§ 71.21 Report of death or illness.

■ 5. In 71.21, revise paragraph (c) to read as follows:

§ 71.21 Report of death or illness.

* * * * *

(c) In addition to paragraph (a) of this section, the master of a ship carrying 13 or more passengers must report 24 hours before arrival the number of cases (including zero) of acute gastroenteritis (AGE) in passengers and crew recorded in the ship's medical log during the current cruise. All cases of acute gastroenteritis (AGE) that occur after the 24 hour report must also be reported not less than 4 hours before arrival.

* * * * *

Dated: June 30, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–14393 Filed 7–7–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS–3819–F2]

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: Final rule; delay of effective date.

SUMMARY: This final rule delays 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 (82 FR 4504). The published effective date for the final rule was July 13, 2017, and this rule delays the effective date for an additional 6 months until January 13, 2018. This final rule also includes two conforming changes to dates that are included in the regulations text.

DATES: The effective date of the final rule published on January 13, 2017 (82 FR 4504) is delayed until January 13, 2018. Additionally, the conforming amendments (to § 484.65 and § 484.115) in this rule are effective January 13, 2018.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer (410) 786–6617, Mary Rossi-Coajou (410) 786–6051, or Maria Hammel (410) 786–1775.

SUPPLEMENTARY INFORMATION:

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 published a proposed rule on April 3, 2017 (82 FR 16150) entitled ''Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies; Delay of Effective Date'' 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 proposed 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 proposed 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 proposed 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 proposed 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. Analysis of and Responses to Public Comments

We received 48 letters of public comment from HHA industry associations, surveyors, HHAs, and individuals. A summary of the major issues and our responses follow.

Comment: The majority of comments that were submitted expressed support for the proposed January 13, 2018 effective date for the January 2017 HHA CoPs final rule. One commenter disagreed with the proposal, stating that HHAs should already be implementing most of the new requirements as part of good practice. Another commenter agreed with the proposed effective date and stated that the date should not be delayed beyond January 13, 2018. However, other commenters stated that the rule should be delayed until July 13, 2018 or until 6 months or 1 year after CMS issues revised Interpretive Guidelines.

Response: We appreciate the support from commenters regarding our proposal to delay the effective date of the January 2017 HHA CoPs final rule for an additional 6 months, until January 13, 2018. While we agree that the changes in the new CoPs reflect good practice, and we continue to believe that many HHAs already implemented a significant number of these changes prior to the issuance of the new CoPs, we also acknowledge that the new CoPs contain numerous changes that require time for planning, testing, training, and implementation. In order to assure that HHAs have adequate time for all preparation activities, we are finalizing the proposed 6 month delay of the effective date of the January 2017 HHA CoPs final rule. The new HHA CoPs will be effective on January 13, 2018. We do not believe that delaying the effective date of the new HHA CoPs beyond January 2018 would be in the interest of improving patient safety and quality of care.

Comment: Several commenters supported the proposed effective date delay for implementing performance improvement projects, as required at § 484.65(d). A commenter did not support the delayed effective date as it was proposed. This commenter stated that the effective date for the entire quality assessment and performance improvement (QAPI) requirement should be delayed 18 months beyond the effective date for the rest of the rule (meaning July 2019).

Response: We appreciate the support of the commenters. As stated in the January 2017 HHA CoPs final rule, we believe that a phased-in implementation timeframe is appropriate for the requirement that HHAs conduct performance improvement projects because it will take additional time to collect the data necessary to identify areas for performance improvement. The additional phase-in period allows HHAs the time necessary to collect data prior to implementing performance improvement projects. Allowing HHAs until July 13, 2018 to implement performance improvement projects provides for a full 18 month period between the date that the final rule was published and the date that we would expect HHAs to initiate performance improvement activities. To delay the entire QAPI requirement for 18 months beyond the effective date for the rest of the rule would not require HHAs to begin data collection until July 2019; HHAs would also need 6 months to collect data before initiating performance improvement activities in January 2020. We do not believe that waiting 3 full years to initiate performance improvement activities is in the best interest of patient safety, patient care efficacy, or patient care efficiency. Therefore, we are finalizing the revised July 13, 2018 phase-in date for performance improvement projects. All other QAPI requirements are effective on January 13, 2018.

Comment: A commenter supported the inclusion of a grandfather clause related to the personnel training and education requirements for HHA administrators at § 484.115(a).

Response: We appreciate the support and are finalizing the proposal at § 484.115(a) without change. HHA administrators that start employment with an HHA beginning on or after January 13, 2018 will be required to meet the training and education requirements set forth in the final rule.

Comment: Several commenters submitted comments regarding the content of the January 2017 HHA CoPs final rule. For example, a commenter submitted comments on the plan of care update requirements while another submitted comments on the requirements for supervision of home health aides and another submitted comments regarding the comprehensive assessment. One commenter requested that the removal of the Condition of Participation entitled ''Group of professional personnel'' become effective on the original effective date of July 13, 2017.

Response: While we understand that commenters have technical questions regarding how to implement the requirements of the January 2017 HHA CoPs final rule, or desire to see changes to the policies set forth in the final rule, these comments are outside the scope of this rule. Likewise, making a single change effective prior to the effective date of the rest of the rule is beyond the scope of our original proposal. Questions related to the content of the January 2017 HHA CoPs final rule and suggestions for future rulemaking may be submitted to *NewHHACoPs@cms.hhs.gov.*

Comment: Numerous commenters requested additional information regarding the expected timeframe for release of the Interpretive Guidelines. Commenters also suggested that CMS work with stakeholders to develop the content of the guidance.

Response: We appreciate the opportunity to provide additional information regarding the Interpretive Guidelines for HHAs. Existing Guidance to Surveyors for HHAs can currently be found in Appendix B of the State Operations Manual (SOM). Updates to the Interpretive Guidelines to reflect the requirements of the January 2017 HHA CoPs final rule are currently under development. We expect to release a preliminary draft of the revised guidelines to HHA stakeholders for informal input in the fall of 2017. Comments from stakeholders will be taken into consideration as the draft is finalized. We intend to publish a final version of the Interpretive Guidelines in December 2017. We note that the Interpretive Guidelines are intended to provide guidance to surveyors when reviewing providers for substantial compliance with the HHA requirements and promote nationwide consistency in the survey process. All deficient practices are cited against the requirements in the regulations. Even absent a final version of the Interpretive Guidelines published in the SOM, surveyors will still be able to survey HHAs to assess compliance with the regulations. A delay in the release of Interpretive Guidelines would not

require a further delay of the effective date for the new HHA CoPs.

Comment: A commenter suggested that CMS should make training regarding the HHA CoPs available to all interested parties.

Response: We will undertake training for state surveyors on an as-needed basis to assure that those individuals have the necessary knowledge to assess compliance with the new regulations. As previously discussed, we have established an email box (*NewHHACoPs@cms.hhs.gov*) for individuals to submit questions regarding the content of the HHA CoPs. We encourage those with specific questions to use this mailbox. We also note that the January 2017 HHA CoPs final rule is intentionally flexible and outcome-oriented to allow for HHA innovation. Our goal is not to specify how HHAs must accomplish the end goal, but rather to establish what the outcome-oriented requirement is and allow HHAs to determine their own processes for achieving it.

Comment: A few commenters submitted suggestions related to guidance for transitioning existing subunits to standalone HHAs or branches. Commenter suggestions ranged from permitting subunits to automatically convert to a parent or branch without completing provider enrollment paperwork and the survey process, permitting a subunit to maintain subunit status while any transition to parent-HHA or branch is pending, permitting a subunit to qualify as a stand-alone HHA automatically with the filing of a CMS–855A that is effective upon filing, modifying the current branch approval process, and creating a separate delayed effective date for the subunit requirement.

Response: Guidance related to the conversion of subunits to standalone HHAs and branches is beyond the scope of this rule. We appreciate these suggestions and have shared them with the appropriate CMS staff. We will continue to monitor our conversion processes for subunits, and will consider future rulemaking to revise the effective date of the subunit elimination should the need arise.

Comment: A few commenters recommended that CMS review the content of the final home health CoPs to ensure they are reasonable and necessary, and rescind any provisions that are found to unduly burden HHA providers.

Response: We believe that the provisions of the home health CoPs final rule are reasonable and necessary, and that all burdens created are directly related to patient health and safety, and to improving the quality of care provided to HHA patients.

Comment: A commenter stated that CMS should align the effective date for the new emergency preparedness regulations with the January 2018 proposed effective date for the new home health CoPs.

Response: Changing the effective date for the emergency preparedness requirements is outside the scope of this rule as the emergency preparedness requirements were established in separate rulemaking (Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, (81 FR 63859)).

Comment: A commenter requested that CMS provide further explanation of home health occupational therapy policy by including specific examples in Chapter 7, Section 30.4 of the Medicare Benefit Policy Manual.

Response: Changes to the Medicare Benefit Policy Manual are not within the scope of this rule. However, we have shared this recommendation with the appropriate CMS staff.

IV. Provisions of the Final Regulations

We are adopting as final the provisions set forth in the January 2017 HHA CoPs final rule with the following modifications:

- Delaying the effective date for the January 2017 HHA CoPs final rule, which is currently set to become effective on July 13, 2017, until January 13, 2018.
- Revising the phase-in date for the requirements at § 484.65(d) by replacing the January 13, 2018 date with a July 13, 2018 date.
- Replacing the July 13, 2017 effective date at § 484.115(a)(1) and (2) with the effective date of January 13, 2018.

V. Waiver of 60-Day Delay in the Effective Date

We ordinarily provide a 60-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date; the Congressional Review Act (5 U.S.C. 801(a)(3)), which requires a 60-day delayed effective date for major rules; and section 1871(e)(1)(B)(i) of the Act prohibits substantive Medicare rules from becoming effective less than 30 days before issuance. However, we can waive the delay in the effective date if the Secretary finds, for good cause, that the delay is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2); section 1871(e)(1)(B)(ii) of the Act.

Providing a 60-day delay in the effective date of this rule is contrary to public interest because it would negate the purpose of this rule, which is to postpone the effective date of the HHA CoP final rule from July 13, 2017 to January 13, 2018. If the changes in this rule do not become effective until 60 days following publication in the **Federal Register**, then HHAs will be required to comply with the July 13, 2017 effective date of the January 2017 HHA CoPs final rule during the 60-day delay period. As discussed above, in response to the 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. Additionally, in response to the April 3, 2017 proposed 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 in order to effectively plan and test implementation strategies, and train staff on those strategies that prove to be effective. We believe that HHAs need additional time for all preparation activities. Implementing all of the changes in July 2017, without adequate planning, testing, and training, may negatively impact patient care and safety, as well as HHA operations. We believe it is in the public interest to avoid these negative impacts; therefore, we believe that good cause exists to waive the statutory delayed-effective-date requirements.

VI. 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.*).

VII. 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 (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 Regulatory Flexibility Act (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 final 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 604 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 final 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. In 2017, that threshold is approximately $148 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). Under E.O. 13771, this rule has been determined to be deregulatory.

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, effective January 13, 2018, the Centers for Medicare & Medicaid Services amends 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 [Amended]

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

§ 484.115 [Amended]

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

Dated: June 28, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 30, 2017.

Thomas E. Price,

Secretary, Department of Health and Human Services.

[FR Doc. 2017–14347 Filed 7–7–17; 8:45 am]

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