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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3351-FN]

Medicare and Medicaid Programs; Application by The Compliance Team for Continued CMS Approval of its Rural Health Clinic Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), 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 for Rural Health Clinics (RHCs) that wish to participate in the Medicare or Medicaid programs.

APPLICABLE DATE: This notice is effective July 18, 2018 through July 18, 2024.

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. Section 1861(aa) and 1905(l)(1) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as a 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 a

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 a provider agreement with the Medicare program, a RHC must first be certified by a state survey agency as complying with the conditions or requirements set forth in 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.

There is an alternative, however, to surveys by state agencies. Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by 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 accrediting organization applying for CMS approval of its accreditation program under 42 CFR part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at §488.5. Section 488.5(e)(2)(i) requires an accrediting organization to reapply for continued approval of its accreditation program every 6 years or as determined by CMS. The Compliance Team's (TCT's) current term of approval for its RHC accreditation program expires July 18, 2018.

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

In the January 23, 2018 **Federal Register** (83 FR 3152), we published a notice announcing TCT's request for continued approval of its RHC accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and §488.5, 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:

- The equivalency of TCT's standards for RHCs as compared with CMS's RHC conditions for certification.
- TCT's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

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

++ TCT's processes and procedures for monitoring a RHC determined to be out of compliance with TCT's program requirements. These monitoring procedures are used only when TCT identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at §488.9(c).

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

++ TCT's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of TCT's staff and other resources, and its financial viability.

++ TCT's capacity to adequately fund required surveys.

++ TCT's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ 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 CMS may require (including corrective action plans).

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

In accordance with section 1865(a)(3)(A) of the Act, the January 23, 2018 proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare Condition for Certification (CfC) for RHCs. We received one comment in response

to our proposed notice. The comment received expressed support for TCT's RHC accreditation program.

V. Provisions of the Final Notice

Conditions and Survey Requirements

We compared TCT's RCH accreditation requirements and survey process with the Medicare CfCs at 42 CFR part 491, the survey and certification process requirements of parts 488 and 489 and survey process as outlined in the State Operations Manual (SOM). TCT's standards crosswalk was also examined to ensure that the appropriate CMS regulations would be included in citations as appropriate. 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 revised its standards and certification processes so that its processes are comparable to CMS requirements:

- Section 491.2(1), to update its standard for nurse practitioner and accompanying crosswalk to remove the duplicative language "by the currently certified".
- Section 491.4, to address staff licensure compliance in its surveyor guidance.
- Sections 491.7(a)(2) through (b)(3), to correct its crosswalk to reflect the correct standard reference ADM 4.0.1.
- Section 491.8(a)(3), to update its standard to address the regulatory requirement that at least one physician assistant or nurse practitioner be employed by the clinic.
- Sections 491.8(c)(1)(i) and 491.9(b)(2), to correct the standard language to clarify the required membership of the group of professional personnel responsible for policy development and implementation.
- Section 491.8(c)(2)(i), to correct erroneously cited CMS regulatory references.

- Section 491.9(b)(4), to update its standard language to clarify the required membership of the group of professional personnel responsible for policy review annually.
- Section 491.10(a)(1), to update its standards and crosswalk to explicitly require the RHC to maintain a clinical record system in addition to maintaining the record system in accordance with written policies and procedures.
- Section 491.12(c)(3)(i), to update its standard to include reference to RHC "staff" and to delete reference to "FQHC."
- Section 491.12(d)(1)(iv), to update surveyor guidance to include specific examples of acceptable methods for documenting the evaluation of the effectiveness of RHC staff training, and the demonstration of RHC staff knowledge and competency.
- To clearly include frequency of monitoring on-going compliance as a required element for acceptable plan of corrections.
- To clarify its Administrative Policy regarding removal and denial of accreditation.
- To ensure each deficiency is cited at the appropriate level according to the scope and severity of the finding.
- To ensure all provider-submitted plans of correction address all non-compliant practices identified on survey.
- To address the inaccurate reporting of facility and survey data to CMS.
- To provide evidence ensuring staff were educated on its policy related required personal file documents to be located on site at the RHC
- To provide evidence ensuring staff are educated on its policy related to deficiencies that are corrected onsite.
- To identify patient medical records while protecting the patient's identity during the

survey event.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that TCT's rural health clinic requirements meet or exceed our requirements, and its survey processes are comparable to ours. Therefore, we approve TCT as a national accreditation organization for hospitals that request participation in the Medicare program, effective July 18, 2018 through July 18, 2024.

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.).

Dated: June 11, 2018.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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