

## Background

The Patient Safety Act, 42 U.S.C. 299b–21 to 299b–26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the Chicago Breast Cancer Quality Consortium to voluntarily relinquish its status as a PSO. Accordingly, the Chicago Breast Cancer Quality Consortium, P0074, was delisted effective at 12:00 Midnight ET (2400) on September 14, 2021.

Chicago Breast Cancer Quality Consortium has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO and of section 3.108(c)(2)(ii) regarding disposition of PSWP consistent with section 3.108(b)(3). According to section 3.108(b)(3) of the Patient Safety Rule, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO’s possession.

More information on PSOs can be obtained through AHRQ’s PSO website at <http://www.pso.ahrq.gov>.

Dated: September 23, 2021.

**Marquita Cullom,**

*Associate Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Rescission of Humanitarian Exemption for All Afghan Evacuees Subject to CDC’s Global Testing Order

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces rescission of the temporary humanitarian exemption to the agency’s Requirement for Negative Pre-Departure COVID–19 Test Result, which was previously granted for individuals relocating to the United States from Afghanistan (“Afghan Evacuees”), including U.S. citizens, lawful permanent residents (LPRs), third country nationals, and Afghans at risk, including Afghan Special Immigrant Visa (SIV) applicants.

**DATES:** This temporary humanitarian exemption to the Global Testing Order was rescinded September 20, 2021.

**FOR FURTHER INFORMATION CONTACT:** Tiffany Brown, Deputy Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–10, Atlanta, GA 30329. Phone: 404–639–7000. Email: [cdcregulations@cdc.gov](mailto:cdcregulations@cdc.gov).

**SUPPLEMENTARY INFORMATION:** On January 12, 2021, CDC issued an Order requiring all air passengers arriving to the U.S. from a foreign country to get tested no more than 3 days before their flight departs and to present the negative result or documentation of having recovered from COVID–19 to the airline or aircraft operator before boarding the flight. A copy of the Order was published in the **Federal Register** on January 21, 2021 (86 FR 6337) and went into effect January 26, 2021.

In August 2021, the U.S. Department of State (DOS) issued a series of Security Alerts for Afghanistan due to increased Taliban activity throughout the country, including the capital of Kabul. In response to a request from DOS on August 15, 2021, CDC and the U.S. Department of Health and Human

Services (HHS) granted a blanket humanitarian exemption to CDC’s Order to expedite the evacuation of U.S. citizens, lawful permanent residents (LPRs), third country nationals, and Afghans at risk, including Afghan Special Immigrant Visa (SIV) applicants, while adhering to other COVID–19 mitigation guidance issued by CDC.

The exemption, which is being administered with the assistance of DOS and other cooperating Federal and state agencies, was granted with the following conditions: (1) The CDC Order requiring mask use for passengers and crew on air conveyances bound for the United States should be followed to the extent possible; (2) all efforts should be made to test for COVID–19 at a transit location prior to arrival in the United States, and to provide test documentation to the traveler, which can be presented upon arrival, and if this cannot be done, individuals (travelers) arriving are required to undergo COVID–19 testing immediately upon arrival to the first port of entry in the United States; (3) individuals who test positive are required to isolate prior to continuing on commercial transportation to their final destination; and (4) family members of those testing positive may be required to adhere to self-quarantine recommendations as stipulated by CDC or state and local health authorities at the arrival location.

Beginning September 20, 2021, all Afghan Evacuees arriving in the United States will have to meet negative pre-departure COVID–19 test requirements or documentation of recovery. This means evacuees will need to be tested no more than three days before departure to the United States and be able to present the negative result or provide documentation of having recovered from COVID–19 within the last 90 days, to the airline or aircraft operator and upon request of United States Government authorities on arrival in the United States.

This requirement applies to all Afghan Evacuees arriving in the United States on any flight including U.S. Government-owned or -contracted, commercial, private, and general and business aviation (chartered) flights coming to the United States.

CDC is rescinding the humanitarian exemption because:

- The Department of State (DOS) has completed the emergency evacuation and concluded the transport of evacuees out of Afghanistan;
- With DOS’s conclusion of emergency evacuation from Afghanistan, there is a need to resume appropriate health interventions, including pre-departure COVID–19

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.*

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## 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