

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3455-FN]

Medicare and Medicaid Programs: Application From The Compliance Team (TCT) for Continued 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 Compliance Team (TCT) for continued 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 final notice is effective July 17, 2024, to July 17, 2028.

FOR FURTHER INFORMATION CONTACT:

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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 Compliance Team (TCT) has requested CMS approval for its RHC program. CMS has reviewed TCT's application as described in the following section and is hereby announcing TCT's 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 the 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 21, 2023, CMS published a proposed notice in the **Federal Register** (88 FR 88393), announcing TCT's request for 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 TCT'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 TCT'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 TCT's survey processes to confirm that a provider or supplier, under TCT's RHC deeming accreditation program, would meet or exceed the Medicare program requirements.

- A documentation review of TCT's survey process to do the following:

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

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

- ++ Evaluate TCT's procedures for monitoring an accredited RHC it has found to be out of compliance with TCT's program requirements. (This pertains only to monitoring procedures when TCT identifies non-compliance. If a SA identifies non-compliance through a validation survey, the SA monitors corrections as specified at § 488.9(c)).

- ++ Assess TCT's ability to report deficiencies to the surveyed RHC and respond to the RHC's plan of correction in a timely manner.

- ++ Establish TCT'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 TCT's staff and other resources.

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

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

- ++ Confirm TCT'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 TCT'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 21, 2023, proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare Conditions for Certification (CfCs) for RHCs. CMS did not receive any public comments.

V. Provisions of the Final Notice

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

We compared TCT'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 TCT'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, TCT has completed revising its standards and certification processes in order to—

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

++ Section 488.5(a)(4)(ii), to provide documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting federal Medicare surveys for the same provider or supplier type to ensure levels of triaging will not negatively impact patient care and outcomes.

++ Section 488.5(a)(12) to specify a triage process for responding to and investigating complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman programs.

++ Section 488.26(b) to ensure citation level of deficiencies are cited appropriately, by conducting additional review of standards and RHC Medicare CfCs, provide a process for ensuring a thorough understanding of manner and degree of deficiency, and surveyor training.

++ Section 491.5(a)(1) to explicitly demonstrate RHC is located in a rural

area, through policies and procedures, ensure surveyor's documentation exhibits the RHC physical name and address where services are provided.

++ SOM Chapter 2, Section 2700A to establish a policy and procedure to protect the integrity and intent of unannounced surveys when surveys are conducted at multiple locations and in close proximity.

++ SOM Chapter 2, Section 2728B, is to clarify an acceptable plan of correction that includes the RHC completing the organizational plan of correction template and documentation implementing the plan for future compliance and monitoring.

++ SOM Chapter 5 Section 5075, to ensure the administrative review and offsite investigation that are generally not permitted is consistent with the compliant policies found in Chapter 5.

++ Provide a revised plan of correction policy comparable to Chapter 2 of the SOM.

In addition to the standards review, CMS reviewed TCT'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, TCT has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Removing TCT's policies to allow patient and staff identifiers to be kept together. Such identifiers need to be kept separately from the surveyor's notes and findings to keep patients and staff private.

++ Revising language prohibiting Protected Health Information from being taken from the clinic. TCT language is inconsistent with CMS policy, which allows surveyors to photocopy documents needed to support deficient findings.

++ Clarifying TCT's policy that gives surveyors the discretion to conduct interviews privately. This policy is inconsistent with CMS policy governing private interviews with patients, staff, and visitors; it is a requirement and not discretionary unless the interviewee refuses.

++ Specifying TCT's policy to allow facilities to audio tape exit conferences, require facilities to provide two tapes and tape recorders and a recording of the meeting simultaneously, and then permitting the surveying team to select one of the tapes at the conclusion of the exit conference.

B. Term of Approval

Based on our review and observations described in section III. and section V.

of this final notice, we approve TCT as a national accreditation organization for RHCs that request participation in the Medicare program. The decision announced in this final notice is effective July 17, 2024, to July 17, 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: NIEHS Support for Conferences and Scientific Meeting R13.

Date: June 11, 2024.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.