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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1466–N]

Medicare Program: Notice of Two Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces two new membership appointments to the Advisory Panel on Hospital Outpatient Payment (the Panel). The two new appointments to the Panel will each serve a 4-year period. The new members will have terms that begin on February 16, 2014 and continue through February 15, 2018. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services concerning the clinical integrity of the Ambulatory Payment Classification groups and their relative payment weights. The Panel also addresses and makes recommendations regarding supervision of hospital outpatient services. The advice provided by the Panel will be considered as we prepare the annual updates for the hospital outpatient prospective payment system.

FOR FURTHER INFORMATION CONTACT: For additional information on the Panel meeting dates, agenda topics, copy of the charter, as well as updates to the Panel's activities, search our Internet Web site: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*. For other information regarding the Panel, contact Carol Schwartz, the Designated Federal Officer (DFO) at CMS, Center for Medicare, Hospital and Ambulatory Policy Group, Division of Outpatient Care, 7500 Security Boulevard, Mail Stop C4–05–17, Baltimore, MD 21244–1850, phone (410) 786–3985.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Health and Human Services (the Secretary) is required by section 1833(t)(9)(A) of the Social Security Act (the Act) (42 U.S.C. 1395l(t)(9)(A)) and section 222 of the Public Health Service Act (PHS Act) (42 U.S.C. 217a) to consult with an expert outside advisory panel on the clinical integrity of the Ambulatory Payment Classification groups and relative payment weights, which are major elements of the Medicare Hospital Outpatient Prospective Payment System (OPPS), and the appropriate supervision level for hospital outpatient services. The Panel is governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels. The Panel Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following calendar year.

The Panel shall consist of a chair and up to 19 members who are full-time employees of hospitals, hospital systems, or other Medicare providers. The Secretary or a designee selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations. New appointments are made in a manner that ensures a balanced membership under the FACA guidelines.

The Panel presently consists of the following members and a Chair.

- Edith Hambrick, M.D., J.D., Chair, CMS Medical Officer.
- Karen Borman, M.D., FACS.
- Kari S. Cornicelli, C.P.A., FHFMA.
- Brian D. Kavanagh, M.D., MPH.
- Scott Manaker, M.D., Ph.D.
- John Marshall, CRA, RCC, CIRCC, RT(R), FAHRA.
- Jim Nelson, M.B.A., C.P.A., FHFMA.
- Leah Osbahr, M.A., MPH.
- Jacqueline Phillips.
- Traci Rabine.
- Michael Rabovsky, M.D.
- Marianna V. Spanaki-Varela, MD, Ph.D., M.B.A.
- Gale Walker.
- Kris Zimmer.

II. Provisions of the Notice

We published a notice in the **Federal Register** on November 1, 2013, entitled ''Medicare Program; Solicitation of Five Nominations to the Advisory Panel on Hospital Outpatient Payment (HOP, the Panel)'' (78 FR 65660). The notice solicited nominations for five new members to fill the vacancies on the Panel beginning September 30, 2013. As a result of that notice, we are announcing two new members to the Panel. The Panel currently consists of 15 members. The two new Panel members appointments are for 4-year terms beginning on February 16, 2014.

New Appointments to the Panel

The two new members of the Panel with terms beginning on February 16, 2014 and continuing through February 15, 2018 are as follows:

- Wendy Resnick, FHFMA.
- Johnathan Pregler, M.D.

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).

Dated: April 17, 2014.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0555]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the tracking of medical devices.

DATES: Submit either electronic or written comments on the collection of information by June 24, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of

information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Device Tracking—21 CFR Part 821 (OMB Control Number 0910–0442)—Extension

Section 211 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115) became effective on February 19, 1998. FDAMA amended the previous medical device tracking provisions under section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(e)(1) and (e)(2)) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629). Unlike the tracking provisions under SMDA, which required tracking of any medical device meeting certain criteria, FDAMA allows FDA discretion in applying tracking provisions to medical devices meeting certain criteria and provides that tracking requirements for medical devices can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule that conformed existing tracking regulations to changes in tracking provisions effected by FDAMA under part 821 (21 CFR part 821).

Section 519(e)(1) of the FD&C Act, as amended by FDAMA, provides that FDA may require by order that a manufacturer adopt a method for tracking a class II or III medical device, if the device meets one of the three following criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences, (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''), or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility.

Tracked device information is collected to facilitate identifying the current location of medical devices and patients possessing those devices, to the extent that patients permit the collection of identifying information. Manufacturers and FDA (where necessary) use the data to: (1) Expedite the recall of distributed medical devices that are dangerous or defective and (2) facilitate the timely notification of patients or licensed practitioners of the risks associated with the medical device.

In addition, the regulations include provisions for: (1) Exemptions and variances; (2) system and content requirements for tracking; (3) obligations of persons other than device manufacturers, e.g., distributors; (4) records and inspection requirements; (5) confidentiality; and (6) record retention requirements.

Respondents for this collection of information are medical device manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The annual hourly burden for respondents involved with medical device tracking is estimated to be 615,380 hours per year. The burden estimates cited in tables 1, 2, and 3 of this document are based on the number of device tracking orders issued in the last 3 years.

This regulation also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by Office of Management and Budget under the PRA (44 U.S.C. 3501–3520). The collections of information found in §§ 821.2(b), 821.25(e), and 821.30(e) have been approved under OMB control number 0910–0183.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Discontinuation of business—821.1(d)	1	1	1	1	1
Exemption or variance—821.2 and 821.30(e)	1	1	1	1	1
Notification of failure to comply—821.25(d)	1	1	1	1	1
Multiple distributor data—821.30(c)(2)	1	1	1	1	1
Total					4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Tracking information—821.25(a)	12	1	12	76	912
Record of tracking data—821.25(b)	12	46,260	555,120	1	555,120
Standard operating procedures—821.25(c) [2]	12	1	12	63	756
Manufacturer data audit—821.25(c)(3)	12	1,124	13,488	1	13,488
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR Part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Preparation for International Cooperation on Cosmetics Regulation; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled, ''International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR–8 Meeting.'' The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR–8 meeting that will be held in Canada from July 8 to 10, 2014.

Date and Time: The meeting will be held on June 4, 2014, from 2 p.m. to 4 p.m.

Location: The meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Auditorium (first floor), College Park, MD 20740.

Contact Person: If you intend to participate in the meeting, you should register with Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, email: *maria.cook@fda.hhs.gov* or FAX: 301–436–2975.

Registration and Requests for Oral Presentations: Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral presentation, to the contact person by May 20, 2014.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook (see *Contact Person*) by May 28, 2014.

SUPPLEMENTARY INFORMATION: You may present proposals for future ICCR agenda items, data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by May 20, 2014, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It also may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20850. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. You should send written requests for a hardcopy or CD–ROM transcript to the Division of Freedom of Information, (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

The Purpose of the Multilateral Framework on the ICCR: The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Directorate General for Health and Consumers; the Ministry of Health,