



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1687-RCN]

RIN 0938-AT21

Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas; Extension of Timeline for Final Rule Publication

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

ACTION: Continuation of effectiveness and extension of timeline for publication of the final rule.

SUMMARY: This document announces the continuation of effectiveness of a Medicare interim final rule and the extension of the timeline for publication of the final rule.

Section 1871(a)(3)(B) of the Social Security Act (the Act) specifies that a Medicare final rule must be published no later than 3 years after the publication date of the proposed or interim final rule, except under exceptional circumstances. In accordance with sections 1871(a)(3)(B) and 1871(a)(3)(C) of the Act, we are providing a notification of continuation for a Medicare interim final rule, announcing the different timeline on which we intend to publish the final rule, and explaining why we were unable to publish the final rule on the regular, required 3-year timeline.

DATES: As of [insert the date of filing for public inspection at the Office of the Federal Register], the Medicare provisions adopted in the interim final rule published on May 11, 2018 (83 FR 21912) continue in effect and the regular timeline for publication of the final rule is extended for an additional year, until May 11, 2022.

FOR FURTHER INFORMATION CONTACT: Alexander Ullman, (410) 786-9671 or DMEPOS@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: In the May 11, 2018 **Federal Register** (83 FR 21912), we published an interim final rule with comment period (IFC) titled “Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas”. The May 2018 IFC made technical amendments to the regulation to reflect the extension of the transition period from June 30, 2016 to December 31, 2016 that was mandated by the 21st Century Cures Act for phasing in fee schedule adjustments for certain durable medical equipment (DME) and enteral nutrition furnished in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) (83 FR 21915). In addition, in the May 2018 IFC, CMS -- (1) amended 42 CFR 414.210(g) to resume the transition period’s blended fee schedule rates for items furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and United States territories) not subject to the CBP from June 1, 2018 through December 31, 2018 (83 FR 21915); (2) made technical amendments to existing DMEPOS regulations to reflect the exclusion of infusion drugs used with DME from the DMEPOS CBP (83 FR 21919); and (3) stated that the fee schedule amounts for wheelchair accessories and back and seat cushions used in conjunction with group 3 power wheelchairs would continue to be based on the unadjusted fee schedule amounts updated by the covered item update specified in section 1834(a)(14) of the Act (83 FR 21919). We stated that the fee schedule amounts for all other accessories used with different types of base equipment would continue to be calculated in accordance with the adjustment methodology set forth in § 414.210(g)(5) of our regulations (83 FR 21919).

Section 1871(a)(3)(B) of the Act requires CMS to publish a Medicare final rule no later than 3 years after the publication of a proposed or interim final rule, except under

exceptional circumstances. In such circumstances, section 1871(a)(3)(B) of the Act allows the Secretary to vary the final regulation publication timeline if the Secretary provides public notice of the different timeline on which it intends to publish the final regulation, and that notice includes a brief explanation of the justification for the variation. The notice must be published by no later than the timeline previously established with respect to the final rule publication date.

The May 2018 IFC was published on May 11, 2018. Therefore, in accordance with section 1871(a)(3)(B) of the Act, we must finalize the May 2018 IFC by May 11, 2021, except under exceptional circumstances. We will not be able to finalize the May 2018 IFC within the required 3-year timeline for publication (by May 11, 2021) for the following reasons:

In the November 4, 2020 **Federal Register** (85 FR 70358), we published a proposed rule titled “Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)” (hereinafter DMEPOS and HCPCS proposed rule). In the DMEPOS and HCPCS proposed rule (85 70373), we stated that we solicited comments on the 2018 Interim Final Rule, but because we have not yet responded to the comments we received, we are signaling our intent to do so in the final rule.

On January 20, 2021, the Assistant to the President and Chief of Staff issued a memorandum concerning “Regulatory Freeze Pending Review” (“Regulatory Freeze memorandum”).¹ The Office of Management and Budget (OMB) issued Memorandum M-21-14 on January 20, 2021, providing guidance on implementing the Regulatory Freeze memorandum.² The Regulatory Freeze memorandum seeks to ensure that the

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/> (86 FR 7424, January 28, 2021).

² <https://www.whitehouse.gov/wp-content/uploads/2021/01/M-21-14-Regulatory-Review.pdf>

President's appointees or designees have the opportunity to review any new or pending rules. Paragraph 1 of the Regulatory Freeze memorandum directs agencies, subject to any exceptions the Director of the OMB allows for emergency situations or other urgent circumstances relating to health, safety, environmental, financial, or national security matters, or otherwise, to propose or issue no rule in any manner — including by sending a rule to the Office of the Federal Register — until a department or agency head appointed or designated by the President after noon on January 20, 2021, reviews and approves the rule. Additionally, paragraph 3 of the Regulatory Freeze memorandum describes the agency option to temporarily postpone agency rules to permit review by an agency head appointed or designated by the President after noon on January 20, 2021.

In light of our efforts to comply with the Regulatory Freeze memorandum, and to allow policy officials in the new administration the opportunity to review the DMEPOS and HCPCS proposed rule and May 2018 IFC, we do not believe we will have sufficient time to finalize the IFC, and relatedly the DMEPOS and HCPCS proposed rule, by the May 11, 2021 deadline. As a result of these exceptional circumstances, we are issuing this notification of continuation and extending the timeline for finalizing the May 2018 IFC by 1 year. This extension will grant policy officials the opportunity to review the DMEPOS and HCPCS proposed rule and the May 2018 IFC. In accordance with section 1871(a)(3)(C) of the Act, this notification of continuation also ensures that the May 2018 IFC continues in effect beyond May 11, 2021. As a result of the publication of this notification of continuation, the timeline for publication of the final rule will be treated as having been extended until May 11, 2022.

Dated: April 21, 2021.

Wilma Robinson,

Deputy Executive Secretary to the Department,

Department of Health and Human Services.

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