systems for the UK population (Ref. 3). This peer-reviewed journal article presented the following findings regarding primary MoM THR: (1) Increased failure rate at 5 years for MoM THR related to larger head sizes; (2) significantly higher risk for revision in female patients (Note: In the United States, labeling discourages use of MoM hips in females of child bearing age with warnings in MoM THR labeling and contraindications in MoM hip resurfacing labeling); and (3) revisions for dislocation in men with MoM replacements were slightly lower, showing some benefit to larger head sizes.

The committee will be asked to discuss the following as it pertains to these devices in the U.S. population: Device mechanisms of failure, metal ion testing, imaging methods, local and systemic complications, preoperative and postoperative patient risk factors, as well as clinical followup considerations for patients with MoM hip systems (total and resurfacing).

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 link.

Procedure: FDA will work with affected industry, professional organizations, and societies that have an interest in the MoM hip arthroplasty systems and who wish to make a presentation separate from the general open public hearing; time slots on June 28, 2012, between approximately 9 a.m. and 10 a.m. Representatives from industry, professional organizations and societies interested in making formal presentations to the committee should notify the contact person on or before May 1, 2012.

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 May 9, 2012. On June 27, 2012 oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.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 1, 2012. 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 2, 2012.

Comments: FDA is opening a docket to allow for public comments to be submitted to the Agency on the issues before the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee beginning on March 30, 2012, and closing on May 9, 2012. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Divisions of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 James Clark, *James.Clark@fda.hhs.gov* or 301–796–5293 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).

I. References

The following references have been placed on display in the Division of Dockets Management (see *Comments*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. American Academy of Orthopedic Surgeons, ''Modern Metal-on-Metal Hip Implants: A Technology Overview'' (July 15, 2011), accessed online at *http://www.aaos.org/research/overviews/Metal_On_Metal.pdf.*
2. Adelaide: Australian Orthopaedic Association, *Australian Orthopaedic Association National Joint Replacement Registry: Annual Report 2010,* 2010.
3. Smith, A.J., P. Dieppe, K. Vernon, et al., ''Failure Rates of Stemmed Metal-on-Metal Hip Replacements: Analysis of Data From the National Joint Registry of England and Wales,'' *Lancet* (March 13, 2012), accessed online at *http://www.thelancet.com/journals/lancet/article/PIIS0140–6736(12)60353-5/fulltext#article_upsell* (doi:10.1016/S0140–6736(12)60353–5).

Dated: March 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–7767 Filed 3–29–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; 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 Council on Migrant Health.

Dates and Times: May 7, 2012, 8:30 a.m. to 5 p.m., May 8, 2012, 8:30 a.m. to 5 p.m.

Place: Westin Denver Downtown Hotel, 1672 Lawrence Street, Denver, Colorado 80202. *Telephone:* (303) 572–9100.

Fax: (303) 572–7288.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

Agenda: The agenda includes an overview of the National Advisory Council on Migrant Health's (The Council) general business activities. The Council will also hear presentations from experts on farmworker

issues, including the status of farmworker health at the local and national levels. Agenda items are subject to change as priorities indicate.

For Further Information Contact: Gladys Cate, Office of Special Population Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Room 15–62, Rockville, Maryland 20857; telephone (301) 594–0367.

Dated: March 22, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–7613 Filed 3–29–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of an Altered System of Records

AGENCY: Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA).

ACTION: Notice of an Altered System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, the Health Resources and Services Administration (HRSA) is publishing a notice to alter the system of records for the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, HHS/HRSA/BHPR. The System of Records Notice (SORN) 09–15–0054 was last published on October 1, 2010 (75 FR 60763). The Health Care Quality Improvement Act of 1986, as amended, title IV of Public Law 99–660 (42 U.S.C. 11101 *et seq.*) authorized the Secretary to establish a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists, and other health care practitioners. By law, the information is releasable only to the specific entities described in the SORN. The law requires the maintenance of records such as medical malpractice payments, adverse licensure and clinical privilege actions, disciplinary actions taken by Boards of Medical Examiners, and professional review actions taken by entities against physicians, dentists, and other healthcare practitioners. Section 1921 of the Social Security Act, as amended, expands reporting to the NPDB to authorize maintenance of records of adverse licensure actions and negative actions or findings taken by a State licensing authority, peer review organization, or private accreditation entity against all health care practitioners or healthcare entities.

The primary purpose of this alteration is to publish the Privacy Act exemptions that became necessary after implementation of Section 1921, which entitles law enforcement agencies to access NPDB information and which therefore requires a similar exemption from certain provisions of the Privacy Act that the Healthcare Integrity and Protection Data Bank (HIPDB) has for investigative materials. Because some of the records may be queried by law enforcement agencies for investigative purposes (i.e., as opposed to employment or other purposes), the system will be exempt from certain Privacy Act requirements to the extent necessary to avoid revealing law enforcement investigative interest and compromising law enforcement investigations. Another purpose of this alteration is to add a new routine use pertaining to system security, which is being added to other SORNs published by HHS.

DATES: As required by the Privacy Act (5 U.S.C. 552a(r)), HRSA filed an altered system of records report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), on 1/25/12. To ensure all parties have adequate time in which to comment, the altered system will become effective 30 days from the publication of this notice or 40 days from the date it was submitted to OMB and Congress, whichever is later, unless HRSA receives comments that require alterations to this notice.

ADDRESSES: Please address comments to Associate Administrator, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 8–103, Rockville, Maryland 20857. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m. (Eastern Standard Time Zone), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Director, Division of Practitioner Data Banks, Bureau of Health Professions, 5600 Fishers Lane, Room 8–103, Rockville, Maryland 20857; Telephone: (301) 443–2300. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The National Practitioner Data Bank (NPDB) is primarily an alert or flagging system intended to facilitate a comprehensive review of health care practitioners' professional credentials for the purpose of protecting the public from unfit practitioners. On January 28, 2010, the Health Resources and Services Administration published a final rule in the **Federal Register** (75 FR 4656) designed to implement section 1921 of the Social Security Act (herein referred to as section 1921). Section 1921 expands the scope of the NPDB. Section 1921 requires each state to adopt a system of reporting to the Secretary certain adverse licensure actions taken against health care practitioners and health care entities by any authority of the state responsible for the licensing of such practitioners or entities. It also requires each state to report any negative action or finding that a state licensing authority, a peer review organization, or a private accreditation entity has finalized against a health care practitioner or entity. Practically speaking, Section 1921 resulted in, among other consequences, the inclusion of the vast majority of information contained in the Healthcare Integrity and Protection Data Bank (HIPDB), a companion data bank, in the NPDB.

The HIPDB was created by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law (Pub. L. 104–191), which required the Secretary of HHS, acting through the Office of Inspector General (OIG) and the United States Attorney General, to establish a new health care fraud and abuse control program to combat health care fraud and abuse. Although their purposes are different, together the HIPDB and NPDB serve to facilitate review of health care practitioners' and entities' backgrounds. The HIPDB is exempt from certain provisions of the Privacy Act (see 45 CFR 5b.11(b)(2)(ii)(F)). In order to maintain the exemption for the HIPDB investigative materials, which are now also available through the NPDB, and other expanded information which law enforcement agencies can access, it was necessary to extend similar Privacy Act exemptions for the HIPDB to the NPDB. The new routine use that is being added for this system pertains to system security. It is not specific to the NPDB system; it is being added to new, existing, and updated SORNs published by HHS for other systems that are affected by the same security requirement.