

In December 2022, the Consolidated Appropriations Act, 2023² amended section 3341 of the PHS Act to direct the Administrator, in consultation with the Secretary of Education, to establish a new research cohort. The cohort must be of sufficient size to conduct future research studies on the health and educational impacts of “exposure to airborne toxins, or any other hazard or adverse condition, resulting from the September 11, 2001, terrorist attacks, including on the population of individuals who were 21 years of age or younger at the time of exposure, including such individuals who are screening-eligible WTC survivors or certified-eligible WTC survivors.”³ The new WTC Health Program youth research cohort is referred to as “WTC Youth.” In accordance with section 3341, the cohort of WTC Youth must:

- Be of sufficient size to conduct future research studies on the health and educational impacts of 9/11 exposures;
- Include in this group sufficient representation of individuals who were 21 years of age or younger at the time of exposure; and
- Include in this group individuals who are screening-eligible WTC survivors or certified-eligible WTC survivors.

The cohort may also include individuals who were 21 years of age or younger on September 11, 2001, who were located outside the NYCDA and in Manhattan not further north than 14th Street; or anywhere within the borough of Brooklyn. Additionally, the cohort may include age-appropriate control populations as needed for research purposes.

In response to these new requirements, the Administrator, following consultation with the Secretary of Education, will engage the public for input on a multi-phased approach for establishing the youth cohort. At this time, the Administrator seeks initial comments on the following approach:

1. *Phase I: Community Engagement:* Gather sufficient information from educators, scientists, and community members on options for establishing a youth cohort that will efficiently support future research.

2. *Phase II: Options Development:* Use the information gathered in Phase I to develop a set of options for moving

forward with establishing the youth cohort.

3. *Phase III: Options Ranking:* Engage community in ranking the options developed in Phase II.

4. *Phase IV: Option Selection and Implementation:* Use the information from Phase III to select the preferred option(s) for establishing the youth cohort.

Request for Information

In this request for information published in the **Federal Register** (88 FR 25406) on April 26, 2023, NIOSH is soliciting information from any interested party, including educators, researchers, clinicians, community members, WTC Health Program members, treatment providers, and government agencies at all levels (Federal, State, Territorial, local, and Tribal), regarding the proposed approach to establishing the WTC Health Program youth cohort.

In particular, NIOSH seeks comments on the following items regarding the general approach to assembling the cohort, as described above:

1. Whether the four-phased approach for establishing the youth cohort is comprehensive and adequately incorporates community involvement in selecting a preferred approach for establishing the youth cohort.

2. Any potential partnerships for future actions for establishing the cohort of WTC Youth.

NIOSH also seeks information on the following scientific parameters, best practices, and approaches for assembling a research cohort that is best suited for future research of WTC Youth:

3. Ideas regarding outreach, recruitment, retention, community involvement, and project oversight. NIOSH is interested in descriptions of any anticipated barriers to the project and propose potential risk mitigation strategies.

4. Health conditions and potential social and educational impacts (*i.e.*, adverse effects of interest) that may be priorities for future research on WTC Youth. In light of these adverse effects to be researched, NIOSH is interested in descriptions of the cohort characteristics believed necessary to support future research, including recommendations on data collection requirements, such as describing methods for and frequency of contact with prospective cohort members.

5. The recruitment and retention of appropriate control group(s) for future observational studies of WTC Youth. For example, recruitment methods may differ between exposed and control

groups given expected differences in participation rates. These differences may lead to a selection bias. A selection bias may also arise given the long period of time between exposure and recruitment (*i.e.*, a survivorship bias). NIOSH is interested in comments regarding selection of controls using methods that reduce the potential for bias in future research.

Commenters are encouraged to offer information and insights into the specific topics described above, or any other aspect of this activity.

NIOSH received a request to extend the comment period from an organization interested in commenting on the RFI. CDC is extending the comment period to allow more time to comment. Accordingly, the comment period is extended through October 23, 2023.

Disclaimer

This notice is intended for planning purposes; it does not constitute a formal announcement for comprehensive applications. In accordance with Federal Acquisition Regulation 48 CFR 15.201(e), responses to this notice are not offers and cannot be accepted by the Government to form a binding award. NIOSH will not provide reimbursement for costs incurred in commenting on this notice.

NIOSH will not respond to individual public comments or publish publicly a compendium of responses. An informational submission in response to this notice does not create any commitment by or on behalf of CDC or HHS to develop or pursue any program or ideas discussed.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3440-FN]

Medicare and Medicaid Programs: Application From the Joint Commission for Continued CMS Approval of Its Critical Access Hospital Accreditation Program

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

²Public Law 117-328 (Dec. 29, 2022).

³WTC survivors include individuals who lived, worked, went to school, or attended child or adult day care in the NYCDA on September 11, 2001, or in the following days, weeks, or months and those otherwise meeting the eligibility criteria in 42 CFR 88.7 or 88.8.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the Joint Commission for continued recognition as a national accrediting organization for critical access hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable November 21, 2023 to November 21, 2027.

FOR FURTHER INFORMATION CONTACT: Caecilia Blondiaux, (410) 786-2190.

SUPPLEMENTARY INFORMATION:**I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services in a critical access hospital (CAH), provided that the facility meets certain requirements. Sections 1820(c)(2)(B), 1820(e) and 1861(mm)(1) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. Our regulations at 42 CFR part 485, subpart F specify the conditions of participation (CoPs) that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs. The regulations at 42 CFR 485.647 specify that a CAH's psychiatric or rehabilitation distinct part unit (DPU), if any, must meet the hospital requirements specified in subparts A, B, C, and D of part 482 in order for the CAH DPU to participate in the Medicare program.

Prior to becoming a CAH, to enter into an agreement, a CAH must first be certified by a state survey agency as a hospital complying with the conditions of participation at 42 CFR part 482. It then can convert to a CAH by complying with the conditions or requirements at part 485, subpart F. Thereafter, the CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare requirements are met or

exceeded, we will deem those provider entities as having met such requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare requirements. A national AO applying for approval of its accreditation program under 42 CFR part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare requirements.

Our regulations concerning the approval of AOs are at §§ 488.4 and 488.5. The regulations at § 488.5(e)(2)(i) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS. This notice is to announce our continued approval of TJC's CAH accreditation program for a period of 4 years.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On March 3, 2023, we published a proposed notice in the **Federal Register** (88 FR 13446), announcing TJC's request for continued approval of its Medicare critical hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of TJC's Medicare CAH accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An administrative review of TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

- A comparison of TJC's accreditation to our current Medicare CAH CoPs.

- A documentation review of TJC's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

- ++ Compare TJC's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ Evaluate TJC's procedures for monitoring CAHs out of compliance with TJC's program requirements. The monitoring procedures are used only when TJC identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at § 488.7(d).

- ++ Assess TJC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ Establish TJC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of staff and other resources.

- ++ Confirm TJC's ability to provide adequate funding for performing required surveys.

- ++ Confirm TJC's policies with respect to whether surveys are unannounced.

- ++ Obtain TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the March 3, 2023 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CoPs for CAHs. We received two comments in response to our proposed notice.

One commenter expressed concerns related to oversight of hospitals and the healthcare industry as a whole, and in particular, beliefs of corruption within

the system and concerns related to the COVID-19 public health emergency response. Another commenter stated the commenter would like Medicare to cover acupuncturists in CAHs and other facilities.

While we appreciate the commenters' concerns, these comments are outside of the scope of this notice. We remain committed to improving the quality and safety of patients in all healthcare settings and providing oversight of all AOs.

V. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's CAH requirements and survey process with the Medicare CoPs and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of TJC's CAH application were conducted as described in section III of this notice and yielded the following areas where, as of the date of this notice, TJC's has completed revising its standards and certification processes in order to:

- Meet the standard's requirements for all of the following regulations:
 - ++ Section 485.604(a)(2), to clarify the requirements for education including a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.

- ++ Section 485.616(c)(4)(iv), to specify the requirement of an internal review of the distant-site physician's or practitioner's performance of the privileges at the CAH whose patients are receiving the telemedicine services.

- ++ Section 485.623(b)(1), to specify that all essential mechanical, electrical and patient care equipment is maintained in safe operating condition.

- ++ Section 485.635(b)(3), to include reference to State law within the standard for radiology services.

In addition to the standards review, CMS also reviewed TJC's comparable survey processes, which were conducted as described in section III of this notice, and yielded the following areas where, as of the date of this notice, TJC has completed revising its survey processes, in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- Revising TJC's surveyor guide to ensure a comprehensive review of environmental safety and life safety requirements are performed.
- Revising TJC's surveyor guide and survey processes to ensure compliance

with the Medicare-conditions are assessed at each provider-based location where care is provided per CAH Appendix W of the SOM.

- Providing training and education to surveyors related to the use of open-ended questions during staff interviews to elicit information, consistent with chapter 2, section 2714 of the SOM.

- Revising the survey instructions and providing education to surveyors to conduct patient interviews. In accordance with CAH Appendix W-Task 3—Information Gathering/Investigation of the SOM, surveyors must observe the actual provision of care and services to patients and conduct patient interviews throughout the course of the survey.

- Review and assess TJC's surveyor time and resource allocations of the number of surveyors on site consistent with § 488.5(a)(5), § 488.5(a)(6) and § 488.5(a)(9) to ensure sufficient time is allotted to conduct all required survey activities.

- Provide additional training and education to surveyors on procedures related to investigation of "immediate jeopardy" situations in accordance with appendix Q-section VI of the SOM.

- Review and revise TJC's complaint investigation process, specifically to ensure the complainant (when not anonymous), receives an acknowledgement letter and closure letter, as outlined within chapter 5, sections 5010.2 and 5080.1 of the SOM.

- Review TJC's elements of performance and survey deficiency findings to ensure any deficiencies are appropriately correlated or matched with a Medicare condition, when appropriate, in accordance with § 488.5(a)(4)(ii).

B. Term of Approval

Based on our review and observations described in section III and section V of this notice, we approve TJC as a national AO for CAHs that request participation in the Medicare program. The decision announced in this final notice is effective November 21, 2023 through November 21, 2027 (4 years).

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 the Centers for Medicare & Medicaid Services (CMS),

Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Assessing ACL's American Indian, Alaskan Natives and Native Hawaiian Programs (OMB Control Number 0985-0059)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is providing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed extension without change information collection and solicits comments on the information collection requirements related to the project titled Assessing ACL's American Indian, Alaskan Natives and Native Hawaiian Programs (OMB Control Number 0985-0059).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 17, 2023.

ADDRESSES: Submit electronic comments on the collection of information to: Administration for Community Living at evaluation@acl.hhs.gov. Submit written comments on the collection of information to the Administration for Community Living, Washington, DC 20201, Attention: Administration for Community Living.

FOR FURTHER INFORMATION CONTACT: The Office of Performance and Evaluation, Administration for Community Living evaluation@acl.hhs.gov.