KING & SPALDING

Health Headlines

July 11, 2011

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CMS Issues Proposed CY 2012 Physician Fee Schedule and Outpatient Prospective Payment System – On July 1, 2011, CMS issued proposed regulations that would update the Physician Fee Schedule and Outpatient Prospective Payment System (OPPS) rules for calendar year (CY) 2012. These proposed changes would be applicable to services furnished on or after January 1, 2012.

Proposed Changes to the Physician Fee Schedule – The proposed changes to the Physician Fee Schedule would update payment policies and rates for physicians and nonphysician practitioners for services paid under the Medicare Physician Fee Schedule in CY 2012. With respect to the potential 30% Medicare payment reduction based on the current formula - the Sustainable Growth Rate - that was adopted in the Balanced Budget Act of 1997, CMS Administrator Dr. Donald M. Berwick said that, "[t]his payment cut would have serious consequences and we cannot and will not allow it to happen." Significant changes in the proposed Physician Fee Schedule include, among others:

- Expansion of the Potentially Misvalued Code Initiative: CMS has conducted a broad review of its misvalued code initiative in an effort to ensure that Medicare is paying accurately for physician services and closely managing payments. Instead of targeting specific codes for review as it has done in the past, CMS is focusing on the highest volume and dollar codes billed by physicians to determine whether such codes are overvalued and if evaluation and management codes are undervalued.
- Payment for Geographic Variation: CMS is replacing some of its data sources in order to improve how it adjusts payment for geographic variation, in addition to implementing other adjustments requested in prior year public comments. These proposals result in minor changes to the indices.
- Health Risk Assessment Criteria: Coverage for a health risk assessment to be used in conjunction with Annual Wellness Visits began January 1, 2011, under the Affordable Care Act, and CMS proposes criteria for such assessment in order to support a systematic approach to patient wellness.
- Expansion of Services Through Telehealth: CMS proposes to expand the list of telehealth services including smoking cessation services. If adopted, this change would impact the services proposed for the telehealth list in CY 2013.
- Quality and Cost Measures: Proposed quality and cost measures would be used in establishing a new value-based modifier that would reward physicians for providing higher quality and more efficient care. Under the Affordable Care Act, CMS is required to begin making payment adjustments to certain physicians and physician groups on January 1, 2015, and to apply the modifier to all physicians by January 1, 2017.

Proposed Changes to the OPPS – The proposed changes to the OPPS would update payment policies and rates for both hospital outpatient departments and ambulatory surgical centers (ASCs) for CY 2012. Key proposed changes to the rule include, among others:

- Supervision of Outpatient Therapeutic Hospital Services: CMS proposes using the Federal Advisory APC Panel

to evaluate supervision standards for outpatient therapeutic services. The default rule is "direct" supervision, which means physically present, interruptible and immediately available.

- New Diabetes Outpatient Quality Measures Proposed for CY 2014: The proposed quality measures for diabetes outpatient services for CY 2014 (using 2012 data) include hemoglobin A1c management, low density lipoprotein cholesterol management, blood pressure management, eye exam, and urine protein screening.
- New Outpatient Quality Measures Proposed for CY 2014: The new quality measures related to outpatient services (using CY 2012 data) include referral of cardiac rehabilitation from outpatient hospital settings; currently, only 18 % of eligible patients are referred. Additional measures include use of a safe surgery checklist and reporting volumes of outpatient surgery categories (cardiovascular, eye, gastrointestinal, genitourinary, musculoskeletal, nervous system, respiratory, and skin).
- Physician-Owned Hospital Provisions: The proposed regulations address how physician-owned hospitals may request an increase in the number of operating rooms, procedure rooms and inpatient/outpatient beds.
- Outpatient Notification Regarding No Physician On Site: The regulations include a proposal to reduce the categories of outpatients who must be notified if a hospital does not have a physician on site 24 hours per day/7 days per week. The hospital would provide written notice only to those outpatients receiving observation, surgery or services involving anesthesia. Notice to emergency department patients could be posted conspicuously in the emergency department.

CMS proposes to implement ASC Quality Reporting Program beginning with the CY 2014 payment determinations, and CMS's stated goal with respect to its proposed changes to the ASC quality reporting program is to harmonize standards across care settings. Data collection will begin in CY 2012. CMS will propose any additions or revisions to the measures in CY 2013 or CY 2014 rulemaking cycles, for CY 2014 or future payment determinations.

The Physician Fee Schedule proposed rule is available **here** and the OPPS proposed rule is available **here**.

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CMS Proposes 3.35% Rate Decrease For Home Health Payments in 2012 and Medicaid Requirement of Face-To-Face Encounters – On July 5, 2011, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule which would decrease calendar year (CY) 2012 Home Health Prospective Payment System (HH PPS) rates by 3.35% or $640 million. On July 5, CMS also released a proposed rule requiring face-to-face encounters for beneficiaries receiving Medicaid home health services but did not specify an effective date for the new requirement. The Medicaid face-to-face encounter requirement would impose similar timing requirements as Medicare face-to-face encounters.

Effective January 1, 2012, The HH PPS proposed rule would update polices for the national standardized 60-day episode rates, the national per-visit rates, and the low utilization payment amount (LUPA), and outlier payments under the Medicare prospective payment system for home health agencies. Section 3401 of the Patient Protection and Affordable Care Act (ACA) requires CMS to apply a 1% reduction to the CY 2012 market basket rate, making the net proposed market basket update 1.5% for CY 2012 (representing $290 million). The proposed rule also reflects an updated wage index of $20 million. In addition, the HH PPS proposed rule proposes a case mix adjustment of negative 5.06%, representing $950 million, to decrease overall Medicare payments by a total of 3.35% for CY 2012, which represents $640 million in savings to the Medicare program.

Comments to the proposed rules, which have not yet been published, are due to CMS within 60 days following publication in the Federal Register. The rules are expected to be published on Tuesday, July 12, 2011.

To view the HH PPS proposed rule, click **here**. To view the Medicaid face-to-face requirements for home health services proposed rule, click **here**.

Reporter, *Stephanie L. Fuller*, Atlanta, +1 404 572 4629, sfuller@kslaw.com.

HHS Office for Civil Rights Announces $865,500 Settlement with University of California – On July 7, 2011, the U.S. Department of Health and Human Services Office for Civil Rights (OCR) announced it had reached an agreement

with the Regents of the University of California, on behalf of the University of California at Los Angeles Health System (UCLAHS), to settle alleged violations of the HIPAA Privacy and Security Rules. Under the Resolution Agreement, UCLAHS has agreed to pay $865,5000 to settle the alleged violations and to enter into a corrective action plan (CAP) to correct the alleged compliance deficiencies in exchange for a release of liability from OCR. UCLAHS, which includes the UCLA Ronald Reagan Medical Center, the UCLA Santa Monica Medical Center and Orthopedic Hospital, the Resnick Neuropsychiatric Hospital and the Faculty Practice Group of UCLA, admitted no liability in entering into the Resolution Agreement and CAP.

The settlement stems from separate complaints filed with OCR on behalf of two celebrity patients alleging that UCLAHS workforce members repeatedly, without permissible reason, accessed their electronic protected health information (PHI). UCLAHS allegedly did not implement sufficient security measures to reduce the risks of impermissible access to PHI by unauthorized users, did not provide and/or document appropriate privacy and security training for workforce members, and did not sanction and/or document sanctions imposed on workforce members who accessed PHI inappropriately. HIPAA requires covered entities to reasonably restrict access to patient information to only those employees who have a legitimate reason to access PHI, to train workforce members on privacy and security policies and procedures, and to sanction any employee who accesses PHI inappropriately. As part of the CAP, UCLAHS will implement privacy and security policies and procedures approved by OCR, conduct regular training sessions for all UCLAHS employees who use PHI, sanction employees who violate the policies and procedures, and designate an independent monitor to assess UCLAHS's compliance with the plan over a three year period. For a copy of the Resolution Agreement and CAP click **here**. For a copy of the HHS press release, click **here**.

Reporter, *Kerrie S. Howze*, Atlanta, +1 404 572 3594, khowze@kslaw.com.

CMS Proposes Retracting Requirement for Physician Signature for Clinical Diagnostic Laboratory Tests – On June 30, 2011, CMS published a proposed rule to retract the policy announced in 2010 requiring the signature of a physician or qualified non-physician practitioner (NPP) on requisitions for clinical diagnostic laboratory tests. 76 Fed. Reg. 38342 (June 30, 2011). Instead, CMS proposed to "reinstate the prior policy that the signature of the physician or NPP is not required on a requisition for Medicare purposes for a clinical diagnostic laboratory test." *Id.*at 38344. The proposed rule follows through on CMS's March 31, 2011 statement that it intended to retract the requirement by year's end. The proposed rule may be found **here**.

The proposed rule permits, but does not mandate, individual laboratories to require a physician's or NPP's signature on requisitions. Laboratories may also ensure compliance through internal and external audits, as well as requests for medical records from physicians or NPPs. *Id.*at 38346.

CMS outlined its interpretation of 42 C.F.R. § 410.32 to require signatures on requisitions for clinical diagnostic laboratory tests in last year's Medicare Physician Fee Schedule final rule. 75 Fed. Reg. 73170, 73483 (Nov. 29, 2010). As outlined in an April 4, 2011 ***Health Headlines***, the final rule required that the requisition contain the physician's (or qualified NPP's) actual signature. Subsequently, on December 20, 2010, CMS told contractors that due to confusion regarding the rule it would spend the first quarter of 2011 conducting an educational campaign before enforcing the regulation. On March 31, 2011, CMS sent an email to its Provider Resource mailing list announcing that it intended to change the rule by the end of the year. The email can be seen **here**.

According to CMS, it decided to change its policy after industry stakeholders "identified many scenarios where it would be difficult to obtain the physician's or NPP's signature." 76 Fed. Reg. at 38344. In addition, CMS noted that it "can see how requiring the physician or NPP to sign the paper requisition could, in some cases, be very inconvenient and disruptive to the physician, NPP, the beneficiary, and other patients." *Id.* In summary, CMS had "underestimated the potential impact on beneficiary health and safety." *Id.* Comments on the proposed rule are due August 29, 2011.

Reporter, Charles E. Smith, Washington, D.C., +1 202 626 5524, csmith@kslaw.com.

CMS Proposes to Change Definition of "Durable" for Medicare Durable Medical Equipment Coverage: Significant Implications for Manufacturers – On Friday, July 8, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rulemaking (Proposed Rule) that would have a significant impact on the categorical eligibility of

certain types of durable medical equipment (DME) for Medicare coverage. *See* 76 Fed. Reg. 40,498, 40,536-40,539 (July 8, 2011). While the relevant provisions are intended to only apply prospectively for new products, the Proposed Rule would, if finalized, present serious problems for manufacturers of certain types of medical devices that do not have a minimum lifetime of three years. CMS is using the Proposed Rule to redefine the term "durable," presumably in an attempt to address legal vulnerabilities arising from several Medicare contractor determinations made earlier this year. CMS will accept comments regarding the Proposed Rule until August 30, 2011.

Click **here** to read the King & Spalding LLP Client Alert issued by the FDA & Life Sciences Practice Group, which provides a more complete description of the Proposed Rule.

King & Spalding Upcoming HIPAA Privacy and Security Roundtable On July 15, 2011 – On Friday, July 15, 2011, we will be hosting a new Webinar designed to update covered entities and business associates on current issues of interest in the world of HIPAA privacy and security.

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**.

Health Headlines – Editor:

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