

**SUPPLEMENTARY INFORMATION:** On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

#### Request for Comment on Information Collection Proposals

The Board invites public comment on the following information collections, which are being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- a. Whether the proposed collections of information are necessary for the proper performance of the Board's functions, including whether the information has practical utility;
- b. The accuracy of the Board's estimate of the burden of the proposed information collections, including the validity of the methodology and assumptions used;
- c. Ways to enhance the quality, utility, and clarity of the information to be collected;
- d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and
- e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

#### Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collections

*Collection title:* Bank Holding Company Applications and Notifications.

*Collection identifier:* FR Y-3, FR Y-3N, and FR Y-4.

*OMB control number:* 7100-0121.

*General description of collection:* These filings collect information on proposals by Bank Holding Companies (BHCs) involving formations, acquisitions, mergers, and nonbanking activities. The Board requires the submission of these filings for regulatory and supervisory purposes and to allow the Board to fulfill its statutory obligations under the Bank Holding Company Act of 1956 (the BHC Act). The Board uses this information to evaluate each individual transaction with respect to financial and managerial factors, permissibility, competitive effects, financial stability, net public benefits, and impact on the convenience and needs of affected communities.

*Proposed revisions:* The Board proposes to revise the FR Y-3, FR Y-3N, and FR Y-4 forms and instructions to update or add certain citations and references; delete language that requires an explanation of the assumptions used in financial projections only if the projections deviate from historical performance; remove the sample publication from the instruction; add questions regarding groups acting in concert, individuals who would own 10 percent or more of the applicant, and companies that would own five percent or more of the applicant; add a requirement that applicants provide a breakdown of pro forma equity; add a requirement that applicants identify any management official of the applicant who is also a management official at another depository institution; and add a question regarding the integration of the target into the applicant.

*Frequency:* Event-generated.

*Respondents:* BHCs and a company seeking to become a BHC.

*Total estimated number of respondents:* 335.

*Total estimated change in burden:* 388.

*Total estimated annual burden hours:* 7,603.<sup>1</sup>

<sup>1</sup> More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR Y-3, FR Y-3N, and FR Y-4.

Board of Governors of the Federal Reserve System, April 25, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024-09274 Filed 4-29-24; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Centers for Medicare & Medicaid Services

[CMS-3463-PN]

#### Medicare Program; Application by the Community Health Accreditation Partner (CHAP) 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 Community Health Accreditation Partner (CHAP) for continued approval by the Centers for Medicare & Medicaid Services (CMS) of CHAP'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 May 30, 2024.

**ADDRESSES:** In commenting, refer to file code CMS-3463-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-3463-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-3463-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 website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website 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 Community Health Accreditation Partner’s (CHAP’s) request for CMS’ continued recognition of its HIT accreditation program. This notice also solicits public comment on whether CHAP’s requirements meet or exceed the Medicare requirements of participation for HIT services.

**III. Evaluation of Deeming Authority Request**

In the April 27, 2020 **Federal Register**, we published CHAP’s initial application for recognition as an accreditation organization for HIT (85 FR 23364). On September 25, 2020, we published notification of their approval as such an organization, effective September 25, 2020 through September 25, 2024 (85 FR 60469). CHAP 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 CHAP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of CHAP’s standards for HIT as compared with CMS’ HIT requirements for participation in the Medicare program.
- CHAP’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 CHAP’s to CMS’ standards and processes, including survey frequency, and the ability to investigate and respond

appropriately to complaints against accredited facilities.

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

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

++ CHAP'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 CHAP's staff and other resources, and its financial viability.

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

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

++ CHAP'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).

++ CHAP'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.

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

++ CHAP'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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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10788]

#### 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 *May 30, 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](http://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:* Prescription Drug and Health Care Spending; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A-10 of the Public Health Service Act (PHS Act) that require group health plans and health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, "the Departments") certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the