registries are required to submit quality measures data once, within 2 months following the reporting period. How much time are reporting entities outside of PQRS afforded to submit quality measures data? What challenges do reporting entities face in reporting data according to current timeframes?

++ What oversight (for example, checks or audits) should be in place to ensure that data is submitted and calculated properly by entities?

• Questions regarding selection of measures related to registry reporting under PQRS for 2014 and subsequent years and for the EHR Incentive Program if registry reporting is established as a reporting method for that program in future years:

++ Should we require that a certain proportion of submitted measures have particular characteristics such as being NQF-endorsed or outcome-based?

++ Should we require that the quality measures data submitted cover a certain number of the six national quality strategy domains?

++ To what extent would third-party entities struggle to meet reporting for measures currently available under PQRS and EHR Incentive Program?

• Questions regarding registry measures reporting criteria:

++ If we propose revised criteria for satisfactory reporting under PQRS and for meeting the CQM component of meaningful use under the EHR Incentive Program, how many measures should an eligible professional be required to report to collect meaningful quality data? For example, for reporting periods occurring in 2014, eligible professionals using CEHRT must report 9 measures covering at least 3 domains to meet the criteria for satisfactory reporting for the 2014 PQRS incentive and meet the CQM component of achieving meaningful use for the EHR Incentive Program. (For more information see the EHR Incentive Program Stage 2 final rule (77 FR 54058) and the CY 2013 Medicare PFS final rule with comment period (77 FR 69192).) If we were to align reporting criteria with reporting requirements for other non-federal reporting programs, in future years, should we propose to require reporting on a different number of measures than what is currently required for the PQRS in 2013 and the EHR Incentive Program under the Stage 2 final rule or should the non-federal reporting programs align with CMS criteria?

++ For PQRS, should eligible professionals still be required to report quality measures data on a certain percentage of their applicable patients, such as 80 percent, for 2014 and subsequent years? Or, should we require that eligible professionals report on a certain minimum number of patients, such as 20, rather than a percentage?

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

Dated: January 9, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–02703 Filed 2–4–13; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Device Good Manufacturing Practice Advisory Committee, certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through December 31, 2013.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations for membership should be sent electronically to *cv@oc.fda.gov*, or by mail to Advisory Committee Oversight & Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on a FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: For specific Committee/Panel questions, contact the following persons listed in table 1 of this document.

TABLE 1

Contact person	Committee/certain device panels of the medical devices advisory committee
LCDR Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301–796–7046, email: *Sara.Anderson@fda.hhs.gov*.	National Mammography Quality Assurance Advisory Committee. Dental Products Panel. Hematology and Pathology Devices Panel. Orthopaedic and Rehabilitation Devices Panel.
Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993, 301–796–6639, email: *Shanika.Craig@fda.hhs.gov*.	Technical Electronic Product Radiation Safety Standards Committee. Anesthesiology and Respiratory Therapy Devices Panel. Gastroenterology and Urology Devices Panel. Microbiology Devices Panel. Obstetrics and Gynecology Devices Panel. Radiological Devices Panel.
Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301–796–5290, email: *Natasha.Facey@fda.hhs.gov*.	Device Good Manufacturing Practice Advisory Committee. General Hospital and Personal Use Devices Panel. Immunology Devices Panel. Ophthalmic Devices Panel. Neurological Devices Panel.

TABLE 1—Continued

Contact person	Committee/certain device panels of the medical devices advisory committee
Pamela D. Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5406, Silver Spring, MD 20993, 301–796–5433, email: *PamelaD.Scott@fda.hhs.gov*.	Medical Devices Dispute Resolution Panel.
Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993, 301–796–3036, email: *Jamie.Waterhouse@fda.hhs.gov*.	Circulatory System Devices Panel. Ear, Nose and Throat Devices Panel. General and Plastic Surgery Devices Panel. Molecular and Clinical Genetics Devices Panel.

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations of voting members for vacancies listed as follows:

TABLE 2

Committee/panel expertise needed	Current and upcoming vacancies	Approximate date needed
Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee—Anesthesiologists, pulmonary medicine specialists, or other experts who have specialized interests in ventilator support, pharmacology, physiology, or the effects and complications of anesthesia.	3	December 1, 2013.
Circulatory System Devices Panel of the Medical Devices Advisory Committee—Interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.	1	July 1, 2013.
Dental Products Panel of the Medical Devices Advisory Committee—Dentists, engineers and scientists who have expertise in the areas of dental implants, dental materials, periodontology, tissue engineering, and dental anatomy.	3	November 1, 2013.
Ear, Nose and Throat Devices Panel of the Medical Devices Advisory Committee—Otologists, neurotologists, audiologists.	3	November 1, 2013.
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee—Transplant specialists, gastroenterologists, urologists and nephrologists.	3 2	Immediately. January 1, 2014.
General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee—Surgeons (general, plastic, reconstructive, pediatric, thoracic, abdominal, pelvic and endoscopic); dermatologists; experts in biomaterials, lasers, wound healing, and quality of life; and biostatisticians.	2	September 1, 2013.
General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee—Internists, pediatricians, neonatologists, endocrinologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.	1 3	Immediately. January 1, 2014.
Hematology and Pathology of the Medical Devices Advisory Committee—Hematologists (benign and/or malignant hematology), hematopathologists (general and special hematology, coagulation and homeostasis, and hematological oncology), gynecologists with special interests in gynecological oncology, cytopathologists, and molecular pathologists with special interests in development of predictive and prognostic biomarkers.	4	March 1, 2013.
Immunology Devices Panel of the Medical Devices Advisory Committee—Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1 1	Immediately. March 1, 2013.
Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee—Experts with broad, cross-cutting scientific, engineering, clinical, analytical or mediation skills who are familiar with the materials and/or operating mechanisms related to addressing complex or contested scientific issues.	1	October 1, 2013.
Microbiology Devices Panel of the Medical Devices Advisory Committee—Infectious disease clinicians, e.g., pulmonary disease specialists, sexually transmitted disease specialists, pediatric infectious disease specialists, experts in tropical medicine and emerging infectious diseases, biofilm development; mycologists; clinical microbiologists and virologists; clinical virology and microbiology laboratory directors, with expertise in clinical diagnosis and in vitro diagnostic assays, e.g., hepatologists; molecular biologists.	1 3	Immediately. March 1, 2013.
Molecular and Clinical Genetics Devices Panel of the Medical Devices Advisory Committee—Experts in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, neonatologists. Individuals with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training, and clinical molecular genetics testing (e.g., genotyping, array CGH, etc.) Individuals with experience in genetics counseling, medical ethics are also desired, and individuals with experience in ancillary fields of study will be considered.	2	June 1, 2013.
Neurological Devices Panel of the Medical Devices Advisory Committee—Neurosurgeons (cerebrovascular and pediatric), neurologists (stroke, pediatric, pain management, and movement disorders), interventional neuroradiologists, psychiatrists, and biostatisticians.	1	December 1, 2013.

TABLE 2—Continued

Committee/panel expertise needed	Current and upcoming vacancies	Approximate date needed
Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee—Experts in perinatology, embryology, reproductive endocrinology, pediatric gynecology, gynecological oncology, operative hysteroscopy, pelviscopy, electrosurgery, laser surgery, assisted reproductive technologies, contraception, postoperative adhesions, and cervical cancer and colposcopy; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; experts in gynecology in the older patient; experts in diagnostic (optical) spectroscopy; experts in midwifery; labor and delivery nursing.	2	February 1, 2013.
Ophthalmic Devices Panel of the Medical Devices Advisory Committee—Ophthalmologists specializing in cataract and refractive surgery and vitreo-retinal surgery, in addition to vision scientists, optometrists, and biostatisticians practiced in ophthalmic clinical trials.	2	November 1, 2013.
Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee—Orthopedic surgeons (joint, spine, trauma, and pediatric); rheumatologists; engineers (biomedical, biomaterials, and biomechanical); experts in rehabilitation medicine, sports medicine, and connective tissue engineering; and biostatisticians.	3	September 1, 2013.
Radiological Devices Panel of the Medical Devices Advisory—Physicians with experience in general radiology, mammography, ultrasound, magnetic resonance, computed tomography, other radiological subspecialties and radiation oncology; scientists with experience in diagnostic devices, radiation physics, statistical analysis, digital imaging and image analysis.	2	February 1, 2013.
Device Good Manufacturing Practice Advisory Committee—Vacancies include a public representative and a government representative.	2	June 1, 2013.
National Mammography Quality Assurance Advisory Committee—Physicians, practitioners, or other health professionals whose clinical practice, research specialization, or professional expertise include a significant focus on mammography.	1	February 1, 2013.
Technical Electronic Product Radiation Safety Standards Advisory Committee—Vacancies include general public representative and a government representative.	2	January 1, 2014.

II. Functions

A. Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions of what the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area performs the following duties: (1) Advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, (2) advises on any possible risks to health associated with the use of devices, (3) advises on formulation of product development protocols, (4) reviews premarket approval applications for medical devices, (5) reviews guidelines and guidance documents, (6) recommends exemption of certain devices from the application of portions of the FD&C Act, (7) advises on the necessity to ban a device, and (8) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

The Medical Devices Dispute Resolution Panel provides advice to the Commissioner on complex or contested scientific issues between FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by FDA, and Agency guidance and policies. The panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to regular advisory panel proceedings or Agency decisions or actions.

B. National Mammography Quality Assurance Advisory Committee

The functions of the committee are to advise FDA on the following topics: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

C. Device Good Manufacturing Practice Advisory Committee

The functions of the committee are to review proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, manufacture, packaging, storage, installation, and servicing of devices, and to make recommendations regarding the feasibility and reasonableness of those proposed

regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

Section 520 of the FD&C Act, (21 U.S.C. 360j), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: (1) Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government; (2) two shall be representatives of the interests of the device manufacturing industry; (3) two shall be representatives of the interests of physicians and other health professionals; and (4) two shall be representatives of the interests of the general public.

D. Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Section 534(f) of the FD&C Act (21 U.S.C. 360kk(f)), as amended by the Safe Medical Devices Act of 1990, provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from governmental Agencies, including State or Federal Governments; five members from the affected industries; and five members from the general public, of which at least one shall be a representative of organized labor.

III. Qualifications

A. Panels of the Medical Devices Advisory Committee

Persons nominated for membership on the panels should have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

B. National Mammography Quality Assurance Advisory Committee

Persons nominated for membership should be physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise include a significant focus on mammography and individuals identified with consumer interests. Prior experience on Federal public advisory committees in the same or similar subject areas will also be considered relevant professional expertise.

The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

C. Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a health professional or officer or employee of any Federal, State, or local government should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

D. Technical Electronic Product Radiation Safety Standards Committee

Persons nominated should be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs at this time for this committee are listed in section I of this document. The term of office is up to 4 years, depending on the appointment date.

IV. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations must include a current, complete resume or curriculum vitae for each nominee, and their current business address and/or home address, telephone number, and email address if available. Nominations must specify the advisory panel(s) or advisory committee(s) for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: February 1, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–02793 Filed 2–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 meetings 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 Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Subcommittee.

Date: March 5–7, 2013.

Open: March 5, 2013, 4:00 p.m. to 4:30 p.m.

Agenda: To review procedures and discuss policy.