



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**42 CFR Parts 400, 410, 414, 415, 423, 424, and 425**

**[CMS-1734-F, CMS-1734-IFC, CMS-1744-F, CMS-5531-F and CMS-3401-IFC] CN**

**RIN 0938-AU10, 0938-AU31, 0938-AU32, and 0938-AU33**

**Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19; Correction**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule and interim final rule; Correction.

**SUMMARY:** This document corrects technical errors in the final rule that appeared in the December 28, 2020, **Federal Register** under the same as title above. Hereinafter, the December 28 rule is referred to as the CY 2021 PFS final rule.

**DATES:** This correction is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], and is applicable beginning January 1, 2021.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Lambert-Lawson, (410) 786-1366, Gaysha Brooks, (410) 786-9649, or Annette Brewer (410) 786-6580.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In FR Doc. 2020–26815 of December 28, 2020, the CY 2021 PFS final rule (85 FR 84472), there were technical errors that are identified and corrected in this correcting document. These corrections are effective and applicable beginning January 1, 2021.

**II. Summary of Errors**

A. Summary of Errors in the Preamble

On page 84545 of the CY 2021 PFS final rule, third column, prior to the first full paragraph, in our discussion of clarifications and proposals related to digitally stored data services/remote physiologic monitoring/treatment management services, we inadvertently deleted, before publication, language summarizing and responding to two sets of public comments. We also inadvertently included language on page 84545 of the CY 2021 PFS final rule, third column, the first partial paragraph at the top of the column.

B. Summary of Errors in the Addenda

On page 85057, in Table B.2. Audiology, second column, second row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85069, in Table B.5. Clinical Social Work, second column, second row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85076, in Table B.8. Diagnostic Radiology, ninth column entry Measure Steward, third row, we inadvertently misidentified the measure steward.

On page 85083, in Table B.10. Endocrinology, second column, third row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85089, in Table B.11. Family Medicine, second column, sixth row, the entry NQF # / eCQM NQF # contains typographical errors.

On page 85110, in Table B.16. Infectious Disease, ninth column entry Measure Steward, fourth row, we inadvertently misidentified the measure steward.

On page 85114, in Table B.17. Internal Medicine, second column, first row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85124, in Table B.19. Mental/Behavioral Health, second column, fifth row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85130, in Table B.21. Neurology, second column, third row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85141, in Table B.24. Obstetrics/Gynecology, third column entry Quality # sixth row, we inadvertently omitted the Quality number.

On page 85146, in Table B.25a. Oncology/Hematology, third column entry Quality #, fifth row, we inadvertently omitted the Quality number.

On page 85157, in Table B.27. Orthopedic Surgery, second column, third row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85171, in Table B.30. Pediatrics, second column, fifth row, the entry NQF # / eCQM NQF # contains typographical errors.

On page 85171, in Table B.30. Pediatrics, ninth column entry Measure Steward, sixth row, we inadvertently misidentified the measure steward.

On page 85173, in Table B.30. Pediatrics, second column, sixth row, the entry NQF # / eCQM NQF # contains typographical errors.

On page 85179, in Table B.32. Physical Therapy/Occupational Therapy, second column, fifth row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85190, in Table B.35. Preventive Medicine, second column, third row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85199, in Table B.38. Skilled Nursing Facility, third column entry Quality #, fifth row, we inadvertently omitted the Quality number.

On page 85203, in Table B.39. Speech Language Pathology, second column, first row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85268, in Table D.26. Preventive Care and Screening: Screening for Depression and Follow-Up Plan, second column, first row, the entry NQF # / eCQM NQF # contains a typographical error.

On page 85333, in Table D.82. Immunizations for Adolescents, second column, first row, the entry NQF # / eCQM NQF # contains a typographical error.

### **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) 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 document does not constitute a rulemaking that would be subject to these requirements. This document merely corrects technical errors in the CY 2021 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 2021 PFS final rule. As a result, the corrections made through this correcting document are intended to resolve inadvertent errors so that the CY 2021 PFS final rule accurately reflects the policies adopted in the final rule. 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 2021 PFS final rule or delaying the effective date of the corrections would be contrary to the public interest because it is in the public interest to ensure that the 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 final rule, but rather, we are simply correcting the **Federal Register** document to reflect the policies that we previously proposed, received public comment on, and subsequently finalized in the CY 2021 PFS final rule. For these reasons, we believe there is good cause to waive the requirements for notice and comment and delay in effective date.

#### **IV. Correction of Errors**

In FR Doc. 2020–26815 (85 FR 84472), published December 28, 2020, make the

following corrections:

A. Correction of Errors in the Preamble

1. On page 84545 of the CY 2021 PFS final rule, third column, the first partial paragraph at the top of the column is corrected by removing the following language:

The medically necessary services associated with all the medical devices for a single patient can be billed by only one practitioner, only once per patient per 30 day period, and only when at least 16 days of data have been collected.

2. On page 84545 of the CY 2021 PFS final rule, third column, prior to the first full paragraph, is corrected by adding the following language:

Comment: Commenters stated that for CPT codes 99457 and 99458, we interpreted “interactive communication” to mean “real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission” and suggested that the required 20 minutes of time associated with CPT codes 99457 and 99458 should be only synchronous time, real-time between a practitioner and a patient. Commenters stated that these two codes include non-face-to-face time as well as real-time two-way audio interactions.

Response: We agree with commenters that our description of the required 20 minutes of time associated with CPT codes 99457 and 99458 should include care management services, as well as synchronous, real-time interactions. That is, we agree that “interactive communication” as we defined it in the CY 2021 PFS proposed rule contributes to the total time, but is not the only activity that should be included in the total time.

After considering comments, we are clarifying for purposes of this final rule, that the 20-minutes of intra-service work associated with CPT codes 99457 and 99458 includes a practitioner’s time engaged in “interactive communication” as well as time engaged in non-face-to-face care management services during a calendar month.

Comment: Commenters disagreed with our statement that the services associated with CPT codes 99453 and 99454 should be billed only once per patient, per 30-day period, and wrote that CMS should clarify that CPT codes 99453 and 99454 can be billed once per provider, per patient, per 30-day period.

Response: We thank commenters for their insights related to billing CPT codes 99453 and 99454. As we stated in the proposed rule, we believe these two codes should be reported for a patient only once during a 30-day period and only when reasonable and necessary. In response to public commenters, we are clarifying that only one practitioner can bill CPT codes 99453 and 99454 during a 30-day period and only when at least 16 days of data have been collected on at least one medical device as defined in section 201(h) of the FFDCA. CPT language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also note that when a more specific code is available to describe a service, CPT indicates that the more specific code should be billed. We believe that there are additional, more specific codes available for billing that allow remote monitoring (for example, CPT code 95250 for continuous glucose monitoring and CPT codes 99473 and 99474 for self-measured blood pressure monitoring). In summary, we are clarifying that CPT codes 99453 and 99454 should be reported only once during a 30-day period; that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30-day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary.

#### B. Correction of Errors in the Addenda

1. On page 85057, in Table B.2. Audiology, second column, second row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.

2. On page 85069, in Table B.5. Clinical Social Work, second column, second row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
3. On page 85076, in Table B.8. Diagnostic Radiology, ninth column, third row, the Measure Steward entry “American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance” is corrected to read “American College of Radiology/ National Committee for Quality Assurance”.
4. On page 85083, in Table B.10. Endocrinology, second column, third row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
5. On page 85089, in Table B.11. Family Medicine, second column, sixth row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”, and in the second column, sixth row, the NQF # / eCQM NQF # entry “1407 / N/A” is corrected to read “N/A / N/A”.
6. On page 85110, in Table B.16. Infectious Disease, the ninth column, fourth row, the Measure Steward entry “Health Resources and Services Administration” is corrected to read “National Committee for Quality Assurance”.
7. On page 85114, in Table B.17. Internal Medicine, second column, first row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
8. On page 85124, in Table B.19. Mental/Behavioral Health, second column, fifth row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
9. On page 85130, in Table B.21. Neurology, second column, third row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
10. On page 85141, in Table B.24. Obstetrics/Gynecology, third column, fifth row, the blank Quality # entry is corrected to read “111”.
11. On page 85146, in Table B.25a. Oncology/Hematology, third column, fifth row, the blank Quality # entry is corrected to read “110”.



12. On page 85157, in Table B.27. Orthopedic Surgery, second column, third row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
13. On page 85171, in Table B.30. Pediatrics, second column, fifth row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
14. On page 85171, in Table B.30. Pediatrics, ninth column, sixth row, the Measure Steward entry “Health Resources and Services Administration” is corrected to read “National Committee for Quality Assurance”.
15. On page 85173, in Table B.30. Pediatrics, second column, sixth row, the NQF # / eCQM NQF # entry “1407 / N/A” is corrected to read “N/A / N/A”.
16. On page 85179, in Table B.32. Physical Therapy/Occupational Therapy, second column, fifth row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
17. On page 85190, in Table B.35. Preventive Medicine, second column, third row, the NQF # / eCQM NQF # “entry 0418 / 0418e” is corrected to read “N/A / 0418e”.
18. On page 85199, in Table B.38. Skilled Nursing Facility, third column, fifth row, the blank Quality # entry is corrected to read “110”.
19. On page 85203, in Table B.39. Speech Language Pathology, second column, first row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
20. On page 85268, in Table D.26. Preventive Care and Screening: Screening for Depression and Follow-Up Plan, second column, first row, the NQF # / eCQM NQF # entry “0418 / 0418e” is corrected to read “N/A / 0418e”.
21. On page 85333, in Table D.82. Immunizations for Adolescents, second column, first row, the NQF # / eCQM NQF # entry “1407 / N/A” is corrected to read “N/A / N/A”.

Dated: January 11, 2021.

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**Wilma M. Robinson,**

Deputy Executive Secretary to the Department,

Department of Health and Human Services.

[FR Doc. 2021-00805 Filed: 1/14/2021 8:45 am; Publication Date: 1/19/2021]