



# Regulatory Review

December 5, 2011

## Long-Awaited MLR Regulations Issued by HHS

Last Friday, the Department of Health and Human Services (HHS) issued its [final regulations](#) implementing the federal medical-loss-ratio (MLR) standard, as mandated by the Patient Protection and Affordable Care Act (PPACA). According to HHS, the final rule streamlines the rebate process for those enrolled in group policies by directing issuers to provide rebates to the group policyholder (usually the employer) through lower premiums or in other ways that are not taxable. The final rule also requires that issuers provide notice of rebates to enrollees and the group policyholder. The first round of rebates must be paid by August 1, 2012. The rule also makes other changes to the calculation of the MLR, including a change that considers some of the costs associated with converting to ICD-10.

In addition, a [Government Accountability Office \(GAO\) report](#) released last week found that most insurers in 2010 would have met or exceeded the 2011 PPACA MLR standards and the impact of various aspects of the PPACA provision varied by market. According to the report, at least 64 percent of all credible insurers would have met or exceeded the 2011 PPACA MLR standards.

## HHS Delays “Meaningful Use” Requirements

To encourage faster adoption of electronic health records (EHRs), HHS Secretary Sebelius [announced](#) that HHS intends to allow providers to adopt health IT this year, without meeting the new meaningful use standards (Stage 2) until 2014.

Under the current requirements, eligible providers that begin participating in the Medicare EHR (electronic health record) Incentive Programs this year would have to meet new standards for the program in 2013. If they did not participate in the program until 2012, they could wait to meet these new standards until 2014 and still be eligible for the same incentive payment.

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## Opportunities to Submit Nominations

|   |                                  |
|---|----------------------------------|
| <a href="#">National Vaccine Advisory Committee</a>   | Nominations due by Dec. 23, 2011 |
| <a href="#">Advisory Panel on Hospital Outpatient Payment (HOP)</a> (formerly the Advisory Panel on Ambulatory Payment Classification Groups) | Nominations due by Dec. 27, 2011 |
| <a href="#">Science Board to the FDA</a>  | Nominations due by Dec. 28, 2011 |
| <a href="#">Medicare Evidence Development &amp; Coverage Advisory Committee</a>   | Nominations due by Jan. 30, 2012 |

## Upcoming Federal Regulatory Meetings

| Agency | Meeting  | Dates & Times                 | Location/Other Logistics  |
|--------|--|-------------------------------|---|
| CMS    | <a href="#">Physician, Nurses and Allied Health Professionals Open Door Forum</a>  | Dec. 13, 2011, 2-3 PM         | Dial 1-800-837-1935, Conference ID 93961202   |
| CMS    | <a href="#">Home Health, Hospice &amp; DME Open Door Forum</a>                     | Jan. 11, 2012, 2 - 3pm        | Audio only streaming web forum  |
| CMS    | <a href="#">Meeting of the Medicare Evidence Development and Coverage Advisory</a> | Jan. 25, 2012, 7:30 am - 4:30 | Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244 or Via |

| Agency | Meeting   | Dates & Times  | Location/Other Logistics   |
|--------|---|--|--|
|        | <a href="#">Committee</a>   | pm   | <a href="#">Webcast</a>  |
| CMS    | <a href="#">Town Hall Meeting on FY 2013 Applications for New Medical Services and Technology Add-On Payments Under the Hospital Inpatient Prospective Payment System</a> | Feb. 14, 2012, 9 am  | Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244   |
| FDA    | <a href="#">Oncologic Drugs Advisory Committee</a>  | Dec. 7, 2011, 8 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   |
| FDA    | <a href="#">Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting</a>   | Dec. 7 and 8, 2011, 8 am to 6 pm                               | Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877  |
| FDA    | <a href="#">Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee</a>                          | Dec. 8, 2011, 8 am to 5 pm                                     | Marriott Inn and Conference Center, University of Maryland University College, The Ballroom, 3501 University Blvd. East, Adelphi, MD   |
| FDA    | <a href="#">Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee re: SEDASYS computer-assisted personalized sedation system</a>             | Dec. 14, 2011, 8 am to 6 pm                                    | Hilton Washington, DC/North, Salons A, B, C, and D of the Ballroom, 620 Perry Pkwy., Gaithersburg, MD  |
| FDA    | <a href="#">Antiviral Drugs Advisory Committee</a>  | 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    | <a href="#">Science Board to the Food and Drug Administration (Science Board)</a>   | 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    | <a href="#">The Development and Evaluation of Human Cytomegalovirus Vaccines Public Workshop</a>  | 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    | <a href="#">Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee</a>  | 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   |
| FDA    | <a href="#">Neurological Devices Panel of the Medical Devices Advisory Committee</a>  | 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    | <a href="#">Dermatologic and Ophthalmic Drugs Advisory Committee</a>  | 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    | <a href="#">Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop</a>  | 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    | <a href="#">Clinical Development Programs for Sedation Products; Public Workshop; Request for Comments</a>  | 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   |
| HRSA   | <a href="#">Advisory Commission on Childhood Vaccines (ACCV)</a>  | Dec. 8, 2011 1 pm to 5 pm, Dec. 9, 2011, 9 am to 12 pm         | Parklawn Building Conference Room 10-65, 5600 Fishers Lane, Rockville, MD 20857 or<br>Via audio conference call<br>Dial 1-(800) 369-3104, Leader's Name: Dr. Geoffrey Evans, Password: ACCV. |

| Agency    | Meeting  | Dates & Times   | Location/Other Logistics   |
|-----------|--|---|--|
| NIH       | <a href="#">State-of-the-Science Conference on the Role of Active Surveillance in the Management of Men With Localized Prostate Cancer</a> | Dec. 5-7, 2011  | NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892<br><a href="#">Registration</a>                   |
| NIH       | <a href="#">Advisory Committee to the Director, National Institutes of Health</a>  | Dec. 8, 2011, 9 am to 4 pm, and Dec. 9, 2011, 8:30 am to 12 pm. | National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892  |
| NIH       | <a href="#">Sixth Annual Philip S. Chen, Jr. Distinguished Lecture on Innovation and Technology Transfer</a>                               | Dec. 9, 2011, 9:30 am   | NIH campus, 9000 Rockville Pike, Bethesda, MD, NIH Clinical Center (Building 10), Masur Auditorium                         |
| NIH       | <a href="#">Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERC)</a>                                       | 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 |
| Other HHS | <a href="#">Meeting of the Advisory Committee on Blood Safety and Availability</a>   | Dec. 5 & 6, 2011, 9 am to 5 pm                                  | National Institutes of Health Conference Room, 5635 Fishers Lane, Terrace Level, Rockville, MD 20852                       |
| Other HHS | <a href="#">Meeting of the Technical Advisory Panel on Medicare Trustee Reports</a>  | Dec. 14, 2011, 9:15 am - 5 pm                                   | HHS headquarters at 200 Independence Ave., SW., Washington, DC, 20201  |

## Opportunities for Public Comment

| Federal Rules, Regulations and Notices  | Effective Date | Comments Due  |
|---|----------------|---------------|
| <a href="#">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</a> |                | Dec. 12, 2011 |
| <a href="#">Center for Drug Evaluation and Research, Approach to Addressing Drug Shortage; Public Workshop; Request for Comments</a>  |                | Dec. 23, 2011 |
| <a href="#">Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation</a>   |                | Dec. 23, 2011 |
| <a href="#">Medicare and Medicaid Program; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction</a>  |                | Dec. 23, 2011 |
| <a href="#">Medicare Program; Changes to the Ambulatory Surgical Centers Patient Rights Conditions for Coverage</a>   | Dec. 23, 2011  |               |
| <a href="#">A Review of FDA's Approach to Medical Product Shortages</a>   |                | Dec. 23, 2011 |
| <a href="#">Permanent Certification Program for Health Information Technology; Revisions to ONC-Approved Accreditor Processes</a>   | Dec. 27, 2011  |               |
| <a href="#">Medicaid Program; Recovery Audit Contractors</a>  | Jan. 1, 2012   |               |
| <a href="#">Medicare Program; Part A Premiums for CY 2012 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement</a>  | Jan. 1, 2012   |               |
| <a href="#">Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2012</a>   | Jan. 1, 2012   |               |
| <a href="#">Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2012</a>  | Jan. 1, 2012   |               |
| <a href="#">Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year</a>  | Jan. 1,        |               |

| <b>Federal Rules, Regulations and Notices</b>   | <b>Effective Date</b> | <b>Comments Due</b> |
|---|-----------------------|---------------------|
| <a href="#">2012</a>  | 2012                  |                     |
| <a href="#">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</a>       | Jan. 1, 2012          | Jan. 3, 2012        |
| <a href="#">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</a> | Jan. 1, 2012          | Jan. 3, 2012        |
| <a href="#">Medicare Program; Final Waivers in Connection With the Shared Savings Program</a>   |                       | Jan. 3, 2012        |
| <a href="#">Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations</a>   | Jan. 3, 2012          |                     |
| <a href="#">Bar Code Technologies for Drugs and Biological Products; Retrospective Review Under Executive Order 13563; Request for Comments</a>   |                       | Jan. 9, 2012        |
| <a href="#">Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices</a>  |                       | Jan. 17, 2012       |
| <a href="#">Orphan Drug Regulations</a>   |                       | Jan. 17, 2012       |
| <a href="#">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</a>                           |                       | Apr. 25, 2012       |

### ***Noteworthy***

- CMS [announced](#) a new application deadline for the Advanced Payment Model. The new deadline for applications for the performance period beginning April 2012 is January 3 – February 1, 2012.