

testing, before travel into the United States;

- Designated U.S. arrival Ports of Entry with specific testing operations and other services for Afghan Evacuees, which were specifically set up for early urgent evacuation arrival support, have been discontinued in the United States; and

- Evacuees who are still outside of the United States are in safe locations where testing can be accessed before traveling.

**Authority:** The CDC Director has issued this Notice authorizing the rescission of this temporary humanitarian exemption for individuals relocating to the United States from Afghanistan and reimposing the agency's Requirement for Negative Pre-Departure COVID-19 Test Result pursuant to Sections 361 of the Public Health Service Act, 42 U.S.C. 264, and implementing regulations at 42 CFR 71.20 and 71.31(b).

This Notice is issued to inform the public of this action.

**Sherri Berger,**

*Chief of Staff, Centers for Disease Control and Prevention.*

[FR Doc. 2021-20987 Filed 9-27-21; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3413-FN]

#### Medicare Program: Application by the Association of Diabetes Care and Education Specialists (ADCES) for Continued CMS Approval of Its Diabetes Outpatient Self-Management Training Program

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

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve the Association of Diabetes Care and Education Specialists (ADCES) application for continued recognition as a national accrediting organization (AO) for accrediting entities that wish to furnish diabetes outpatient self-management training services to Medicare beneficiaries.

**DATES:** This final notice is effective on September 27, 2021 through September 27, 2027.

**FOR FURTHER INFORMATION CONTACT:** Shannon Freeland, (410) 786-4348. Caroline Gallaher, (410) 786-8705.

Lillian Williams, (410) 786-8636.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Diabetes outpatient self-management training services are defined in section 1861(qq)(1) of the Social Security Act (the Act) as “educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual’s diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual’s diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual’s condition.”

In addition, section 1861(qq)(2)(A) of the Act describes a “certified provider” as a physician, or other individual or entity designated by the Secretary of the Department of Health and Human Services (the Secretary), that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title. Section 1861(qq)(2)(B) of the Act further specifies that a physician, or such other individual or entity, must meet the quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

Section 1865 of the Act also permits the Secretary to use accrediting bodies to determine whether a provider entity meets Medicare regulatory quality standards, such as those established for diabetes outpatient self-management training programs. These accrediting bodies determine whether a diabetes outpatient self-management training supplier meets the Medicare regulatory quality standards established for diabetes outpatient self-management

training service programs. A national accrediting organization (AO) must be approved by the Centers for Medicare & Medicaid Services (CMS) and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for Medicare deeming authority.

Our regulations regarding the application procedures for diabetes outpatient self-management training AOs seeking CMS approval are set forth at 42 CFR 410.142. A national accreditation organization applying for deeming authority must provide CMS with reasonable assurance that it will require the diabetes outpatient self-management training suppliers it accredits to meet the CMS’ quality standards, the National Standards for Diabetes Self-Management Education and Support (NSDSMES) standards, or an alternative set of standards that meet or exceed our requirements that have been developed by that AO and that have been approved by CMS (see 42 CFR 410.144).

Section 410.142(a) of our regulations states that “CMS may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training.” Therefore, all diabetes outpatient self-management training AOs must be not-for-profit organizations.

Section 410.142(b) of our regulations require a diabetes outpatient self-management training AO to submit specific documents and information with their application, as discussed in section II of this final notice.

##### II. Provisions of the Proposed Notice

On April 27, 2021, we published a proposed notice in the **Federal Register** (86 FR 22208) acknowledging receipt of the Association of Diabetes Care and Education Specialists (ADCES) request for continued CMS approval of its diabetes outpatient self-management training accreditation program. In that proposed notice, we detailed our evaluation criteria.

Under section 1861(qq) of the Act and our regulations at § 410.142, we conducted a review of the ADCES’s diabetes outpatient self-management training program application using the criteria specified by our regulations, which include authorization for CMS to conduct an onsite visit to verify information contained in the organization’s application. For an onsite visit, the CMS review team travels to the AO’s corporate office to review specific information and documents. An onsite visit is typically part of every application review. However, due to the

COVID-19 pandemic, it was not possible for us to conduct an onsite visit for the ADCES. We conducted our review virtually, using remote means to access and review the necessary information. During this virtual review, we reviewed documentation including the ADECS's: (1) Corporate policies; (2) financial and human resources records; (3) policies and procedures, including those for training, monitoring, and evaluation of its surveyors and investigating and responding appropriately to complaints against accredited diabetes outpatient self-management training suppliers; and (4) survey review and decision-making process for accreditation. This is the same information that would have been reviewed during an onsite visit.

Also, as part of our application review, we reviewed and assessed the following documents submitted by the ADCES:

- A detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).
- Detailed information about the organization's accreditation process, including all of the following information:
  - ++ Frequency of accreditation.
  - ++ Copies of accreditation forms, guidelines, and instructions to evaluators.
  - ++ Descriptions of the following:
    - The accreditation review process and the accreditation status decision making process.
    - The procedures used to notify a deemed entity of deficiencies in its diabetes outpatient self-management training program and procedures to monitor the correction of those deficiencies.
    - The procedures used to enforce compliance with the accreditation requirements and standards.
  - Detailed information about the individuals who perform evaluations for the organization, including all of the following information:
    - ++ The education and experience requirements for the individuals who perform evaluations.
    - ++ The content and frequency of continuing education furnished to the individuals who perform evaluations.
    - ++ The process used to monitor the performance of individuals who perform evaluations.
    - ++ The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

- A description of the organization's data management and analysis system for its accreditation activities and decisions, including the kinds of reports, tables, and other displays generated by that system.

- A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

- A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

- A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

- A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

- The name and address of each person with an ownership or control interest in the organization.

- Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

- A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

- A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§ 410.142 through 410.146.

- Any additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

The April 27, 2021, proposed notice also solicited public comments regarding whether the ADCES's requirements meet or exceed the NSDSMES, which are the accreditation standards used for certification of the diabetes outpatient self-management training programs accredited by the

ADCES, pursuant to § 410.144(b) and § 410.142(e)(1).

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

We received six public comments in response to the April 27, 2021 proposed notice; however, only one of these comments were within the scope of the comment solicitation.

The comment and our response is addressed below.

*Comment:* One commenter stated that diabetes outpatient self-management training is an evidence-based vital service for people with diagnosed diabetes and it has been proven that this service helps to enhance their clinical outcomes. The commenter further stated that it is imperative that the ADCES continue to offer its services as an AO for diabetes outpatient self-management training suppliers.

*Response:* We thank the commenter for their support of the CMS diabetes outpatient self-management training program and for their recommendation that the ADCES continue as a CMS-approved diabetes outpatient self-management training AO.

### IV. Provisions of the Final Notice

#### A. Comparison of the ADCES's Standards and Requirements for Accreditation to the NSDSMES and the Medicare Application Requirements

We compared the ADCES's diabetes outpatient self-management training accreditation requirements and survey process with the NSDSMES requirements, and the CMS application requirements in 42 CFR part 410, subpart H, as described in section II of this final notice.

We found the ADCES accreditation standards and process to be consistent with the NSDSMES standards and the CMS requirements.

#### B. Term of Approval

Based on the review and observations described in section II of this final notice, we have determined that the ADCES's requirements for diabetes outpatient self-management training meet our requirements. Therefore, we approve the ADCES as a national accreditation organization for diabetes outpatient self-management training programs that request participation in the Medicare program, effective September 27, 2021 through September 27, 2027.

### V. 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 Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2021.

**Lynette Wilson,**

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

[FR Doc. 2021-20957 Filed 9-27-21; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-70, CMS-R-72 and CMS-10783]

#### Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by November 29, 2021.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

##### CMS-R-70

Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations

##### CMS-R-72

Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals

##### CMS-10783

Generic Beneficiary and Family Centered-Care Quality Improvement Organization (BFCC-QIO) Data Collection Research

Under the 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 requires federal agencies to publish a 60-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.

#### Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: Obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment. *Form Number:* CMS-R-70 (OMB control number: 0938-0426); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profits; *Number of Respondents:* 53,850; *Total Annual Responses:* 436,984; *Total Annual Hours:* 404,208. (For policy questions regarding this collection contact Kimberly Harris at 617-565-1285.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request