- Agenda item and application number;
- Email address;
- Any special assistance requests (will be considered if the registration is submitted by 5 p.m. ET, October 25, 2024);
- Whether the registrant is a primary speaker or a 5-minute speaker for an agenda item; and
- Whether the primary speaker will use a PowerPoint presentation.

B. Speakers and Attendees

1. Primary Speakers

Each applicant that submitted a HCPCS Level II code application that will be discussed at the virtual public meetings is permitted to designate a primary speaker. Fifteen minutes is the total time interval for a primary speaker per agenda item. Any unused time from the primary speaker will be forfeited and cannot be delegated to another speaker. The deadline for primary speakers to register and submit any supporting PowerPoint presentation is 5 p.m. ET, October 25, 2024. CMS will accept PowerPoint presentations if those materials are emailed to *HCPCS@cms.hhs.gov* by the stated deadline. Due to the timeframe needed for the planning and coordination of the HCPCS virtual public meetings, materials that are not submitted in accordance with this deadline cannot be accommodated.

All PowerPoint presentation materials must not exceed 10 slides and should be in PowerPoint presentation format, not PDF. We will not play videos, transitions, or animations during the public meeting sessions and request that the speakers exclude these materials from their PowerPoint presentation and instead submit any relevant video or animation materials along with their written comments. We request that speakers ensure the presentation does not include any inappropriate content before submission.

Every primary speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS Level II application that the primary speaker presented, or any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant.

2. 5-Minute Speakers

Any individual related to the public meeting agenda item, including but not limited to, an employee, interested parties, competitor, insurer, public consumer, etc., may register and speak as a 5-minute speaker. The deadline for registering to be a 5-minute speaker is 5 p.m. ET, October 25, 2024.

Every 5-minute speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturer of the item that is the subject of the HCPCS Level II code application or agenda item that the 5-minute speaker presented, or with any competitors of that manufacturer with respect to the item. This includes any payment, salary, remuneration, or benefit provided to that speaker by the applicant. We will not accept any other written materials, outside of the written comments, from a 5-minute speaker.

3. All Other Attendees

All individuals who plan to attend the virtual public meetings to listen and do not plan to speak, may access the virtual public meeting using the Zoom link posted on the HCPCS Level II website at *https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system* as well as the guidelines document.

Individuals who require special assistance must register and request special assistance services by 5 p.m. ET, October 25, 2024.

IV. Written Comments

The primary and 5-minute speaker(s) must email a brief, written summary (one paragraph) of their comments and conclusions. Written comments from anyone, including the primary and 5-minute speaker(s), will only be accepted when emailed to: *HCPCS@cms.hhs.gov* before 5 p.m. ET on the date of the virtual public meeting at which the HCPCS Level II code application that is the subject of the comments is discussed.

V. Additional Information

The HCPCS section of the CMS website also includes details regarding the public meeting process for new revisions to the HCPCS Level II code set, including information on how to join the meeting remotely, and guidelines for an effective presentation. The HCPCS section of the CMS website also contains a document titled ''Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures (PDF),'' which is a description of the HCPCS Level II coding process, including a detailed explanation of the procedures CMS uses to make HCPCS Level II coding determinations.

When CMS refers to a HCPCS code or HCPCS Level II coding application above, CMS may also be referring to circumstances when a HCPCS code has already been issued, but a Medicare benefit category and/or payment has not been determined. CMS is working diligently to address Medicare benefit category and payment determinations for new items and services that may be DME, prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. Please check the CMS website listed above for the final agenda.

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.*).

The Administrator of 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. 2024–21297 Filed 9–18–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3464–FN]

Medicare Program; Application by the National Association of Boards of Pharmacy (NABP) 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 National Association of Boards of Pharmacy (NABP) 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 26, 2024 through September 26, 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 of 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 National Association of Boards of Pharmacy (NABP) HIT accreditation program expires September 26, 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 26, 2024 **Federal Register** (89 FR 32434), we published a proposed notice announcing NABP'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 NABP'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 NABP'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 NABP's standards for HIT as compared with CMS' HIT conditions for participation.
- NABP'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 NABP's to CMS' standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

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

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

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

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

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

++ NABP'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 NABP's evidence of standards compliance).

- The adequacy of NABP's staff and other resources, and its financial viability.
- NABP's agreement or policies for voluntary and involuntary termination of suppliers.
- NABP's agreement or policies for voluntary and involuntary termination of the HIT AO program.
- NABP'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 26, 2024, proposed

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