 400 7th St. SW, Washington, DC 20506, Telephone: 202–682–5418.

SUPPLEMENTARY INFORMATION:

1. Background

On December 12, 2017 the NEA issued a final rule entitled ''Federal Civil Penalties Adjustments'' [1] which finalized the NEA's June 15, 2017 interim final rule entitled ''Implementing the Federal Civil Penalties Adjustment Act Improvements Act'',[2] implementing the 2015 Act (section 701 of Pub. L. 114–74), which amended the Inflation Adjustment Act (28 U.S.C. 2461 note) requiring catch-up and annual adjustments to the NEA's CMPs. The 2015 Act requires agencies make annual adjustments to its CMPs for inflation.

A CMP is defined in the Inflation Adjustment Act as any penalty, fine, or other sanction that is (1) for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; (2) assessed or enforced by an agency pursuant to Federal law; and (3) assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

These annual inflation adjustments are based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the month of October preceding the date of the adjustment, relative to the October CPI–U in the year of the previous adjustment. The formula for the amount of a CMP inflation adjustment is prescribed by law, as explained in OMB Memorandum M–16–06 (February 24, 2016), and therefore the amount of the adjustment is not subject to the exercise of discretion by the Chairman of the National Endowment for the Arts (Chairman).

The Office of Management and Budget has issued guidance on implementing and calculating the 2022 adjustment under the 2015 Act.[3] Per this guidance, the CPI–U adjustment multiplier for this annual adjustment is 1.06222. In its prior rules, the NEA identified two CMPs, which require adjustment: The penalty for false statements under the PFCRA and the penalty for violations of the NEA's Restrictions on Lobbying. With this rule, the NEA is adjusting the amount of those CMPs accordingly.

2. Dates of Applicability

The inflation adjustments contained in this rule shall apply to any violations assessed after January 15, 2022.

3. Adjustments

Two CMPs in NEA regulations require adjustment in accordance with the 2015 Act: (1) The penalty associated with the Program Fraud Civil Remedies Act (45 CFR 1149.9) and (2) the penalty associated with Restrictions on Lobbying (45 CFR 1158.400; 45 CFR part 1158, app. A).

A. Adjustments to Penalties Under the NEA's Program Fraud Civil Remedies Act Regulations.

The current maximum penalty under the PFCRA for false claims and statements is currently set at $11,802. The post-adjustment penalty or range is obtained by multiplying the pre-adjustment penalty or range by the percent change in the CPI–U over the relevant time period and rounding to

[1] 82 FR 58348.

[2] 82 FR 27431.

[3] OMB Memorandum M–22–07 (December 15, 2021).