



# Regulatory Review

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August 15, 2011

## **GAO Issues Report on Medicare Physician Feedback Program**

Last week, the Government Accountability Office (GAO) issued a report, [Medicare Physician Feedback Program: CMS Faces Challenges with Methodology and Distribution of Physician Reports](#), describing difficulties the agency is facing with the program. GAO is recommending that CMS use methodological approaches that increase physician eligibility for reports, statistically analyze the impact of its methodological decisions on report reliability, identify and address factors that may have prevented physicians from reading reports, and obtain input from a sample of physicians on the usefulness and credibility of reports.

## **HHS, Treasury Announce Proposed Rules, Grants for Affordable Insurance Exchanges**

The Departments of Health and Human Services (HHS) and Treasury posted three proposed rules related to its Affordable Insurance Exchanges initiative, which was mandated under the Affordable Care Act (ACA). The three rules focus on access to coverage for consumers and small business, health insurance premium tax credit, and Medicaid eligibility. HHS also awarded \$185 million to 13 States and the District of Columbia to help them build Affordable Insurance Exchanges, according to an agency announcement. The rules will be published in the Federal Register on August 17, 2011.

## **CMS' Announces Medicaid Emergency Psychiatric Demo**

A new Medicaid Emergency Psychiatric Demonstration designed to provide states with more flexibility and resources to care for Medicaid beneficiaries with mental illnesses was recently announced by CMS. According to the agency, the demonstration provides up to \$75 million in funding to states over three years, as authorized by the Affordable Care Act, to help care for Medicaid patients (aged 21 through 64) with psychiatric emergencies, in private inpatient psychiatric facilities with 17 or more beds, also known as institutions for mental diseases (IMDs).

CMS is now accepting applications to participate in this demonstration from interested State Medicaid Directors. States will be selected competitively based on their application proposals.

Learn more on [CMS' dedicated web page](#).

## **CMS and NQF to Co-host Patient Safety Webinar: *Decreasing Surgical Site Infections***

The Centers for Medicare and Medicaid Services (CMS) Innovation Center, as part of its Partnership for Patients initiative, announced the fifth in a series of webinars focused on patient safety. The upcoming

webinar, co-hosted with the National Quality Forum (NQF), will take place on August 16, 2011 at 1:00 PM and feature the following speakers:

**Frank Opelka, MD, FACS**, Chair of Surgical Quality Alliance, Louisiana State University, NPP Partner

**Dale Bratzler, DO, MPH**, Professor and Associate Dean, University of Oklahoma, College of Public Health

**Jean Rexford**, Executive Director, Connecticut Center for Patient Safety

**Vincent Kerr, MD**, President, Care Solutions, United Healthcare

**Bernie Rosof**, NPP Co-Chair (Moderator)

[Registration](#) is still open.

## HHS Announces Healthcare-Associated Infections Webinar

HHS announced its first event in the [Healthy People 2020](#) webinar series, which will focus on healthcare-associated infections (HAIs). The webinar will be held Tuesday, August 16, 2011 from 12:00 pm to 1:30 pm EDT. Meeting objectives include raise awareness of the burden of HAIs, providing an opportunity for leaders in the field of HAIs to discuss policies and strategies to prevent central-line associated bloodstream infections (CLABSI) and methicillin-resistant *Staphylococcus aureus* (MRSA) infection, providing examples of outstanding leadership in CLABSI prevention, and stimulating further action to reduce HAIs in healthcare facilities, public health organizations, and local communities nationwide.

[Register](#) now to attend.

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## Opportunities to Submit Nominations

[HHS Chronic Fatigue Syndrome Advisory Committee \(CFSAC\)](#)

[HHS National Biodefense Science Board](#)

[FDA CDER public advisory committees](#)

[FDA Medical Imaging Drugs Advisory Committee](#)

[BHHS Board of Scientific Counselors](#)

[Advisory Committee on Immunization Practices \(ACIP\)](#)

Nominations due by August 17, 2011

Nominations due by August 19, 2011

Nominations due by August 29, 2011

Nominations due by September 27, 2011

Nominations due by October 31, 2011

Nominations due by November 18, 2011

## Upcoming Federal Regulatory Meetings

### Agency for Healthcare Research and Quality (AHRQ)

**Guidelines International Network (G-I-N) Conference 2011:** August 28-31, 2011, Seoul, Korea. [Register](#) online.

2011 Annual Conference: [Leading Through Innovation and Collaboration](#): September 18-21, Bethesda North Marriott Convention Center in Bethesda, MD.

## ***Centers for Disease Control and Prevention (CDC)***

**Clinical Laboratory Improvement Advisory Committee (CLIAC)**: August 31, 2011 from 8:30 a.m.-5 p.m. and September 1, 2011 from 8:30 a.m.-12 p.m., CDC, 1600 Clifton Road, NE., Tom Harkin Global Communications Center, Building 19, Room 232, Auditorium B, Atlanta, Georgia 30333.

**Advisory Committee on Breast Cancer in Young Women (ACBCYW)**: 9 a.m.-5 p.m., September 21, 2011, 8 a.m.-4:30 p.m., September 22, 2011, 8 a.m.-2:30 p.m., and September 23, 2011. CDC, Building 19, Auditorium B, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

## ***Centers for Medicare and Medicaid Services (CMS)***

The CMS announced the following Special Open Door Forums and Listening Sessions:

- ***Home Health, Hospice, and DME Open Door Forum***: Wednesday, August 17th. Streaming Open Door Forums are available on [www.cms.gov/LIVE/](http://www.cms.gov/LIVE/).
- ***Hospital, Hospital Quality Open Door Forum***: Wednesday, August 24, 2011 from 2pm-3pm ET. To participate dial 1-800-837-1935 Conference ID 83512247.

**Accountable Care Organization Accelerated Development Learning Sessions**: September 15th and 16th, 2011, Hyatt Regency San Francisco Airport at 1333 Bayshore Highway, Burlingame, CA 94010. [Register](#) online.

**Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)**: Wednesday, September 21, 2011 from 7:30 a.m. until 4:30 p.m., CMS, 7500 Security Boulevard, Baltimore, MD 21244. [Registration](#) is available online.

## ***Food and Drug Administration (FDA)***

**Development of a Generic Drug User Fee Program**: August 25, 2011, from 2 to 3:30 p.m., FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993-0002.

**General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee**: August 30 and 31, 2011, from 8 a.m. to 6 p.m., Hilton Washington DC North/Gaithersburg, Ballroom, 620 Perry Pkwy., Gaithersburg, MD. [Docket](#) for comments opened until August 26, 2011.

**Workshop: FDA/NHLBI/NSF Workshop on Computer Methods for Medical Devices**: September 7, 8, and 9, 2011, from 9 a.m. to 5 p.m. An optional FDA Microstructure Modeling session will be held from 1 to 5 p.m. on September 6, 2011, FDA White Oak Campus, 10903 New Hampshire Ave, Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. [Register](#) by August 23, 2011.

**Cardiovascular and Renal Drugs Advisory Committee:** September 8, 2011, from 8 a.m. to 5 p.m., Marriott Inn and Conference Center, University of Maryland University College (UMUC), The Ballroom, 3501 University Blvd. East, Adelphi, MD 20783-7998.

**Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee:** September 8 and 9, 2011, from 8 a.m. to 6 p.m., Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879.

**Workshop:** **Effects of ischemia/reperfusion injury (IRI) on outcomes in kidney transplantation:** September 8, 2011, from 9 a.m. to 6 p.m. and on September 9, 2011, from 8 a.m. to 3 p.m., Crowne Plaza, 8777 Georgia Ave., Silver Spring, MD 20910.

**Workshop:** **Mobile Medical Applications Draft Guidance:** September 12 and 13, 2011, FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Comments accepted until October 19, 2011.

**Workshop:** **Unique Device Identification for Postmarket Surveillance and Enforcement:** September 12, 2011, from 1 to 5 p.m. and on September 13, 2011, from 9 a.m. to 5 p.m., Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Road, Bethesda, MD 20852 and via web conference. [Register online. Submit electronic and written comments](#) by October 13, 2011.

**Arthritis Advisory Committee:** September 13, 2011, from 8 a.m. to 5:30 p.m., FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002.

**Workshop:** **Quarantine Release Errors in Blood Establishments:** September 13, 2011, from 8:30 a.m. to 5 p.m., Universities at Shady Grove Conference Center, 9630 Gudelsky Dr., Rockville, MD 20850-5820.

**Oncologic Drugs Advisory Committee:** September 14, 2011, from 8 a.m. to 5 p.m., FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002.

**Workshop:** **13th International Paul-Ehrlich-Seminar: Allergen Products for Diagnosis and Therapy: Regulation and Science:** September 14-17, 2011 at the Hyatt Regency Washington on Capitol Hill, 400 New Jersey Ave., NW., Washington, DC 20001. [Register](#) online.

**Workshop:** **The Development and Evaluation of Next-Generation Smallpox Vaccines:** September 16, 2011, from 8 a.m. to 5:30 p.m., Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

**Recommendations Proposed in Institute of Medicine Report:** September 16, 2011, from 8:30 a.m. to 5 p.m., Silver Spring Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. Comments accepted until September 30, 2011.

**Vaccines and Related Biological Products Advisory Committee:** September 20, 2011, from 8 a.m. to approximately 5:15 p.m., Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20977. The meeting will also be [web cast](#).

**Pediatric Advisory Committee:** Thursday, September 22, 2011, from 2 p.m. to 6:30 p.m. and on Friday, September 23, 2011, from 8 a.m. to 5:30 p.m., Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

**Town Hall Discussion with the Director of the Center for Devices and Radiological Health and Other Senior Center Management:** Thursday, September 22, 2011, from 8 a.m. to 12 noon PDT., Embassy Suites Hotel, San Francisco Airport, 250 Gateway Blvd., South San Francisco, CA 94080. [Register](#) online.

**Cellular, Tissue and Gene Therapies Advisory Committee:** September 22 and 23, 2011, from 8 a.m. to 5 p.m., Hilton Hotel, Washington, DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20977.

**Workshop: CDER's approach to addressing drug shortages:** September 26, 2011, from 8:30 a.m. to 4:30 p.m., FDA, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 B and C (Great Room), Silver Spring, MD 20993. [Register](#) by September 19, 2011.

**Advancing Regulatory Science for Highly Multiplexed Microbiology/Medical Countermeasure Devices:** October 13, 2011; Via webcast or in-person, FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993-0002. [Register](#) and/or submit [comments](#) by September 13, 2011.

**Immunology Devices Panel of the Medical Devices Advisory Committee:** October 14, 2011, from 8 a.m. to 6 p.m.; Hilton Washington DC North/Gaithersburg, salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

**Peripheral and Central Nervous System Drugs Advisory Committee:** October 17, 2011, from 8 a.m. to 5 p.m., FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

**Workshop: Discussion about measurement principles for clinical outcome assessments (COAs) for use in clinical trials for new drugs:** October 19, 2011, from 8:30 a.m. to 5 p.m., FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

**Clinical Investigator Training Course:** November 7 and 8, 2011, from 8 a.m. to 5 p.m. and on November 9, from 8 a.m. to 3:00 p.m., National Labor College, 10000 New Hampshire Avenue, Silver Spring, Maryland 20903. [Registration](#) ends November 28, 2011.

## ***Health Resources and Services Administration (HRSA)***

**[Negotiated Rulemaking Committee on Designation of Medically Underserved Populations \(MUPs\) and Health Professional Shortage Areas \(HPSAs\)](#)**: August 16, 2011, 1 p.m.-5 p.m.; August 17, 2011, 1 p.m.-5 p.m. via webinar.

**[Advisory Committee on Organ Transplantation \(ACOT\)](#)**: August 23, 2011, 1 p.m. to 5 p.m. and August 24, 2011, 8:30 a.m. to 5 p.m., Georgetown University Hotel and Conference Center, 3800 Reservoir Road, NW, Washington, DC 20057.

**[Advisory Commission on Childhood Vaccines \(ACCV\)](#)**: September 1, 2011, 1 p.m. to 5 p.m. EDT, September 2, 2011, 9 a.m. to 12 p.m. EDT, FDA Parklawn Building Conference Room 10-65, 5600 Fishers Lane, Rockville, MD 20857, and via conference call at 1-800-369-3104. Use Leader's Name: Dr. Geoffrey Evans and Password: ACCV.

## ***National Institutes of Health (NIH)***

**[National Advisory Environmental Health Sciences Council](#)**: September 1, 2011, 8:30 a.m. to 2 p.m., Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

**[National Diabetes and Digestive and Kidney Diseases Advisory Council](#)**: September 7, 2011 from 8:30 a.m. to 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

**[National Advisory Council for Biomedical Imaging and Bioengineering \(NACBIB\)](#)**: September 12, 2011 from 9 a.m. to 1 p.m., Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room (2nd Level), Bethesda, MD 20817.

**[National Advisory General Medical Sciences Council](#)**: September 16, 2011, 8 a.m. to Adjournment, National Institutes of Health, Natcher Building, Conference Rooms E1 & E2, 45 Center Drive, Bethesda, MD 20892.

**[National Advisory Allergy and Infectious Diseases Council](#)**: September 19, 2011, National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

**[National Advisory Council for Nursing Research](#)**: September 20, 2011, 1 p.m. to 5 p.m., National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.

**[National Advisory Council on Aging](#)**: September 21, 2011, 8 a.m. to 1:30 p.m., National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892.

**[Interagency Breast Cancer and Environmental Research Coordinating Committee](#)**: September 26-27, 2011, 8:30 a.m. to 5 p.m., Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

**Board of Scientific Counselors, Lister Hill Center for Biomedical Communications:** September 26, 2011, 9 a.m. to 11:30 a.m. and September 27, 2011, 10 a.m. to 11:15 a.m.; National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

**International Workshop on Alternative Methods for Human and Veterinary Rabies Vaccine Testing: State of the Science and Planning The Way Forward:** October 11-13, 2011, 8:30 a.m. to 6 p.m., Center for Veterinary Biologics at the USDA National Centers for Animal Health, 1920 Dayton Avenue, Ames, Iowa 50010.

**Interagency Breast Cancer and Environmental Research Coordinating Committee:** October 12, 2011, October 26, 2011, and November 10, 2011 from 1 p.m. to 3 p.m., and October 11, 2011, November 11, 2011, and December 6, 2011 from 3 p.m. to 5 p.m., Via conference call. Register by [email](#) 10 days in advance of meeting date.

**State-of-the-Science Conference on the Role of Active Surveillance in the Management of Men With Localized Prostate Cancer:** December 5-7, 2011, NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. [Register](#) online.

### ***Office of the National Coordinator (ONC)***

**Office of the National Coordinator for Health Information Technology (ONC) HIT Standards & Policy Committee and related workgroups** meet almost daily on various topics. Visit the ONC web site for the full schedule. Most meetings are held both in-person and via webcast.

### ***Other Meetings***

**National Committee on Vital and Health Statistics, Full Committee:** August 26, 2011, 3 p.m.-5 p.m., E.D.T., via Teleconference. Dial-In Number: 1-877-939-9305, participant code is 4431134.

**Advisory Committee on Minority Health (ACMH):** Monday, August 29, 2011 from 9 a.m. to 5 p.m. and Tuesday, August 30, 2011 from 9 a.m. to 1 p.m., Doubletree Hotel, 1515 Rhode Island Ave., NW, Washington, DC 20005.

**Presidential Commission for the Study of Bioethical Issues:** Monday and Tuesday, August 29 and 30, 2011; The Ritz-Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

**Board of Regents of the National Library of Medicine:** October 4-5, 2011, 9 a.m. to 4:30 p.m. and 9 a.m. to 12 p.m., National Library of Medicine, Building 38, 2nd Floor, Board Room, 8600 Rockville Pike, Bethesda, MD 20892.

## Opportunities for Public Comment

### Federal Rules and Regulations

| Item  | Effective Date  | Comments Due  |
|---|-----------------|---|
| <a href="#">Effective Date of Requirement for Premarket Approval for an Implantable Pacemaker Pulse Generator</a>   |                 | October 25, 2011  |
| <a href="#">Effective Date of Requirement for Premarket Approval for a Pacemaker Programmer</a>   |                 | Change in classification, August 19, 2011; Comments, November 2, 2011 |
| <a href="#">Medical Devices; General and Plastic Surgery Devices; Classification of the Focused Ultrasound Stimulator System for Aesthetic Use; Final Rule</a>  | August 19, 2011 |   |
| <a href="#">Cardiovascular Devices; Classification of Electrocardiograph Electrodes</a>   | August 22, 2011 |   |
| <a href="#">Effective Date of Requirement for Premarket Approval for Cardiovascular Permanent Pacemaker Electrode</a>   |                 | Change in classification, August 23, 2011; Comments, November 7       |
| <a href="#">Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator</a>  |                 | Change in classification, August 23, 2011; Comments, November 7       |
| <a href="#">Medical Devices; Neurological Devices; Classification of Repetitive Transcranial Magnetic Stimulation System</a>  | August 25, 2011 |   |
| <a href="#">Medicare Program; Clinical Laboratory Fee Schedule: Signature on Requisition</a>  |                 | August 29, 2011   |
| <a href="#">Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012; Proposed Rule</a>  |                 | August 30, 2011   |
| <a href="#">Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Provider Agreement Regulations on Patient Notification Requirements; Proposed Rule</a> |                 | August 30, 2011   |
| <a href="#">Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, End-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; Ambulance Fee Schedule; and Durable Medical Equipment; Proposed Rule</a>                      |                 | August 30, 2011   |
| <a href="#">World Trade Center Health Program Requirements for the Addition of New WTC-Related Health Conditions</a>  |                 | August 30, 2011   |

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|---|-----------------|--------------------|
| <a href="#">World Trade Center Health Program Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement; Interim Final Rule</a>   | July 1, 2011    | August 30, 2011    |
| <a href="#">Medicare Program; Evaluation Criteria and Standards for Quality Improvement Program Contracts (10th Statement of Work)</a>  | August 1, 2011  | September 2, 2011  |
| <a href="#">Medicaid and Children's Health Insurance Programs; Disallowance of Claims for FFP and Technical Corrections</a>   |                 | September 2, 2011  |
| <a href="#">Administrative Simplification: Adoption of Operating Rules for Eligibility for a Health Plan and Health Care Claim Status Transactions; Interim Final Rule</a>  | June 30, 2011   | September 6, 2011  |
| <a href="#">Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012</a>   |                 | September 6, 2011  |
| <a href="#">Medicare and Medicaid Programs; Quarterly Listing of Program Issuances- January Through March 2011 and Proposal for Future Notices</a>  |                 | September 7, 2011  |
| <a href="#">Immunology and Microbiology Devices; Reclassification of the Herpes Simplex Virus Serological Assay Device</a>  |                 | September 8, 2011  |
| <a href="#">Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health</a>  |                 | September 12, 2011 |
| <a href="#">Removal of Certain Requirements Related to the Prescription Drug Marketing Act; Opportunity for Public Comment</a>  |                 | September 12, 2011 |
| <a href="#">Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms</a>   |                 | September 15, 2011 |
| <a href="#">Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use</a>   |                 | September 15, 2011 |
| <a href="#">Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program; Proposed Rule</a>   |                 | September 16, 2011 |
| <a href="#">Amendments to Sterility Test Requirements for Biological Products</a>   |                 | September 19, 2011 |
| <a href="#">Metadata Standards To Support Nationwide Electronic Health Information Exchange</a>   |                 | September 23, 2011 |
| <a href="#">Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators</a>  |                 | September 26, 2011 |
| <a href="#">Reprocessing of Reusable Medical Devices</a>  |                 | September 26, 2011 |
| <a href="#">Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans</a>   |                 | September 28, 2011 |
| <a href="#">Patient Protection and Affordable Care Act; Standards Related to Reinsurance, Risk Corridors and Risk Adjustment; Proposed Rule</a>   |                 | September 28, 2011 |
| <a href="#">Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act</a>  | August 1, 2011  | September 30, 2011 |
| <a href="#">Medicare Program; Hospice Wage Index for Fiscal Year 2012; Final Rule</a>   | October 1, 2011 |                    |
| <a href="#">Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2012; Changes in Size and Square Footage of Inpatient Rehabilitation Units and Inpatient Psychiatric Units; Final Rule</a> | October 1, 2011 |                    |
| <a href="#">Medicare Program; Prospective Payment System and Consolidated Billing</a>   | October 1,      |                    |

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|---|------|-----------------|
| <a href="#">for Skilled Nursing Facilities for FY 2012; Final Rule</a>  | 2011 |                 |
| <a href="#">NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012: Proposed Additions and Deletions to the NIOSH Hazardous Drug List</a> |      | October 3, 2011 |

### **FDA Guidance Documents**

| <b>Item</b>  | <b>Comments Due</b> |
|--|---------------------|
| <a href="#">Guidance for Industry: Bar Code Label Requirements--Questions and Answers</a>  | Anytime             |
| <a href="#">Guidance on E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions</a>   | Anytime             |
| <a href="#">Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays</a>   | Anytime             |
| <a href="#">Draft Guidance for Industry; Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology</a>   | August 15, 2011     |
| <a href="#">Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics</a>   | August 16, 2011     |
| <a href="#">Draft Guidance for Industry on Enforcement Policy for Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application</a>  | August 16, 2011     |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus Species Detection</a>  | August 16, 2011     |
| <a href="#">Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions</a>   | August 30, 2011     |
| <a href="#">Draft Guidance on Q11 Development and Manufacture of Drug Substances</a>   | September 1, 2011   |
| <a href="#">Draft Guidance for Industry and FDA Staff on In Vitro Companion Diagnostic Devices</a>   | September 12, 2011  |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Methicillin-Resistant Staphylococcus Aureus for Culture-Based Devices</a>   | September 13, 2011  |
| <a href="#">Draft Guidances for Industry and Food and Drug Administration Staff: Classification of Products as Drugs and Devices and Additional Product Classification Issues; and Interpretation of the Term "Chemical Action" in the Definition of Device Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act</a> | September 19, 2011  |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering To Optimize Medical Device Design</a>   | September 19, 2011  |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose Suspend Device Systems</a>   | September 20, 2011  |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff; Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices</a>   | October 11, 2011    |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff; Mobile Medical Applications</a>  | October 19, 2011    |

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|--|------------------|
| <a href="#">Draft Guidance for Industry: Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma</a> | October 20, 2011 |
| <a href="#">Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device</a>                       | October 25, 2011 |

### **Other**

[Modifications to the List of Recognized Standards, Recognition List Number: 027](#): Submit comments at any time.

The CDC announced the availability of the “First Periodic Review of Scientific and Medical Evidence Related to Cancer for the World Trade Center Health Program” The Review can be found at: <http://www.cdc.gov/niosh/topics/wtc/prc/prc-1.html>.

The CMS issued a request for applications for Pioneer ACOs. Letters of intent must be submitted by June 30, 2011 as described on the Innovation Center Web site <http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco>. Applications must be received on or before August 19, 2011.

The NIH Office of Biotechnology Activities (OBA) has opened a [comment period for Appendix B of the NIH Guidelines](#). [Comments](#) should be submitted by September 9, 2011.

The FDA announced the availability of the [standard operating procedure \(SOP\) for “Notice to Industry” Letters](#). [Submit information and either electronic or written comments](#) by September 19, 2011.

The FDA announced the availability of a draft report for comments entitled, “[Identifying CDER's Science and Research Needs](#).” Comments should be submitted by September 26, 2011.

The FDA announced the availability of a draft report for comment entitled, “[Medical Devices and the Public's Health, The FDA 510\(k\) Clearance Process at 35 Years](#).” Comments should be submitted by September 30, 2011.

### **Noteworthy Items**

HHS announced that it has renewed the charter for the [Presidential Advisory Council on HIV/AIDS](#).

HHS announced the re-charter of the [National Vaccine Advisory Committee](#).

CMS has extended the deadline for submitting supporting information to request a temporary code under the [Treatment of Certain Complex Diagnostic Laboratory Tests Demonstration](#). The new deadline is September 6, 2011.

[Medical Device User Fee Rates for Fiscal Year 2012](#): Effective October 1, 2012.

[Prescription Drug User Fee Rates for Fiscal Year 2012](#): Effective October 1, 2012.