

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. 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:* Application for Enrollment in Medicare Part B (Medical Insurance); *Use:* Medicare Part B is a voluntary program, financed from premium payments by enrollees, together with contributions from funds appropriated by the Federal government. The Social Security Act (the Act) at section 226(a) provides that individuals who are age 65 or older and eligible for, or entitled to, Social Security or Railroad Retirement Board (RRB) benefits shall be entitled to premium-free Part A upon filing an application for such benefits. Section 1836 of the Act permits individuals with Medicare premium-free Part A to enroll in Part B.

The CMS-40B provides the necessary information to determine eligibility and to process the beneficiary's request for enrollment for Medicare Part B coverage. This form is only used for enrollment by beneficiaries who already have Part A, but not Part B. Form CMS-40B is completed by the person with Medicare or occasionally by an SSA representative using information provided by the Medicare enrollee during an in-person interview. The form is owned by CMS, but not completed by CMS staff. SSA processes Medicare enrollments on behalf of CMS. *Form Number:* CMS-40B (OMB control number: 0938-1230); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:*

1,132,000; *Number of Responses:* 1,132,000; *Total Annual Hours:* 192,440. (For policy questions regarding this collection, contact Candace Carter at 410-786-8466.)

2. *Type of Information Collection Request:* Extension without change of currently approved collection; *Title of Information Collection:* National Implementation of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey; *Use:* The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey is the first national, standardized, publicly reported survey of patients' perspectives of their hospital care. HCAHPS is a 29-item survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. Since 2008, HCAHPS has allowed valid comparisons to be made across hospitals locally, regionally and nationally.

Three broad goals have shaped HCAHPS. First, the standardized survey and implementation protocol produce data that allow objective and meaningful comparisons of hospitals on topics that are important to consumers. Second, public reporting of HCAHPS results creates new incentives for hospitals to improve quality of care. Third, public reporting enhances accountability in health care by increasing transparency of the quality of hospital care provided in return for the public investment. *Form Number:* CMS-10102 (OMB control number: 0938-0981); *Frequency:* Occasionally; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 2,304,450; *Number of Responses:* 2,304,450; *Total Annual Hours:* 282,366. (For policy questions regarding this collection, contact William G. Lehrman at 410-786-1037.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* CMS Health Equity Award—Call for Nominations; *Use:* CMS Office of Minority Health (OMH) is going to announce a call for nominations for the 2024 CMS Health Equity Award. This award will recognize organizations who demonstrate they have advanced health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, reducing avoidable differences in health outcomes experienced by people who are underserved, and provided the care and support that CMS enrollees need to thrive.

The goals of the award are to encourage organizations to identify and address their health disparities, to disseminate best practices, and to show that progress is possible by having a results-oriented focus. By identifying organizations who are successfully closing gaps and reducing disparities, CMS can show our stakeholders how health equity work can be initiated, targeted, measured, and successfully reduce disparities among communities nationwide.

CMS Representatives collect Company Name, Point of Contact Information (email, phone# & name) along with information from the organizations regarding their programs to improve the health quality, outcomes, and access to care for the communities that they serve. The CMS selection committee uses a scoring rubric to score the applicants on demonstrated measurable results in reducing a disparity in one or more of the CMS priority populations. *Form Number:* CMS-10866 (OMB control number: 0938-NEW); *Frequency:* Annually; *Affected Public:* Federal Government, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 50; *Number of Responses:* 50; *Total Annual Hours:* 100. (For policy questions regarding this collection, contact Ashley Peddicord-Austin at 410-786-0757.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31; *Use:* Certain Medicaid providers that are subject to offsets for the collection of Medicaid overpayments may terminate or substantially reduce their participation in Medicaid, leaving the state Medicaid agency unable to recover the amounts due. Recovery procedures allow for determining the amount of overpayments and offsetting the overpayments by withholding the provider's Medicare payments. To effectuate the withholding, the state agency must provide their respective CMS regional office with certain documentation that identifies the provider and the Medicaid overpayment amount. The agency must also demonstrate that the provider was notified of the overpayment and that demand for the overpayment was made. An opportunity to appeal the overpayment determination must be afforded to the provider by the Medicaid state agency. Lastly, Medicaid state agencies must notify CMS when to terminate the withholding; *Form*

Number: CMS–R–21 (OMB control number: 0938–0287); Frequency: Occasionally; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 54; Total Annual Responses: 27; Total Annual Hours: 81. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

Dated: November 20, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1816–NC]

Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from a hospital that has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated organ procurement organization (OPO). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, by January 23, 2024.

ADDRESSES: In commenting, refer to file code CMS–1816–NC.

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 <https://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–1816–NC, P.O. Box 8010, 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–1816–NC, 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: Randy Thronset, (410) 786–0131.

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. 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