Medicaid Services (CMS) is the recipient agency, and the Department of Homeland Security (DHS), United States Citizenship and Immigration Services (USCIS) is the source agency.

Authority for Conducting the Matching Program

The principal authority for conducting the program is 42 U.S.C. 18001 *et seq.*

Purpose(s)

The program will provide CMS with USCIS data which CMS and state-based administering entities will use to determine individuals' eligibility for:

- initial enrollment in a Qualified Health Plan through an Exchange established under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (42 U.S.C. 18001 *et seq.*);
- Insurance Affordability Programs (IAPs);
- certificates of exemption from the shared responsibility payment; and
- redeterminations and renewal decisions, including appeal determinations.

IAPs include advance payments of the premium tax credit and cost sharing reductions; Medicaid; Children's Health Insurance Program; and Basic Health Program.

Categories of Individuals

The individuals whose information will be used in the program are consumers (applicants and enrollees) who receive the eligibility determinations and redeterminations described in the preceding PURPOSE(S) section.

Categories of Records

The categories of records used in the program are identity, citizenship, and immigration status records. The data elements are described below.

To request information from USCIS, CMS will query USCIS' Systematic Alien Verification for Entitlements (SAVE) system using these data elements: Last Name; First Name; Middle Name; Date of Birth; One or More Immigration Number(s) (*e.g.,* Alien Registration/USCIS Number, Arrival-Departure Record I–94 Number, SEVIS ID Number, Certificate of Naturalization Number, Certificate of Citizenship Number, or Unexpired Foreign Passport Number); and Other Information from Immigration Documentation (*e.g.* Country of Birth, Date of Entry, Employment Authorization Category).

When the above-listed data that CMS uses to query the SAVE system matches USCIS data in SAVE, USCIS will return query results to CMS that include these additional data elements about each individual, as relevant: Verification Case Number; Citizenship or Immigration Data (*e.g.,* immigration status/category, immigration class of admission, and/or employment authorization); and Sponsorship Data (*e.g.,* name, address, and Social Security number of Form I–864/I–864EZ sponsors and Form I–864A household members, when applicable).

System(s) of Records

The records used in this program will be disclosed from the following systems of records, as authorized by routine uses published in the System of Records Notices (SORNs) cited below:

- CMS Health Insurance Exchanges System (HIX), System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013) and amended at 83 FR 6591 (Feb. 14, 2018). Routine use 3 permits CMS' disclosures to USCIS.
- DHS/USCIS–004 Systematic Alien Verification for Entitlements Program, 85 FR 31798 (May 27, 2020). Routine use I permits USCIS' disclosures to CMS.

[FR Doc. 2023–19174 Filed 9–5–23; 8:45 am]

BILLING CODE 4120–03–P

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 (c)(5)(iii), (iv), and (v) of this section do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of paragraphs of (c)(5)(i) and (ii) of this section for all patients.

++ 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**.

Dated: August 31, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–19195 Filed 9–5–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1981]

Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs; Guidance for Industry; 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 final guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs.'' This guidance identifies the standards necessary to facilitate adoption of secure, interoperable, electronic data exchange among the pharmaceutical distribution supply chain, and clarifies the trading partners, products, and transactions subject to such standards. This guidance finalizes the revised draft guidance of the same title, ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs,'' issued in July 2022, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on September 6, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1981 for ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain