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: December 4, 2012.

Martique Jones,

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

[FR Doc. 2012–29627 Filed 12–6–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10333 and CMS–10381]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Consumer Assistance Program Grants *Use:* Section 1002 of the Affordable Care Act provides for the establishment of consumer assistance (or ombudsman) programs, starting in FY 2010. Federal grants will support these programs. These programs will assist consumers with filing complaints and appeals, assist consumers with enrollment into health coverage, collect data on consumer inquiries and complaints to identify problems in the marketplace, educate consumers on their rights and responsibilities, and with the establishment of the new Exchange marketplaces, resolve problems with premium credits for Exchange coverage. Importantly, these programs must provide detailed reporting on the types of problems and questions consumers may experience with health coverage, and how these problems and questions are resolved. In order to strengthen oversight, the law requires programs to report data to the Secretary of the Department of Health and Human Services (HHS). ''As a condition of receiving a grant under subsection (a), an office of health insurance consumer assistance or ombudsman program shall be required to collect and report data to the Secretary on the types of problems and inquiries encountered by consumers'' (Sec. 2793 (d)). Analysis of this data reporting will help identify patterns of practice in the insurance marketplaces and uncover suspected patterns of noncompliance. HHS must share program data reports with the Departments of Labor and Treasury, and state regulators. Program data also can offer CCIIO one indication of the effectiveness of state enforcement, affording opportunities to provide technical assistance and support to state insurance regulators and, in extreme cases, inform the need to trigger federal enforcement.

The 60-day **Federal Register** notice published on July 27, 2012, and the comment period ended September 25, 2012. We received a total of 21 comments. All comments were summarized, consolidated (where overlap existed), and addressed. The majority of comments involved feedback on providing CAPs with more flexibility in collecting and reporting data. The implementation of a new progress report will allow CAPs to provide more information about their progress and activities. In addition, CMS received comments suggesting that collection of all of the CMS-required data elements is difficult and that adjustments to pre-existing databases is too expensive and laborious. CMS recognizes these concerns and acknowledges that CAPs are in the best situation to determine the level of information that is able to be collected for any given consumer. CMS also received comments suggesting that CMS provide guidance to CAPs on how to accurately measure savings to consumers. CMS has provided CAPs with suggestions on ways to calculate recovered benefits and will explore whether more comprehensive guidance is necessary. The comments received in response to the 60-day notice have not resulted in a change in burden estimates. *Form Number:* CMS–10333 (OCN: 0938–1097); *Frequency:* Quarterly and Annual; *Affected Public:* Private Sector: State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 504; *Total Annual Hours:* 261 hours. (For policy questions regarding this collection contact Eliza Bangit at 301–492–4219. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* ICD–10 Industry Readiness Assessment; *Use:* The Congress addressed the need for a consistent framework for electronic transactions and other administrative simplification issues in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, enacted on August 21, 1996. Through subtitle F of title II of HIPAA, the Congress added to title XI of the Social Security Act (the Act) a new Part C, entitled ''Administrative Simplification.'' Part C of title XI of the Act now consists of sections 1171 through 1180, which define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and certain health care providers concerning the transmission of health information. Specifically, HIPAA requires the Secretary of HHS to adopt standards that covered entities are required to use in conducting certain health care administrative transactions, such as claims, remittance, eligibility, and claims status requests and responses. Findings from the ICD–10 industry readiness assessment will be used by CMS to understand each sector's progress toward compliance and to determine what communication and educational efforts can best help affected entities obtain the tools and resources they need to achieve timely compliance with ICD–10. Insights gleaned from the proposed research will be valid for education and outreach purposes only, and will not be used for policy purposes. *Form Number:* CMS–10381 (OMB#: 0938–1149); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits, Not-for-profits; *Number of Respondents:* 1,200; *Total Annual Responses:* 1,200; *Total Annual Hours:* 204. (For policy questions regarding this collection contact Rosali Topper at 410–786–7260. 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 Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on January 7, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: December 4, 2012.

Martique Jones,

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

[FR Doc. 2012–29626 Filed 12–6–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 22, 2013, from 8 a.m. to 6 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993–0002, *Natasha.Facey@fda.hhs.gov,* 301–796–5290, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 22, 2013, the committee will discuss, make recommendations and vote on information regarding the premarket approval application (PMA) for the NeuroPace Responsive Neurostimulation (RNS) System sponsored by NeuroPace, Inc.

The RNS System is indicated for use as an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures from no more than two foci that are refractory to two or more antiepileptic medications.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 13, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 4, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 6, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 3, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–29538 Filed 12–6–12; 8:45 am]

BILLING CODE 4160–01–P