[FR Doc. 2024–09429 Filed 4–30–24; 8:45 am]
BILLING CODE 6820–FM–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3451–FN]

Medicare and Medicaid Programs: Application From the Joint Commission for Initial CMS-Approval of Its Rural Health Clinic (RHC) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for initial recognition as a national accrediting organization (AO) for rural health clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable June 1, 2024, to June 1, 2028.

FOR FURTHER INFORMATION CONTACT: Caecilia Andrews (410) 786–2190.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a rural health clinic (RHC) provided certain requirements are met by the RHC. Sections 1861(aa)(1) and (2) and 1905(l)(1) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as an RHC. 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, subpart A. The regulations at 42 CFR part 491, subpart A, specify the conditions that an RHC must meet to participate in the Medicare program. The scope of covered services and the conditions for Medicare payment for RHCs are set forth at 42 CFR part 405, subpart X.

Generally, to enter into an agreement, an RHC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 491 of CMS regulations. Thereafter, the RHC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, there is an alternative to surveys by State survey agencies. Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an 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 Health and Human Services 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 CMS approval of their accreditation program under 42 CFR 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 § 488.5.

The Joint Commission (TJC) has requested initial approval by CMS for its RHC program. CMS has reviewed TJC's application as described later in this rule and is hereby announcing TJC's initial term of approval for a period of four years.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 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 us 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

On December 7, 2023, CMS published a proposed notice in the **Federal Register** (88 FR 85290), announcing TJC's request for initial approval of its Medicare rural health clinic (RHC) accreditation program. In that proposed notice, we detailed our evaluation criteria.

Under section 1865(a)(2) of the Act and in our regulations at § 488.5 and § 488.8(h), we conducted a review of TJC's RHC application in accordance with the criteria specified by our regulations, which include, but are not limited to, the following:

- An administrative review of TJC's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its RHC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited RHCs; and (5) survey review and decision-making process for accreditation.
- A review of TJC's survey processes to confirm that a provider or supplier, under TJC's RHC deeming accreditation program, would meet or exceed the Medicare program requirements.
- A documentation review of TJC's survey process to do the following:

++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

++ Compare TJC's processes to those we require of State survey agencies (SA), including periodic resurvey and the ability to investigate and respond appropriately to complaints against TJC-accredited RHCs.

++ Evaluate TJC's procedures for monitoring an accredited RHC it has found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC 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 TJC's ability to report deficiencies to the surveyed RHC and respond to the RHC's plan of correction in a timely manner.

++ Establish TJC'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 TJC's staff and other resources.

++ Confirm TJC's ability to provide adequate funding for performing required surveys.

++ Confirm TJC's policies with respect to surveys being unannounced.

++ Confirm TJC'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 TJC'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 December 7, 2023, proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare Conditions for Certification (CfCs) for RHCs. We did not receive any public comments.

V. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's RHC accreditation requirements and survey process with the Medicare conditions set forth at 42 CFR part 491, subpart A, the survey and certification process requirements of parts 488 and 489, and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of TJC's RHC application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its standards and certification processes to—

- Meet the Medicare CfC requirements for all of the following regulations:

++ Section 491.2, to clarify the definition of a rural health clinic, specifically that a rural health clinic is not a rehabilitation agency or a facility primarily for the care and treatment for mental diseases, and also to include the definition of the Secretary.

++ Section 491.4, to explicitly reference that an RHC must be in compliance with applicable Federal, State and local laws and regulations.

++ Section 491.4(a) and 491.4(b), to specify that an RHC must be licensed pursuant to applicable State and local law and that staff are licensed, certified or registered in accordance with applicable State and local laws.

++ Section 491.10(a)(2), to include the term ''designated member of the professional staff,'' who are responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

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

++ Removing language suggesting survey activities could be completed virtually (as temporarily allowed during the COVID–19 Public Health Emergency (PHE)), since the conclusion of the PHE has occurred.

++ Clarifying that mid-level staffing waivers are only applicable to existing CMS-certified RHCs and that initial enrollment applications for CMS-certification must meet all staffing requirements at 42 CFR 491.8, in accordance with the State Operations Manual (SOM), Appendix G, and SOM Chapter 2.

++ Clarifying, in accordance with SOM, Appendix G, Task 1, that TJC's survey composition includes a Registered Nurse.

++ Ensuring survey procedures align with SOM, Appendix G, Interpretive guidelines at § 491.5(a)(3)(iii), which require that an RHC with additional locations must enroll each permanent unit separately, and each must independently and fully comply with the RHC CfCs.

++ To ensure survey processes align with SOM, Appendix G, Task 3-Observation Methods, related to patient and staff identifiers.

++ Clarifying instructions related to the selection of active patient records consistent with SOM, Appendix G, Task 3.

++ Revise survey documentation, including the survey report and evidence of standard compliance, to include the RHC's name and address, not that of the health system to which it might belong, consistent with regulations at § 413.65 and § 491.5(a)(1).

++ To provide additional surveyor training related to the evaluation of emergency preparedness at § 491.12, specifically related to review of the RHC's risk assessment to ensure that risk assessments account for the patient population served.

++ To provide a survey process for calculating the required time of mid-level staff based on the hours of operations to assess staffing in accordance with § 491.8(a)(6), specifically to ensure a nurse practitioner, physician assistant, or certified nurse-midwife (CNM) is available to furnish patient care services at least 50 percent of the time the RHC operates, even when a physician is also present in the clinic.

++ To provide additional surveyor training related to staffing requirements, including physicians providing medical direction within the RHC, consistent with § 491.8(b)(1).

++ To ensure surveyor guidance includes inspecting all areas within patient care rooms, comparable to SOM, Appendix G, to assess the RHC's physical plant and environment at § 491.6.

++ To update TJC's survey procedures to be comparable to SOM, Appendix G, survey protocol for § 491.9(a)(2) and § 491.9(c)(1) to adequately assess that the RHC is primarily engaged in providing outpatient health services and the RHC staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system, which includes medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

++ To reassess survey time and allocation of survey teams consistent with § 488.5(a)(5) and § 488.5(a)(6), especially for a new deeming program and initial surveys.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve TJC as a national accreditation organization for RHCs that request participation in the Medicare program. The decision announced in this final notice is effective June 3, 2024, to June 3, 2028 (4 years).

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. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for

purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–09426 Filed 4–30–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Publication of Common Agreement for Nationwide Health Information Interoperability (Common Agreement) Version 2.0

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice fulfills an obligation under the Public Health Service Act (PHSA) that requires the National Coordinator for Health Information Technology to publish on the Office of the National Coordinator for Health Information Technology's public internet website, and in the **Federal Register**, the trusted exchange framework and common agreement developed under the PHSA. This notice is for publishing an updated version of the Common Agreement (Version 2.0).

FOR FURTHER INFORMATION CONTACT: Mark Knee, Office of the National Coordinator for Health Information Technology, 202–664–2058.

SUPPLEMENTARY INFORMATION: This notice fulfills the obligation under section 3001(c)(9)(C) of the Public Health Service Act (PHSA) (42 U.S.C. 300jj–11(c)(9)(C)) to publish the trusted exchange framework and common agreement, developed under section 3001(c)(9)(B) of the PHSA (42 U.S.C. 300jj–11(c)(9)(B)), in the **Federal Register**. This publication consists of the following document:

BILLING CODE 4150–45–P

Common Agreement for Nationwide Health Information Interoperability (Common Agreement) Version 2.0