notice also solicited public comments regarding whether NABP's requirements met or exceeded the Medicare conditions for participation for HIT. No comments were received in response to our proposed notice.

V. Provisions of the Final Notice

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

We compared NABP's HIT accreditation requirements and survey process with the Medicare Conditions for Coverage of 42 CFR part 486, and the survey and certification process requirements of part 488. Our review and evaluation of NABP's HIT application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, NABP has completed revising its standards and certification processes to meet the conditions at §§ 486.500 to 486.525.

- Section 486.520(a), to address the requirement that all patients must be under the care of an applicable provider.
- Section 486.520(b), to address the requirement that the plan of care must be established by a physician and that it prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.
- Section 486.520(c), to address the requirement that the plan of care for each patient must be periodically reviewed by the physician.
- Section 486.525(a), to address the requirement that the HIT supplier must provide the following services on a 7-day a week, 24 hour-a-day basis in accordance with the plan of care:

++ Section 486.525(a)(1), to provide professional services, including nursing services.

++ Section 486.525(a)(2), to address the requirement for patient training and education and not otherwise paid for as durable medical equipment.

++ Section 486.525(a)(3), to address the requirement of remote monitoring services for the provision of HIT services and home infusion drugs.

Section 486.525(b), to address the requirement that all home infusion therapy suppliers must provide HIT services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that NABP's requirements for HIT meet or exceed our requirements. Therefore, we approve NABP as a national accreditation organization for HITs that request participation in the Medicare program, effective September 26, 2024 through September 26, 2030.

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. 2024–21409 Filed 9–18–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3462–FN]

Medicare Program; Application by The Compliance Team (TCT) for Continued CMS Approval of Its Home Infusion Therapy (HIT) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), 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 that accredits suppliers of home infusion therapy (HIT) services that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this final notice is effective September 28, 2024, through September 28, 2030.

FOR FURTHER INFORMATION CONTACT: Shannon Freeland, (410) 786–4348.

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 December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines ''home infusion therapy'' 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. Sections 1861(iii)(A) and (B) of the Act require that the individual (patient) 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, which 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 HIT AOs and for reviewing and modifying the list of designated HIT AOs. These statutory factors are as follows:

- The ability of the accrediting organization to conduct timely reviews of HIT accreditation applications.
- The ability of the accrediting organization to take into account the capacities HIT suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the accrediting organization has established reasonable fees to be charged to HIT 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)(i)(III) of the Act requires a ''qualified home infusion therapy supplier'' to be accredited by a CMS-approved AO, pursuant to section 1834(u)(5) of the Act.

The current term of approval for The Compliance Team (TCT) HIT

accreditation program expires September 28, 2024.

II. Approval of Deeming Organization

Section 1834(u)(5) of the Act and § 488.1010 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 CMS with the necessary data.

Our rules at 42 CFR 488.1020(a) require 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. Pursuant to our rules at 42 CFR 488.1010(d), 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

In the April 29, 2024, **Federal Register** (89 FR 33354), we published a proposed notice announcing TCT's request for continued recognition as a national accrediting organization for suppliers providing HIT services that wish to participate in the Medicare or Medicaid programs. 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 include, but are not limited to, the following:

- An administrative review of TCT's:

++ Corporate policies;

++ Financial and human resources available to accomplish the proposed surveys;

++ Procedures for training, monitoring, and evaluation of its HIT surveyors;

++ Ability to investigate and respond appropriately to complaints against accredited HITs; and

++ Survey review and decision-making process for accreditation.

- The equivalency of TCT's standards for HIT as compared with CMS' HIT conditions for participation.

- 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 to CMS' standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

++ TCT's processes and procedures for monitoring a HIT supplier found out of compliance with TCT's program requirements;

++ TCT's capacity to report deficiencies to the surveyed HIT facilities and respond to the facility's evidence of standards compliance in a timely manner;

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

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

++ TCT's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced; and

++ 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 or TCT's evidence of standards compliance).

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

- TCT's agreement or policies for voluntary and involuntary termination of suppliers.

- TCT's agreement or policies for voluntary and involuntary termination of the HIT AO program.

- 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.

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

In accordance with section 1834(u)(5) of the Act, the April 29, 2024, proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare conditions for participation for HIT. No comments were received in response to our proposed notice.

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 HIT accreditation requirements and survey process with the Medicare Conditions for Coverage of 42 CFR part 486, and the survey and certification process requirements of part 488. Our review and evaluation of TCT's HIT application, which were 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 to meet the conditions at §§ 486.500 to 486.525.

- Section 486.520(a), to address the requirement of all patients must be under the care of an applicable provider.
- Section 486.520(b), to address the requirement that the plan of care must be established by a physician and that it prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.
- Section 486.520(c), to address the requirement that the plan of care for each patient must be periodically reviewed by the physician.
- Section 486.525(a), to address the requirement that the HIT supplier must provide the following services on a 7-day a week, 24 hour-a-day basis in accordance with the plan of care:

++ Section 486.525(a)(1), to provide professional services, including nursing services.

++ Section 486.525(a)(2), to address the requirement for patient training and education and not otherwise paid for as durable medical equipment.

++ Section 486.525(a)(3), to address the requirement of remote monitoring services for the provision of HIT services and home infusion drugs.

- Section 486.525(b), to address the requirement that all home infusion therapy suppliers must provide HIT services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations.

B. Term of Approval

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 September 28, 2024 through September 28, 2030.

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. 2024–21410 Filed 9–18–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–372(S) and CMS–R–284]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 21, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Section 1915(c) Home and Community-Based Services Waivers and Supporting Regulations; *Use:* We use this report to compare actual data to the approved waiver estimates. In conjunction with the waiver compliance review reports, the information provided will be compared to that in the Medicaid Statistical Information System (MSIS) (CMS–R–284; OMB control number: 0938–0345) report and FFP claimed on a State's Quarterly Expenditure Report (CMS–64; OMB control number: 0938–1265), to determine whether to continue the State's home and community-based services waiver. States' estimates of cost and utilization for renewal purposes are based upon the data compiled in the CMS–372(S) reports. *Form Number:* CMS–372(S) (OMB control number: 0938–0272); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 47; *Total Annual Responses:* 259; *Total Annual Hours:* 11,396. (For policy questions regarding this collection contact George Failla at 410–786–7561.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Transformed—Medicaid Statistical Information System (T–MSIS); *Use:* The data reported in T–MSIS are used by Federal, State, and local officials, as well as by private researchers and corporations to monitor past and projected future trends in the Medicaid program. The data provide the only national level information available on enrollees, beneficiaries, and expenditures. It also provides the only national level information available on Medicaid utilization. The information is the basis for analyses and for cost savings estimates for the Department's cost sharing legislative initiatives to Congress. The collected data are also crucial to our actuarial forecasts. *Form Number:* CMS–R–284 (OMB control number: 0938–0345); *Frequency:* Quarterly and monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual Responses:* 648; *Total Annual Hours:* 7,290. (For policy questions regarding this collection contact Connie Gibson at 410–786–0755.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–21444 Filed 9–18–24; 8:45 am]

BILLING CODE 4120–01–P