KING & SPALDING

Health Headlines

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CMS Issues Final Rule Implementing Value-Based Purchasing Program – On Friday, April 29, 2011, CMS released its final rule implementing the value-based purchasing (VBP) program required by Section 3001 of the Patient Protection and Affordable Care Act (PPACA) (Pub. L. No. 111-148). The VBP program as finalized by CMS adheres closely to the lines proposed by CMS in its proposed rule issued on January 7, 2011. A more general discussion of the contours of the VBP program is provided in the **January 10, 2011** ***Health Headlines*** discussing CMS's proposal. One of the few significant changes to the program from CMS's proposal is that CMS classified an additional five clinical process measures as "topped out," using the latest data available to it, and therefore excluded these measures from the program. The number of clinical process measures used for FFY 2013 incentive payments has therefore been reduced from a proposed 17 to just 12. In addition, CMS abandoned its proposal to use an 18-month evaluation period for the outcome-based measures, which will be implemented beginning in FFY 2014, and agreed with some commenters that the same 12-month evaluation period that applies to the other measures was more appropriate. Finally, CMS did not finalize its proposal for adding and retiring measures using a "subregulatory" process that would forgo notice and comment. Instead, CMS has proposed in the hospital inpatient PPS rule FY 2012 to allow CMS to simultaneously adopt one or more measures for both the Hospital quality reporting program and the Hospital VBP program. Other important aspects of the program remain largely as CMS had previously proposed. In particular, some of the broad parameters of the finalized VBP program are as follows:

- The FFY 2013 performance period will start on July 1, 2011 and end on March 31, 2012.
- The base period against which CMS will measure a hospital's "improvement" for FFY 2013 will be July 1, 2009 through March 31, 2010.
- CMS will notify each hospital of the estimated amount of its value-based incentive payment for FY 2013 at least 60 days prior to October 1, 2012 but will not notify hospitals of the exact amount until November 1, 2012.
- Future performance periods will be a full year.

The final rule also contains the specific "achievement thresholds" for each measure (i.e., minimum score necessary to receive any points for that measure) in Table 4 (see pg 84). The clinical process of care achievement thresholds range from 0.6548 to 0.9766. CMS also published the "benchmark" scores for each measure (i.e., the scores necessary to receive the full 10 points) in Table 6 (see pg. 95). The clinical process of care benchmarks range from 0.9191 to 1.0 (i.e., 100% compliance with the standard).

As part of its "regulatory impact analysis," the final rule includes charts detailing CMS's estimates on how the roughly $850 million of incentive payments will be distributed among different types of hospitals and geographic regions (pgs 178-182).

Neither the final VBP rule nor the proposed hospital inpatient PPS rule explains how VBP payments will be made.

CMS said that the appeal procedures will be the object of a future rulemaking and did not finalize any appeal procedures here.

The final rule is available **here**.

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CMS Issues Final Rule For Inpatient Psychiatric Facilities PPS – The Centers for Medicare & Medicaid Services (CMS) recently issued its final rule (Final Rule) updating prospective payment rates to inpatient psychiatric facilities (IPFs) for discharges occurring during the rate year (RY) beginning July 1, 2011 through September 30, 2012. CMS estimates that changes included in the Final Rule will result in an increase of approximately $120 million for estimated RY 2012 payments compared to estimated RY 2011 payments. According to CMS, the estimated $120 million increase is the result of a $130 million increase due to payment rate updates and a $10 million decrease from updates to the outlier threshold amount. Updates to the outlier threshold amount are expected to decrease outlier payments from approximately 2.2 percent in RY 2011 to 2.0 percent in RY 2012. CMS estimates that the revenue impact of the Final Rule on all IPFs will be an increase in Medicare payments of approximately 2.74 percent. In addition to payment updates, the Final Rule also provides for temporary adjustments to FTE caps to reflect residents added due to closure of an IPF or IPF residency training program. The IPF must request the temporary adjustment from its Medicare contractor.

In the Final Rule, CMS is also changing the payment rate update period to a rate year (RY) that corresponds with a fiscal year (FY) update. To make the change to a FY update period that is October 1 – September 30, RY 2012 will be a 15-month period, from July 1, 2011 through September 30, 2012. Following RY 2012, the next update to the IPF PPS rates will be the FY 2013 update from October 1, 2012 through September 30, 2013. CMS stated that the change in the annual update period would align the IPF PPS update with the annual update of the ICD-9-CM codes. The Final Rule, which may be read **here**, will be published in the Federal Register on May 6, 2011.

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CMS Releases March 2011 Report On National RAC Program – CMS has released a March 2011 report on the national Medicare fee-for-service Recovery Audit Contractor (RAC) Program. Since the nationwide permanent RAC program began on October 1, 2009, $313.2 million in overpayments have been returned to Medicare and $52.6 million in underpayments have been paid to providers. The 3-year demonstration program, which ran from March 2005 through March 2008, reported total corrections in the amount of $992.7 million for overpayments and $37.8 million for underpayments.

Top overpayment issues identified by RACs include incorrect coding and errors involving separate billing of bundled services. The RACs for the various regions specifically cited the following issues:

Region A, Diversified Collection Services

Ventilator Support of 96+ hours – Ventilation hours begin with the intubation of the patient (or time of admittance if the patient is admitted while on mechanical ventilation) and continue until the endotracheal tube is removed, the patient is discharged/transferred, or the ventilation is discontinued after a weaning period. Providers are improperly adding the number of ventilator hours resulting in higher reimbursement.

Region B, CGI, Inc.

Extensive Operating Room Procedure Unrelated to Principal Diagnosis – The principal diagnosis and principal procedure codes for an inpatient claim should be related. Errors occur when providers bill an incorrect principal and/or secondary diagnosis that results in an incorrect Medicare Severity Diagnosis-Related Group assignment.

Region C, Connolly, Inc., and Region D, HealthDataInsights

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Provided During an Inpatient Stay – Medicare does not make separate payment for DMEPOS when a beneficiary is in a covered inpatient stay. Suppliers are inappropriately receiving separate DMEPOS payment when the beneficiary is in a covered inpatient stay.

CMS's March 2011 RAC report is available by clicking **here**.

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Forest Labs Announces HHS-OIG Contemplating Exclusion Of Its CEO – Forest Laboratories, Inc. (Forest Labs) announced that the Office of Inspector General of the Department of Health and Human Services notified Forest Labs' CEO and President, Howard Solomon, by letter on April 12, 2011, that it was considering excluding him from participation in federal healthcare programs because he is an individual "associated with" Forest Labs. Forest Labs' subsidiary Forest Pharmaceuticals, Inc. entered into a global settlement with the government in late 2010 concerning civil claims and criminal charges related to the marketing and distribution of Levothroid, Celexa, and Lexapro.

In September 2010, Forest Pharmaceuticals, Inc. reached a global settlement paying in excess of $313 million, and in November 2010 it pleaded guilty to obstruction of an FDA investigation and to strict liability misdemeanor violations of the Food, Drug and Cosmetic Act for distributing an unapproved new drug in interstate commerce and distributing a misbranded drug in interstate commerce. Forest Labs' press release notes that "[a]t no time during the government's six year investigation of Forest was Mr. Solomon ever accused of any wrongdoing in connection with the matters settled in 2010." HHS-OIG appears to be relying on Section 1128(b)(15)(A)(ii) of the Social Security Act, 42 U.S.C. 1320a–7(b)(15)(A)(ii), which gives the agency permissive exclusion authority to proceed against "an officer or managing employee" of a sanctioned entity convicted of certain offenses. OIG's guidance indicates that knowledge is not required, as "Officers and managing employees . . . may be excluded under section 1128(b)(15)(A)(ii) based solely on their position within the entity."

Mr. Solomon has 30 days from the April 12 letter to respond and to describe why he should not be excluded. Forest Labs' press release is accessible by clicking **here**, FDA's press release describing Forest Pharmaceuticals' plea agreement is accessible by clicking **here**, and OIG's Permissive Exclusion Guidance is accessible **here**.

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CMS Proposes To Grant Medicare Coverage For MRIs Provided To Patients With *Certain* Pacemakers – In a quick reversal of its prior position on this issue, on April 26, CMS published a Proposed Decision Memo relating to Magnetic Resonance Imaging (MRI) coverage for patients with implanted pacemakers. CMS proposed that Medicare will cover MRIs for patients with implanted pacemakers *if* the pacemaker is FDA-approved for use in the MRI environment. CMS's prior position (published on February 24, 2011) was that Medicare would *not* cover MRIs for patients with cardiac pacemakers, except when provided through Coverage with Evidence Development/Coverage with Study Participation in approved clinical studies. However, after receiving a request from Medtronic, Inc., which recently received FDA approval for use of its RevoMRI SureScan Pacing System in the MRI environment, CMS began the process of reconsidering its noncoverage policy. CMS intends to change the language in section 220.2.C.1 of the National Coverage Determinations Manual to incorporate this decision. The Proposed Decision Memo is available **here**.

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