4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3477-PN]

Medicare and Medicaid Programs; Continued Approval of the American Association for Accreditation of Ambulatory Surgery Facilities' Rural Health Clinic Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities (DBA "QUAD A") for continued recognition as a national accrediting organization (AO) for rural health clinics 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, the Secretary, through the Centers for Medicare & Medicaid Services (CMS), publishes a notice that identifies the AO 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-3477-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-3477-PN,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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-3477-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: Caecilia Andrews (410) 786-2190.

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. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an 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

Under the Medicare program, eligible beneficiaries may receive covered services in a rural health clinic (RHC) provided certain requirements are met. Sections 1861(aa) and 1905(*l*)(1) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the general provisions for survey and certification of facilities are at 42 CFR part 488, subpart A. The regulations at 42 CFR part 491, subpart A specify the conditions that an RHC must meet to participate in the Medicare program, and 42 CFR 405, subpart X sets forth the scope of covered services and the conditions for Medicare payment for RHCs .

Generally, to enter into an agreement with Medicare, an RHC must first be certified by a State survey agency as complying with the conditions or requirements set forth in 42 CFR part 491. Thereafter, the RHC 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. Section 1865(a)(1)(A) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national AO that all applicable Medicare conditions are met or exceeded, we must deem that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

Our regulations concerning the approval of accrediting organizations are set forth at 42 CFR 488.5 (Application and re-application procedures for national accrediting organizations).

The QUAD A is requesting continued CMS-approval for its RHC program. QUAD A's current term of approval expires March 23, 2026.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our review and approval of a national accrediting organization's application 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 us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Due to the Federal lapse in appropriated funding, certain parts of CMS operations were temporarily halted on September 30, 3025. Therefore, this notice was impacted and did not publish on or before October 24, 2025 (60 days of the receipt of the complete application). 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 QUAD A's request for continued CMS-approval for its RHC accreditation program. This notice also solicits public comments on whether QUAD A's requirements meet or exceed the Medicare conditions for certification (CfCs) for RHCs.

III. Evaluation of Deeming Authority Request

QUAD A submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its RHC accreditation program. This application was determined to be complete on August 25, 2025. Under section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of QUAD A may include:

- The equivalency of QUAD A's standards for RHCs as compared with CMS' RHC CfCs.

● QUAD A's survey process to determine the following:

++ QUAD A's capacity to adequately fund the required surveys.

++ The comparability of QUAD A's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited RHCs.

++ QUAD A's processes and procedures for monitoring RHCs found out of compliance with QUAD A's program requirements. These monitoring procedures are used only when QUAD A identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at 42 CFR 488.9(c).

++ QUAD A's capacity to report deficiencies to the surveyed RHCs and respond to the RHC's plan of correction in a timely manner.

++ QUAD A's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

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

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

++ QUAD A'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.

++ QUAD A's agreement to provide us 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. 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 CMS, Mehmet Oz, 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.**

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Trenesha Fultz-Mimms,

Federal Register Liaison,

Center for Medicare & Medicaid Services.

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