



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 414, 416, 419, 482, 485, 512

[CMS-1736-CN]

RIN 0938-AU12

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots; Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19); Correction

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

ACTION: Final rule with comment period and interim final rule; correction.

SUMMARY: This document corrects technical and typographical errors in the final rule with comment period and interim final rule with comment period published in the **Federal Register** on December 29, 2020, titled "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-owned Hospitals; Notice of

Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots; Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)”.

DATES: Effective date: This correction is effective [Insert date of publication in the **Federal Register**].

Applicability date: The corrections in this correcting document are applicable beginning January 1, 2021.

FOR FURTHER INFORMATION CONTACT: Elise Barringer via email Elise.Barringer@cms.hhs.gov or at (410) 786–9222.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020-26819 of December 29, 2020 (85 FR 85866), there were a number of technical and typographical errors that are identified and corrected in the Correction of Errors section below. The corrections in this correction document are applicable as if they had been included in the document that was issued on December 4, 2020, and published December 29, 2020. Accordingly, each correction is applicable on January 1, 2021.

II. Summary of Errors

A. Summary of Errors in the Preamble

1. Hospital Outpatient Prospective Payment System (OPPS) Corrections

On page 85987 of the “OPPS APC-Specific Policies” section, we inadvertently omitted a summary of a public comment and response related to existing CPT codes 0607T and 0608T. Therefore, we are adding a new subsection titled “31. Other Procedures/Services” that includes a summary of this public comment and our response.

On page 86033, we are correcting an inadvertent reference to the quarter for which ASP data will be used to calculate payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B: it is the second quarter of CY 2020, not the third quarter of CY 2020.

On Page 86035, we inadvertently referred to CY 2018, rather than CY 2021, as the year in which the proposed packaging status of each drug and biological with HCPCS codes that describe different dosages of the same drug or biological would apply.

On Page 86063, in Table 42: Skin Substitute Assignments to High Cost and Low Cost Groups for CY 2021, we inadvertently stated in the column titled “Final CY 2021 High/Low Cost Assignment” that HCPCS code Q4222 is assigned to the “Low” cost group rather than “High” cost group.

On Page 86273, we inadvertently described the increase in total OPPI payments in CY 2021 as a result of the update to the conversion factor, the CY 2021 frontier wage index adjustment, and other adjustments (not including the effects of outlier payments or the pass-through payment estimates) as 0.2 percent, rather than 2.6 percent.

2. Ambulatory Surgical Center (ASC) Payment System Corrections

On pages 86154 and 86165, in Tables 59 and 60, we incorrectly listed the final CY 2021 ASC payment indicator for CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency) as “G2” instead of “J8”. As stated on page 86016, we assigned device-intensive status to CPT code 0404T and finalized a default device offset percentage of 31 percent to reflect the device costs associated with that code for CY 2021. However, we inadvertently did not assign device-intensive status to CPT code 0404T or utilize the default device offset percentage under the ASC payment system for CPT code 0404T when calculating ASC payment rates for CY 2021.

On page 86175, we inadvertently did not refer to the revised modifications to the labor market areas contained in OMB Bulletins 18–03 and 18–04. While we used these

updated delineations to calculate the ASC wage index for CY 2021, which we used to calculate the ASC payment system rates, we unintentionally did not include conforming language in the ASC wage index section of the preamble to refer to these bulletins.

Therefore, we are correcting the ASC wage index section by including language referring to the revised labor market areas issued in the OMB Bulletins 18-03 and 18-04.

On pages 86176 and 86282, we are correcting references to the weight scalar used in ASC payment rate calculations from “0.8591” to “0.8547” to include the effect of our policy to unpackage HCPCS code J1097 (phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml) for CY 2021 (85 FR 86172). We also inadvertently omitted prospective expenditures related to HCPCS code J1097 for CY 2021 in our calculation of the ASC budget neutrality adjustment. We note that the ASC weight scalar of 0.8547 includes this correction, the correction noted above for CPT code 0404T, and accounts for the increase in CY 2021 Medicare Physician Fee Schedule payment amounts of 3.75 percent, which is required by section 101(a) of Division N, Title I of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116-260). For office-based covered surgical procedures and certain covered ancillary radiology services and diagnostic tests under the ASC payment system, the payment rate is the lower of the final CY 2021 MPFS nonfacility PE RVU-based amount multiplied by the MPFS conversion factor or the OPFS-relative weight-based CY 2021 ASC payment amount, and accordingly, it was necessary to update the MPFS-based ASC rates for CY 2021.

3. Hospital Outpatient Quality Reporting Program Correction

On page 86182, in footnote 107, the url in the following reference is corrected: “The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at <https://>

www.cms.gov/Research-Statistics-DataandSystems/Computer-Data-and-Systems/IDR/index.html.” The url is corrected to read: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR>.

4. Ambulatory Surgical Center Quality Reporting Program Correction

On page 86192, in footnote 110, the url in the following reference is not correct: “For more information on the ECE policy, we refer stakeholders to the QualityNet website at <https://www.qualitynet.org/asc/datasubmission#tab2>.” The url is corrected to read: <https://www.qualitynet.org/asc/ascqr/participation#tab2>.

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

In Addendum A of the CY 2021 OPPS/ASC final rule with comment period, APC 9370 had an incorrect payment rate of \$0.752. We corrected the following:

- For APC 9370 (Fluoroestradiol f 18), we included an incorrect payment rate.

Specifically, we are correcting the payment rate from \$0.752 to \$626.583.

In Addendum B of the CY 2021 OPPS/ASC final rule with comment period, HCPCS codes G2061, G2062, and G2063 are incorrectly shown as active codes with status indicator “A” to indicate that they should be paid under a fee schedule or payment system other than the OPPS. These codes have been deleted effective December 31, 2020, and therefore should be assigned status indicator “D” to indicate that they are discontinued codes. These codes have been replaced with CPT codes 98970, 98971, and 98972, respectively. CPT codes 98970, 98971, and 98972 were incorrectly assigned to status indicator “B” to indicate that another more appropriate code should be reported. But because these codes are replacing HCPCS codes G2061, G2062, and G2063, they should be assigned status indicator “A”. Therefore, in the Addendum B (Final OPPS Payment by HCPCS code for CY 2021), we corrected the following:

- HCPCS code G2061 (Qual nonmd est pt 5-10m): We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “A” to “D”.

- HCPCS code G2062 (Qual nonmd est pt 11-20m): We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “A” to “D”.

- HCPCS code G2063 (Qual nonmd est pt 21>min): We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “A” to “D”.

- CPT code 98970 (Qnhp ol dig asmt&mgmt 5-10): We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “B” to “A”. We are also assigning 98970 to comment indicator “CH” to indicate that its status indicator has changed.

- CPT code 98971 (Qnhp ol dig asmt&mgmt 11-20): We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “B” to “A”. We are also assigning 98971 to comment indicator “CH” to indicate that its status indicator has changed.

- CPT code 98972 (Qnhp ol dig asmt&mgmt 21+): We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “B” to “A”. We are also assigning 98972 to comment indicator “CH” to indicate that its status indicator has changed.

In Addendum B of the CY 2021 OPPS/ASC final rule with comment period, HCPCS codes G2010 and G2012 were incorrectly assigned to status indicator “A” to indicate that they should be paid under a fee schedule or payment system other than the OPPS. However, because these codes were replaced with HCPCS codes G2250 and G2251 for certain non-physician practitioners, including rehabilitation therapists,

effective January 1, 2021, we assigned them to status indicator “B” under the OPPS to indicate that other more appropriate codes should be reported. Therefore, in the Addendum B (Final OPPS Payment by HCPCS code for CY 2021), we corrected the following:

- HCPCS code G2010 (Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment). We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “A” to “B”.

- HCPCS code G2012 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion). We made a typographical error in the status indicator assignment. Specifically, we are correcting the status indicator from “A” to “B”.

In Addendum B of the CY 2021 OPPS/ASC final rule with comment period, HCPCS code G2211 was incorrectly assigned to status indicator “N” to indicate that it should be packaged under the OPPS. We intended to assign this code to status indicator “B” to indicate that it should not be payable under the OPPS because this code is an add-on code to existing Evaluation and Management code(s) that are assigned to status indicator “B”. Therefore, in the Addendum B (Final OPPS Payment by HCPCS code for CY 2021), we corrected the following:

- HCPCS code G2211 (Visit complexity inherent to evaluation and management

associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)). We made a typographical error in the status indicator assignment.

Specifically, we are correcting the status indicator from “N” to “B”.

In Addendum B of the CY 2021 OPPS/ASC final rule with comment period, HCPCS code A9591 had an incorrect payment rate of \$0.752. We corrected the following:

- For HCPCS A9591 (Fluoroestradiol f 18, diagnostic, 1 millicurie), we included an incorrect payment rate. Specifically, we are correcting the payment rate from \$0.752 to \$626.583.

In Addendum C of the CY 2021 OPPS/ASC final rule with comment period, APC 9370, HCPCS code A9591 had an incorrect payment rate of \$0.752. We corrected the following:

- For APC 9370 (Fluoroestradiol f 18), HCPCS code A9591 (Fluoroestradiol f 18, diagnostic, 1 millicurie), we included an incorrect payment rate. Specifically, we are correcting the payment rate from \$0.752 to \$626.583.

In Addendum P, in the tab titled “2021 FR Device Intensive List”, we inadvertently omitted CPT code 0404T from this list. CPT code 0404T was finalized as a device-intensive procedure for CY 2021 with a device offset percentage of 31 percent. We have added this procedure to the list of device-intensive procedures on this tab in Addendum P.

To view the corrected CY 2021 OPPS status indicators, comment indicators, APC assignments, relative weights, payment rates, copayment rates, device-intensive status, and short descriptors in Addenda A, B, C, and P, we refer readers to the Addenda and

supporting files that are posted on the CMS website at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html). Select “CMS-1736-CN” from the list of regulations. All corrected Addenda for this correcting document are contained in the zipped folder titled “2021 OPSS Final Rule Addenda” at the bottom of the page for CMS-1736-CN.

2. ASC Payment System Addenda Posted on the CMS Website

In Addenda AA and BB, we inadvertently applied an incorrect ASC weight scalar to calculate payment rates under the ASC payment system. In our CY 2021 OPSS/ASC final rule with comment period, we finalized a policy to unpackage HCPCS code J1097 (phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml) for CY 2021 (85 FR 86172). However, in our budget neutrality adjustment calculation, we inadvertently omitted prospective expenditures related to J1097 for CY 2021. This error impacted the calculation of the ASC weight scalar and ASC payment rates. Accordingly, we have updated Addenda AA and BB to accurately reflect the ASC payment rates based on the revised ASC weight scalar, as corrected in this notice and updated to include the increased MPFS rates required by section 101(a) of Division N, Title I of the Consolidated Appropriations Act, 2021.

In Addendum BB of the CY 2021 OPSS/ASC final rule with comment period, HCPCS code A9591 had an incorrect payment rate of \$0.75. We corrected the following:

- For HCPCS A9591 (Fluoroestradiol f 18, diagnostic, 1 millicurie), we included an incorrect payment rate. Specifically, we are correcting the payment rate from \$0.75 to \$626.58.

To view the corrected final CY 2021 ASC payment indicators, payment weights, payment rates, and multiple procedure discounting indicator in Addenda AA and BB, we refer readers to the Addenda and supporting files on the CMS website at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html>. Select “CMS-1736-CN” from the list of regulations. All corrected ASC addenda for this correcting document are contained in the zipped folder titled “Addendum AA, BB, DD1, DD2, and EE” at the bottom of the page for CMS-1736-CN.

III. Waiver of Proposed Rulemaking, 60-Day Comment Period, 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 proposed rulemaking 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 notice of the proposed rulemaking in the **Federal Register** and 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 notice and comment and delay in effective date 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 are impracticable, unnecessary, or contrary to the public interest. In addition, both sections 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 rule that would be subject to the notice and comment or delayed effective date requirements. This document

corrects technical and typographic errors in the preamble, addenda, payment rates, tables, and appendices included or referenced in the CY 2021 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 with comment period. As a result, this correcting document is intended to ensure that the information in the CY 2021 OPPS/ASC final rule with comment period accurately reflects the policies adopted in that document.

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 2021 OPPS/ASC final rule accurately 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, received comment on, and subsequently finalized. This correcting document is intended solely to ensure that the CY 2021 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 effective date requirements. 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 the corrections in this correcting document 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 2021 OPPS/ASC final rule with comment period accurately reflects our policies.

IV. Correction of Errors

In FR Doc. 2020–26819 of December 29, 2020 (85 FR 85866), make the following corrections:

1. On page 85987, third column, after the second full paragraph ending with “Addendum B is available via the internet on the CMS website.” and before the section titled “IV. OPPS Payment for Devices,” the following section and text are added:

31. Other Procedures/Services

For CY 2021, we proposed to continue to assign CPT code 0607T to APC 5012 (Clinic Visits and Related Services) with status indicator “V” (Clinic or Emergency Department Visit. Paid under OPPS; separate APC payment) and a proposed payment rate of \$120.88. In addition, we proposed to continue to assign CPT code 0608T to APC 5741 (Level 1 Electronic Analysis of Devices) with status indicator “S” (Procedure or Service, Not Discounted When Multiple. Paid under OPPS; separate APC payment) and a proposed payment rate of \$37.76. Below are the long descriptors for CPT codes 0607T and 0608T:

- 0607T: Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment; and

- 0608T: Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid

levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (e.g., ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional.

Comment: A commenter requested that we reassign CPT codes 0607T and 0608T to non-payable OPSS status indicators because the commenter contended that the service associated with the codes is not provided to hospital outpatients during a hospital outpatient encounter. The commenter specifically requested that both codes be reassigned to either status indicator “B” (Codes that are not recognized by OPSS. Not paid under OPSS) or “M” (Items and Services Not Billable to the MAC. Not paid under OPSS) for both codes. The commenter reported that the services are prescribed by individual physicians, and are not currently provided to either hospital inpatients or outpatients, or in conjunction with any hospital service. According to the commenter, there is no hospital in the U.S. that possesses the technology to provide a remote pulmonary fluid monitoring system and further stated that ambulatory fluid monitoring system is only available through a single Independent Diagnostic Testing Facility (IDTF) in Pittsburgh, Pennsylvania. The commenter explained that an individual physician will prescribe the ambulatory fluid monitoring device for their patient and submit the medical order to the IDTF. Thereafter, the IDTF is ultimately responsible for the transmission, analysis, and creation of reports to the prescribing physician.

Response: Based on our review of the codes and input from our medical advisors, the services described by CPT codes 0607T and 0608T may be provided in an HOPD setting. While the commenter has indicated that the services described by the codes are currently performed by one IDTF, we believe that the services can be performed by HOPDs. Consequently, for CY 2021, we believe that we should continue to assign these codes to APCs 5012 and 5741 so that HOPDs can be paid separately if they provide these

services in the HOPD setting. Therefore, we are finalizing our proposal, without modification, to assign CPT codes 0607T and 0608T to APCs 5012 and 5741, respectively. The final CY 2021 payment rate for the codes can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

2. On page 86033, first column, first full paragraph, in line 5 and 6, “third quarter of CY 2020” is corrected to read “second quarter of CY 2020”.

3. On page 86035, third column, first partial paragraph, in line 4, the year “CY 2018” is corrected to read “CY 2021”.

4. On Page 86063, Table 42, in the entry for HCPCS code Q4222, under the column for “Final CY 2021 High/Low Cost Assignment,” “Low” is corrected to read “High”.

5. On page 86154, Table 59, in the entry for CPT code 0404T, under the column “Final CY 2021 ASC Payment Indicator,” “G2” is corrected to read “J8”.

6. On page 86165, Table 60, in the entry for CPT code 0404T, under the column “Final CY 2021 ASC Payment Indicator,” “G2” is corrected to read “J8”.

7. On page 86175, third column, after the first partial paragraph, add the following text:

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–04 may be obtained at <https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf>. We are utilizing the revised delineations as set forth in the April 10, 2018 OMB Bulletin No. 18-03 and the September 14, 2018 OMB Bulletin No. 18–04 to calculate the CY 2021 ASC wage index effective beginning January 1, 2021.”

8. On page 86176, third column, first full paragraph, in line 10, the figure “0.8591” is corrected to read “0.8547.”
9. On page 86182, in footnote 107, the url “<https://www.cms.gov/Research-Statistics-DataandSystems/Computer-Data-and-Systems/IDR/index.html>” is corrected to read “<https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR>”.
10. On page 86192, in footnote 110, the url “<https://www.qualitynet.org/asc/data-submission#tab2>” is corrected to read: “<https://www.qualitynet.org/asc/ascqr/participation#tab2>”.
11. On page 86273, second column, third full paragraph, in lines 7 and 8, the figure “0.2 percent” is corrected to read “2.6 percent”.
12. On page 86282, second column, in the first paragraph under “2. Estimated Effects of CY 2021 ASC Payment System Changes,” in line 10, the figure “0.8591” is corrected to read “0.8547.”

Dated: February 19, 2021.

Wilma M. Robinson,

Deputy Executive Secretary to the Department,

Department of Health and Human Services.