KING & SPALDING

Health Headlines

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CMS Issues Proposed Rule Implementing Value-Based Purchasing Program – On January 7, 2011, the Centers for Medicare and Medicaid Services (CMS) announced the issuance of a proposed 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 provides incentive payments, beginning with discharges on or after October 1, 2012, to hospitals that perform well, as determined by CMS, on the quality information submitted under the Hospital Inpatient Quality Reporting Program. The incentive payments must be budget-neutral and are funded through across the board reductions to DRG payments starting with a one percent reduction for discharges beginning on October 1, 2012, and increasing to a two percent reduction in FFY 2017. Among other things, CMS has announced the specific measures it will include in determining the FFY 2013 incentive payments and that the performance period for evaluation will start on July 1, 2011, and end on March 31, 2012. The specific measures CMS will be evaluating are listed in a chart included in CMS's fact-sheet and proposed rule and consists of seventeen clinical quality measures (three quality measures each for acute myocardial infarction, heart failure, and surgical care improvement categories and four quality measures each for the healthcare-associated infections and pneumonia categories) and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results. The proposed rule also discusses CMS's proposed scoring methodology for calculating the amount of the incentive payment.

Under the statute, a measure has to have been included on the Hospital Compare website for at least one year prior to the beginning of the performance period before it can be used as part of the VBP program. Social Security Act (Act) § 1886(b)(3)(B)(viii). CMS has expressed its intention to automatically convert all quality reporting measures that meet this requirement into part of the VBP program going forward through a "sub-regulatory" process that would not require notice and comment rulemaking. CMS proposes to exclude "topped-out" measures where the majority of hospitals consistently achieve extremely high compliance rates because these measures do not allow for comparisons between hospitals and may skew CMS's data.

As required by statute, *see* Act § 1886(o)(5)(B)(i), CMS will evaluate each hospital's performance using the higher of an achievement score or an improvement score. CMS is proposing to require hospitals that have at least four measures with ten cases each to participate in the VBP program. Under CMS's proposal, a hospital would earn 0-10 points for achievement based on where its performance for a particular measure fell within "a scale between an achievement threshold and a benchmark." CMS's proposes to set the "achievement threshold" at the average national score for the measure and the "achievement benchmark" as the median score achieved by the top decile of hospitals on that measure. A hospital would receive a single point for each interval between the threshold and benchmark. A hospital that did not meet the "achievement threshold" by scoring at least in the top half of hospitals nationwide on a measure, would receive no points for that measure. A hospital that achieves the benchmark threshold, *i.e.*, that scored better than half of the hospitals in the top performing decile for that measure, would receive the full ten points for the measure. Similarly, for the improvement score, CMS proposes to give a hospital a point for each interval of improvement between the hospital's base period score, using data from July 1, 2009, and March 31, 2010, and the national benchmark score.

Using the higher of a hospital's achievement score on a measure, CMS proposes to then calculate a "Total Performance Score" for each hospital by combining its scores on all of the measures within each domain, multiplying its performance score on each domain by the proposed weight for the domain (70% for clinical process of care measures and 30 percent for patient experience measures), and adding the weighted scores for the domains. The incentive payments will then be based on each hospital's total performance score using a "linear exchange function" which is intended to provide "the same marginal incentives to both lower- and higher-performing hospitals." CMS has not yet announced what the actual payment amounts will be.

Other elements of interest in the proposed rule include the following:

- CMS has proposed to 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 "on or about Nov. 1, 2012."
- CMS has proposed to add three mortality measures, eight hospital-acquired conditions measures, and nine Patient Safety Indicators (PSIs), Inpatient Quality Indicators (IQIs), and Composite Measures to its evaluation for FFY 2014.
- CMS has stated that it anticipates that future performance periods will be a full year and that the performance period for the outcome driven measures will be eighteen months.
- Once outcome driven measures are introduced in 2014, CMS expressed its intention to weigh those measures more heavily then the other measures.
- The statute requires CMS to establish an appeal procedure limited to the review of "the calculation of a hospital's performance assessment with respect to the performance standards." Act § 1886(o)(11)(A). CMS has stated it will establish those appeal procedures in a "future-rulemaking" and specifically requested comments "on the appropriateness of a process that would establish an agency-level appeals process under which CMS personnel having appropriate expertise in the Hospital VBP program would decide the appeal."

CMS will accept public comments on the proposed rule through March 8, 2011, and states that it will issue a final rule "some time in 2011."

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CMS Issues New Cost Reporting Instructions for Hospitals – On December 30, 2010, CMS issued a transmittal introducing new Medicare cost reporting instructions for hospitals at a new Form CMS 2552-10. The transmittal introduces a new Chapter 40 to Part 2 of the Provider Reimbursement Manual. Among the changes is the addition of cost centers for certain high cost medical devices. As a result of these changes, when data from the new cost reports is used for the DRG recalibration process, which will probably not be until 2013, DRG weights for cases involving high cost devices, such as implantable cardiac defibrillators, should increase. The transmittal also contains a redesign of Worksheet S-7, which captures cost reporting data for skilled nursing facilities. The instructions also introduce new worksheets to be completed by inpatient psychiatric providers, inpatient rehabilitation providers, and long term care hospital providers. A new worksheet requires acute care and critical access hospitals to report costs associated with participation in the Medicare EHR Incentive Program. The transmittal also instructs providers to report graduate medical education costs, including those formerly paid through the ESRD composite rate, at Worksheet E-4. The instructions are effective retroactively on May 1, 2010 and are available by clicking here.

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OIG Releases Report Regarding Inappropriate Billing by SNFs – On December 22, 2010, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published its report titled "Questionable Billing by Skilled Nursing Facilities." The report, based on a review of Medicare Part A claims from 2006 and 2008 and data from the Online Survey, Certification and Reporting system, raises concerns regarding potentially inappropriate use of higher paying resource utilization groups (RUGs) by SNFs, especially investor-owned SNFs.

SNFs place each beneficiary into a RUG, based on the amount of care required by the beneficiary, and each RUG has a different per diem rate. The OIG found that from 2006 to 2008, SNFs billed for higher paying RUGs, while the

population of SNF beneficiaries (including their ages and diagnoses at admission) remained relatively similar during those years. Additionally, the OIG study cited that billing practices were dependent on the type of SNF ownership, stating that "for-profit SNFs were far more likely than nonprofit or government SNFs to bill for higher paying RUGs." Noting that, on average, for-profit SNFs had longer lengths of stay than SNFs with other ownership, the OIG stated that the differences did not appear to result from different populations of beneficiaries at the SNFs owned by for-profits compared to those beneficiary populations at non-profit or government owned SNFs. Additionally, the OIG indicates that it identified 348 SNFs that were in "the top 1 percent for the use of ultra high therapy, RUGs with high [activities of daily living (ADL)] scores, or long average lengths of stay."

The OIG recommended that CMS should: (1) monitor the payment rates to SNFs, and if necessary, modify those rates; (2) modify the method by which the SNF determines how much therapy a beneficiary will require; (3) intensify the monitoring of SNFs that are billing for higher paying RUGs; and (4) review those SNFs identified by the OIG as having questionable billing practices. CMS concurred with all but the second recommendation but has its own initiatives planned for reviewing the utilization of therapy in different settings. With respect to the third recommendation, the OIG noted that CMS should pay close attention to for-profit SNFs owned by large chains, as they were cited by the OIG as more likely to bill for higher paying RUGs. The OIG suggested that CMS contractors should determine for each SNF "the percentage of RUGs for ultra high therapy, the percentage of RUGs with high ADL scores, and the average length of stay." Any SNFs identified by the OIG in its study as having questionable billing practices will be referred to CMS for further action. The report may be read here in its entirety.

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CMS Announces Preliminary DSH Allotments for FY 2011 – On January 3, 2011, CMS published a Federal Register notice announcing the preliminary federal share of the disproportionate share hospital (DSH) allotments for fiscal year (FY) 2011. According to CMS, the FY 2011 DSH allotments are, in the aggregate, approximately $365 million less than the FY 2009 and FY 2010 allotments, largely due to the end of a 2.5% increase for DSH levels as mandated for those two prior years by the American Recovery and Reinvestment Act.

CMS also announced the preliminary FY 2011 limitations on the amount of DSH payments that a state can make to institutions for mental disease (IMD) and other mental health facilities. The preliminary FY 2011 IMD DSH Limits are down by approximately $23 million as compared to the preliminary FY 2010 IMD DSH Limits. According to CMS, the decrease reflects the fact that the limitations are based on the regular FY 2011 preliminary DSH allotments, which decreased.

In addition, the notice announces the final FY 2009 DSH allotments and includes background information describing the methodology for determining the amount of states' FY DSH allotments.

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ONC's Permanent Certification Final Rule Among Recent Health IT Developments – On January 3, 2011, the Office of the National Coordinator for Health IT released a final rule establishing a permanent certification program for EHR technology. The rule states that ONC will designate an organization, a so-called ONC-Approved Accreditor (ONC-AA), to accredit entities to certify complete EHRs and EHR modules. ONC will select an ONC-AA every three years. ONC's temporary certification program, released in June 2010, will remain in effect until the permanent certification program becomes operational in January 2012. The permanent certification rule states that as ONC develops new certification criteria, certifying entities will provide "gap certification" of those new elements for previously-certified EHR products. The permanent certification rule is available by clicking here.

Meanwhile, CMS announced the first Medicaid EHR incentive payments to an eligible hospital, University of Kentucky Healthcare, and payments to two eligible professionals in Oklahoma. Kentucky and Oklahoma are among 11 states with approved State Medicaid HIT plans that began registering eligible hospitals and professionals on January 3, 2011. Three more states will open registration in February 2011. A complete list of states with open registration is available by clicking here. Registration for both the Medicare and Medicaid EHR Incentive Programs is available by clicking here.

Lastly, CMS and ONC have updated two meaningful use educational resources. First, ONC clarified two of its FAQs to require that certified EHR technology must have the ability to satisfy all 24 Stage 1 meaningful use objectives, even if an eligible hospital or professional plans to submit data on only the minimum requirement of 19. The FAQ is available by clicking here (see No. 17). CMS also has updated its specification sheet for the CPOE meaningful use measure, stating that an order entered using CPOE would count in the numerator of the measure if the order is made in the EHR before any action is taken on that order. The order must be entered by someone exercising clinical judgment who could respond to any alert generated by the EHR at the time of entry. The complete list of meaningful use criteria specification sheets is available by clicking here.

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CMS Solicits Comments for the Development of the Part C and Part D RAC Program – On December 27, 2010, CMS published a notice in the *Federal Register* requesting comments concerning the development of the Medicare Part C and Part D Recovery Audit Contractor (RAC) program. Section 6411 of The Patient Protection and Affordable Care Act (PPACA) requires the expansion of the RAC program to Medicare Part C and Part D. As reported in a previous Health Headline article, CMS has already pursued steps to implement the Medicaid RAC program.

Noting the differences between the Medicare fee-for-service (FFS) and the Medicare Part C and Part D programs, CMS solicits comments on several topics including the following:

- Methods for RACs to identify overpayments and underpayments;
- Criteria or qualifications necessary to enable a RAC to knowledgeably review Medicare Part C and Part D payments;
- Conflict of interest rules applicable to the Medicare Part C and Part D RAC program;
- Establishment of an oversight entity for Medicare Part C and Part D issue approval;
- Identification and resolution of underpayments in the Medicare Part C and Part D RAC programs;
- Prudence of allowing Part C and Part D plan sponsors to use RACs within their own plans to identify overpayments;
- Information concerning overpayment recoupment models used by managed care companies and the extent to which these models should apply to Part C; and
- Information on how purchasers have identified overpayments and underpayments made by capitated plans and to what extent the savings were shared between the plan and the purchaser.

In addition to identifying overpayments and underpayments, and the recoupment of overpayments, section 6411 of PPACA establishes additional tasks for Part C and Part D RACs.

- Ensure that each managed care plan and Part D plan has anti-fraud plans in place and review the effectiveness of the anti-fraud plans;
- Examine claims for reinsurance payments to determine whether prescription drug plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under the statute; and
- Review estimates submitted by prescription drug plans with respect to the enrollment of high cost beneficiaries (as defined by the Secretary) and compare such estimates with the numbers of such beneficiaries actually enrolled by such plans.

Like Medicare Parts A and B RACs, Part C and Part D RACs will be compensated pursuant to a contingency basis. CMS, however, notes that some of the additional tasks for Part C and Part D RACs, such as reviewing anti-fraud plans, will not result in recoveries or overpayments. Thus, CMS is soliciting comments on how to pay RACs on a contingency basis for tasks that do not result in recoveries or overpayments.

Comments must be received by February 25, 2011. The notice is available by clicking here.

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Client Alert: New Required Informed Consent Element – Disclosure that Clinical Information Will Be Entered into ClinicalTrials.gov – The Food and Drug Administration (FDA) issued a final rule on January 4, 2011 that amends 21 C.F.R. § 50.25 and the requirements for informed consent documentation and process in FDA-regulated clinical trials of drugs, biological products, and medical devices. 76 Fed. Reg. 256 (Jan. 4, 2011).

The final rule responds to Section 801 of the FDA Amendments Act of 2007 (FDAAA), *see* § 801(b)(3)(A) of the FDA Amendments Act of 2007 (Pub. L. 110-85, Sept. 27, 2007), which requires registration and results posting in the federal data bank, ClinicalTrials.gov, for "applicable clinical trials" of FDA-regulated drugs and medical devices. *See* 42 U.S.C. § 282(j)(1)(A) (defining "applicable clinical trial"). FDAAA mandated that FDA's drug regulations be updated "to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigations has been or will be submitted for inclusion in the registry data bank." The final rule requires the following statement to be included in the informed consent documents and process of "applicable clinical trials" for both drugs (including biological products) *and* medical devices:

"A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The new rule has important implications for sponsors of FDA-regulated clinical trials conducted in the United States and other countries. A copy of the complete Client Alert is available by clicking here.

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