



Regulatory Review

February 7, 2011

National Coordinator for Health Information Technology Resigns

David Blumenthal, MD, MPP, National Coordinator for Health Information Technology, announced last week that he would step down from his post as the head of ONC to resume a career in academia. Blumenthal has served in this role since March 2009, leading a number of efforts including the development of the meaningful use criteria.

Medicare Quality Improvement Organization's to Field Beneficiary "Quality of Care" Complaints

The Centers for Medicare and Medicaid Services (CMS) issued a [proposed rule](#) that expands the Medicare-participating providers and suppliers that must provide Medicare beneficiaries written notice about their right to contact a Medicare Quality Improvement Organization (QIO) with concerns about the quality of care they receive under the Medicare program.

The following care settings are impacted by this proposal:

- Clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language-pathology services
- Comprehensive outpatient rehabilitation facilities
- Critical access hospitals
- Home health agencies
- Hospices
- Hospitals
- Long-term care facilities
- Ambulatory Surgical Centers
- Portable x-ray services
- Rural health clinics and Federally Qualified Health Centers

CMS will accept comments on the proposed rule until April 3, 2011.

Recommendations for Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surgical Care Survey

Analyses conducted over the last year by the AHRQ CAHPS Consortium prompted a recommendation that users of the surgical CAHPS, which was designed to assess patients' experiences with surgeons and their staff, report on the following composite measures:

- Information to help you prepare for surgery

- How well surgeon communicates with patients before surgery
- Surgeon's attentiveness on day of surgery
- Information to help you recover from surgery
- How well surgeon communicates with patients after surgery
- Helpful, courteous, and respectful staff at surgeon's office

Additionally, users should report on the following patient rating:

- Patients' rating of the surgeon on a scale of 0 to 10

Learn more about the CAHPS Surgical Care survey at

https://www.cahps.ahrq.gov/content/products/sc/PROD_SC_Surgical_Care.asp.

Institute of Medicine Seeks Input on Health Information Technology

Last week, the Institute of Medicine (IOM) Committee on Patient Safety and Health Information Technology announced that it had opened a comment period for the public to provide input regarding experiences with health information. The committee is looking for comment on the following:

- Any occurrences of how your health IT system has impacted patient safety (positively or negatively).
- Any "near-misses" in which your health IT system could have negatively impacted patient safety if the near-miss had not been caught in time.
- Internal or external reporting mechanisms you use to communicate negative safety concerns.

Submit comments to hitsafety@nas.edu by February 18. Please note that responses to the questions are a matter of public record.

Draft Technology Assessment on Health Risk Appraisal Released

CMS released a [draft technology assessment](#) on Health Risk Appraisals (HRAs) aimed at describing key features of HRAs and examining how they apply to the Medicare population. The Agency for Healthcare Research and Quality (AHRQ), in collaboration with the McMaster University Evidence-based Practice Center conducted the study, researching 111 unique studies on the topic of HRAs. Comment on the draft at <http://www.ahrq.gov/clinic/ta/tareview.htm>.

IOM Report on Future Directions Available

Last week, the Institutes of Medicine (IOM) issued a [report](#), including several recommendations, related to the future of health care in the US. By way of background, the Agency for Healthcare Research and Quality (AHRQ) requested a review of its past reports, the National Healthcare Quality Report (NHQR)

and National Healthcare Disparities Report (NHDR), by the IOM. Specifically, the IOM was asked to “provide a vision so that the reports can contribute to advancing the quality of health care for all persons in the United States.” A newly formed IOM committee addressed the request, concluding that “while the [AHRQ] reports alone will not improve the quality of health care, they can make a compelling case for closing the gap between current performance levels and recommended standards of care.”

Recommendations from the committee are as follows:

- Align the content of the reports with nationally recognized priority areas for quality improvement to help drive national action.
- Select measures that reflect health care attributes or processes that are deemed to have the greatest impact on population health.
- Affirm through the contents of the reports that achieving equity is an essential part of quality improvement.
- Increase the reach and usefulness of AHRQ's family of report-related products.
- Revamp the presentation of the reports to tell a more complete quality improvement story.
- Analyze and present data in ways that inform policy and promote best-in-class achievement for all actors.
- Identify measure and data needs to set a research and data collection agenda.

AHRQ Effective Health Care Program Draft Research Review Open for Comment

AHRQ posted a [draft research review](#) entitled, Diagnosis and Comparative Effectiveness of Treatments for Urinary Incontinence in Adult Women. The draft is open for comment until March 2.

Nominations Being Accepted for Appointment to the National Vaccine Advisory Committee

The National Vaccine Advisory Committee (NVAC) will accept nominations for appointment to the committee until 5 p.m. EDT on April 4, 2011. Send nominations to Bruce G. Gellin, M.D., M.P.H., Executive Secretary, NVAC, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue, SW., Room 715-H, Hubert H. Humphrey Building, Washington, DC 20201.

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](#).

CMS will host a **Town Hall meeting regarding the Physician Quality Reporting System (PQRS)** on February 9, 2011. CMS anticipates posting an audio download and/or transcript of the Town Hall meeting on the CMS Web site, <http://www.cms.hhs.gov/PQRI>, following the meeting. For more information, please see the Federal Register meeting notice posted at <http://edocket.access.gpo.gov/2010/pdf/2010-31301.pdf>. Details about this meeting and past meetings can be obtained by visiting [CMS' PQRS dedicated web page](#).

HHS' [National Committee on Vital and Health Statistics \(NCVHS\), Full Committee Meeting](#) will be held on February 9, 2011, 9 a.m.-2:30 p.m. February 10, 2011, 10 a.m.-3 p.m. at the St. Regis Hotel, 923 16th Street, NW., Washington, DC 20006.

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 or call 202-690-5566 to preregister.

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.

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 **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 orally or in person, please refer to the [Federal Register meeting announcement](#).

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.

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,

Opportunities for Public Comment

[Children's Health Insurance Program \(CHIP\) \(CMS-21 and CMS-21B\)](#): Comments due February 8, 2011 11:59 PM ET

[Meetings: Development of Additional Imaging Efficiency Measures for Use in Hospital Outpatient Quality Data Reporting Program](#): Comments due February 10, 2011 11:59 PM ET

[Implementation of Section 2695 \(42 U.S.C. 300ff-131\) of Public Law 111-87: Infectious Diseases and Circumstances Relevant to Notification Requirements](#): Comments due February 11, 2011 11:59 PM ET

[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.