

December 19, 2011

MedPAC Assesses Payment Adequacy for Physicians, ASCs & Hospice

On December 15-16, 2011, the [Medicare Payment Advisory Commission \(MedPAC\)](#) discussed the adequacy of Medicare payments to physicians, ambulatory surgery centers (ASCs), hospices, and other providers.

With respect to physician payments, MedPAC reiterated recommendations approved in October that would reduce the cost of replacing the flawed sustainable growth rate (SGR) formula by reducing payments to specialists by 5.9 percent for 3 years, followed by a 7-year freeze, and a 10-year freeze for primary care. MedPAC recommended a 0.5 percent increase for ASCs and hospices for 2013.

The Commission will vote on these recommendations at its next meeting scheduled for January 12-13, 2012.

“Sunshine” Rules Issued by CMS

Last week, the Centers for Medicare & Medicaid Services (CMS) announced a [proposed rule](#) that will increase public awareness of financial relationships between drug and device manufacturers and certain health care providers, as mandated by the Affordable Care Act. According to CMS, the proposed rule would require manufacturers of drugs, devices, biologicals, and medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program to report to CMS payments or other transfers of value they make to physicians and teaching hospitals.

The proposed rule would also require manufacturers and group purchasing organizations (GPOs) to disclose to CMS physician ownership or investment interests. CMS will provide these entities an opportunity to review and correct information prior to its publication.

CMS is proposing that manufacturers and GPOs will be required to submit a partial year on Mar. 31, 2013, depending on the timing of the final rule. Once the data has been submitted, CMS will aggregate manufacturer submissions at the individual physician and teaching hospital level, provide them with a 45-day period to confidentially review and, if necessary, correct the data, and make the data publicly available by Sep. 30, 2013.

CMS will accept comments on the proposed rule until Feb. 17, 2012.

CCIIO Releases Essential Benefits Bulletin

The Center for Consumer Information and Insurance Oversight (CCIIO) released its [essential health benefits bulletin](#). According to Health and Human Services (HHS), the bulletin “describes an inclusive, affordable and flexible proposal and informs stakeholders about the approach that HHS intends to pursue in rulemaking to define essential health benefits.”

Under the proposal, states would have the flexibility to select an existing health plan to set the “benchmark” for the items and services included in the essential health benefits package. The benefits and services included in the health insurance plan selected by the state would be the essential health benefits package. Plans could modify coverage within a benefit category so long as they do not reduce the value of coverage.

The bulletin addresses only the services and items covered by a health plan, not the cost sharing, such as deductibles, copayments, and coinsurance. The cost-sharing features will be addressed in future bulletins and cost-sharing rules will determine the actuarial value of the plan.

Comments are due by Jan 31, 2012 and can be sent to: EssentialHealthBenefits@cms.hhs.gov.

Advisory Panel on Hospital Outpatient Payment Announces First Meeting

CMS [announced](#) last week that the Advisory Panel on Hospital Outpatient Payment (HOP), formerly known as the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) would host its first semi-annual meeting in in February 2012. The schedule is listed below:

- Monday, February 27, 2012, 1 p.m. to 5 p.m. EST
- Tuesday, February 28, 2012, 9 a.m. to 5 p.m. EST
- Wednesday, February 29, 2012, 9 a.m. to 5 p.m. EST

The deadline for presentations and comments is set for 5 p.m. EST, Friday, December 30, 2011. Registration is set for 5 p.m. EST, Friday, January 27, 2012.

Opportunities to Submit Nominations

[National Vaccine Advisory Committee](#)

[Advisory Panel on Hospital Outpatient Payment \(HOP\)](#) (formerly the Advisory Panel on Ambulatory Payment Classification Groups)

[Science Board to the FDA](#)

[Board of Scientific Counselors \(BSC\), Office of Infectious Diseases \(OID\)](#)

[Advisory Committee on Blood Safety and Availability](#)

[Medicare Evidence Development & Coverage Advisory Committee](#)

Nominations due by Dec. 23, 2011

Nominations due by Dec. 27, 2011

Nominations due by Dec. 28, 2011

Nominations due by Dec. 30, 2011

Nominations due by Jan. 27, 2012

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 | 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 Devices Panel of the Medical Devices Advisory Committee | Jan. 11, 2012, 8 am to 6 pm | Hilton Washington, DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877 |

| Agency | Meeting | Dates & Times | Location/Other Logistics |
|-----------|--|---|---|
| FDA | Pediatric Advisory Committee | Jan. 30, 2012, 8 am- 4 pm & Jan. 31, 2012, 9 am-12 pm | Hilton Gaithersburg Hotel, 620 Perry Pkwy., Gaithersburg, MD 20877 |
| FDA | Anesthetic and Analgesic Drug Products Advisory Committee | Feb. 9, 2012, 8:30 am-4 pm | Hilton Washington DC/Silver Spring (scheduled to be renamed in January 2012 to DoubleTree by Hilton Hotel Washington DC/Silver Spring), 8727 Colesville Road, Silver Spring, MD 20910 |
| 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 | 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 | National Advisory Council on Aging | Jan.25, 2012, 8 am- 1:15 pm | National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 10, Bethesda, MD 20892 |
| NIH | National Institute of Allergy and Infectious Diseases Meetings | Jan. 30, 2012, May 14, 2012 & Sept. 24, 2012 (see link for full schedule) | National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 |
| NIH | NIH Advisory Board for Clinical Research | Jan. 30, 2012, 10 am-1:15 pm | National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4-2551, Bethesda, MD 20892 |
| NIH | National Arthritis and Musculoskeletal and Skin Diseases Advisory Council | Jan. 31, 2012, 8:30 am-12 pm | National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892 |
| 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 | 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 |
|--|----------------|---------------|
| Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop; Request for Comments | | Dec. 23, 2011 |

| Federal Rules, Regulations and Notices | Effective Date | Comments Due |
|---|-----------------------|---------------------|
| 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 Accreditor Processes | Dec. 27, 2011 | |
| 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 |
| Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program | Feb. 13, 2012 | |
| Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review | | Feb. 13, 2012 |
| Organ Procurement and Transplantation Network | | Feb. 14, 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 Agency for Healthcare Research and Quality (AHRQ) is [seeking scientific information submissions](#) from manufacturers of intravascular diagnostic and imaging medical devices, including: Fractional Flow Reserve (FFR), Coronary Flow Reserve (CFR), Intravascular Ultrasound (IVUS), Intravascular Ultrasound (VH-IVUS) with Virtual

Histology, Optical Coherent Tomography (OCT), Near-Infrared Spectroscopy (NIR), Angioscopy, Intravascular Magnetic Resonance Imaging (MRI), Elastography, and Thermography. Scientific information is being solicited to inform our Comparative Effectiveness Review of Intravascular Diagnostic Procedures and Imaging Techniques versus Angiography Alone, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. Submission Deadline on or before January 13, 2012.

