DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3438-FN]

Medicare and Medicaid Programs: Application from the Accreditation Commission for Healthcare (ACHC) for Continued CMS-Approval of its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the Accreditation Commission for Healthcare (ACHC) for continued recognition as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable on September 25, 2023 through September 25, 2027.

FOR FURTHER INFORMATION CONTACT: Danielle Adams, (410) 786-8818; or Lillian Williams, (410) 786-8636.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a hospital provided that certain requirements are met. Section 1861(e) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospital. 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 482 specify the minimum conditions that a hospital must meet to participate in the Medicare program.

Generally, to enter into an agreement, a hospital must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in 42 CFR part 482 of
our regulations. Thereafter, the hospital is subject to regular surveys by a SA to determine whether it continues to meet these requirements.

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

If an AO 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 AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of AOs are set forth at §§ 488.4, 488.5 and 488.5(e)(2)(i). The regulations at § 488.5(e)(2)(i) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The Accreditation Commission for Healthcare’s (ACHC) current term of approval for their hospital accreditation program expires September 25, 2023.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the Federal Register that identifies the national accrediting body making the request,
describes the request, and provides no less than a 30-day public comment period. At the end of
the 210-day period, we must publish a notice in the Federal Register approving or denying the
application.

III. Provisions of the Proposed Notice

On April 14, 2023, we published a proposed notice in the Federal Register
(88 FR 23088), announcing ACHC’s request for continued approval of its Medicare hospital
accreditation program. In the April 14, 2023 proposed notice, we detailed our evaluation criteria.
Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of
ACHC’s Medicare hospital accreditation application in accordance with the criteria specified by
our regulations, which include, but are not limited to the following:

- An administrative review of ACHC’s: (1) corporate policies; (2) financial and human
  resources available to accomplish the proposed surveys; (3) procedures for training, monitoring,
  and evaluation of its hospital surveyors; (4) ability to investigate and respond appropriately to
  complaints against accredited hospital; and (5) survey review and decision-making process for
  accreditation.

- The comparison of ACHC’s Medicare hospital accreditation program standards to our
  current Medicare hospital conditions of participation (CoPs).

- A documentation review of ACHC’s survey process to do the following:
  ++ Determine the composition of the survey team, surveyor qualifications, and ACHC’s
  ability to provide continuing surveyor training.
  ++ Compare ACHC’s processes to those we require of state survey agencies, including
  periodic resurvey and the ability to investigate and respond appropriately to complaints against
  ACHC accredited hospitals.
  ++ Evaluate ACHC’s procedures for monitoring accredited hospitals it has found to be
  out of compliance with ACHC’s program requirements. (This pertains only to monitoring
procedures when ACHC identifies non-compliance. If noncompliance is identified by a SA through a validation survey, the SA monitors corrections as specified at §488.9(c)).

++ Assess ACHC’s ability to report deficiencies to the surveyed hospitals and respond to the hospitals plans of correction in a timely manner.

++ Establish ACHC’s ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of ACHC’s staff and other resources.

++ Confirm ACHC’s ability to provide adequate funding for performing required surveys.

++ Confirm ACHC’s policies with respect to surveys being unannounced.

++ Confirm ACHC’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.

++ Obtain ACHC’s agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the April 14, 2023, proposed notice also solicited public comments regarding whether ACHC’s requirements met or exceeded the Medicare CoPs for hospitals. We received one comment in response to our proposed notice.

The commenter expressed concern about hospital accreditation programs overall and the responsibility of patient safety in hospitals. The comment was not specific to ACHC.

We appreciate this comment and the concern for patient safety and quality of care. We continue to prioritize patient safety and our responsibility for oversight of AOs. As described in Section III, “Provisions of the Proposed Notice” of this final notice, we take various steps when considering to approve or not approve a national AO. Each AO wishing to be recognized by
Medicare as a national AO must go through a rigorous process for CMS approval. We remain steadfast in our commitment to keeping the public informed of our evaluation process for AOs seeking approval from CMS.

V. Provisions of the Final Notice

A. Differences Between ACHC’s Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared ACHC’s hospital accreditation requirements and survey process with the Medicare CoPs of 42 CFR part 482, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of ACHC’s hospital accreditation application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this final notice, ACHC has completed revising its standards and certification processes in order to—

- Meet the standard’s requirements of all the following regulations:

  ++ Section 482.22 (c)(5)(iii), to fully address the requirement that an assessment of the patient (in lieu of the requirements of paragraphs (c)(5)(i) and (ii) of this section) be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

  ++ Section 482.22 (c)(5)(iv), to fully address the requirement that the medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements of paragraph (c)(5)(iii) of this section would apply. The provisions of paragraphs
Section 482.22 (c)(5)(v), to fully address the requirement that the medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in paragraph (c)(5)(iii) of this section would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on.

Section 482.41(b)(2), to address the requirements regarding Life Safety Code (LSC) waivers.

Section 482.41(b)(7), to address the requirements regarding alcohol-based hand rub (ABHR) dispensers.

In addition to the standards review, CMS also reviewed ACHC’s comparable survey processes, which were conducted as described in section III., of this notice, and yielded the following areas where, as of the date of this final notice, ACHC has completed revising its survey processes to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising the complaint response policies and processes to align with the State Operations Manual, Chapter 5 guidance. ACHC revised its Administrative Review Offsite Investigation process to align with CMS’ triage process to track and trend for potential focus areas during the next onsite survey or complete an onsite complaint investigation.

- Revising ACHC’s hospital accreditation process policies to include the applicable sections of the Health Care Facilities Code National Fire Protection Agency (NFPA 99) in accordance with section 482.41(c).

- Ensuring that all hospital LSC surveyors have received comparable and adequate training or have sufficient experience to make them qualified to survey health care facilities for
compliance with both the 2012 LSC and 2012 NFPA 99 requirements.

- Providing guidance and instruction to surveyors on determining the appropriate level of citation for LSC deficiencies.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve ACHC as a national accreditation organization for hospitals that request participation in the Medicare program. The decision announced in this final notice is effective September 25, 2023, through September 25, 2027 (4 years). In accordance with §488.5(e)(2)(i) the term of the approval will not exceed 6 years.

While ACHC has taken actions based on the findings annotated in section V.A., of this final notice, (Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under §488.8, we will continue ongoing review of ACHC's hospital processes to ensure full implementation and sustained compliance. In keeping with CMS’s initiative to increase AO oversight broadly and ensure that our requested revisions by ACHC are fully implemented, CMS expects more frequent review of ACHC's activities in the future.

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.).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the Federal Register.

Evell J. Barco Holland,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.