



Regulatory Review

April 4, 2011

ACO's Defined in CMS' Proposed Rule on Medicare's Shared Savings Program, Other Federal Agencies Weigh-in

On March 31, 2011, the Centers for Medicare and Medicaid Services (CMS) released its long-awaited proposed regulation on [Medicare's Shared Savings Program](#), which defines Accountable Care Organizations (ACOs). In addition, several Federal agencies issued documents addressing legal issues regarding ACOs participating in the Shared Savings Program.

- **CMS and HHS' Office of Inspector General (OIG)** jointly issued a [notice with comment period](#) outlining proposals for waivers of certain Federal laws-the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law-in connection with the Shared Savings Program.
- The **Federal Trade Commission (FTC) and the Department of Justice (DOJ)** jointly issued a "[Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program](#)" (Antitrust Policy Statement).
- The **Internal Revenue Service (IRS)** issued a [notice](#) requesting comments regarding the need for guidance on participation by tax-exempt organizations in the Shared Savings Program through ACOs.

Read more at CMS' dedicated [Shared Savings Program web page](#).

Upcoming MedPAC Meeting Agenda Announced

The Medicare Payment Advisory Commission (MedPAC) will meet this Thursday and Friday to discuss a host of issues related to Medicare reimbursement and quality. The meeting will be held downtown in the Horizon Ballroom at the Ronald Reagan Building International Trade Center at 1300 Pennsylvania Avenue. The agenda is as follows:

Thursday, April 7, 2011

9:00 AM – 10:30 AM: Improving payment accuracy and appropriate use of ancillary services
(Ariel Winter)

10:30 AM – 12:00 PM: Enhancing Medicare's technical assistance to and oversight of providers
(Anne Mutti, John Richardson)

1:00 PM – 2:30 PM: Medicare's fee-for-service benefit design (Julie Lee, Joan Sokolovsky, Scott Harrison)

2:30 PM – 3:15 PM: Improving the accuracy of payments to physicians and other health professionals (Kevin Hayes, Ariel Winter)

3:15 PM – 4:45 PM: The Sustainable Growth Rate system: policy considerations for adjustments and alternatives (Cristina Boccuti, Kevin Hayes)

4:45 PM – 5:45 PM: Private-sector payment rates for physician and hospital services (Julie Lee, Carlos Zarabozo)

Friday, April 8, 2011

8:30 AM – 10:30 AM: Rural patient care systems (Jeff Stensland, Adaeze Akamigbo; Dr. Bruce Hamory, Executive Vice President/Managing Partner, Geisinger Consulting Services, and Jim Long, Chief Executive Officer of West River Health Services, Hettinger, North Dakota)

More details and issues briefs on each topic can be found at www.medpac.gov.

AHRQ Researchers Study How Community-Acquired Methicillin-Resistant Staphylococcus aureus Is Managed in Health Care Settings

Findings from three new AHRQ-funded reports on community-acquired methicillin-resistant Staphylococcus aureus (MRSA) have recently been posted to the AHRQ web site. The reports result from two-year projects conducted by AHRQ's Practice-Based Research Networks in Colorado, Iowa, and North Carolina. The reports are listed below.

- [Management by Primary Care Clinicians of Patients Suspected of Having Community-Acquired Methicillin-Resistant Staphylococcus Aureus Infections](#)—State Network of Colorado Ambulatory Practices and Partners.
- [Community-Acquired Skin Infections in the Age of Methicillin-Resistant Organisms](#)—Iowa Research Network Practices, University of Iowa.
- [Cellulitis and Abscess Management in the Era of Resistance to Antibiotics \(CAMERA\)](#)—Cecil G. Sheps Center for Health Services Research, University of North Carolina at Chapel Hill & Duke Clinical Research Institute.

AHRQ 2011 Comparative Database Report Now Posted

AHRQ posted its [Hospital Survey on Patient Safety Culture 2011 Comparative Database Report](#), including data from 1,032 hospitals and 472,397 hospital staff respondents. In addition, the 2011 report includes a chapter on trending that presents results showing change over time for 512 hospitals that administered the survey and submitted data more than once. The report consists of a narrative description of the findings and four appendices presenting results by hospital characteristics and respondent characteristics.

AHRQ Report Shows Low Health Literacy Linked to Higher Risk of Death and More Emergency Room Visits and Hospitalizations

According to a [new report](#) by AHRQ, low health literacy in older Americans is linked to poorer health status and a higher risk of death. According to the report, differences in health literacy level were

consistently associated with increased hospitalizations, greater emergency care use, lower use of mammography, lower receipt of influenza vaccine, poorer ability to demonstrate taking medications appropriately, poorer ability to interpret labels and health messages, and, among seniors, poorer overall health status and higher mortality.

Call for Papers on Integrating Primary Care and Public Health

AHRQ announced that it is co-sponsoring, with other government agencies, a special journal supplement on primary care and public health in the American Journal of Preventive Medicine (AJPM) and American Journal of Public Health (AJPH). Papers are invited in the following areas:

- Science—*What factors promote integration? How has integration measurably impacted population health and health equity?*
- Education—*How can integration be promoted during professional training and practice?*
- Practice—*What are promising practices for integration? What are incentives and disincentives to integration?*
- Policy—*What policies are effective in promoting integration? What are opportunities to promote integration in the Affordable Care Act?*

Manuscripts are due to AJPH on August 1, 2011, and should be submitted at <http://ajph.edmgr.com>. For further information, please contact the guest editors at AJPH-AJPMpapers@hrsa.gov.

Opportunities to Submit Nominations

CMS is [soliciting nominations](#) of two new members to the Advisory Panel on Ambulatory Payment Classification (APC) Groups. There will be two vacancies on the Panel as of September 30, 2011. CMS will consider nominations received no later than 5 p.m. ET on May 24, 2011.

Upcoming Meetings – CMS Open Door Forums & Listening Sessions

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

Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs Conference Call Series:
Wednesday, April 6, 1:30-3:00 p.m. ET – Registration for [Eligible Hospitals](#)

Physicians, Nurses & Allied Health Professionals Open Door Forum: Tuesday, April 5, 2011 beginning at 2 pm ET. To participate, dial 1-800-837-1935 & Reference Conference ID 44695577.

2011 Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Programs: Physician Quality Reporting System/E-Prescribing Success Stories: Thursday, April 14, 2011, from 2:30pm-3:30pmET. To participate, dial 1-800-837-1935 Conference ID 44767416.

Upcoming Meetings - Other

CMS announced it will host free webinars during Version 5010 Test Education Week, April 4-8, 2011. The webinars will feature speakers from the CMS, provider and payer organizations, and will offer practical information and early lessons learned on:

- Testing for Large and Small Practices and Facilities
- How to Test with Medicare Fee-for-Service
- Testing with Commercial Payers and Clearinghouses

To sign up, visit the Get Ready 5010 website at <http://getready5010.org>.

CMS announced its 2011 [public meeting schedule](#) for all new requests for revision to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations.

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 FDA's [Vaccines and Related Biological Products Advisory Committee](#) will meet on April 6, 2011, between approximately 9 a.m. and 4 p.m. and on April 7, 2011, between approximately 8:30 a.m. and 3:30 p.m. at the Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

The FDA will host a meeting ["510\(k\) Implementation: Discussion of an Online Repository of Medical Device Labeling and of Making Device Photographs Available in a Public Database Without Disclosing Proprietary Information"](#) April 7, 2011, from 8:30 a.m. to 5 p.m. at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20903.

AHRQ's [National Advisory Council for Healthcare Research and Quality](#) will meet on Friday, April 8, 2011, from 8:30 a.m. to 3 p.m. at the Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

HHS' [Advisory Group on Prevention, Health Promotion, and Integrative and Public Health](#) will meet on April 12-13, 2011 at the Federal Trade Commission Conference Center; 601 New Jersey Avenue, NW., Washington, DC 20001. Information about the Advisory Group and the meeting agenda can be obtained at: <http://www.healthcare.gov/center/councils/nphpphc/index.html>.

The HHS [Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2020](#) will meet online April 13, 2011 from 1 p.m. to 3 p.m. ET. Please visit the "Secretary's Advisory Committee" [Web page](#) of the Healthy People Web site and click on "Register to Attend."

The Health Resources and Services Administration (HRSA) [Negotiated Rulemaking Committee on Designation of Medically Underserved Populations and Health Professional Shortage Areas](#) announced that it will meet on April 13, 2011, 9:30 a.m. to 6 p.m.; April 14, 2011, 9 a.m. to 6 p.m.; and April 15,

2011, 9 a.m. to 4 p.m. at the Legacy Hotel and Meeting Centre, 1775 Rockville Pike, Rockville, Maryland 20852.

The FDA's Center for Drug Evaluation and Research (CDER) issued the following notice: [Training Program for Regulatory Project Managers; Information Available to Industry](#), regarding the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). Pharmaceutical companies interested in participating in this program should contact CDER by April 18, 2011 at elizabeth.duvalldmiller@fda.hhs.gov.

The FDA announced it will host a workshop entitled, "[Medical Device Epidemiology Network \(MDEpiNet\) 2011: Second Annual Public Workshop](#)" on April 25, 2011 from 8 a.m. to 5 p.m. ET at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993. Registration will begin at 7 a.m.

FDA's Cincinnati District, in co-sponsorship with Xavier University, will host a public conference entitled "[FDA/Xavier University Global Medical Device Conference](#)" on May 4, 2011, from 8:30 a.m. to 5 p.m.; May 5, 2011, from 8:30 a.m. to 5 p.m.; and May 6, 2011, from 8:30 a.m. to 1 p.m. at Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207.

The FDA will host a "[Town Hall Discussion With the Director of the Center for Devices and Radiological Health and Other Senior Center Management](#)" on May 5, 2011, from 8 a.m. to 12 noon EST at the Sheraton Orlando Downtown Hotel, 400 West Livingston St., Orlando, FL 32801.

NIH's [National Diabetes and Digestive and Kidney Diseases Advisory Council](#) will meet on May 11, 2011. The open public session will be held from 8:30 a.m. to 12 p.m. at the National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

NIH's [National Advisory Council for Biomedical Imaging and Bioengineering \(NACBIB\)](#) will meet on May 20, 2011. The open public session will be held from 9:15 a.m. to 12 p.m. at the Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room (2nd Level), Bethesda, MD 20817.

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/about/whoWeAre/councilCommittees/Pages/default.aspx>.

Opportunities for Public Comment – Proposed and Final Rulemaking

[Medicare Program; Revisions to the Reductions and Increases to Hospitals' FTE Resident Caps for Graduate Medical Education Payment Purposes](#): Comments due on April 13, 2011.

[Privacy Act; Exempt Record System](#): Comments due on April 18, 2011.

Opportunities for Public Comment – FDA Guidance Documents

The FDA initiated a [public comment](#) period for its Draft Guidance for Industry and Food and Drug Administration Staff on Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets. To ensure your comments are considered in the final version of this guidance, submit [comments](#) by April 18, 2011.

The FDA initiated a [public comment](#) period for its draft guidance for industry entitled “Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework.” To ensure your comments are considered in the final version of this guidance, submit [comments](#) by May 16, 2011.

Submit [electronic comments](#) on the following FDA guidance documents at any time:

[Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims](#)

[Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products](#)

Opportunities for Public Comment – *Other*

AHRQ's Effective Health Care (EHC) Program announced that key questions for the following comparative effectiveness reviews:

- [Closing the Quality Gap Series: Comparative Effectiveness of Medication-Adherence Interventions](#) is available and open for comment April 8, 2011.
- [Effectiveness of Interventions Addressing Concomitant Mental Health and Chronic Medical Conditions in the Primary Care Setting](#), is available for comment until April 15, 2011.
- [Intravascular Diagnostic Procedures and Imaging Techniques Compared With Angiography Alone](#), is available for comment until April 19, 2011.

The CDC issued a notice requesting public comment on the draft action plan – [A Public Health Action Plan to Combat Antimicrobial Resistance](#). The draft Action Plan and supporting documents can be found at <http://www.regulations.gov>. Comments must be received on or before April 15, 2011.

HHS' Office of the National Coordinator for Health Information Technology (ONC) announced that the public comment period for the [Federal Health IT Strategic Plan 2011 - 2015](#) is open through Friday, April 22 at 11:59 p.m. ET. In order for your comments to be read and considered, you must submit your comment via the Federal Health IT Buzz Blog: <http://www.healthit.gov/buzz-blog/>.

The FDA [extended the public comment period](#) for The National Antimicrobial Resistance Monitoring System (NARMS) entitled "[NARMS Strategic Plan 2011-2015](#)." Comment must be received by May 24, 2011.