DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS-1720-RCN]

RIN 0938-AT64

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations Extension of Timeline for Publication of Final Rule

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

ACTION: Extension of timeline for publication of final rule.

SUMMARY: This notice announces an extension of the timeline for publication of a Medicare final rule in accordance with the Social Security Act, which allows us to extend the timeline for publication of the final rule.

DATES: As of [Insert date of display at the Office of the Federal Register], the timeline for publication of the final rule to finalize the provisions of the October 17, 2019 proposed rule (84 FR 55766) is extended until August 31, 2021.

FOR FURTHER INFORMATION CONTACT: Lisa O. Wilson, (410) 786-8852.

SUPPLEMENTARY INFORMATION: In the October 17, 2019 Federal Register (84 FR 55766), we published a proposed rule that addressed undue regulatory impact and burden of the physician self-referral law. The proposed rule was issued in conjunction with the Centers for Medicare & Medicaid Services’ (CMS) Patients over Paperwork initiative and the Department of Health and Human Services’ (the Department or HHS) Regulatory Sprint to Coordinated Care. In the proposed rule, we proposed exceptions to
the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers; a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; a new exception for donations of cybersecurity technology and related services; and amendments to the existing exception for electronic health records (EHR) items and services. The proposed rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

This notice announces an extension of the timeline for publication of the final rule and the continuation of effectiveness of the proposed rule.

Section 1871(a)(3)(A) of the Social Security Act (the Act) requires us to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation. In accordance with section 1871(a)(3)(B) of the Act, the timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but may not be longer than 3 years except under exceptional circumstances. In addition, in accordance with section 1871(a)(3)(B) of the Act, the Secretary may extend the initial targeted publication date of the final regulation if the Secretary, no later than the regulation's previously established proposed publication date, publishes a notice with the new target date, and such notice includes a brief explanation of the justification for the variation.

We announced in the Spring 2020 Unified Agenda (June 30, 2020, www.reginfo.gov) that we would issue the final rule in August 2020. However, we are
still working through the complexity of the issues raised by comments received on the proposed rule and therefore we are not able to meet the announced publication target date. This notice extends the timeline for publication of the final rule until August 31, 2021.

**Dated:** August 24, 2020.

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Wilma M. Robinson,

Deputy Executive Secretary to the Department,

Department of Health and Human Services.

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