KING & SPALDING

Health Headlines

May 9, 2011

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OIG Informs Providers That ACO Waivers Will Probably Be Consistently Applied To ACOs And Not Issued On A Case-By-Case Basis – During an April 28, 2011, telephone conference sponsored by the Health Care Compliance Association, Vicki L. Robinson, Chief of the Industry Guidance Branch and Senior Advisor for Health Care Reform of the Office of the Inspector General, Department of Health and Human Services (OIG), informed providers that the OIG and the Centers for Medicare and Medicaid Services (CMS) envision that Accountable Care Organization (ACO) waivers will be applied consistently to all ACOs rather than on a case-by-case basis. Therefore, according to the OIG, ACO waivers will most likely not be granted using an approach similar to the Advisory Opinion process. This elaborates upon the comments of OIG and the CMS in their recent joint notice soliciting comments on proposed ACO waivers. In such notice published in the *Federal Register* on April 7, 2011, CMS and OIG informed providers that the agencies are contemplating promulgating waivers in the publication of the final regulations for the Medicare Shared Savings Program that are to be applied consistently and uniformly to all ACOs.

As stakeholders expressed concern that implementation of the Medicare Shared Savings Program and the development of ACOs would be impeded by certain fraud and abuse laws, the Patient Protection and Affordable Care Act (PPACA) authorizes the Secretary of the Department of Health and Human Services to waive the Stark Law, Anti-Kickback Statute and certain other laws as necessary to implement the program. CMS and OIG issued the April 7, 2011 notice under this authority, and the comment period ends on June 6, 2011.

The notice sets forth proposals for waiving application of the Stark Law, the Anti-Kickback Statute and the civil monetary penalty law that prohibits hospitals from paying physicians to reduce or limit services provided (the CMP Law). In all proposals, the ACO would be required to enter into an agreement with CMS to participate in the Medicare Shared Savings Program and the ACO participants, providers and suppliers would be required to comply with the agreement and all of the requirements applicable to the program.

The agencies propose waiving the application of the Stark Law and the Anti-Kickback Statute to distributions of shared savings received by an ACO from CMS under the program "to or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned" that are for activities "necessary for and directly related to" the ACO's participation in the Medicare Shared Savings Program. Interestingly, the notice also proposes to waive application of the Anti-Kickback Statute and the CMP Law to any financial relationship between or among the ACO, ACO participants and ACO providers and suppliers that are directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Stark Law but fully complies with one of its exceptions.

CMS also solicits public input on the application of waivers to other related scenarios, such as arrangements that relate to the establishment of an ACO. For a copy of the April 7, 2011, Federal Register notice, click **here**.

Reporter, *Catherine Stern*, Atlanta, +1 404 572 4661, kstern@kslaw.com.

CMS Issues Ruling Acquiescing In Court Decisions Invalidating Hospice Cap Regulation – CMS issued a Ruling in the May 9, 2011 Federal Register acquiescing in the holdings of many federal district courts invalidating the agency's hospice cap calculation methodology at 42 C.F.R. § 418.309(b)(1). See, e.g., Russell-Murray Hospice, Inc. v. Sebelius, 724 F. Supp. 2d 43 (D.D.C. 2010), appeal pending, No. 10-5311 (D.C. Cir.); Affinity Healthcare Servs., Inc. v. Sebelius, 2010 WL 4258989 (D.D.C. 2010), appeal pending, No. 11-5037 (D.C. Cir.). The Ruling establishes a remand process whereby hospices with properly pending administrative appeals challenging the methodology will have their aggregate cap amounts recalculated according to the relevant provisions of the Medicare statute.

By statute, payments to hospices cannot exceed a per-beneficiary cap amount multiplied by the total number of beneficiaries a hospice treats in a given year. When a beneficiary's hospice benefit period spans multiple cap years, the Medicare statute requires that CMS proportionately allocate the number of days the beneficiary received hospice care across each year. However, CMS's regulation at 42 C.F.R. § 418.309(b)(1) counts a beneficiary's entire stay in the cap year in which the beneficiary received "the preponderance of care." See 48 Fed. Reg. 56008, 56022 (Dec. 16, 1983). The Ruling requires that a hospice's properly pending appeal challenging this regulation shall be remanded to the hospice's Medicare contractor for proportional recalculation according to the statute.

The Ruling requires Medicare contractors to make proportional allocations using a fraction for each beneficiary for each cap year. The numerator of the fraction will be the number of hospice benefit days a beneficiary received during a particular cap year. The denominator of the fraction will be the total number of hospice benefit days a beneficiary received during all cap years. The contractor will then sum the fractions for all of the beneficiaries the hospice treated during the particular cap year, and arrive at a total beneficiary count. The contractor will multiply the count by the per-beneficiary cap amount to arrive at the hospice's aggregate cap on hospice payments for the cap year.

For beneficiaries who are still receiving hospice care at the time of the recalculation, CMS instructs contractors to use the beneficiary's number of benefit days at the time of the calculation. Determinations will then be subject to adjustments on reopening once those beneficiaries cease receiving hospice benefits.

The Ruling applies to all properly pending appeals of the regulation before the Provider Reimbursement Review Board, the CMS Administrator, a fiscal intermediary hearing officer or CMS reviewing official. Upon notice from a hospice's Medicare contractor that a hospice's appeal is subject to the Ruling, the tribunal is to remand the appeal to the contractor. In the event a hospice's appeal also contains issues not covered by the Ruling, those issues remain in the appeal and only the challenge to the allocation methodology shall be remanded. Once the contractor has completed the reallocation, the hospice may appeal the new determination under regular administrative and judicial review procedures. Hospices that have not challenged CMS's allocation methodology may have their hospice cap amount calculated under the current regulation for cap years ending on or before October 31, 2011. CMS also proposed to revise 42 C.F.R. § 418.309(b) to conform with the statute in the FY 2012 Hospice Wage Index proposed rule. The Ruling is available **here** and the proposed rule is available **here**.

Reporter, *Christopher Kenny*, Washington, D.C., +1 202 626 9253, ckenny@kslaw.com**.**

HHS Requests Comments On "Mystery Shopper" Plan To Determine Primary Care Physicians' Availability To Accept New Patients – On April 28, 2011, the Department of Health and Human Services (HHS) published an information collection request in the Federal Register soliciting comments on a proposed plan to assess the availability of primary care physicians (PCPs) across nine states to accept new patients. The plan, developed by the HHS **Office of the Assistant Secretary for Planning and Evaluation** (ASPE), proposes to utilize a "mystery shopper approach" to collect data from physicians' offices in order to "gauge availability of PCPs accepting new patients, timeliness of services from PCPs, and gain insight into the precise reasons that PCP availability is lacking." ASPE is the principal advisory office to the HHS Secretary on policy development and is responsible for major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.

Under the proposed plan, ASPE will contact 4,185 PCPs across nine states (465 in each state) two times each, once posing as a privately insured patient and once posing as a publicly insured patient. The contacts will simulate a prospective

patient seeking care for an urgent medical need or requesting a routine examination. ASPE plans to collect standardized information from each contact according to a standard protocol for each "mystery shopper" scenario.

In addition, ASPE plans to contact 465 PCPs across the nine states for a third time, informing the PCPs about the purpose of the study, and asking directly if they are accepting new patients and how long it would take to obtain an appointment.

ASPE estimates that it would take each PCP five minutes to respond to each contact, making the total burden on PCPs created by the proposed program 737 hours. ASPE is currently seeking Office of Management and Budget (OMB) approval for the plan and estimates that the data collection portion of the program would be completed within four months of OMB approval.

Public comments on the necessity and utility of the ASPE "mystery shopper" plan are due by June 27, 2011. The Federal Register publication (76 Fed. Reg. 23816) can be found **here**.

Reporter, *J. Austin Broussard*, Atlanta, +1 404 572 4723, jabroussard@kslaw.com.

CMS Issues Final Rule Streamlining Privileging And Credentialing Process For Telehealth Providers – On May 2, 2011, CMS issued a final rule simplifying the process for the credentialing and privileging of telehealth providers serving Medicare hospitals. The current process requires a hospital or CAH receiving telemedicine services to go through a burdensome credentialing and privileging process for each physician and practitioner providing telemedicine services to its patients. Formerly, hospitals accredited by The Joint Commission (TJC) were "deemed" to have met the Medicare Conditions of Participation (CoPs) if they met TJC's telehealth credentialing and privileging requirements. TJC's requirements allowed "privileging by proxy" whereby a TJC-accredited facility could accept the privileging decisions of another TJC-accredited facility through a streamlined process.

As of July 15, 2010, however, facilities using the TJC-approved method were no longer deemed in compliance with Medicare CoPs and CMS instructed facilities to comply with a rigorous individualized credentialing and privileging process. After reflecting on public comments on the proposed rule, CMS concluded that its present requirement was "duplicative and burdensome," particularly for small and rural hospitals and CAHs "which often lack adequate resources to fully carry out the traditional credentialing and privileging process." Under the new rule, hospitals receiving telemedicine services may rely on the privileging and credentialing determinations of the facility where the provider is located. That facility (known as the "distant site") need not participate in Medicare, but must have an agreement and provide proof that it is in compliance with CMS standards. The final rule will go into effect July 2, 2011. A full copy of the rule is available **here**.

Reporter, *Martha S. Henley*, Atlanta, +1 404 572 2775, mhenley@kslaw.com.

TRICARE Issues Letters To Hospitals Seeking To Resolve Outpatient Reimbursement – Last week TRICARE, the health care program of the Department of Defense, began issuing letters to hospitals notifying them of an opportunity to participate in an "untimely but discretionary appeal" under the TRICARE appeal procedures in order to obtain "discretionary net adjusted payments" for outpatient radiology claims. According to the more detailed discussion on the **TRICARE Management Activity website**, the agency has identified approximately $98 million in potential underpayments for outpatient radiology claims for services during the period between August 1, 2003 to May 1, 2009. The website contains a detailed description of the data analysis and calculation process that will be used to process appeals. The potential underpayments are an outgrowth of the delayed implementation of the TRICARE outpatient prospective payment system (OPPS) and the National Defense Authorization Act of 2002, which required the use of Medicare rates for hospitals to the extent practicable. While there were questions raised to the agency regarding its interpretation and implementation of the relevant regulations, the TRICARE letter asserts that, for "hospital outpatient services during that period [August 1, 2003 to May 1, 2009], payments ….were correct." But, "as it specifically concerns hospital outpatient radiology services, however, TRICARE may have directed payment of amounts, which in some cases were less, and in some cases more than the comparable Medicare fair payment." The letter invites hospitals to request that their claims data be reviewed for "appropriate discretionary adjusted payments." However, in order to participate in the payment adjustment process, which is designed to mete out the $98 million in potential net adjustments, hospitals must execute a "release by the hospital of any hospital outpatient services claims against the agency, TRICARE

beneficiaries, and TRICARE Managed Care Support Contractors." Given the questions that were raised regarding the agency's interpretation and implementation of its hospital outpatient reimbursement methodology, hospitals should carefully review the TRICARE letters with their counsel and consultants to determine the appropriate course of action.

Reporter, *Gregory N. Etzel*, Houston, +1 713 751 3280, getzel@kslaw.com.

CMS Releases The Third Issue Of The Medicare Quarterly New Provider Compliance Newsletter – In April 2011, the Centers for Medicare & Medicaid Services (CMS) released the third issue of the Medicare Quarterly Provider Compliance Newsletter (Compliance Newsletter), a Medicare Learning Network (MLN) educational product. The Compliance Newsletter identifies some of the top compliance issues of the particular quarter, as identified by the Medicare Claims Processing Contractors – Recovery Auditors, Program Safeguard Contractors (PSCs), Zone Program Integrity Contractors (ZPICs) and other government organizations, including the Department of Health and Human Services Office of Inspector General (OIG). The Compliance Newsletter is designed to help Medicare Fee-For-Service (FFS) providers and suppliers avoid billing and compliance errors.

The third issue of the Compliance Newsletter includes the following findings:

- Incorrect Discharge Status Code Inpatient Rehabilitation Facility ("IRF") –Overpayment. *Provider Type Affected: IRF*
- Incorrect Patient Status Code IRF – Underpayment. *Provider Type Affected: IRF*
- Coagulation Disorders – Improper Coding of MS-DRG 813 Coagulation Disorders. *Provider Type Affected: Inpatient Hospital*
- Human Immunodeficiency Virus ("HIV") Disease – Wrong Diagnosis Code or Wrong Principal Code Billed. *Provider Type Affected: Inpatient Hospital*
- Oxaliplatin – Dose vs. Billed Units. *Provider Type Affected: Outpatient Hospital*
- Extensive OR Procedure Unrelated to Principal Diagnosis DRG 468 MS-DRG 981, 982, 983. *Provider Type Affected: Inpatient Hospital*
- Untimed Codes – Excessive Units. *Provider Types Affected: Physician, Non-Physician Practitioners and Outpatient Hospital*
- Technical Component of Radiology. *Provider Types Affected: Radiology Suppliers, Physician, Non-Physician Practitioners*

In addition to describing the compliance findings, the Compliance Newsletter includes steps CMS has taken to make providers and suppliers aware of the problems, and guidance on how providers and suppliers can avoid such compliance problems. The Compliance Newsletter also includes MLN Matters Special Edition ("SE") articles regarding OIG findings. The third issue of the Compliance Newsletter identifies the following MLN Matters SE articles:

- SE1102 – Inappropriate Medicare Payments for Transforaminal Epidural Injection Services.
- SE1103 – Capped Rental DME: Enforcement of Payment Requirements for Beneficiary-owned Capped Rental Durable Medical Equipment.
- SE1104 – The Importance of Correctly Coding the Place of Service by Physicians and Their Billing Agents.

The third issue of the Compliance Newsletter is available by clicking **here**.

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FTC Holds Workshop On Accountable Care Organizations – On May 9, the Federal Trade Commission (FTC) hosted a public workshop on its Proposed Statement of Antitrust Enforcement Policy, which it released in conjunction with the Department of Justice on March 31, 2011. Following the workshop, a transcript will be made available by clicking **here**. The comment period on the FTC's Proposed Statement ends on May 31, 2011.

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King & Spalding Upcoming Roundtable On Medicare Value-Based Purchasing For Hospitals On May 24, 2011 – On Tuesday, May 24, 2011, we will be hosting a new Webinar focused on the final rule implementing the new Value-Based Purchasing program for Medicare-participating hospitals. The Webinar will take place from 1:00 p.m. to 2:30 p.m. Eastern. You can read additional information on the agenda and register to attend the Webinar by clicking **here**.

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