



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 409, 410, 418, 440, 484, 485 and 488

[CMS-3819-P2]

RIN 0938-AG81

#### Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies;

#### Delay of Effective Date

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would delay the effective date for the final rule entitled "Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies" published in the **Federal Register** on January 13, 2017. The current effective date for the final rule is July 13, 2017, and this rule proposes to delay the effective date for an additional 6 months until January 13, 2018. This proposed rule would also make two conforming changes to dates that are included in the regulations text.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

**ADDRESSES:** In commenting, please refer to file code CMS-3819-P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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-3819-P2,

P.O. Box 8010,

Baltimore, MD 21244-1850.

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-3819-P2,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Room 445-G, Hubert H. Humphrey Building,  
200 Independence Avenue, SW.,  
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
7500 Security Boulevard,  
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

**FOR FURTHER INFORMATION CONTACT:**

Danielle Shearer (410) 786-6617.

Mary Rossi-Coajou (410) 786-6051.

Maria Hammel (410) 786-1775.

#### **SUPPLEMENTARY INFORMATION:**

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

#### **I. Background**

On October 9, 2014, we published the proposed rule “Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies” (hereinafter “October 2014 HHA CoPs proposed rule”) in the **Federal Register** (79 FR 61164) and provided a 60 day comment period. On December 1, 2014, in response to public comments requesting additional time to respond to the proposed rule, we published a notice of extension of the comment period (79 FR 71081), which extended the public comment period for the October 2014 HHA CoPs proposed rule an

additional 30 days, from December 8, 2014 to January 7, 2015. The vast majority of commenters on the October 2014 HHA CoPs proposed rule made suggestions related to the effective date of the final rule (“Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies”, January 13, 2017, (82 FR 4504), hereinafter “January 2017 HHA CoPs final rule”). Commenters strongly expressed a need for a significant period of time to prepare for implementation of the new rules, noting that HHAs would need to adjust resource allocation, staffing, and potentially even infrastructure. Recommended effective date time frames ranged from 6 months after publication of the final rule to 5 years after publication of the final rule. The most frequent recommendation received was to finalize an effective date that was 1 year after the publication of the final rule. We agreed with commenters that it was appropriate to allow additional time for HHAs to prepare for the changes being set forth in the HHA CoPs final rule. Therefore, when we published the January 2017 HHA CoPs final rule in the **Federal Register** on January 13, 2017, we finalized an effective date of July 13, 2017 (that is, 6 months after the final rule was published in the **Federal Register**).

The January 2017 HHA CoPs final rule revised the CoPs that HHAs must meet in order to participate in the Medicare and Medicaid programs. The requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers. We believe that the overall approach of the CoPs provides HHAs with greatly enhanced flexibility.

At the same time, we believe the new requirements help HHAs achieve needed and desired outcomes for patients, increasing patient satisfaction with the services provided.

## **II. Provisions of the Proposed Regulations**

Following publication of the January 2017 HHA CoPs final rule, we received inquiries that represented a large number of HHAs requesting that the agency delay the effective date for the new HHA CoPs. The inquiries asserted that HHAs were not able to effectively implement the new CoPs until CMS issued its revised Interpretive Guidelines (State Operations Manual, CMS Pub. 100-07, Appendix B). In addition, one of the inquiries stated that HHAs were unable to effectively implement the new CoPs until CMS issued further sub-regulatory guidance related to converting subunits to branches or independent HHAs, which would impact 216 HHAs nationwide. One of the inquiries cited the estimated \$300 million cost to implement the new requirements as a reason for delaying the effective date.

We believe that the concerns expressed in the inquiries have merit, so in response to the concerns summarized above, we propose to delay the effective date of the January 2017 HHA CoPs final rule for an additional 6 months. The effective date for the January 2017 HHA CoPs final rule, which is currently set to become effective on July 13, 2017, would be delayed until January 13, 2018.

We also propose to make two conforming changes to dates that appear in the regulations text of the January 2017 HHA CoPs final rule. First, we included a phase-in date for the requirements at §484.65(d) -- “Standard: Performance improvement projects.” This phase-in date allowed HHAs an additional 6 months after the January 2017 HHA CoPs final rule became effective to collect data before implementing data-driven performance improvement projects.

We continue to believe that it is appropriate to phase-in the performance improvement project requirement 6 months after the provisions of the January 2017 HHA CoPs final rule become effective. Therefore, we propose to revise the phase-in date for the requirements at §484.65(d) by replacing the January 13, 2018 date with a July 13, 2018 date.

Second, we propose to revise §484.115(a) -- “Standard: Administrator, home health agency.” In this provision, we grandfathered in all administrators employed by HHAs prior to the effective date of the January 2017 HHA CoPs final rule, meaning that those administrators employed by an HHA prior to July 13, 2017 would not have to meet the new personnel requirements. We propose to replace the July 13, 2017 effective date at §484.115(a)(1) and (2) with the proposed effective date of January 13, 2018.

### **III. Collection of Information Requirements**

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 Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

### **IV. Response to Comments**

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

### **V. Regulatory Impact Statement**

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$146 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017). Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or

otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's interim guidance, issued on February 2, 2017, <https://www.whitehouse.gov/the-press-office/2017/02/02/interim-guidance-implementing-section-2-executive-order-january-30-2017>, explains that for Fiscal Year 2017 the above requirements only apply to each new "significant regulatory action that imposes costs." It has been determined that this proposed rule is not a "significant regulatory action that imposes costs" and thus does not trigger the above requirements of Executive Order 13771.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects**42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

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

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to delay the effective date for the final rule published on January 13, 2017 **(82 FR 4504)** and to further amend 42 CFR chapter IV as set forth below:

**PART 484 -- HOME HEALTH SERVICES**

1. The authority citation for part 484 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

**§484.65 [Amend]**

2. In §484.65, amend paragraph (d) by removing the date “January 13, 2018” and adding in its place “July 13, 2018”.

**§484.115 [Amend]**

3. In §484.115, amend paragraphs (a)(1) and (2) by removing the date “July 13, 2017” and adding in its place “January 13, 2018”.

**Dated:** March 28, 2017.

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**Seema Verma,**  
Administrator,  
Centers for Medicare & Medicaid Services.

**Dated:** March 28, 2017.

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**Thomas E. Price,**  
Secretary,  
Department of Health and Human Services.

**BILLING CODE 4120-01-P**

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