DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3287-FN]

Medicare and Medicaid Programs; Initial Approval of The Compliance Team's (TCT's) Rural Health Clinic (RHC) Accreditation Program.

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Compliance Team (TCT) for initial recognition as a national accrediting organization for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective July 18, 2014 through July 18, 2018.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a RHC provided certain requirements are met. Section 1861(aa) and 1905(l)(1) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a RHC. The minimum requirements that a RHC must meet to participate in Medicare are set forth in regulation at 42 CFR part 491, subpart A. The conditions for Medicare payment for RHCs are set forth at 42 CFR 405, subpart X. 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.

For an RHC to enter into a provider agreement with the Medicare program, the RHC must first be certified by a state survey agency as complying with the conditions or requirements set forth in section 1861(aa) of the Act and 42 CFR part 491. 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 agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

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 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 have met the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide us 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 and §488.8(d)(3).

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 February 24, 2014, we published a proposed notice in the **Federal Register** (79 FR 10162) announcing TCT's request for approval of its RHC accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.4 and §488.8, we conducted a review of TCT's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite 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 surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.

- The comparison of TCT's accreditation requirements to our current Medicare RHC conditions for certification.

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

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

++ Compare TCT's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate TCT's procedures for monitoring RHCs out of compliance with TCT's program requirements. The monitoring procedures are used only when TCT identifies non-compliance. If non-compliance is identified by the state survey agency through validation surveys, the state survey agency monitors corrections as specified at §488.7(d).

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

++ Establish TCT's ability to provide us 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 whether surveys are announced or unannounced.

++ 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.

In accordance with section 1865(a)(3)(A) of the Act, the February 24, 2014 proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare conditions for certification for RHCs. We received eight comments in response to our proposed notice. All of the comments received expressed unanimous support for TCT's RHC accreditation program.

IV. Provisions of the Final Notice

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

We compared TCT's RHC requirements and survey process with the Medicare

conditions for certification and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of TCT's RHC application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at §491.2, TCT revised its standards to include the definition of "Secretary" and "Rural Area."

- To meet the requirements at §491.5(a)(3), TCT revised its standards to address the requirement that RHCs can be both permanent and mobile units.

- To meet the requirements at §491.5(d)(1)(i), TCT revised its standards to ensure the requirements related to designation of a shortage area included the ratio of primary care physicians practicing within the area to the resident population.

- To meet the requirements at §491.7(b)(2)-(3), TCT revised its crosswalk to include standards concerning the disclosure of the names and addresses of the person principally responsible for directing the operation of the clinic or center and the person responsible for medical direction.

- To meet the requirements at §491.8(a)(1), TCT revised its standards to address the requirement to have one or more physicians and one or more physician's assistants or nurse practitioners.

- To meet the requirements at §491.8(b)(1)(iii), TCT revised its standards address the role of the physician in providing medical orders and medical care services to patients of the clinic or center.

- To meet the requirements at §491.9(b)(4), TCT revised its standards to address the requirement that patient care policies are reviewed at least annually, and as necessary by the clinic or center.

- To meet the requirements at §491.9(c)(2), TCT revised its standards to ensure

laboratory services are provided in accordance with the requirements at 42 C.F.R. Part 493 and Section 353 of the Public Health Service Act.

- To meet the requirements at §491.9(d)(1), TCT revised its standards to require the clinic or center have an agreement or arrangement with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients.

- TCT developed an action plan to ensure compliance with its own policies regarding RHCs receiving the correct accreditation date on their notice of survey results.

- To meet the requirements at §488.4(a)(6), TCT revised its policies to ensure timeframes for investigation of complaints are comparable with the requirements in section 5075.9 of the State Operations Manual.

- To meet the requirements at §489.13(b), TCT revised its policies to clarify that the effective date of the agreement or approval is determined by the CMS Regional Office and may not be earlier than the latest of the dates of which CMS determines that all applicable federal requirements are met. TCT revised all Clinic Advisor On-Site Worksheets to include a descriptive title for the requirement of each worksheet for increased clarity.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that TCT's RHC accreditation program requirements meet or exceed our requirements. Therefore, we approve TCT as a national accreditation organization for RHCs that request participation in the Medicare program, effective July 18, 2014 through July 18, 2018.

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.

CMS-3287-FN

Dated: July 8, 2014_

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Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

BILLING CODE: 4120-01-P

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