workshop will be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m. on June 14, 2013. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and connection access information after June 19, 2013. An archived file of the Webcast will be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list).

Workshop format: This workshop will begin with plenary sessions to outline the three primary areas of focus for the CDRH HoW Program. In each area, panels will examine major themes using data-driven case studies with a focus on practical strategies relevant to particular challenges in the medical device arena. Participants will then rotate through breakout sessions, collectively building an action plan for each activity area. The meeting will conclude with specific commitments by stakeholder groups to partner with CDRH and each other in a collaborative effort to educate, enable, enlist and explore, with a common goal of improving the health of women.

Comments: In order to permit the widest possible opportunity to obtain public information from interested persons on the workshop topics, FDA is opening the docket to gather electronic or written comments on the three areas of focus for the HoW workshop identified in section II. Comments received will be reviewed by FDA as part of this effort. The deadline for submitting comments related to this public workshop topic is July 31, 2013.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Please identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The mission of the CDRH Health of Women (HoW) Program:

To improve the health of women by:

- Improving the availability, consistency, and communication of sex-specific information for the safe and effective use of medical devices in women;
- addressing identified gaps and unmet needs through targeted resources; and
- fostering the development of innovative strategies, technology, and clinical study paradigms.

A key priority in regulatory science for CDRH is improving the health of special populations and addressing their unique health-related issues.[1] CDRH recognizes women as a special population, and seeks to identify and address differences in the safety, effectiveness, and utilization of medical devices for women. There are unique issues in the regulation of medical devices for use by women, which include:

- Uncertainty about medical device performance in women due to inconsistent data analysis and under-representation of women in clinical trials
- Baseline differences in anatomy, physiology, risk factors, disease signs/symptoms, and comorbidities that may be associated with different outcomes of device use
- Potential differences in health communication/health seeking behavior that may impact FDA communication of medical device benefit-risk information to this population
- Different considerations regarding effects of hormones through life stages (first menstrual period (menarche) to menopause; hormone replacement therapy)
- Unique risks and needs related to medical device research involving women of childbearing potential
- Unique risks and needs for pregnant females associated with the use of medical devices, including risk of birth defects (teratogenicity) or complications of pregnancy arising from medical device components such as drugs, chemicals, and certain biomaterials

[1] Food and Drug Administration, ''Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health,'' *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm274162.pdf*.

II. Topics for Discussion in the Docket and at the Public Workshop

Topics for discussion include:

1. Device-specific clinical study recruitment and retention strategies;
2. Analysis and communication of sex-specific findings to providers and patients; and
3. Priority research road map for the HoW device ecosystem.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08015 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms OMB No. 0915–0126—Revision

Abstract: This is a request for a revision of OMB approval of the information collections contained in regulations found at 45 CFR part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in registering with, reporting information to, and requesting information from the NPDB. Section 6403 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) Public Law 111–148 requires the transfer of all data in the Healthcare Integrity and Protection Data Bank

(HIPDB) to the NPDB. Data collection will not change; however, the merger will consolidate forms from OMB No. 0915–0239 for HIPDB under OMB No. 0915–0126 for NPDB. Responsibility for NPDB implementation and operation resides in the Bureau of Health Professions, Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS). Operation of the HIPDB was delegated by the HHS Office of the Inspector General to HRSA. This rule eliminates duplicative data reporting and access requirements between the HIPDB [established through the Health Insurance Portability and Accountability Act of 1996 (HIPPA) under Section 1128(b)(5) of the Social Security Act (42 U.S.C. 1320a–7e)] and the NPDB [established through the Health Care Quality Improvement Act of 1986 under Title IV (42 U.S.C. 11101 *et seq.*) and expanded by Section 1921 of the Social Security Act (42 U.S.C. 1396r–2)]. Information previously collected and disclosed through the HIPDB will be collected and disclosed through the NPDB. Section 6403 of the Affordable Care Act consolidates the collection and disclosure of information from both data banks under Title 45 part 60 of the Code of Federal Regulations (CFR). HHS will subsequently remove Title 45 part 61, which implemented the HIPDB.

The intent of NPDB is to improve the quality of health care by encouraging hospitals, state licensing boards, professional societies, and other entities providing health care services, to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent health care practitioners, providers, or suppliers to move from state to state without disclosure of previous damaging or incompetent performance. It also serves as a fraud and abuse clearinghouse for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care practitioners, providers, or suppliers by health plans, federal agencies, and state agencies.

The NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information is collected from, and disseminated to, eligible entities (entities that are entitled to query and/or report to the NPDB under the three aforementioned statutory authorities) on the following: (1) Medical malpractice payments, (2) licensure actions taken by Boards of Medical Examiners, (3) state licensure and certification actions, (4) federal licensure and certification actions, (5) negative actions or findings taken by peer review organizations or private accreditation entities, (6) adverse actions taken against clinical privileges, (7) federal or state criminal convictions related to the delivery of a health care item or service, (8) civil judgments related to the delivery of a health care item or service, (9) exclusions from participation in federal or state health care programs, and (10) other adjudicated actions or decisions. It is intended that NPDB information should be considered with other relevant information in evaluating credentials of health care practitioners, providers, and suppliers.

The reporting forms and the request for information forms (query forms) are accessed, completed, and submitted to the NPDB electronically through the NPDB Web site at *http://www.npdb-hipdb.hrsa.gov/.* All reporting and querying is performed through this secure Web site.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The annual estimate of burden is as follows:

Regulation citation	Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal.	38,785	1	38,785	.25	9,696
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment.	14,193	1	14,193	.75	10,645
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & § 60.9: Reporting licensure and certification actions taken by States.	State Licensure	28,700	1	28,700	.75	21,525
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	499	1	499	.75	374
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	10	1	10	.75	8
	Accreditation	10	1	10	.75	8
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions.	962	1	962	.75	722
	Professional Society	71	1	71	.75	53

Regulation citation	Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
§ 60.13: Reporting Federal or State criminal convictions to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial).	1,023	1	1,023	.75	767
	Deferred Conviction or Pre-Trial Diversion.	126	1	126	.75	95
	Nolo Contendere (No Contest) Plea.	63	1	63	.75	47
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	10	1	10	.75	8
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment	2,402	1	2,402	.75	1,802
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative	2,682	1	2,682	.75	2,012
	Health Plan Action	561	1	561	.75	421
§ 60.18 Requesting Information from the NPDB.	One Time Query for an Individual.	986,552	1	986,552	.08	78,924
	One Time Query for an Organization.	18,892	1	18,892	.08	1,511
	Self-Query on an Individual	154,824	1	154,824	.42	65,026
	Self-Query on an Organization.	1,095	1	1,095	.42	460
	Continuous Query	387,767	1	387,767	.08	31,021
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute.	3,347	1	3,347	.75	2,510
	Request for Secretarial Review.	83	1	83	8	664
Administrative	Entity Registration (Initial)	35,915	1	35,915	1	35,915
	Entity Registration (Renewal & Update).	15,461	1	15,461	.08	1,237
	Agent Registration (Initial)	100	1	100	.25	25
	Agent Registration (Renewal & Update).	100	1	100	.25	25
	Electronic Transfer of Funds (EFT)Authorization.	562	1	562	.25	141
	Authorized Agent Designation.	1,290	1	1,290	.25	323
	Account Discrepancy	20	1	20	.25	5
Total		1,696,115		1,696,115		265,978

ADDRESSES: Submit your comments to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: April 1, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–08071 Filed 4–5–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: May 14–15, 2013.