the program, CMS is requiring contractors to submit semi-annual cost reports. The purpose of the cost reports is to enable the ESRD Networks to report costs in a standardized manner. This will allow CMS to review, compare and project ESRD Network costs during the life of the contract. *Form Number:* CMS–685 (OMB Control Number: 0938–0657); *Frequency:* Reporting—Semi-annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 36; *Total Annual Hours:* 108. (For policy questions regarding this collection contact Benjamin Bernstein at 410–786–6570).

Dated: December 19, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–27822 Filed 12–23–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3377–FN]

Medicare and Medicaid Programs: Application From Accreditation Association of Hospitals/Health Systems—Healthcare Facilities Accreditation Program (AAHHS-HFAP) for Continued CMS-Approval of Its Critical Access Hospital (CAH) Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve an application from Accreditation Association of Hospitals/Health Systems—Healthcare Facilities Accreditation Program for continued recognition as a national accrediting organization for critical access hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective December 27, 2019 through December 27, 2025.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636. Anita Moore, (410) 786–2161.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH) provided certain requirements are met by the CAH. Section 1861(mm) of the Social Security Act (the Act), sets out definitions for ''critical access hospital'' and for inpatient and outpatient CAH services. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart F specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.

Generally, to enter into an agreement, a CAH must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 485 of our regulations. Thereafter, the CAH is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative; however, to surveys by State agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide the Centers for Medicare and Medicaid Services (CMS) with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. The regulations at § 488.5(e)(2)(i) require an accrediting organization to reapply for continued approval of its accreditation program every 6 years or as determined by CMS. The Accreditation Association of Hospitals/Health Systems—Healthcare Facilities Accreditation Programs (AAHHS-HFAP) current term of approval for its CAH accreditation program expires December 27, 2019.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at 42 CFR 488.5 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

III. Provisions of the Proposed Notice

In the July 31, 2019 **Federal Register** (84 FR 37302), we published a proposed notice announcing AAHHS-HFAP's request for continued approval of its Medicare CAH accreditation program. AAHHS-HFAP submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its CAH accreditation program. This application was determined to be complete on May 31, 2019. Under Section 1865(a)(2) of the Act and our regulations at § 488.5 (Application and re-application procedures for national accrediting organizations), our review and evaluation of AAHHS-HFAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAHHS-HFAP's standards for CAHs as compared with CMS' CAH conditions of participation (CoP).
- AAHHS-HFAP's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of AAHHS-HFAP's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ AAHHS-HFAP's processes and procedures for monitoring a CAH found

out of compliance with AAHHS-HFAP's program requirements. These monitoring procedures are used only when AAHHS-HFAP identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys conducted by the State survey agency, the State survey agency monitors corrections as specified at § 488.9.

++ AAHHS-HFAP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ AAHHS-HFAP's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of AAHHS-HFAP's staff and other resources, and its financial viability.

++ AAHHS-HFAP's capacity to adequately fund required surveys.

++ AAHHS-HFAP's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ AAHHS-HFAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

++ AAHHS-HFAP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

In accordance with section 1865(a)(3)(A) of the Act, the July 31, 2019 proposed notice also solicited public comments regarding whether AAHHS-HFAP's requirements met or exceeded the Medicare CoPs for CAHs. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between AAHHS-HFAP's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared AAHHS-HFAP's CAH accreditation requirements and survey process with the Medicare CoPs of part 485, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of AAHHS-HFAP's CAH application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, AAHHS-HFAP has completed revising its standards and certification processes in order to meet the requirements at:

- § 485.623(c)(6) through § 485.623(c)(6)(ii), to revise its standards to clarify that either evacuation or a fire watch is required.
- § 485.625(d)(1)(i), to address the requirement that initial training in emergency preparedness policies, procedures, including prompt reporting and extinguishing of fire, protection, and where necessary, evacuation of patients, personnel, and guest, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, and individuals providing services under arrangement, and volunteers, consistent with their expected roles.
- § 485.625(e)(3), to revise its standard that CAHs that do not maintain an onsite fuel source to power emergency generators are not required to have a plan for maintaining such fuel source in emergency circumstances.
- § 488.26(b), to ensure that surveyors are assessing compliance with the hospital CoPs in CAH psychiatric and rehabilitation Distinct Part Unit (DPUs).

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have approved AAHHS/HFAP's as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 27, 2019 through December 25, 2025.

V. 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. Chapter 35).

Dated: December 11, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–27836 Filed 12–23–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4739]

Requesting Food and Drug Administration Feedback on Combination Products; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Requesting FDA Feedback on Combination Products.'' The purpose of this guidance is to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. These interactions can occur through application-based mechanisms, such as the pre-submission process used in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics and Research (CBER) and the formal meetings used in the Center for Drug Evaluation and Research (CDER) and CBER, or through Combination Product Agreement Meetings (CPAMs), as appropriate.

DATES: Submit either electronic or written comments on the draft guidance by February 24, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that