

State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR 460.136(a)(5)). *Form Number:* CMS-10525 (OMB control number: 0938-1264); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 134; *Total Annual Responses:* 1,143; *Total Annual Hours:* 173,664. (For policy questions regarding this collection contact Donna Williamson at 410-786-4647.)

3. Type of Information Collection

Request: Reinstatement; *Title of Information Collection:* Establishment of an Exchange by a State and Qualified Health Plans; *Use:* The Patient Protection and Affordable Care Act, Public Law 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111-152, enacted on March 30, 2010 (collectively, “Affordable Care Act”), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP).

As directed by the rule *Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers* (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. *Form Number:* CMS-10593 (OMB Control Number: 0938-1312); *Frequency:* Monthly, Annual; *Affected Public:* Private Sector; *Number of*

Respondents: 20; *Number of Responses:* 361; *Total Annual Hours:* 51,805. (For policy questions regarding this collection contact Courtney Williams at 301-492-5157.)

Dated: September 23, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3386-FN]

Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy 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 for initial recognition as a national accrediting organization for home infusion therapy suppliers that wish to participate in the Medicare program. A home infusion therapy supplier that participates must meet the Medicare conditions for coverage.

DATES: The approval announced in this final notice takes effect October 1, 2020 through October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786-2441. Shannon Freeland, (410) 786-4348. Lillian Williams, (410) 786-8636.

SUPPLEMENTARY INFORMATION:

I. Background

Home Infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114-255, enacted on December 13, 2016) added sections 1861(iii) and 1834(u) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines HIT as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must be furnished by a qualified HIT supplier and furnished in the individual’s home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT not later than January 1, 2021. Section 1861(iii)(3)(D) of the Act defines “qualified home infusion therapy suppliers” as being accredited by a CMS-approved AO.

In the March 1, 2019 **Federal Register**, we published a solicitation notice entitled, “Medicare Program; Solicitation of Independent Accrediting Organizations To Participate in the Home Infusion Therapy Supplier Accreditation Program” (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. Complete applications will be considered for the January 1, 2021 designation deadline if received by February 1, 2020.

Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and

approval of a national AO's requirements consider, among other factors, the applying AO'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 CMS with the necessary data.

Section 488.1020(a) requires that we publish, after 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. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to approve or deny the application.

III. Provisions of the Proposed Notice

In the May 4, 2020 **Federal Register** (85 FR 26477), we published a proposed notice announcing The Compliance Team's (TCT's) request for initial approval of its Medicare HIT accreditation program. In that proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of TCT's Medicare HIT accreditation application in accordance with the criteria specified by our regulations, which included, 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 home infusion therapy surveyors; (4) ability to investigate and respond appropriately to complaints against accredited home infusion therapies; and (5) survey review and decision-making process for accreditation.

- The ability for TCT to conduct timely review of accreditation applications.

- The ability of TCT to take into account the capacities of suppliers located in a rural area.

- The comparison of TCT's Medicare HIT accreditation program standards to our current Medicare home infusion therapy conditions for coverage (CfCs).

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

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

- ++ Compare TCT's processes, including periodic resurvey and the

ability to investigate and respond appropriately to complaints against accredited home infusion therapies.

- ++ Evaluate TCT's procedures for monitoring home infusion therapies it has found to be out of compliance with TCT's program requirements.

- ++ Assess TCT's ability to report deficiencies to the surveyed home infusion therapy and respond to the home infusion therapy'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.

- ++ Review 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.

The May 4, 2020 proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare CfCs for home infusion therapy. No comments were received in response to our proposed notice.

IV. 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 HIT accreditation requirements and survey process with the Medicare CfCs of part 486, subpart I and the survey and certification process requirements of part 488, subpart L. Our review and evaluation of TCT's HIT 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 condition at:

- § 486.520(b), to address the requirement of the plan of care must be established by a physician prescribing the type, amount and duration for home infusion therapy.

- § 486.525(a), to include the language "must" and "qualified" to

meet the requirements for home infusion suppliers.

- § 486.525(a)(1) through (3) and (b), to restructure and revise submitted standard language to meet the requirements for professional services, patient training and education, remote monitoring, and standards of practice.

- § 488.1010(a)(6), to revise TCT's procedures for surveys.

B. Term of Approval

As authorized under § 488.1040(a), we reserve the right to conduct onsite observations of accrediting organization operations at any time as part of the ongoing review and continuing oversight of an accrediting organization's performance. Based on the review and observations described in section III. of this final notice, we have determined that TCT's requirements for HIT meet or exceed our requirements. Therefore, we approve TCT as a national accreditation organization for HITs that request participation in the Medicare program, effective October 1, 2020 through October 1, 2024.

IV. Collection of Information Requirements

This document does not impose information collection and 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), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register Liaison**, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid.

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