

August 22, 2011

## NCHS Data Brief Presents Findings on Use of Non-Physician Practitioners

The Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) released a new Data Brief based on data from the National Ambulatory Medical Care Survey, 2009 related to non-physician practitioners. The CDC has describe the employment of several NPPs, including nurse practitioners, certified nurse midwives, and physician assistants, as the expansion of care delivered by these providers is often cited as a solution to the predicted surge in demand for health care services and calls for an examination of current reliance on these providers.

The following are highlights from the data brief:

- In 2009, 49.1% of office-based physicians were in practices that used nurse practitioners (NPs), certified nurse midwives (CNMs), or physician assistants (PAs).
- Primary care physicians were more likely to have NPs, CNMs, or PAs than physicians of other specialties.
- Physicians in larger and multi-specialty group practices were more likely to work with NPs, CNMs, or PAs than those in smaller and single-specialty group practices.
- Older physicians were less likely than middle-aged physicians to be in practices that had NPs, CNMs, or PAs.
- Physicians in practices with a higher proportion of revenue from Medicaid and a lower proportion from Medicare were more likely to work with NPs, CNMs, or PAs.

## Efforts Made to Expand Health IT Infrastructure in Rural America

The Office of the National Coordinator for Health Information Technology (ONCHIT) and the Health Resources and Services Administration (HRSA) announced collaborative efforts to work with the U.S. Department of Agriculture (USDA) to ensure that rural health care providers can use USDA's Rural Development grants and loans to support the acquisition of health IT infrastructure. According to an announcement, HHS and USDA signed a Memorandum of Understanding (MOU) linking rural hospitals and clinicians to existing capital loan programs that enable them to purchase software and hardware needed to implement health IT.

The announcement identified two key USDA Rural Development programs that can help expand health IT infrastructure in rural America, which are listed below.

**Community Facilities Program**, which provides direct and guaranteed loans as well as grants for community facilities projects in rural areas. This program may help offset the costs of electronic health records implementation for rural health care providers.

**Distance Learning and Telemedicine Grant Program**, which may provide grants to help bring telemedicine services to rural communities.

Learn more about these efforts at [healthit.hhs.gov](http://healthit.hhs.gov).

## Newly Released CDC Publications and Upcoming Webinars

The CDC released its [Public Health Emergency Response Guide for State, Local, and Tribal Public Health Directors](#), which is an all-hazards reference tool for health professionals who are responsible for initiating the public health response during the first 24 hours (i.e., the acute phase) of an emergency or disaster. According to CDC, this tool provides useful information on the activation and integration of a jurisdiction's public health system into the existing emergency response structure during the acute phase of an incident.

CDC also announced the following webinars for Emergency and Crisis Communicators, Clinicians, Health Educators, and Public Information Officers:

[Ethical Considerations for Emergency Preparedness](#): Wednesday, August 24 at 3:00 PM

[Expanding Capacity and Capability: Inclusion of Participatory Culture, Technology and Open Data in Crisis Management](#): Wednesday, August 24 at 3:00 PM

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## Opportunities to Submit Nominations

[A CDER public advisory committees](#)

Nominations due by August 29, 2011

[A Medical Imaging Drugs Advisory Committee](#)

Nominations due by September 27, 2011

[HS Board of Scientific Counselors](#)

Nominations due by October 31, 2011

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

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.

[ICD-9-CM Coordination and Maintenance Committee Meeting](#): September 14, 2011, 9 a.m.-5:30 p.m., Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland 21244.

[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:

**Hospital Quality Open Door Forum:** Wednesday, August 24, 2011 from 2pm-3pm ET. To participate dial 1-800-837-1935 Conference ID 83512247.

**Physician, Nurses and Allied Health Professionals Open Door Forum:** Tuesday, September 20, 2011 from 2pm-3pm ET. To participate dial 1-800-837-1935, Conference ID 83521027.

**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.

**Workshop:** [Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice](#): November 16 and 17, 2011, from 8 a.m. to 5 p.m., Sheraton Philadelphia City Center Hotel, 201 North 17th St., Philadelphia, PA 19103.

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

[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.

[Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas](#): September 20 and 21, 2011, 9:30 a.m. to 6 p.m.; and September 22, 2011, 9 a.m. to 3 p.m., Legacy Hotel and Meeting Centre, 1775 Rockville Pike, Rockville, Maryland 20852.

### ***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.

**National Arthritis and Musculoskeletal and Skin Diseases Advisory Council:** September 27, 2011, 8:30 a.m. to 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, 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)***

**HIT Policy Committee Advisory Meeting:** September 14, 2011, 10 a.m. to 3 p.m. ET, Washington Marriott Hotel, 1221 22nd Street, NW, Washington, DC, or via webcast.

#### **HIT Policy Committee Workgroups:**

*Privacy & Security Tiger Team* – September 9 and September 23, 2 to 4 p.m. ET – webcast only.

*Meaningful Use Workgroup* – September 15th, 10 to 12 p.m. ET – webcast only.

**HIT Standards Committee Advisory Meeting:** September 28, 2011, 9 a.m. to 3 p.m. ET, Washington Marriott Hotel, 1221 22nd Street, NW, Washington, DC, or via webcast.

#### **HIT Standards Committee Workgroups:**

*Implementation Workgroup* – September 22, 2011, 3 to 5 p.m. ET – webcast only.

## Other HHS 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 Three Class III Preamendments Devices</a>	August 23, 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
<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 for Skilled Nursing Facilities for FY 2012; Final Rule</a>	October 1, 2011	

<a href="#">Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment</a>	October 1, 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
<a href="#">Effective Date of Requirement for Premarket Approval for an Implantable Pacemaker Pulse Generator</a>		October 25, 2011
<a href="#">Medicaid Program; Eligibility Changes Under the Affordable Care Act of 2010; Proposed Rule</a>		October 31, 2011
<a href="#">Patient Protection and Affordable Care Act; Exchange Functions in the Individual Market: Eligibility Determinations; Exchange Standards for Employers; Proposed Rule</a>		October 31, 2011
<a href="#">Effective Date of Requirement for Premarket Approval for a Pacemaker Programmer</a>		November 2, 2011

### **Other**

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.

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**

[Determination That Halflytely and Bisacodyl Tablets Bowel Prep Kit \(Containing Two Bisacodyl Delayed Release Tablets, 5 Milligrams\) Was Withdrawn From Sale for Reasons of Safety or Effectiveness](#)