Dated: May 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0882]

Medical Devices; Exemption From Premarket Notification: Wheelchair Elevator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received a petition requesting exemption from the premarket notification requirements for wheelchair elevator devices commonly known as inclined platform lifts and vertical platform lifts. These devices are used to provide a means for a disabled person to move a wheelchair from one level to another. FDA is publishing this notice to obtain comments in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit either electronic or written comments by July 2, 2012.

ADDRESSES: You may submit comments, identified with the FDA docket number found in brackets in the heading of this document, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this notice. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527, FAX: 301–847–8122.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295)), as amended by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the FD&C Act. Section 510(m)(1) of the FD&C Act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the FD&C Act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance is available through the Internet at *http://www.fda.*

gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf or by sending an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 159 to identify the guidance you are requesting.

III. Proposed Class II Device Exemptions

FDA has received the following petition requesting an exemption from premarket notification for a class II device: Richard Keller, on behalf of Bruno Independent Living Aids, Inc., for wheelchair elevator devices (commonly known as inclined platform lifts and vertical platform lifts), classified under 21 CFR 890.3930.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[Docket Number OIG–1204–N2]

Revision of Performance Standards for State Medicaid Fraud Control Units

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice sets forth OIG guidance regarding standards OIG will apply in assessing the performance of State Medicaid Fraud Control Units (MFCU or Unit). These standards replace and supersede standards published on September 26, 1994 (59 FR 49080). OIG will apply these standards in certifying and recertifying each Unit and to determine if a Unit is effectively and efficiently carrying out its duties and responsibilities.

DATES: *Effective Date:* These standards are effective on June 1, 2012.

FOR FURTHER INFORMATION CONTACT: Richard B. Stern, OIG Office of Evaluation and Inspections, (202) 619–0480. Patrice S. Drew, Office of External Affairs, (202) 619–1368.

I. Background

The mission of the MFCUs, as established in Federal statute, is to investigate and prosecute Medicaid provider fraud and patient abuse and neglect. The States are responsible for operation of the MFCUs and receive reimbursement for a percentage of their costs from the Federal Government. Under section 1903(a)(6) of the Social Security Act (Act), States are reimbursed for 90 percent of their costs for the first 3 years of a MFCU's operation and 75 percent for subsequent years. All MFCUs are currently reimbursed at 75 percent of the costs of operating a certified MFCU.

OIG is delegated authority under 1903(q) and 1903(a)(6) of the Act to certify and annually recertify Units as eligible for Federal Financial Participation (FFP), and to reimburse States for costs incurred in operating a MFCU. Through the certification and recertification process, OIG ensures that the Units meet the requirements for FFP set forth in section 1903(q) of the Act and in Federal regulations found at 42 CFR part 1007. The performance standards set forth in this guidance document constitute the standards that OIG applies in determining the effectiveness of State Units in carrying out MFCU required functions. As part of the recertification process, OIG reviews reports from the Units, obtains information from other Federal and State agencies, and conducts periodic onsite reviews.

Under 1903(q), a MFCU must be a ''single, identifiable entity of the State government'' and be ''separate and distinct'' from the State Medicaid agency. The Unit must be an office of the State Attorney General's office or another State government office with statewide prosecutorial authority or operate under a formal arrangement with the State Attorney General's office. The MFCU must investigate and prosecute Medicaid fraud cases, according to the laws of the State in which with MFCU operates. Federal regulations also require MFCUs to enter into agreements with the State Medicaid agency to ensure the referral of suspected provider fraud cases.

Under 1903(q), a MFCU must also have procedures for investigating and prosecuting (or referring for prosecution) allegations of patient abuse and neglect in Medicaid-funded facilities. A MFCU may also investigate and prosecute abuse and neglect in ''board and care'' facilities, such as assisted living facilities, even if such facilities do not receive Medicaid payments. Finally, 1903(q) and regulations require that MFCUs be composed of a team of attorneys, auditors, and investigators.

Under section 1902(a)(61) of the Act, as added by Public Law 103–66 § 13625 (1994), all States must operate MFCUs unless they demonstrate to the Secretary of HHS that they can operate without a Unit. Currently, 49 States and the District of Columbia have established MFCUs and 1 State, North Dakota, operates without a MFCU after receiving permission from HHS in 1994. Under section 1902(a)(61), States must operate a MFCU that effectively carries out the functions and requirements described in 1903(q), as determined in accordance with standards established by the Secretary of HHS. Consistent with this section, this notice establishes the performance standards OIG will consider in determining whether State MFCUs are effectively carrying out their statutory functions under 1903(q).

II. OIG Development and Use of These Standards

These standards amend and update performance standards that were initially published in 1994 (59 FR 49080). The standards provide guidance to MFCUs regarding how OIG will exercise its discretion in assessing a Unit's performance and, as such, do not require OIG to use formal notice-and-comment procedures. Nevertheless, on October 6, 2011, we published proposed revisions to the 1994 performance standards (76 FR 62074) to invite MFCUs and other interested parties to review and comment on our approach. We received seven sets of comments, all of which we have carefully considered. In addition, we met with one commenter, the National Association of Medicaid Fraud Control Units (the Association), which submitted extensive comments on each of the standards. We accepted many of the commenters' suggestions and recommendations and revised the standards accordingly.

One topic raised in comments by the Association was the use of statistics in assessing MFCU performance. Under the 1994 standards, Standard 7 stated that ''[a] Unit should have a process for monitoring the outcome of cases. In meeting this standard, the Unit's monitoring of the following case factors and outcomes will be considered [including numbers of arrests, convictions, overpayments, and civil