



Regulatory Review

June 27, 2011

E-Prescribing Incentive Program Penalty Update

Beginning in 2012, eligible professionals (EPs) who do not demonstrate that they were successful electronic prescribers within the first 6 months of 2011 (January 1 to June 30, 2011) will be subject to a 1% payment adjustment (penalty) on their Medicare Part B Physician Fee Schedule covered professional services. **To avoid the 1% penalty in 2012 for not e-prescribing, EPs must submit at least 10 claims-based electronic prescriptions during the first 6 months of calendar year 2011 (January 1 to June 30, 2011).**

To avoid the 1.5% payment adjustment for 2013, you must report a total of 25 claims-based electronic prescriptions in 2011; 10 between January 1, 2011, and June 30, 2011, and a minimum of 15 between June 30, 2011, and December 31, 2011.

A [MedLearn Matters](#) article provides detailed information about this payment adjustment, how to avoid it, and hardship exemption information.

Partnership for Patients Funding Announcement

The Department for Health and Human Services (HHS) announced last week the availability of funding for hospitals, health care provider organizations, and others to become "Hospital Engagement Contractors." These contractors will collaborate with the agency in an effort to redesign care processes that will improve care and stop millions of preventable injuries and complications related to health care acquired conditions and unnecessary readmissions.

Specifically, the contractors will be asked to:

- Design intensive programs to teach and support hospitals in making care safer;
- Conduct trainings for hospitals and care providers;
- Provide technical assistance for hospitals and care providers; and
- Establish and implement a system to track and monitor hospital progress in meeting quality improvement goals.

The first round of funding for this effort totals up to \$500 million. Entities interested in submitting a proposal should visit www.fbo.gov.

AHRQ Effective Health Care Program: New Chapters, New Series, New Reports

The Agency for Health Care Research and Quality (AHRQ) Effective Health Care (EHC) Program released two new draft chapters of the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* for comment. Use the links below to review and comment on the specific chapters until July 21, 2011:

- "Assessing the Risk of Bias of Individual Studies when Comparing Medical Interventions." To access and comment on this chapter, please visit: <http://www.effectivehealthcare.ahrq.gov/index.cfm/research-available-for-comment/comment-draft-reports/?pageaction=displayDraftCommentForm&topicid=322&productID=714>
- "Avoiding Bias in Selecting Studies." To access and comment on this chapter, please visit: <http://www.effectivehealthcare.ahrq.gov/index.cfm/research-available-for-comment/comment-draft-reports/?pageaction=displayDraftCommentForm&topicid=321&productID=713>

In addition, AHRQ released a new publication series titled [*Closing the Quality Gap: Revisiting the State of the Science*](#), a new research report, [*Empirical Evidence of Associations Between Trial Quality and Effect Size*](#), and a new Data Points report titled [*Prevalence and Medicare Reimbursement by Recurrent International Classification of Diseases Categories, 2006-2009*](#). All of these items are available on the AHRQ web site.

AHRQ Commentaries on HIT, Medical Liability

Last week, AHRQ posted commentaries on health IT, medical liability and healthcare-associated infections (HAIs). The commentaries can be accessed using the links below.

- [Health Information Technology: Turning the Patient-Centered Medical Home from Concept to Reality](#)
- [Patient Safety and Medical Liability Reform: Putting the Patient First](#)
- [Preventing Healthcare-Associated Infections: Initiating Promising Solutions and Expanding Proven Ones](#)

Opportunities to Submit Nominations

AHRQ is soliciting nominations of 15 experts on pediatric quality measures for the Children's Health Insurance Program Reauthorization Act (CHIPRA) Pediatric Quality Measures Program. Nominations should be e-mailed to chipra@AHRQ.hhs.gov by June 30, 2011.

National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) is soliciting nominations to serve on the World Trade Center Health Program Science/Technical Advisory Committee (WTCHP-STAC). Nominations may be submitted electronically to the [NIOSH Docket](#) by July 7, 2011.

Opportunities to Submit Proposals & Requests for Information

[Medicare Program; Solicitation for Proposals for the Medicare Community-Based Care Transitions Program](#); Contact Juliana Tionson at (410) 786-0342 or by e-mail at CareTransitions@cms.hhs.gov for more information.

[Analgesic Clinical Trials Innovation, Opportunities, and Networks \(ACTION\) Initiative](#); Important dates are as follows:

- The anticipated start date is July 14, 2011.

Visit the [FDA website](#) for details.

Upcoming Federal Regulatory Meetings

Agency for Healthcare Research and Quality (AHRQ)

AHRQ announced that the **Guidelines International Network (G-I-N) Conference 2011** will be held August 28-31, 2011 in Seoul, Korea. [Register online](#) now.

AHRQ announced that its 2011 Annual Conference, [Leading Through Innovation and Collaboration](#), will be held on September 18-21 at the Bethesda North Marriott Convention Center in Bethesda, MD.

Centers for Medicare and Medicaid Services (CMS)

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

- **Physician, Nurses and Allied Health Professionals Open Door Forum:** Tuesday, June 28, 2011 from 2pm-3pm ET. To participate, dial 1-800-837-1935 Conference ID 59680265.
- **Hospital Quality Open Door Forum:** Wednesday, July 13, 2011 from 2pm-3pm ET. To participate, dial 1-800-837-1935 Conference ID 68627432.

Food and Drug Administration (FDA)

The FDA will hold a [hearing](#) on its **proposal to withdraw approval of the breast cancer indication for bevacizumab (Avastin)** on June 28 and 29 from 8 AM ET to 5 PM ET at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg 31, Rm. 1503 (Great Room), Silver Spring, MD 20993.

The FDA [Cellular, Tissue and Gene Therapies Advisory Committee](#) will meet on June 29, 2011, from 8 a.m. to 5 p.m. at the Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD, 20910.

The FDA [Oncologic Drugs Advisory Committee](#) will meet July 14, 2011, from 8 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002.

The FDA [Circulatory System Devices Panel of the Medical Devices Advisory Committee](#) will meet on July 20 and 21, 2011, from 8 a.m. to 6 p.m. at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

The FDA [Gastrointestinal Drugs Advisory Committee](#) will meet on July 21, 2011, from 8 a.m. to 4 p.m. at the Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910.

National Institutes of Health (NIH)

The NIH [National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group, Digestive Diseases and Nutrition C Subcommittee](#) will meet on June 27-28, 2011, at the Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814. The open public session will be held on June 27, 2011, 8 a.m. to 8:30 a.m.

The NIH [Council of Councils](#) will meet on June 29, 2011, with an open public session from 8:30 a.m. to 12:30 p.m. ET and 2:20 p.m. to 5:30 p.m. ET at the National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

The NIH [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.

Office of the National Coordinator (ONC)

The [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 HHS Meetings

A meeting of the [Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020](#) has been announced for June 30, 2011, from Noon to 2 p.m. It will be held on the Internet via WebEx software. Visit the [dedicated web page](#) to register.

A meeting of the [Technical Advisory Panel on Medicare Trustee Reports \(Panel\)](#) will be held on July 7, 2011 from 9 a.m. to 5 p.m. at the HHS headquarters, 200 Independence Ave., SW., Washington, DC 20201, Room 738G.

Opportunities for Public Comment

Federal Rules and Regulations

[Periodic Review of Existing Regulations; Retrospective Review Under E.O. 13563](#): Comments due by June 27, 2011.

[Examination of Online Direct-to-Consumer Prescription Drug Promotion](#): Comments due by June 27, 2011.

[Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Disclosures of Ownership and Additional Disclosable Parties Information; Proposed Rule](#): Comments due by June 27, 2011.

[Reducing Regulatory Burden; Retrospective Review Under Executive Order 13563](#): Comments due by June 30, 2011.

[Medicaid Program; Methods for Assuring Access to Covered Medicaid Services](#): Comments due by July 5, 2011.

[Medicare Program; Hospice Wage Index for Fiscal Year 2012](#): Comments due by July 8, 2011.

[Disqualification of a Clinical Investigator](#): Comments due by July 12, 2011.

[Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program](#): Comments due by July 19, 2011.

[Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes](#): Comments due by July 25, 2011.

[Medicare Program; Proposed Changes to the Electronic Prescribing \(eRx\) Incentive Program](#): Comments due on July 25, 2011.

[Medicare Program; Five Year Review of Work Relative Value Units Under the Physician Fee Schedule](#): July 25, 2011.

[HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act](#): Comments due on August 1, 2011.

[Medicare Program; Availability of Medicare Data for Performance Measurement; Proposed Rule](#): Comments due on August 8, 2011.

[Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms](#): Comments due on September 15, 2011.

[Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use](#): Comments due on September 15, 2011.

[Amendments to Sterility Test Requirements for Biological Products](#): Comments due on September 19, 2011.

FDA Guidance Documents

[Draft Guidance for Industry on Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act](#): Submit comments by July 12, 2011.

[Draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators](#): Submit comments by July 25, 2011.

[Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](#): Submit comments by August 1, 2011.

[Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia Trachomatis and/or Neisseria Gonorrhoeae: Screening and Diagnostic Testing](#): Submit comments by August 9, 2011.

[Draft Guidance for Industry; Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology](#): Submit comments by August 15, 2011.

[Draft Guidance for Industry on Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics](#): Submit comments by August 16, 2011.

[Draft Guidance for Industry on Enforcement Policy for Over-the-Counter Sunscreen Drug Products Marketed Without an Approved Application](#): Submit comments by August 16, 2011.

[Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus Species Detection](#): Submit comments by August 16, 2011.

[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](#): Submit comments by August 30, 2011.

[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](#): Submit comments by September 13, 2011.

[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](#): Submit comments by September 19, 2011.

[Draft Guidance for Industry and Food and Drug Administration Staff: Applying Human Factors and Usability Engineering To Optimize Medical Device Design](#): Submit comments by September 19, 2011.

[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](#): Submit comments by September 20, 2011.

Other

The CMS issued a [request for information on opportunities for alignment under Medicaid and Medicare](#). Respond to this request as outlined in the notice by July 11, 2011.

The FDA has [extended the public comment period](#) for its notice of public meeting on generic drug user fees. Comments are now due by August 1, 2011.

The NIH has opened a public comment for the [NINR End-of-Life and Palliative Care Science Needs Assessment: Funding Source Questionnaire](#). The comment period ends August 5, 2011.

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.

Final Regulations Released

[Medical Devices; Neurological Devices; Clarification of Classification for Human Dura Mater; Technical Amendment](#): Effective June 24, 2011.

[Medical Devices; Exception From General Requirements for Informed Consent](#): Effective June 24, 2011.