(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS–3295–RCN]

RIN 0938–AS21

Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Extension of Timeline for Publication of the Final Rule

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

ACTION: Extension of timeline for publication of a final rule.

SUMMARY: This document announces the extension of the timeline for publication of the ''Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care'' final rule. We are issuing this document in accordance with section 1871(a)(3)(B) of the Social Security Act (the Act), which requires notice to be provided in the **Federal Register** if there are exceptional circumstances that cause us to publish a final rule more than 3 years after the publication date of the proposed rule. In this case, the complexity of the rule, its substantive nature, and the scope of comments received all warrant the extension of the timeline for publication.

DATES: As of June 7, 2019, the timeline for publication of the final rule to finalize the provisions of the June 16, 2016 proposed rule (81 FR 39447) is extended until June 16, 2020.

FOR FURTHER INFORMATION CONTACT: CAPT Scott Cooper, USPHS, (410) 786–9465.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1871(a)(3)(A) of the Social Security Act (the Act) requires the Secretary of the Department of Health and Human Services (the Secretary), in consultation with the Director of the Office of Management and Budget (OMB), to establish a regular timeline for the publication of a final rule based on the previous publication of a proposed rule or an interim final rule.

Section 1871(a)(3)(B) of the Act allows the timeline for publishing Medicare final regulations to vary based on the complexity of the regulation, the number and scope of comments received, and other related factors. The timeline for publishing the final rule, however, cannot exceed 3 years from the date of publishing the proposed regulation unless there are exceptional circumstances. The Secretary may extend the initial targeted publication date of the final rule if the Secretary provides public notice thereof, including a brief explanation of the justification for the variation, no later than the rule's previously established proposed publication date.

After consultation with the Director of OMB, the Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), published a notice in the December 30, 2004 **Federal Register** (69 FR 78442) establishing a general 3-year timeline for publishing Medicare final rules after the publication of a proposed or interim final rule.

II. Notice of Continuation

Sections 1861(e)(1) through (8) of the Act provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, Conditions of Participation (CoPs) for Hospitals. Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii) and § 440.20(a)(3)(ii), hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

On May 26, 1993, CMS published a final rule in the **Federal Register** entitled ''Medicare Program; Essential Access Community Hospitals (EACHs) and Rural Primary Care Hospitals (RPCHs)'' (58 FR 30630) that implemented sections 6003(g) and 6116 of the Omnibus Budget Reconciliation Act (OBRA) of 1989 and section 4008(d) of OBRA 1990. That rule established requirements for the EACH and RPCH providers that participated in the seven-state demonstration program that was designed to improve access to hospital and other health services for rural residents.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated and certified as a Critical Access Hospital (CAH). CAHs participating in the MRHFP must meet the conditions for designation specified in the statute under section 1820(c)(2)(B) of the Act, and to be certified must also meet other criteria the Secretary may require, under section 1820(e)(3) of the Act. Under this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

In the June 16, 2016 **Federal Register** (81 FR 39447), we published a proposed rule entitled, ''Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care,'' which would update the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. Consistent with section 1871(a)(3)(B) of the Act, the final rule for the June 16, 2016 proposed rule was to be published by June 14, 2019.

The revisions contained in the June 16, 2016 proposed rule were intended to conform the requirements to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns. In response to the proposed rule, we received 200 public comments. Commenters included individuals, healthcare professionals and corporations, national associations and coalitions, state health departments, patient advocacy organizations, and individual facilities that would be impacted by the regulation. Generally, most comments centered on expressing

support for the regulatory changes, especially those concerning use of the term ''licensed independent practitioner,'' aspects of those aimed at infection control and antibiotic stewardship, and those focused on reducing burden and costs for CAHs in the provision of dietary and nutritional services while increasing the effectiveness and benefits of those vital services for patients. However, some commenters expressed concern that we underestimated the time and effort required for compliance with the antibiotic stewardship and Quality Assessment and Performance Improvement (QAPI) requirements, especially for smaller hospitals, including CAHs. Commenters requested a delayed implementation for these particular requirements.

This document announces an extension of the timeline for publication of the final rule due to exceptional circumstances. We were not able to meet the 3-year timeline for the publication of the final rule due to the complexity and substantive nature of the provisions proposed in the June 16, 2016 proposed rule. Additional time is needed to fully consider all the comments and provisions, and to ensure that we most appropriately modernize and revise the requirements of the CoPs for hospitals and CAHs. Some of these proposed changes include provisions to address—(1) use of the term ''Licensed Independent Practitioners;'' (2) requirements that do not fully conform to current standards for infection control; (3) requirements for antibiotic stewardship programs to help reduce inappropriate antibiotic use and antimicrobial resistance; (4) the use of quality reporting program data by hospital QAPI programs; (5) a new requirement for CAHs that mirrors the existing QAPI requirements for hospitals; and (6) a new provision that would allow CAHs to grant qualified dietitians and nutrition professionals ordering privileges for dietary services, mirroring an existing provision in the hospital CoPs.

As stated in the Fall 2018 Unified Agenda of Regulatory and Deregulatory Actions (*https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=0938-AS21*), we may finalize the June 16, 2016 proposed rule by merging some of the provisions into other related rulemaking documents. Currently, we are reviewing comments to determine whether to finalize at least one of the provisions from the June 16, 2016 proposed rule regarding patient rights in hospitals. We plan to address the remaining provisions of the June 16, 2016 proposed rule in future rulemaking.

We stress that our decision in this matter to extend the timeline for issuing a final rule should not be viewed as a diminution of the Department's commitment to timely and effective rulemaking. Our goal remains to publish, as expeditiously as feasible, a final rule that supports improvements in the quality of patient care through adoption of current standards of practice, while also minimizing the burden on providers to the maximum possible extent. At this time, we believe we can best achieve this balance by issuing this continuation document.

Therefore, this document extends the timeline to finalize the provisions in the June 16, 2016 proposed rule for 1 year, until June 16, 2020.

III. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the OMB under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 6, 2019.

Ann C. Agnew,

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

[FR Doc. 2019–12216 Filed 6–7–19; 11:15 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Ch. IV

[CMS–6082–NC]

RIN 0938–ZB54

Request for Information; Reducing Administrative Burden To Put Patients Over Paperwork

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Department of the Treasury.

ACTION: Request for information.

SUMMARY: CMS is committed to transforming the health care delivery system—and the Medicare and Medicaid programs—by putting additional focus on patient-centered care, innovation, and outcomes. As part of our continuing Patients over Paperwork initiative, we have actively solicited feedback from the medical community through Requests for Information (RFIs), listening sessions, and clinical onsite engagements with front-line clinicians and staff to learn how our administrative requirements and processes affect their daily work and ability to innovate in care delivery. This RFI solicits additional public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families. Through these efforts, we aim to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 12, 2019.

ADDRESSES: In commenting, refer to file code CMS–6082–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6082–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6082–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Morgan Taylor, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786–3458.

Mary G. Greene, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786–1244.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for