

approval process, FDA identifies the established pharmacologic class for each approved medical product if appropriate. An established pharmacologic class is one that FDA has determined is scientifically valid and clinically meaningful according to the principles outlined in the guidance for industry and review staff "Labeling for Human Prescription Drugs and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information," published in October 2009.

For SPL indexing, the established pharmacologic class is represented by an established pharmacologic class term or phrase. FDA also uses the Department of Veterans Affairs National Drug File Reference Terminology to identify other scientifically valid and clinically meaningful SPL indexing terms for each active ingredient that are representative of mechanism of action, physiologic effect, and chemical structure.

On the FDA Data Standards Council Web site, FDA has posted a Microsoft Excel spreadsheet containing a list of proposed established pharmacologic classes and indexing concepts completed to date for each active ingredient associated with approved human prescription drug and biological products.¹

III. Indexing Indications Information

FDA has determined that another high priority for indexing of product labeling information, as resources permit, is the medical product indications category.

With indexing of indications, the goal is to determine terms or phrases that represent the recognized disease or condition, manifestation of a recognized disease or condition, or symptoms associated with a recognized disease or condition that accurately capture the approved indication appearing in the Indications section of labeling. The current intent is to index the basic indication concepts without the more specific usage and limitations of use information. Criteria are under development to determine the appropriate level of granularity and consistency in the choice of concepts indexed.

After consideration of existing alternatives including the National Library of Medicine's Clinical Observations Recording and Encoding (CORE) subset of Systematized Nomenclature of Medicine Clinical

Terms (SNOMED CT), FDA chose the Veterans Health Administration and Kaiser Permanente (VA/KP) Problem List subset of SNOMED CT as the terminology for SPL indexing of product labeling information on indication.²

SNOMED CT is a comprehensive clinical terminology that includes expressions for body structures, clinical findings, procedures, and hundreds of thousands of other clinical concepts. More information on SNOMED CT is available at http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html.

IV. Request for Comments

FDA is establishing an open docket for comments to obtain public input on the indexing process. Representatives of the human prescription drug and biological product industries, health care providers, and other health care professionals are particularly encouraged to participate and submit comments.

FDA is asking for comment on all aspects of indexing the content of labeling. In particular, FDA is asking for comments on the following:

1. FDA is currently indexing pharmacologic class and indications. When indexing of these categories is complete, FDA plans to index additional labeling information categories. For example, warnings and precautions, other adverse reactions, drug interactions, pediatric, or pregnancy information may be useful categories of information for future indexing. Other categories may also be identified. Please comment on the subsequent labeling categories that should be indexed by FDA as well as the priority order for indexing these categories.

2. For each indexing category, FDA will develop a series of principles to ensure the consistent assignment of indexing concepts. Please comment on the type of principles that may be useful for this task.

3. FDA chose the VA/KP Problem List subset of SNOMED CT as the indexing terminology for indications for the following reasons:

- The VA/KP Problem List is the named SPL data standard terminology for indexing the medical condition.³
- The subset represents conditions at a level of discreteness that are clinically relevant.

² FDA News: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2006/ucm108642.htm>

³ SNOMED CT VA/KP subset: http://www.nlm.nih.gov/research/umls/Snomed/snomed_problem_list.html

Please comment on the use of the VA/KP Problem List for the indexing of indications.

4. For indications, the degree of complexity indexed is limited by FDA's intention to first capture the main focus of the indication as a single existing concept using the 01312010 version of the SNOMED CT VA/KP Problem List subset. Additional indication modifiers found in approved product labeling such as disease severity or chronicity will not always be indexed. Please comment on this approach.

5. FDA will use the SPL standard to disseminate indexing information. Once entered into the SPL file, the indexed elements will be available for uploading into computer systems for sorting and other data manipulations. We believe this approach is more user friendly than the Microsoft Excel spreadsheet format we are currently using to showcase pharmacologic class on the Data Standards Web site. Please comment on this approach to make SPL indexing information available to interested parties.

V. 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. It is no longer necessary to send two copies of mailed 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: June 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-14047 Filed 6-10-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1576-N]

Medicare and Medicaid Programs; Procedure for Hospitals Seeking To Enter Into an Agreement With a Different Organ Procurement Organization Following an 1138(a)(2) Waiver

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

ACTION: Notice.

¹ See <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductfxsp0:Labeling/ucm162549.htm>.

SUMMARY: This notice announces the procedures that will be used when a hospital, that has previously been granted a waiver under sections 1138(a)(2) of the Social Security Act (the Act), seeks to enter into an agreement with a different Organ Procurement Organization (OPO). The procedures are modeled after the public process required by 1138(a)(2) of the Act. The process affords the public an opportunity to comment on the proposed change and to submit information and material with respect to whether the change is likely to increase organ donation and will assure equitable treatment for patients in both affected OPO service areas.

DATES: *Effective Date:* This notice is effective June 11, 2010.

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786-4554.

SUPPLEMENTARY INFORMATION:

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of transplantable organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act), and our regulations at § 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with its designated OPO.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the

Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver: (1) Is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to comment in writing during the 60-day period beginning on the publication date in the **Federal Register**.

Several hospitals have asked for and been granted waivers to work with a hospital other than the designated OPO. The statute does not expressly establish procedures for the situation where a hospital that had previously been granted a waiver, desires to enter into an agreement with a different OPO or return to work with the OPO that has been designated for the relevant geographic area. Given the importance of the hospital-OPO relationship for all potential transplant patients in the affected service areas, we are establishing an open and transparent process for addressing these situations. Specifically, using the same framework provided in section 1138(a)(2), the Secretary will enable hospitals that had been granted a waiver to apply to enter into an agreement with a different OPO. A specific notice will be published in the **Federal Register** within 30 days of the agency's receipt of such a request. We will provide the public an opportunity to submit information and material with respect to whether the proposed change would be expected to increase organ donation and would ensure the equitable treatment for transplant patients in both of the affected OPO service areas.

II. Request Procedures

A hospital that has previously been granted a waiver under section 1138(a)(2) but desiring to enter into an agreement with a different OPO, may file a request by submitting it to CMS at the following address: Director, Centers for Medicare and Medicaid Services, Division of Technical Payment Policy, 7500 Security Blvd, C4-25-02, Baltimore, MD 21244-1850.

The letter should supply sufficient information and data to address how changing OPOs:

1. Is expected to increase organ donation; and
2. Will assure equitable treatment of patients referred for transplant within the existing OPO service area, within the service area of the OPO with which the hospital wishes to enter an agreement.

In making a change in OPO determination, the Secretary may consider, among other factors:

1. Cost effectiveness;
2. Improvements in quality;
3. Whether there has been a change in a hospital's service due to a change in definition of metropolitan statistical area (MSA); and
4. The length and continuity of a hospital relationship with the OPO with which the hospital wants to align.

Upon receipt of such a request, we would publish a **Federal Register** notice to solicit public comments, consistent with the procedures set forth in section 1138(a)(2)(D) of the Act.

Under these procedures, we will review the request and comments received. During the review process, we may consult on an as-needed basis with the Health Resources Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the request and notify the hospital and the designated and requested OPOs.

By providing an open and transparent public process with an opportunity to consider public comments, information and materials, the Secretary will be able to make better decisions concerning whether the proposed change in the OPO will be expected to increase organ donation and will assure equitable treatment for patients in both affected OPO service areas.

III. Collection of Information Requirements

We anticipate receiving less than 10 hospital requests in a 12-month period.

Therefore, in accordance with 5 CFR 1320.3(c), the reporting requirements in this notice are not defined as information collection requirements.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: June 3, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2010-14098 Filed 6-10-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meeting

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

A Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or a long period of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for the OS ARRA: Clinically-Enhanced State Data for Analysis for CE Impact (R01) applications are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

SEP Meeting on: OS ARRA: Clinically-Enhanced State Data for Analysis for CE Impact (R01).

Date: July 2, 2010. (Open on July 2 from 8 a.m. to 8:15 a.m. and closed for the remainder of the meeting.)

Place: Hyatt Regency Bethesda Hotel, 7400 Wisconsin Avenue, 1 Bethesda Metro Center, Conference Room TBD, Bethesda, MD 20814.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the non-confidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427-1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: May 27, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010-13982 Filed 6-10-10; 8:45 am]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Research 2 Practice and Construction Research Application, Request for Application (RFA) OH09-001, Initial Review

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the aforementioned meeting:

Time and Date: 3 a.m.–5 p.m., July 7, 2010 (Closed).

Place: National Institute for Occupational Safety and Health (NIOSH), 2400 Century Parkway, NE., Fourth Floor, Atlanta, Georgia 30345, Telephone: (404) 498-2530.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92-463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to “Research 2 Practice and Construction Research Application, RFA OH09-001”.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Chris Langub, PhD, Scientific Review Officer, NIOSH, CDC, 2400 Century Center, Atlanta, GA 30333, Telephone: (404) 498-2543.

The Director, Management Analysis and Services Office has been delegated the

authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 4, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-14074 Filed 6-10-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0268]

Dental Products 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: Dental Products 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 December 14 and 15, 2010, from 8 a.m. to 6 p.m.

Location: Holiday Inn-Gaithersburg, Main Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879.

Contact Person: Olga I. Claudio, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, rm. 1553, Silver Spring, MD 20993-0002, 301-796-7608 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 301-451-2518. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Comments: FDA is opening a docket for public comment on this document.