



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3464-PN]

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), HHS.

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the National Association of Boards of Pharmacy (NABP) for continued approval by the Centers for Medicare & Medicaid Services (CMS) of NABP's national accrediting organization program for suppliers providing home infusion therapy (HIT) services and that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, CMS will publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by [Insert date 30 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, refer to file code CMS-3464-PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3464-PN,
P.O. Box 8016,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3464-PN,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

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

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments. We will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual.

We continue to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

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. HIT 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 to 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 no 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.

On March 1, 2019, 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. We stated that complete applications would 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 Deeming Organization

Section 1834(u)(5) of the Act and regulations at 42 CFR 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 that identifies the national accrediting body making the request, describes the nature of the request, and provides 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.

The purpose of this proposed notice is to inform the public of the National Association of Boards of Pharmacy's (NABP's) request for CMS' continued recognition of its HIT accreditation program. This notice also solicits public comment on whether NABP's requirements meet or exceed the Medicare requirements of participation for HIT services.

III. Evaluation of Deeming Authority Request

In the April 28, 2020 Federal Register, we published NABP's initial application for recognition as an accreditation organization for HIT (85 FR 23519). On September 28, 2020, we published notification of their approval as such an organization, effective September 26, 2020 through September 26, 2024 (85 FR 60793). NABP has since submitted all the necessary materials to enable us to make a determination concerning its request for continued recognition of its HIT accreditation program. This application was determined to be complete on February 28, 2024. Under section 1834(u)(5) of the Act and 42 CFR 488.1010 (Application and re-application procedures for national home infusion therapy accrediting organizations), our review and evaluation of NABP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of NABP's standards for HIT as compared with CMS' HIT requirements for participation in the Medicare program.
- 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 facilities and respond to the facility's plan of correction 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.

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

++ 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.

++ 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).

++ NABP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

++ NABP's agreement or policies for voluntary and involuntary termination of HIT suppliers.

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

IV. 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.).

V. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "**DATES**" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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.

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