

VII. Files Available to the Public via the Internet

This section lists the Addenda referred to in the preamble of this notice. Beginning in CY 2012, the Addenda for the annual hospice wage index proposed and final rulemakings or notices will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the Internet. We will continue to post the Addenda through the Internet.

The following addenda are posted to the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html>:

Addendum A: The FY 2013 Hospice Wage Index for Urban Areas
Addendum B: The FY 2013 Hospice Wage Index for Rural Areas

Readers who experience any problems accessing the Addenda that are posted on the CMS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Hospice/index.html> should contact Anjana Patel at (410) 786-2120.

(Catalog of Federal Domestic Assistance Program No. 93.778, No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 5, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 16, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012-18336 Filed 7-24-12; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3259-FN]

Medicare Program; Application by the American Association of Diabetes Educators (AADE) for Continued Recognition as a National Accreditation Organization for Accrediting Entities To Furnish Outpatient Diabetes Self-Management Training

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

ACTION: Final Notice.

SUMMARY: This final notice announces the approval of an application from the

American Association of Diabetes Educators for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries.

DATES: *Effective Date:* This notice is effective on August 27, 2012.

FOR FURTHER INFORMATION CONTACT:

Jacqueline Leach, (410) 786-4282.

Kristin Shifflett, (410) 786-4133.

Maria Hammel, (410) 786-1775.

SUPPLEMENTARY INFORMATION

I. Background

Under the Medicare program, eligible beneficiaries may receive outpatient diabetes self-management training (DSMT) when ordered by the physician (or qualified non-physician practitioner) treating the beneficiary's diabetes, provided certain requirements are met by the provider. Pursuant to our regulations at 42 CFR 410.141(e)(3), we use national accrediting organizations (NAOs) to assess whether provider entities meet Medicare requirements when providing DSMT services for which Medicare payment is made. If a provider entity is accredited by an approved accrediting organization, it is "deemed" to meet applicable Medicare requirements.

Under section 1865(a)(1)(B) of the Social Security Act (the Act), a NAO must have an agreement in effect with the Secretary, and meet the standards and requirements specified by the Secretary in part 410, subpart H, to qualify for deeming authority. The regulations pertaining to application procedures for NAOs for DSMT are specified at § 410.142 (CMS process for approving national accreditation organizations).

A NAO applying for deeming authority must provide us with reasonable assurance that the accrediting organization requires accredited entities to meet requirements that are at least as stringent as our requirements.

We may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish DSMT. The accreditation organization, after being approved and recognized by CMS, may accredit an entity to meet one of the sets of quality standards in § 410.144 (Quality standards for deemed entities).

Section 1865(a)(2) of the Act further requires that we review the applying accreditation organization's requirements for accreditation, as follows:

- Survey procedures.
- Ability to provide adequate resources for conducting required surveys.
- Ability to supply information for use in enforcement activities.
- Monitoring procedures for providers found out of compliance with the conditions or requirements.
- Ability to provide CMS with necessary data for validation.

We then examine the NAO's accreditation requirements to determine if they meet or exceed the Medicare conditions as we would have applied them. Section 1865(a)(3)(A) of the Act requires that we publish a notice identifying the national accreditation body making the request within 30 days of receipt of a completed application. The notice must describe the nature of the request and provide at least a 30-day public comment period. We have 210 days from receipt of the request to publish a finding of approval or denial of the application. If we recognize an accreditation organization in this manner, any entity accredited by the national accreditation body's CMS-approved program for that service will be "deemed" to meet the Medicare conditions for coverage.

II. Provisions of the Proposed Notice

On February 24, 2012, we published a proposed notice in the **Federal Register** (77 FR 11130) entitled, "Application by the American Association of Diabetes Educators (AADE) for Continued Recognition as a National Accreditation Organization for Accrediting Entities to Furnish Outpatient Diabetes Self-Management Training," to notify the public of the AADE's request for continued approval of its accreditation to deem entities furnishing DSMT services.

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

We received 1 public comment in response to the February 24, 2012 proposed notice. A summary of the comment and our response is set forth below.

Comment: A commenter supported the approval of the AADE to deem DSMT programs. The commenter stated that the AADE provides guidance for its members and represents the values of the profession. The commenter further stated that qualified diabetes educators can lead the way toward a healthier population by guiding those with chronic conditions toward healthier lifestyles and stronger self-advocacy.

Response: We thank the commenter for his or her comment. The goal of the DSMT program is to provide

beneficiaries with tools to better manage their diabetes and to achieve good clinical and behavioral outcomes. Based on the information submitted by the AADE, we believe that the AADE is striving to meet the same goals we developed for quality DSMT.

IV. Provisions of the Final Notice

AADE's application to continue as an accredited NAO to deem entities for the purposes of DSMT is approved for a period of 3 years. The accreditation is effective on August 27, 2012. This approval is subject to renewal subsequent to the receipt of an application from the AADE and subject to review, evaluation, and approval of its program.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare-Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: July 3, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012-17293 Filed 7-26-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0630]

Draft Guidance for Industry and Food and Drug Administration Staff; Safety Considerations for 510(k) Submissions To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications." The use of common connector designs, such as luer

connectors, has led to unintended connections between devices that have different intended uses and has resulted in serious and sometimes fatal consequences to patients. This guidance provides recommendations to 510(k) submitters regarding the submission expectations regarding design and testing to reduce the risk of unintended connections between enteral and nonenteral devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 25, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Safety Considerations for 510(k) Submissions To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Priya Venkataraman-Rao, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G222, Silver Spring, MD 20993-0002, 301-796-6243.

I. Background

Multiple publications regarding patient injury and death from tubing and catheter misconnections indicate that reports of misconnections have gradually increased in frequency. On July 9, 2010, FDA issued a letter to health care professionals, hospital purchasing departments, and manufacturers of enteral feeding tubes

regarding luer lock misconnections. FDA advised manufacturers to assess the risks of misconnections for their devices and provide proposed solutions with validation for premarket review. At that time, some manufacturers were using color coding and labeling to reduce the risk of misconnections; others were creating proprietary connectors designed to be incompatible with nonenteral devices. However, recent reports of adverse events have demonstrated that reliance on color-coding of enteral devices alone cannot adequately mitigate the risk of misconnections, especially with similarly color-coded PICC (percutaneously inserted central catheter) lines on the market.

This guidance provides updated recommendations to manufacturers on the submission requirements for 510(k)s for small-bore connectors used in enteral applications. The guidance recommends that 510(k) submitters (1) Design and test enteral connectors based on the Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI)/International Organization for Standardization (ISO) 80369-1, "Small-Bore Connectors for Liquids and Gases in Healthcare Applications—Part 1: General Requirements" standard; (2) no longer rely strictly on color coding and tagging to prevent misconnections; and (3) perform risk assessments to demonstrate that the proposed design and testing has effectively mitigated the risk of the proposed enteral connector misconnecting to nonenteral devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on mitigating the risks of misconnections with small-bore connectors intended for enteral applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To