

presence of naltrexone, an opioid antagonist, in the formulation. The committees will be asked to discuss whether the data submitted by the Applicant are sufficient to support labeling of the product with the properties expected to deter abuse.

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: On June 8, 2016, from 9:30 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before May 24, 2016. 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 May 16, 2016. 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 May 17, 2016.

Closed Committee Deliberations: On June 8, 2016, from 8 a.m. to 9:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the drug development program of an investigational abuse-deterrent opioid product.

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 disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky 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: March 11, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-05999 Filed 3-16-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Committee on Rural Health and Human Services.

Date And Time: April 18, 2016, 8:30 a.m.–5:00 p.m., April 19, 2016, 8:30 a.m.–5:15 p.m., April 20, 2016, 8:30 a.m.–11:00 a.m.

Place: Keyserling Cancer Center, 1680b Ribaut Road, Port Royal, SC 29935, (843) 522-7800.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: The meeting on Monday, April 18, will be called to order at 8:30 a.m. by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The Committee will examine the issue of Opioid Abuse Disorder in rural areas and alternatives for emergency care in rural communities at

risk of losing their hospital. The day will conclude with a period of public comment at approximately 5:00 p.m.

The Committee will break into Subcommittees and depart for site visits Tuesday morning, April 19, at approximately 8:30 a.m. Subcommittees will visit the Beaufort County Department of Social Services and the Keyserling Cancer Center. The day will conclude at the Keyserling Cancer Center with a period of public comment at approximately 5:00 p.m.

The Committee will meet to summarize key findings and develop a work plan for the next quarter and the following meeting on Wednesday morning, April 20, at 8:30 a.m. at the Keyserling Cancer Center.

FOR FURTHER INFORMATION CONTACT:

Steve Hirsch, MSLS, Administrative Coordinator, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, 17W61, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

Persons interested in attending any portion of the meeting should contact Pierre Joseph at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 945-0897 or by email at PJoseph@hrsa.gov. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed above at least 10 days prior to the meeting. The Committee meeting agenda will be posted on the Committee's Web site at <http://www.hrsa.gov/advisorycommittees/rural/>.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016-05998 Filed 3-16-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on National Bioethics Advisory Bodies

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues is requesting public comment on the role of past, present, and future national bioethics bodies, such as this one, in the United States and elsewhere.

DATES: To ensure consideration, comments must be received by July 1, 2016. Comments received after this date will not be considered as time permits.

ADDRESSES: Individuals, groups, and organizations interested in commenting on this topic may submit comments by email to info@bioethics.gov or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C-100, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Lisa M. Lee, Executive Director, Presidential Commission for the Study of Bioethical Issues. Telephone: 202-233-3960. Email: Lisa.Lee@bioethics.gov. Additional information may be obtained at <http://www.bioethics.gov>.

SUPPLEMENTARY INFORMATION: On November 24, 2009, the President established the Presidential Commission for the Study of Bioethical Issues (the Commission) to advise him on bioethical issues generated by novel and emerging research in biomedicine and related areas of science and technology. The Commission is charged with identifying and promoting policies and practices that ensure ethically responsible conduct of scientific research and health care delivery. Undertaking these duties, the Commission seeks to identify and examine specific bioethical, legal, and social issues related to potential scientific and technological advances; examine diverse perspectives and possibilities for international collaboration on these issues; and recommend legal, regulatory, or policy actions as appropriate.

The Commission will conclude at the end of the Presidential administration, and in its two final meetings will reflect on the past, present, and future of national bioethics advisory bodies. These meetings will include discussion of the role of national advisory bodies in the developing public policy in the United States and elsewhere, and consideration of the future of U.S. national bioethics advisory bodies that might follow.

The Commission is interested in receiving comments from individuals, groups, and professional communities who wish to join the Commission in reflecting on the past, present, and future of national bioethics advisory bodies in the United States and elsewhere. The Commission is particularly interested in receiving public commentary regarding:

- The advantages and disadvantages of different models for national bioethics advisory bodies, e.g., standing

or temporary, narrowly or broadly focused (examining one topic or issue or a variety of issues);

- The lessons we can learn from national bodies in other countries to inform how U.S. bodies might work;
- The influence of national bioethics bodies on bioethics as a field; other academic fields, such as science, medicine, and technology; and public policy;
- The future of national bioethics advisory groups in the United States.

To this end, the Commission is inviting interested parties to provide input and advice through written comments. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: March 1, 2016.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2016-06015 Filed 3-16-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS-OS-0945-0003-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for revision of the approved information collection assigned OMB control number #0945-0003, which expires on January 1, 2017. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before May 16, 2016.

ADDRESSES: Submit your comments to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS-OS-0945-0003-60D for reference.

Information Collection Request Title: HIPAA Privacy, Security, and Breach Notification Rules, and Supporting Regulations Contained in 45 CFR parts 160 and 164.

Abstract: This revision does not change any requirements of the HIPAA Privacy, Security, and Breach Notification Rules. Among other updates summarized below, the ICR requests to rename the information collection and incorporate into it the substance of two other information collections (#0945-0004, set to expire on May 31, 2016; and #0945-0001, expiring on September 30, 2016), which then would be discontinued. The ICR addresses the burden on regulated entities for compliance with the information collection requirements of the HIPAA Privacy, Security, and Breach Notification Rules; the voluntary burden on members of the public for obtaining information from covered entities regarding breaches of their protected health information; and the information collection burden on the Office for Civil Rights (OCR) associated with administering aspects of the HIPAA Breach Notification program. Combining the three existing information collections identified above will allow the regulated community, the public, and OCR to more easily view and track the estimated burdens associated with the HIPAA Rules that are administered and enforced by OCR. In addition to combining the ICRs, the proposed updates take into account our experience administering the Rules to more accurately reflect the burdens of compliance with the applicable regulatory requirements; remove the estimated burden of initial compliance with the Omnibus HIPAA Final Rule, because we are well past the compliance dates; and incorporate increases in wages for the job categories that we expect to be involved in compliance activities.

Need and Proposed Use of the Information: The HIPAA Rules require covered entities, and in many respects their business associates, to protect the privacy and security of individually identifiable health information (called “protected health information” or “PHI”); fulfill individuals’ rights under HIPAA with respect to their health information; and provide notification in case of a breach of unsecured protected health information. The information collections associated with these regulatory requirements include