

annual update to the standard Federal rate for discharges occurring during a rate year, beginning in FY 2014. One of the quality measures LTCHs are required to collect and submit data on is the Percent of Residents with Pressure Ulcers That Are New or Have Worsened.

Currently, there are no mandatory standardized data sets being used in LTCHs. Therefore, we have created a new data set to be used in LTCHs, which incorporates data items contained in other, well known and clinically established pressure ulcer data sets, including but not limited to the Minimum Data Set 3.0 (MDS 3.0) and CARE data set (Continuity Assessment Records & Evaluation).

Beginning on October 1, 2012, LTCHs will begin to use a data collection document entitled the "LTCH CARE Data Set" as the vehicle by which to collect the pressure ulcer data for the LTCH quality reporting program. This data set consists of the following components: (1) Pressure ulcer documentation; (2) selected covariates related to pressure ulcers; (3) patient demographic information; and; (4) a provider attestation section. The use of the LTCH CARE Data Set is necessary in order to allow CMS to collect LTCH quality measures data in compliance with Section 3004 of the Affordable Care Act. There are no other reasonable alternatives available to CMS for the collection and submission of pressure ulcer data. *Form Number:* CMS-10409 (OCN: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 3,531; *Total Annual Responses:* 3,531; *Total Annual Hours:* 883. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *November 1, 2011*:

1. *Electronically.* You may submit 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) 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.

Dated: August 30, 2011.

**Martique Jones,**

*Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0556]

#### **Center for Devices and Radiological Health 510(k) Clearance Process; Recommendations Proposed in Institute of Medicine Report: "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years"; Public Meeting; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Friday, August 12, 2011 (76 FR 50230). The document announced a public workshop entitled "Recommendations Proposed in Institute of Medicine Report: 'Medical Devices and the Public's Health, The FDA 510(k) Clearance Process at 35 Years.'" The document was published with an outdated address in the section entitled "Will there be transcripts of the meeting?" This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993-0002, 301-796-9148.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-20575, appearing on page 50230 in the **Federal Register** of Friday, August 12, 2011, the following correction is made:

1. On page 50231, in the second column, under the section entitled

"Will there be transcripts of the meeting?" the address for the Division of Freedom of Information is corrected to read "Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857."

Dated: August 29, 2011.

**Nancy K. Stadel,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### **Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Tobacco Products Scientific Advisory Committee, Center for Tobacco Products.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

**DATES:** Nominations received on or before November 1, 2011 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after November 1, 2011 will be considered for nomination to the committee if nominees are still needed.

**ADDRESSES:** All nominations for membership should be sent electronically to [cv@oc.fda.gov](mailto:cv@oc.fda.gov), or by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002.

#### **FOR FURTHER INFORMATION CONTACT:**

Regarding all nomination questions for membership, the primary contact is:

Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose Option 4), FAX: 240-276-3761, [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov).