DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6062–N]

Medicare Program; Updates to the List of Durable Medical Equipment (DME) Specified Covered Items That Require a Face-to-Face Encounter and a Written Order Prior to Delivery

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

ACTION: Notice.

SUMMARY: This notice updates the Healthcare Common Procedure Coding System (HCPCS) codes on the Durable Medical Equipment (DME) List of Specified Covered Items that require a face-to-face encounter and a written order prior to delivery.

DATES: March 27, 2015.

FOR FURTHER INFORMATION CONTACT: Charlene Harven (410) 786–8228.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 1832, 1834, and 1861 of the Act establish that the provision of durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) is a covered benefit under Part B of the Medicare program.

Section 1834(a)(11)(B)(i) of the Act, as redesignated by the Affordable Care Act, authorizes us to require, for Specified Covered Items, that payment may only be made under section 1834(a) of the Act if a physician has communicated to the supplier a written order for the item before delivery of the item. Section 1834(b)(3) of the Act states that section 1834(a)(11) of the Act applies to prosthetic devices, orthotics, and prosthetics in the same manner as it applies to items of DME. Section 1834(a)(11)(B)(ii) of the Act requires a physician to document that a physician, physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist (CNS) has had a face-to-face encounter examination with a beneficiary in the 6 months prior to the written order for certain items of durable medical equipment (DME) or during a different reasonable timeframe determined by the Secretary.

In the Calendar Year (CY) 2013 Physician Fee Schedule (PFS) final rule with comment period, which appeared in the November 16, 2012 **Federal Register** (77 FR 69147), we implemented section 1834(a)(11)(B) of the Act by making revisions to 42 CFR 410.38(g). Among other things, we established a list of Specified Covered Items that require a written order prior to delivery and a face-to-face encounter during the 6 months prior to the written order. (See 42 CFR 410.38(g)(2).) The list of Specified Covered Items contains items that meet at least one of the following three criteria:

- Any item described by a Healthcare Common Procedure Coding System (HCPCS) code for the following types of durable medical equipment:
  - ++ Transcutaneous electrical nerve stimulation (TENS) unit.
  - ++ Rollabout chair.
  - ++ Oxygen and respiratory equipment.
  - ++ Hospital beds and accessories.
  - ++ Traction-cervical.
- Any item of durable medical equipment that appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000.
- Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

II. Provisions of the Notice

In the CY 2013 Physician Fee Schedule final rule with comment period (77 FR 69154), we stated that we would publish annually an updated List of Specified Covered Items. (See also 42 CFR 410.38(g)(2).) We specified that we would—(1) Add to the list any item of DME (described by an HCPCS code) that in the future appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000; and (2) remove from the list any item of DME with a HCPCS code that is no longer covered by Medicare or that has been discontinued.

The purpose of this notice is to provide the annual update to the DME List of Specified Covered Items as stated in the CY 2013 Physician Fee Schedule final rule (77 FR 69154) and as specified in our regulations at § 410.38(g).

This year's update does not reflect any additions because there are no new items that appear on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000. There are also no new HCPCS codes for any of the five types of durable medical equipment listed previously. However, the following two HCPCS codes were removed from the list because they are for items that are no longer payable by Medicare:

HCPCS code	Short descriptor
E0457	Chest shell.
E0459	Chest wrap.

The full updated list is available in the download section of the following CMS Web site: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html*.

III. 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 (44 U.S.C. 35).

IV. Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The CY 2013 expenditures for the two HCPCS codes being removed via this notice was approximately $9,000. Therefore, this notice does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have

determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This notice will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: March 10, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Modification of National Customs Automation Program (NCAP) Test Concerning Automated Commercial Environment (ACE) Cargo Release for Type 03 Entries and for Truck Carriers

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces U.S. Customs and Border Protection's (CBP's) plan to modify the National Customs Automation Program (NCAP) test concerning Automated Commercial Environment (ACE) cargo release to allow importers and customs brokers to file type 03 entries for all modes of transportation and to file, for cargo transported in the truck mode, entries for split shipments or partial shipments and entry on cargo which has been moved in-bond from the first U.S. port of unlading.

DATES: The ACE Cargo Release Test modifications became effective on March 1, 2015. The ACE Cargo Release Test will continue until CBP publishes in the **Federal Register** an announcement of its conclusion.

ADDRESSES: Comments or questions concerning this notice and indication of interest in participation in ACE Cargo Release Test should be submitted, via email, to Steven Zaccaro at *steven.j.zaccaro@cbp.dhs.gov.* In the subject line of your email, please use, ''Comment on ACE Cargo Release 03 Entries and Truck Mode.'' The body of the email should identify the ports where filings are likely to occur.

FOR FURTHER INFORMATION CONTACT: For policy questions related to ACE, contact Josephine Baiamonte, Acting Director, Business Transformation, ACE Business Office, Office of International Trade, at *josephine.baiamonte@dhs.gov.* For policy questions related to ISF, contact Craig Clark, Program Manager, Cargo and Conveyance Security, Office of Field Operations, at *craig.clark@cbp.dhs.gov.* For technical questions, contact Steven Zaccaro, Client Representative Branch, ACE Business Office, Office of International Trade, at *steven.j.zaccaro@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

I. The National Customs Automation Program

This test notice, and the Customs related electronic functions it describes, are part of the National Customs Automation Program (NCAP). NCAP was established in Subtitle B of Title VI—Customs Modernization, in the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (Customs Modernization Act). *See* 19 U.S.C. 1411. Through NCAP, the initial focus of customs modernization was on trade compliance and the development of the Automated Commercial Environment (ACE), the planned successor to the legacy Customs Automated Commercial System (ACS). ACE is an automated and electronic system for commercial trade processing. ACE will streamline business processes, facilitate growth in trade, ensure cargo security, and foster participation in global commerce, while ensuring compliance with U.S. laws and regulations and reducing costs for CBP and all its communities of interest. The ability to meet these objectives depends upon successfully modernizing CBP's business functions and the information technology that supports those functions. CBP's modernization efforts are accomplished through phased releases of ACE component functionality, designed to introduce a new capability or to replace a specific legacy ACS function. Each release will begin with a test, and will end with mandatory compliance with the new ACE feature, thus retiring the legacy ACS function. Each release builds on previous releases, and sets the foundation for subsequent releases.

The ACE Cargo Release test was previously known as the Simplified Entry Test, because the test simplified the entry process by reducing the number of data elements required to obtain release for cargo transported by air. The original test notice required participants to be a member of the Customs-Trade Partnership Against Terrorism (C–TPAT) program. Through phased releases of ACE component functionality, this test has been expanded to allow all eligible participants to join the test for an indefinite period regardless of the C–TPAT status of an importer self-filer or a customs broker. CBP also expanded the ACE Cargo release test to allow ACE-participating brokers and importers to file for release of cargo transported by air, ocean, or rail. *See* 79 FR 6210 (February 3, 2014). For these three modes of transportation, CBP limited the ACE Cargo Release test to formal consumption entries, which ACS termed Type 01 entries; and to informal entries, which ACS termed Type 11 entries. *See* 79 FR 6210.