



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

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

#### **42 CFR Part 410**

**[CMS-1717-F3]**

**RIN-0938-AT74**

**Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots; Correcting Amendment**

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

**ACTION:** Correcting amendment.

**SUMMARY:** In the November 12, 2019 issue of the Federal Register, we published a final rule with comment period that made changes to the conditions for therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service. This correcting amendment corrects a technical error in the regulations resulting from an error in that final rule with comment period.

**DATES:** This correcting amendment is effective [insert date of publication in the Federal Register] and is applicable beginning January 1, 2020.

## **FOR FURTHER INFORMATION CONTACT:**

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email at [Joshua.McFeeters@cms.hhs.gov](mailto:Joshua.McFeeters@cms.hhs.gov) or at (410)786-9732.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

In FR Doc. 2019–24138 of November 12, 2019 (84 FR 61142), “Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children’s Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots” (hereinafter referred to as the CY 2020 OPPTS/ASC final rule with comment period), there was a technical error in the regulations text that is identified and corrected in this correcting amendment. The provisions of this correcting amendment are treated as if the technical error in the regulations text at §410.27 that resulted from the error in the document published November 12, 2019 had not occurred. Accordingly, the corrections are applicable beginning January 1, 2020.

### **II. Summary of Error in the Regulations Text**

On page 61490 of the CY 2020 OPPTS/ASC final rule with comment period, we made a technical error in an amendatory instruction which resulted in the unintended removal of paragraphs (a)(1)(iv)(C), (D), and (E) from §410.27 of the CFR.

Accordingly, we are amending §410.27 to accurately reflect the intent as described in the

preamble language included in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), but which was not properly reflected in the regulatory text portion of the rule. In the amendatory instruction, we stated that “§410.27 is amended by revising paragraph (a)(1)(iv).” The amendatory instruction should have read “§410.27 is amended by revising paragraphs (a)(1)(iv) introductory text, (a)(1)(iv)(A), and (B). This error in the amendatory instruction resulted in §410.27(a)(1)(iv)(C) through (E) being erroneously removed. Therefore, this correcting amendment corrects this error by adding paragraphs (a)(1)(iv)(C), (D), and (E).

### **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 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 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 amendment does not constitute a rulemaking that would be subject to these requirements. This correcting amendment corrects a technical error in the regulations text included in the CY 2020 OPPS/ASC final rule with comment period but does not make substantive changes to the policies that were adopted in the final rule with comment period. As a result, the corrections made through this correcting amendment are intended to ensure that the information in the CY 2020 OPPS/ASC final rule with comment period accurately reflects the policies adopted.

In addition, even if this were a rulemaking 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 with comment period or delaying the effective date would be contrary to the public interest because it is in the public's interest to ensure that the CY 2020 OPPS/ASC final rule with comment period 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 policies, but rather, we are simply correctly implementing the policies that we previously proposed, received comment on, and subsequently finalized. This correcting amendment is intended solely to ensure that the CY 2020 OPPS/ASC final rule with comment period accurately reflects these policies. For these reasons, we believe we have good cause to waive the notice and comment and effective date requirements.

**List of Subjects in 42 CFR Part 410**

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendment:

**PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

1. The authority citation for part 410 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

2. Section 410.27 is amended by adding paragraphs (a)(1)(iv)(C), (D), and (E) to read as follows:

**§410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.**

\* \* \* \* \*

(a) \* \* \*

(1) \* \* \*

(iv) \* \* \*

(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§410.47 and 410.49, respectively; and

(E) For nonsurgical extended duration therapeutic services (extended duration services), which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically

performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. Initiation means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision; and

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CMS-1717-F3

Dated: February 6, 2020.

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

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