

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. CMS 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. CMS continues 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

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must establish protocols, which require the hospital to notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every hospital must have an agreement only with its designated OPO to identify potential donors.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary of the Department of Health and Human Services (the Secretary) under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in

section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to submit comments during the 60-day comment period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under section 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

### II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A-95-11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

### III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Renown South Meadows Medical Center, Reno, Nevada, is requesting a waiver to work with:

Nevada Donor Network, Inc, 2055 E Sahara Ave., Las Vegas, NV 89104

The Hospital's Designated OPO is: Donor Network West, 12667 Alcosta Blvd. #500, San Ramon, CA 94583

### 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

We will consider all comments we receive by the date specified in the **DATES** section of this document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: November 17, 2023.

**Chyana Woodyard,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2023-25903 Filed 11-22-23; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS 3453-PN]

### Medicare Program; Application by the Accreditation Commission for Health Care (ACHC) 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:** Notice with request for comment.

**SUMMARY:** This notice acknowledges the receipt of an application from the Accreditation Commission for Health Care (ACHC) for continued approval by the Centers for Medicare & Medicaid Services (CMS) of ACHC'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 December 26, 2023.

**ADDRESSES:** In commenting, refer to file code CMS-3453-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-3453-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-3453-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: <http://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 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.

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 CMS-3453-PN request for CMS' continued recognition of its HIT accreditation program. This notice also solicits public comment on whether ACHC's requirements meet or exceed the Medicare requirements of participation for HIT services.

### III. Evaluation of Deeming Authority Request

In the November 25, 2019 **Federal Register**, we published ACHC's initial application for recognition as an accreditation organization for HIT (84 FR 64904). On April 24, 2020, we published notification of their approval as such an organization, effective April 23, 2020 through April 23, 2024 (84 FR 23046). ACHC 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 September 26, 2023. 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 ACHC will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of ACHC's standards for HIT as compared with CMS' HIT requirements for participation in the Medicare program.

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

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

- ++ ACHC's capacity to report deficiencies to the surveyed supplier and respond to the supplier's plan of correction in a timely manner.

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

- ++ ACHC's capacity to adequately fund required surveys.

- ++ ACHC's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

- ++ ACHC'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).

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

- ++ ACHC agreement or policies for voluntary and involuntary termination of the HIT AO program.

- ++ ACHC'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. 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 Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: November 17, 2023.

**Chyana Woodyard,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: Document Identifiers: CMS-40B, CMS-10102, CMS-10866, and CMS-R-21]

### 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 December 26, 2023.

**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>.