



Regulatory Review

April 11, 2011

MedPAC Makes Recommendations on Imaging, QIO's

Last week, the Medicare Payment Advisory Commission (MedPAC) discussed a host of issues related to Medicare physician reimbursement at its final meeting before the next cycle begins in September. Recommendations aimed at improving payment accuracy and appropriateness of ancillary services were made. Specifically, MedPAC recommending the following:

Recommendation 1: *The Secretary should accelerate and expand efforts to package discrete services in the physician fee schedule into larger units for payment.*

Recommendation 2: *The Congress should direct the Secretary to apply a multiple procedure payment reduction to the professional component of diagnostic imaging services provided by the same practitioner in the same session.*

Recommendation 3: *The Congress should direct the Secretary to reduce the physician work component of imaging and other diagnostic tests that are ordered and performed by the same practitioner.*

Recommendation 4: *The Congress should direct the Secretary to establish a prior authorization program for practitioners who order substantially more advanced diagnostic imaging services than their peers.*

Votes on the first three recommendations were unanimous; however, the final recommendation was opposed by one Commissioner, a private practicing urologist from Florida.

MedPAC also voted on recommendations aimed at enhancing Medicare's technical assistance to and oversight of providers, a significant majority of which is now provided by Medicare's Quality Improvement Organizations (QIO's).

Recommendation 1: *The Congress should redesign the current QIO program to allow the Secretary to provide funding for time limited technical assistance directly to providers and communities. The Congress should require the Secretary to develop an accountability structure to ensure these funds are used appropriately.*

Recommendation 2: *The Congress should authorize the Secretary to define criteria to qualify technical assistance agents so that a variety of entities can compete to assist providers and to provide community level quality improvement. The Congress should remove requirements that the agents be physician-sponsored, serve a specific State, and have regulatory responsibilities.*

Recommendation 3: *The Secretary should make low-performing providers and community-level initiatives a high priority in allocating resources for technical assistance for quality improvement.*

Recommendation 4: *The Secretary should regularly update Conditions of Participation so that the requirements incorporate and emphasize evidence-based methods of improving quality of care.*

Recommendation 5: *The Congress should require the Secretary to expand interventions that promote systemic remediation of quality problems for persistently low-performing providers.*

Recommendation 6: *The Secretary should establish a public recognition program for high-performing providers that participate in collaboratives or learning networks or otherwise act as mentors to improve the quality of lower performing providers.*

These recommendations were approved unanimously.

A presentation on improving the accuracy of payments to physicians was presented by MedPAC staff, which included findings from a study of alternative approaches to valuing practitioner services. CMS is planning to validate fee schedule relative values (RVUs) as it also has concerns that the values, which are primarily based on time estimates collected by specialty societies, are too high. Commissioner Robert Berenson, MD pointed to time estimates for the physician work associated with electrocardiography (EKG), as an example of time estimates that are high.

Commissioner Karen Borman, MD, noted that time estimates as part of the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) might be a worthwhile comparison to the currently available time estimates. Another commissioner suggested using time estimates that might be found in practice management systems.

MedPAC next turned to the sustainable growth rate (SGR) formula, focusing discussion on what tradeoffs elimination of the SGR could be contingent upon. There is broad support by MedPAC for Congress to “write-off” the SGR debt.

Commissioners also addressed Medicare’s fee-for-service benefit design, but did not make any specific recommendations.

A transcript, as well as the presentation slides and other details can be found at www.medpac.gov.

AHRQ Announces Advice Column on Health IT

The Agency for Healthcare Research and Quality announced a new advice column from AHRQ Director, Carolyn Clancy, MD, entitled "[Health IT Tools Help with Care and Cost.](#)" This first column focuses on the electronic health record (EHR). More columns will be posted in coming weeks, which will address how to recognize high-quality health care, how to be an informed health care consumer, and how to choose a hospital, doctor, and health plan.

First Graduating Class of HIT Students from ONC Funded Community Colleges

HHS' Office of the National Coordinator for Health Information Technology (ONC) funded 82 community colleges with the goal of training a Health IT workforce to help providers with the adoption of health information technologies (HIT). Last week, ONC announced that 3000 Health IT professionals, who have either healthcare or IT backgrounds, will be graduating from the ONC programs this month.

Screening for Testicular Cancer: U.S. Preventive Services Task Force Reaffirmation

The April 5 issue of Annals of Internal Medicine includes a reaffirmed “Grade D” recommendation against screening for testicular cancer in adolescent and adult males without any symptoms from the U.S. Preventive Services Task Force (USPSTF). The recommendation can also be found at <http://www.uspreventiveservicestaskforce.org/uspstf/uspstest.htm>.

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.

AHRQ is [soliciting nominations](#) of seven new members to the National Advisory Council for Healthcare Research and Quality (the Council). Submit nominations to Karen Brooks at karen.brooks@ahrq.hhs.gov.

Upcoming Meetings – CMS Open Door Forums & Listening Sessions

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

2011 Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Programs: Physician Quality Reporting System/E-Prescribing Success Stories: Thursday, April 14, 2011, from 2:00pm-3:30pm ET. To participate, dial 1-800-837-1935 Conference ID 44767416.

Physician, Nurses and Allied Health Professionals Open Door Forum: Tuesday, May 17, 2011 from 2pm-3pm ET. To participate, dial 1-800-837-1935 Conference ID 50103486.

Upcoming Meetings - Other

HHS’ Office of the Assistant Secretary for Planning and Evaluation announced a meeting of the [Technical Advisory Panel on Medicare Trustee Reports](#), which will be held April 12, 2011, 9 a.m. to 5 p.m. ET at HHS headquarters, Room 425A, 200 Independence Ave., SW., Washington, DC 20201.

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](#).

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 [Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee](#) will meet on May 2, 2011, from 8 a.m. to 4 p.m. ET at the FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

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.

The FDA will host a two-day public meeting, [Safety and Efficacy of Hypnotic Drugs](#), on Tuesday, May 10, and Wednesday, May 11, 2011, from 8 a.m. to 5 p.m. ET at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

The Health Research Services Administration (HRSA) [Advisory Council on Blood Stem Cell Transplantation](#) will meet on May 11, 2011, 8 a.m. to 4:30 p.m. at the Georgetown University Hotel and Conference Center, 3800 Reservoir Road, NW., Washington, DC 20057.

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.

AHRQ will host a free webcast, “**Who Are You Talking To? New Insights Into the Audience for Consumer Reports on Health Care Quality**” on Wednesday, May 11, 2011 from 2:00 – 3:00 pm E.T. [Register](#) for this event on the AHRQ web site.

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.

FDA’s [Cellular, Tissue, and Gene Therapies Advisory Committee](#) will meet on May 31, 2011, from 2:30 p.m. to 6:15 p.m. at National Institutes of Health (NIH) Campus, 29 Lincoln Dr., Bldg. 29B, Conference Rooms A and B, Bethesda, MD 20892.

The [14th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference: New Regulatory Challenges](#) will be held on June 8 and 9, 2011, from 7:30 a.m. to 5 p.m. at the Irvine Marriott Hotel, 18000 Von Karman Ave., Irvine, CA 92612. [Register](#) for this meeting online.

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.

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.

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.

[Medicare Program; Revisions to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies \(DMEPOS\) Suppliers Safeguards](#): Comments due on June 3, 2011.

[Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center](#): Comments due on June 6, 2011.

[Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations](#): Comments due on June 6, 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](#)

[Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent for Emergency Research](#)

Opportunities for Public Comment – Other

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

- [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.

HHS' Office of the Secretary is seeking [public comment](#) on two draft chapters of the [National Health Security Strategy Biennial Implementation Plan](#). Comments may be submitted to HHS/ASPR by April 18, 2011 to the following: <http://www.phe.gov/nhss> or nhss@hhs.gov.