



# Regulatory Review

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February 14, 2011

## **New Web Portal Includes Health Indicator Data**

Last week, Health and Human Services (HHS) launched a new web portal known as the Health Indicators Warehouse, which provides nearly 1200 health indicators derived from over 170 different HHS data sources. According to a press announcement, the health indicator data sets and the web tools provided by the warehouse are expected to support technology development leading to a wide array of applications (apps) and data services.

Learn more about the Health Indicators Warehouse at <http://healthindicators.gov>.

## **FDA Issues Draft Guidance Regarding Powered Exam Gloves**

FDA made available a draft guidance entitled "[Recommended Warning for Surgeon's Gloves and Patient Examination Gloves that Use Powder](#)," which offers a recommended warning statement related to medical gloves that contain powder or use donning or dusting powder, specifically surgeon's gloves and patient examination gloves. The draft warning being considered by FDA, to be included on these products, reads as follows:

*Warning: Powdered gloves may lead to foreign body reactions and the formation of granulomas in patients. In addition, the powder used on gloves may contribute to the development of irritant dermatitis and Type IV allergy, and on latex gloves may serve as a carrier for airborne natural latex leading to sensitization of glove users.*

A public docket has been opened to collect public comments regarding the draft guidance. Comments are requested by April 25, 2011.

## **Electronic Health Record (EHR) Incentive Program List-Serv Announced**

CMS announced last week its new EHR Incentive Program [listserv](#), which aims to provide the most up-to-date information about the program to registered participants. According to CMS' web site, the agency will keep participants abreast of upcoming deadlines and provide answers to questions raised by eligible providers that may be of interest to the broader provider community. Interested stakeholders are encouraged to sign up.

## ***Upcoming Meetings***

The IOM announced several upcoming meetings and workshops, including [additional meetings on the determination of essential benefits](#), which are planned for the weeks ahead. The complete updated schedule is available on the [IOM web site](#).

The **Office of the National Coordinator for Health Information Technology (ONC) HIT Standards & Policy Committee and related workgroups** have announced their upcoming meeting schedule. Meeting dates can be found on the [ONC web site](#).

The **National Vaccine Advisory Committee (NVAC)** will hold a meeting on February 16, 2011 from 8:30 a.m. to 5 p.m., EDT, and February 17, 2011 from 8:30 am to 4 p.m., EDT. The meeting agenda will be posted at <http://www.hhs.gov/nvpo/nvac> at least one week prior to the meeting. Preregistration to attend or participate in the open public comment is required; send your name, organization and e-mail address to [nvpo@hhs.gov](mailto:nvpo@hhs.gov) or call 202-690-5566 to preregister.

HHS announced a meeting of the **Technical Advisory Panel on Medicare Trustee Reports** on February 17, 2011, 9 a.m. to 6 p.m. e.t., at HHS headquarters, 200 Independence Ave., SW., Washington, DC, 20201, Room TBA.

The **CDC's Task Force on Community Preventive Services** (Task Force) meeting will be held on Wednesday, February, 16, 2011 from 8:30 a.m. to 5:30 p.m. EST and Thursday, February 17, 2011 from 8:30 a.m. to 1 p.m. EST at the Atlanta Marriott Century Center, 2000 Century Blvd., NE., Atlanta, GA.

The **CDC's Advisory Committee on Immunization Practices** (ACIP) will meet on February 23, 2011, 8 a.m.-6 p.m. and February 24, 2011, 8 a.m.-5 p.m. at the CDC's, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent ``Oz'' Nelson Auditorium, Atlanta, Georgia 30333.

CMS will host a **Special Open Door Forum: Designing A Home Health Value-Based Purchasing Program** on Thursday, February 24, 2011 from 1:30-3:30pm ET. To participate, dial 1-800-837-1935 and reference Conference ID 37941789.

The **Vaccines and Related Biological Products Advisory Committee** will meet on February 25, 2011, between approximately 8:30 a.m. and 1:50 p.m. at the DoubleTree Hotel Bethesda and Executive Meeting Center, 8120 Wisconsin Ave., Bethesda, MD 20814. Background material will be available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm> at least 2 days prior to the meeting. To make a public comment orally or in writing, please refer to the [Federal Register meeting announcement](#).

The **Presidential Commission for the Study of Bioethical Issues** will conduct its fourth meeting on Monday, February 28, 2011, from 9 a.m. to approximately 4:30 p.m., and Tuesday, March 1, 2011, from 9 a.m. to approximately 12:30 p.m., at the St. Regis Hotel, Washington, DC, 923 16th and K Streets, NW., Washington, DC 20006.

The **Advisory Committee for Pharmaceutical Science and Clinical Pharmacology** will meet on March 2, 2011, from 7:15 a.m. to 3 p.m. at the Hyatt Regency Dallas at Reunion, Landmark Ballroom, 300 Reunion Blvd., Dallas, TX 75207. Background material will be available at least 2 days prior to the meeting at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. To make a public comment in writing or in person, please refer to the [Federal Register meeting announcement](#).

The **NIAID Town Hall Meeting** on the New National Institute of Allergy and Infectious Diseases (NIAID) Leadership Group for a Clinical Research Network on Infectious Diseases Other than HIV will be held on March 7, 2011 at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814. Register for the meeting at <http://www.blsmeetings.net/TownHallNIAID>.

The **FDA's Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee** will meet on March 8 and 9, 2011, from 8 a.m. to 6 p.m. to discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims. Interested persons may submit comments from February 7, 2011, through March 1, 2011. To learn more about making a comment in writing or in person, please refer to the [Federal Register meeting announcement](#).

NIH announced a meeting of the **Recombinant DNA Advisory Committee** on March 8, 2011, from 11 a.m. to 3:30 p.m. at the Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817. More information can be found at [http://oba.od.nih.gov/rdna\\_rac/rac\\_meetings.html](http://oba.od.nih.gov/rdna_rac/rac_meetings.html).

The FDA announced its **"Town Hall Discussion with the Director of the Center for Devices and Radiological Health and Other Senior Center Management,"** which will be held on March 10, 2011, from 8 a.m. to 12 noon CST at the Irving Convention Center at Las Colinas, 500 West Las Colinas Blvd., Irving, TX 75039.

The FDA announced a **public workshop** on March 15, 2011, from 8 a.m. to 5:30 p.m. at the FDA's White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31, Room 1503 (Salons B & C), Silver Spring, MD 20993, to solicit public feedback on select actions outlined in the Center for Devices and Radiological Health's (CDRH) **"Medical Device Innovation Initiative"** (report). FDA is seeking input on a number of identified challenges associated with incentivizing innovation, and the proposed solutions. In addition, the agency requests comments on the Innovation Pathway proposed under the initiative. Submit either [electronic](#) or written comments on the report by April 11, 2011. [Register](#) for this event by 5 p.m. on March 4, 2011.

The **FDA's Anti-Infective Drugs Advisory Committee** will meet on April 5, 2011, from 8:30 a.m. to 4 p.m. at the Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The committee will discuss new drug application (NDA) 20-1699, for FIDAXOMICIN tablets, submitted by Optimer Pharmaceuticals, Inc., for the requested indication of treatment of adults with Clostridium difficile infection (CDI), also known as Clostridium difficile-associated diarrhea (CDAD), and prevention of recurrences.

An FDA public "industry exchange" workshop entitled **"The Future of Medical Products Regulation: Ensuring Safety and Integrity in a Global Market,"** will be held on June 20 and 21, 2011, from 8 a.m. to

5 p.m. at the Marriott Dallas/Plano at Legacy Town Center, Plano, Texas, 7120 Dallas Pkwy., Plano, Texas 75024.

The [NIH's National Advisory Allergy and Infectious Diseases Council](#) and related subcommittees will hold a series of meetings on September 19, 2011 at the National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892. The open meetings are as follows:

*National Advisory Allergy and Infectious Diseases Council*

Open: 10:30 a.m. to 11:40 a.m. in Conference Rooms E/1E2

Agenda: Report from the Institute Director

*Allergy, Immunology and Transplantation Subcommittee*

Open: 1 p.m. to adjournment in Conference Room D

Agenda: Report from the Division Director and other staff

*Acquired Immunodeficiency Syndrome Subcommittee*

Open: 1 p.m. to adjournment in Conference Rooms E1/E2

Agenda: Program advisory discussions and reports from division staff

*Microbiology and Infectious Diseases Subcommittee*

Open: 1 p.m. to adjournment in Conference Rooms F1/F2

Agenda: Report from the Division Director and other staff

An agenda and additional information will be available at <http://www.niaid.nih.gov/facts/facts.htm>.

NIH's [National Advisory Council on Minority Health and Health Disparities](#) will hold an open public meeting on February 22, 2011 at the Marriott Bethesda, 5151 Pooks Hill Road, Bethesda, MD 20814, from 9:30 a.m. to 5 p.m. The agenda will include opening remarks, administrative matters, Director's Report, NIH Health Disparities update, and other business of the Council.

***Opportunities for Public Comment***

[Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR section 423.505 \(CMS-10185\)](#): Comments due February 15, 2011 11:59 PM ET

[Medicare Program: Emergency Medical Treatment and Labor Act: Applicability to Hospital and Critical Access Hospital Inpatients and Hospitals with Specialized Capabilities](#): Comments due February 22, 2011 11:59 PM ET

The FDA is reopening the [comment period](#) for the notice of public meeting entitled Generic Drug User Fee; Public Meeting; Request for Comments. Submit either [electronic](#) or written comments by February 23, 2011.

[Medicare Program: Development of a Recovery Audit Contractor Program for the Medicare Part C and D Programs](#): Comments due February 25, 2011 11:59 PM ET

[Medicare Program: Hospital Inpatient Value-Based Purchasing Program](#): Comments due March 8, 2011 11:59 PM ET

The FDA announced the availability for [public comment](#) of a document for The National Antimicrobial Resistance Monitoring System (NARMS) entitled ``NARMS Strategic Plan 2011-2015." Submit either [electronic](#) or written comments by March 25, 2011.