



Regulatory Review

December 12, 2011

MedPAC to Assess Payment Adequacy for Physicians, ASCs & Hospice

On December 15-16, 2011, the [Medicare Payment Advisory Commission \(MedPAC\)](#) will discuss the adequacy of Medicare payments to Medicare providers, including physicians, ambulatory surgery centers (ASCs), hospital inpatient and outpatient services, and hospices. The meeting will be held at the Ronald Reagan Building International Trade Center in the Horizon Ballroom. The full agenda is detailed below.

Thursday, December 15, 2011

9:00 AM – 10:45 AM: Assessing payment adequacy: hospital inpatient and outpatient services

10:45 AM – 11:45 AM: Assessing payment adequacy: outpatient dialysis services

1:00 PM – 2:30 PM: Assessing payment adequacy: physician and ambulatory surgical center services

2:30 PM – 4:00 PM: Assessing payment adequacy: skilled nursing facility services

4:00 PM – 5:00 PM: Assessing payment adequacy: home health care services

5:00 PM – 5:45 PM: Encouraging the use of lower-cost medications by beneficiaries receiving Part D's low-income subsidy

Friday, December 16, 2011

8:15 AM – 9:15 AM: Assessing payment adequacy: hospice services

9:15 AM – 10:30 AM: Assessing payment adequacy: inpatient rehabilitation facility services

10:30 AM – 11:30 AM: Assessing payment adequacy: long-term care hospital services

A briefing on each agenda item is available on MedPAC's web site. The Commission's next meeting will be January 12-13, 2012 at the Ronald Reagan International Trade Center.

FDA Hosts Fourth Annual Sentinel Initiative Public Workshop

On Wednesday, January 18, 2012, the Food and Drug Administration (FDA) and the Engelberg Center for Health Care Reform at Brookings will host the [Fourth Annual Sentinel Initiative Public Workshop](#) at the Washington Marriott at Metro Center. According to FDA's announcement, the workshop will bring together the stakeholder community for a productive discussion on a variety of topics in active medical product surveillance, including an update on the U.S. Food and Drug Administration's (FDA's) Sentinel Initiative, including current activities and future plans, efforts to support the advancement of safety science, and stakeholder perspectives on the Sentinel Initiative's progress and future direction.

Dr. Stephen Spielberg, the FDA's newly appointed Deputy Commissioner for Medical Products and Tobacco, will provide the morning keynote address

Upcoming Health Care Innovation Challenge Webinars

CMS' Innovation Center announced its third and fourth webinars focused on the [Health Care Innovation Challenge](#), a new initiative designed to test creative ways to deliver high quality medical care and reduce costs across the country. During the third webinar, scheduled for tomorrow, December 13, 2011, from 2-3 pm EST, CMS Innovation Center staff will be presenting an explanation of "Total Cost of Care" and how potential applicants can demonstrate their path to achieving lower costs through improvement. A fourth webinar has been scheduled for 2-3pm EST on Monday, December 19th, 2011 to discuss how potential innovative proposals can demonstrate measurable impact on

the aims of better care and better health in addition to considerations for operational planning for potential applications.

Slides and a recording will be available following the webinar on the [Health Care Innovation Challenge](#) home page.

Opportunities to Submit Nominations

National Vaccine Advisory Committee	Nominations due by Dec. 23, 2011
Advisory Panel on Hospital Outpatient Payment (HOP) (formerly the Advisory Panel on Ambulatory Payment Classification Groups)	Nominations due by Dec. 27, 2011
Science Board to the FDA	Nominations due by Dec. 28, 2011
Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID)	Nominations due by Dec. 30, 2011
Advisory Committee on Blood Safety and Availability	Nominations due by Jan. 27, 2012
Medicare Evidence Development & Coverage Advisory Committee	Nominations due by Jan. 30, 2012

Upcoming Federal Regulatory Meetings

Agency	Meeting	Dates & Times	Location/Other Logistics
CMS	Home Health, Hospice & DME Open Door Forum	Jan. 11, 2012, 2 - 3pm	Audio only streaming web forum
CMS	Meeting of the Medicare Evidence Development and Coverage Advisory Committee	Jan. 25, 2012, 7:30 am - 4:30 pm	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 or Via Webcast
CMS	Town Hall Meeting on FY 2013 Applications for New Medical Services and Technology Add-On Payments Under the Hospital Inpatient Prospective Payment System	Feb. 14, 2012, 9 am	Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
FDA	Antiviral Drugs Advisory Committee	Dec. 14, 2011, 8 am to 5 pm and on Dec. 15, 2011, 8 am to 1 pm	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	Biologics Price Competition and Innovation Act of 2009; Proposed Recommendations for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Notice of Public Meeting	Dec. 16, 2011, 9 am - 1 pm	FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993-0002
FDA	Generic Drug User Fee; Public Meeting	Dec. 19, 2011, 10 am – 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, rm. 2047, Silver Spring, MD 20993
FDA	Science Board to the Food and Drug Administration (Science Board)	Jan. 6, 2012, 9 am to 4 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002
FDA	The Development and Evaluation of Human Cytomegalovirus Vaccines Public Workshop	Jan. 10 & 11, 2012, 8:30 am to 5:30 pm	Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894
FDA	Gastroenterology and Urology	Jan. 11, 2012,	Hilton Washington, DC North/Gaithersburg, salons A,

Agency	Meeting	Dates & Times	Location/Other Logistics
	Devices Panel of the Medical Devices Advisory Committee	8 am to 6 pm	B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877
FDA	Neurological Devices Panel of the Medical Devices Advisory Committee	Feb. 10, 2012, 8 a.m. to 6 p.m.	Hilton Washington, DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877
FDA	Dermatologic and Ophthalmic Drugs Advisory Committee	Feb. 27, 2012, 9 am to 5 pm	Hilton Washington DC/Silver Spring (scheduled to be renamed in January 2012 to DoubleTree by Hilton Hotel Washington DC/ Silver Spring), 8727 Colesville Rd., Silver Spring, MD
FDA	Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop	Apr. 12, 2012, 8:30 am to 5:30 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm 1503), Silver Spring, MD 20993-0002
FDA	Clinical Development Programs for Sedation Products; Public Workshop; Request for Comments	May 3, 2012, 8:30 am to 5 pm	FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002
NIH	Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERC)	Dec. 14, 2011, 11 am - 2 pm	NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709
NIH	National Advisory Council for Biomedical Imaging and Bioengineering; NACBIB January 2012	Jan. 20, 2012, 9 am – 1 pm	Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room, 2nd Level, Bethesda, MD 20817
NIH	AIDS Research Advisory Committee, NIAID, AIDS Vaccine Research Subcommittee	Jan. 31-Feb.1, 2012, 8:30 am - 5 pm	Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852
Other HHS	Meeting of the Technical Advisory Panel on Medicare Trustee Reports	Dec. 14, 2011, 9:15 am - 5 pm	HHS headquarters at 200 Independence Ave., SW., Washington, DC, 20201
Other HHS	Secretary's Advisory Committee on Heritable Disorders in Newborns and Children	Jan. 26, 2012, 8:30 am – 5 pm, Jan. 27, 2012, 8:30 am – 3:30 pm	Park Hyatt Hotel, 1201 24th Street NW., Washington, DC 20037

Opportunities for Public Comment

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities; Proposed Rule		Dec. 12, 2011
Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop; Request for Comments		Dec. 23, 2011
Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation		Dec. 23, 2011
Medicare and Medicaid Program; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction		Dec. 23, 2011
Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage	Dec. 23, 2011	
A Review of FDA's Approach to Medical Product Shortages		Dec. 23, 2011
Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved	Dec. 27, 2011	

Federal Rules, Regulations and Notices	Effective Date	Comments Due
Accreditor Processes		
Medicaid Program; Recovery Audit Contractors	Jan. 1, 2012	
Medicare Program; Part A Premiums for CY 2012 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement	Jan. 1, 2012	
Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2012	Jan. 1, 2012	
Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2012	Jan. 1, 2012	
Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2012	Jan. 1, 2012	
Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule	Jan. 1, 2012	Jan. 3, 2012
Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements	Jan. 1, 2012	Jan. 3, 2012
Medicare Program; Final Waivers in Connection With the Shared Savings Program		Jan. 3, 2012
Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations	Jan. 3, 2012	
Medical Loss Ratio Requirements Under the Patient Protection and Affordable Care Act	Jan. 3, 2012	Jan. 6, 2012
Medical Loss Ratio Rebate Requirements for Non-Federal Governmental Plans	Jan. 3, 2012	Feb.6, 2012
Medicare Program; Availability of Medicare Data for Performance Measurement; Final Rule	Jan. 6, 2012	
Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563; Request for Comments		Jan. 9, 2012
Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices		Jan. 17, 2012
Orphan Drug Regulations		Jan. 17, 2012
Center for Biologics Evaluation and Research Report of Scientific and Medical Literature and Information on Non-Standardized Allergenic Extracts in the Diagnosis and Treatment of Allergic Disease; Availability		Apr. 25, 2012

Noteworthy

- The FDA's Center for Biologics Evaluation and Research (CBER) announced an invitation for participation in its Regulatory Site Visit Training Program (RSVP). The program intends to give CBER staff an opportunity to visit biologics facilities and directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. Biologics facilities should notify CBER of their interest in participating by January 5, 2012.