KING & SPALDING

Health Headlines

August 22, 2011

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CMS Announces Results of the Section 5503 Redistribution of Residency Slots – On August 15, 2011, CMS revealed the final results of which teaching hospitals are receiving reductions to their full-time equivalent (FTE) resident caps, and which are receiving increases, pursuant to the redistribution of residency slots mandated by § 5503 of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148). In particular, 267 hospitals had their "excess" direct graduate medical education (GME) and indirect graduate medical education (IME) FTE caps reduced by an aggregate of 726.08 and 628.05 slots, respectively, effective July 1, 2011. Those 726 GME slots and 628 IME slots were redistributed to 58 hospitals that received increases in their FTE caps, effective July 1, 2011.

Pursuant to § 5503, 70% of the resident slots had to be distributed to hospitals located in States with resident-to-population ratios in the lowest quartile, while 30% of the slots had to be distributed to hospitals located in rural areas or hospitals located in the top 10 in terms of the ratio of Health Professional Shortage Area population to the total population. Of the 58 hospitals that received increases in their residency caps, then, 39 received FTE slots from the 70% pool and the remaining 19 hospitals, 5 of which were rural, received FTE slots from the 30% pool. Although 87 hospitals submitted applications for the § 5503 cap increases by the January 21, 2011 deadline, the remaining hospitals either had deficient applications or were simply too low on the priority list to receive any cap increase.

A chart prepared by CMS listing each hospital that had its FTE caps reduced or increased, and the amount of the reduction or increase, can be found in the Downloads section at **CMS's website** by clicking on the file named "**Section 5503 Cap Decreases and Increases**."

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Medicare Providers Enrolled Prior to March 25, 2011 to Begin Revalidation – Between now and March 23, 2013, providers and suppliers (providers) who enrolled in Medicare prior to March 25, 2011 will have to revalidate their enrollment information under the new enrollment screening criteria required by Section 6401(a) of the Affordable Care Act. Providers should not begin revalidation, however, until receiving notification to revalidate from their Medicare Administrative Contractor. Providers who enrolled after March 25, 2011 have already been subject to the new screening requirements and, thus, do not have to revalidate at this time. CMS recently released a **Medicare Learning Network article** to explain the revalidation process.

CMS published the new enrollment screening criteria on **February 2, 2011** as a final rule with comment period. The final rule categorizes providers as either limited, moderate or high risk and then applies various screening tools, such as license verification, database checks and unannounced site visits, based on the provider's associated level of risk. Additionally, unless qualifying for a hardship exception, institutional providers must pay an application fee ($505 for calendar year 2011, to be adjusted in subsequent years by the CPI-U).

Upon receipt of notification to revalidate, providers should:

- update enrollment through the internet-based PECOS or complete the paper 855;
- sign the certification statement on the application;
- pay the applicable fee through **https://www.pay.gov** and print out a copy of the payment receipt;
- immediately mail supporting documents, the certification statement and the payment receipt to the MAC.

Providers have 60 days upon receipt of the revalidation request to submit complete enrollment forms. Failure to do so may result in deactivation of the provider's billing privileges.

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

CMS Issues Press Release and Fact Sheet Regarding Next Steps for Expansion of DMEPOS Competitive Bidding Program – On August 19, 2011, CMS issued a press release and a fact sheet describing the next steps that will be taken to expand the durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. The competitive bidding program, established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), replaces the DMEPOS fee schedule for certain DMEPOS products in certain competitive bidding areas (CBAs) with competitive bid pricing. The MMA required that the DMEPOS competitive bidding program be implemented in phases. Round one, which consisted of ten DMEPOS products and ten CBAs, was implemented by CMS on July 1, 2008. However, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) temporarily delayed round one and required the termination of all round one DMEPOS supplier contracts. The round one rebid, which consisted of nearly the same DMEPOS products and CBAs as round one, was fully implemented on January 1, 2011. According to CMS, the competitively bid pricing obtained through the round one rebid process has resulted in savings of 35% compared to the DEMPOS fee schedule.

In the press release and fact sheet, CMS provided details regarding round two of the DMEPOS competitive bidding program, which will involve an expansion of the program to 91 additional metropolitan areas (MSAs) and additional DMEPOS product categories. A list of the 91 additional MSAs is available by clicking **here**. CMS announced that the DMEPOS product categories that will be subject to round two are:

- Oxygen, oxygen equipment, and supplies
- Standard (Power and Manual) wheelchairs, scooters, and related accessories
- Enteral nutrients, equipment, and supplies
- Continuous Positive Airway Pressure (CPAP) devices and Respiratory Assist Devices (RADs) and related supplies and accessories
- Hospital beds and accessories
- Walkers and related accessories
- Negative Pressure Wound Therapy pumps and related supplies and accessories
- Support surfaces (Ground 2 mattresses and overlays)

The specific items within each of the above DEMPOS product categories is available by clicking **here**.

CMS provided the following timeline for the completion of round two:

- Summer 2011. CMS will begin pre-bidding supplier awareness program
- Fall 2011. CMS will announce the bidding schedule, begin a bidder education program, and begin bidder registration to obtain user identifications and passwords
- Winter 2012. Bidding will begin
- July 1, 2013. Implementation of round two pricing

Contemporaneous with round two, CMS will also conduct a national mail order competition for diabetic testing supplies. CMS's press release is available by clicking **here.** CMS's fact sheet is available by clicking **here**.

Reporter, *Adam Robison*, Houston, +1 713 276 7306, arobison@kslaw.com.

Federal Agencies Release Proposed Regulations for Health Plan Information Summaries – On August 22, 2011, the Department of Health and Human Services (HHS) , the Department of Labor (DOL), and the Department of the Treasury (DOT) (collectively, the Agencies) issued proposed regulations under the Patient Protection and Affordable Care Act (PPACA) governing disclosures of information about group and individual health plans mandated by section 2715 of the Public Health Service Act (PHS Act), which was added by PPACA. Section 2715 requires the Agencies to develop standards for group health plans and insurance issuers to create and distribute a summary of benefits and coverage (SBC). The statute mandated that a working group of the National Association of Insurance Commissioners (NAIC) be consulted in developing such standards. The proposed rule adopts all of the NAIC working group's recommendations and establishes who must issue an SBC, when an SBC must be issued and updated, the form in which an SBC must be distributed, to whom the SBC must be distributed, and the content of an SBC (including hypothetical benefits scenarios that are to be included with each SBC). The Agencies also proposed a uniform glossary of key insurance-related terms that will be used in drafting an SBC. Under PPACA, any group health plan or issuer that willfully fails to provide an SBC as required by the statute is subject to a fine of no more than $1,000 for each such failure.

In conjunction with the proposed rule, the Agencies also issued a solicitation of comments regarding a proposed template for the SBC, uniform glossary, sample instructions and calculations, and related documents developed in conjunction with the NAIC working group. The Agencies have solicited public comments regarding the proposed standards, including the uniform glossary, template and related documents. Comments are due by Friday, October 21, 2011.

The proposed rule is available by clicking **here** and the solicitation of comments is available by clicking **here**. Information regarding the recommendations and proposals of the NAIC working group is available by clicking **here**.

Reporter, *Adam Laughton*, Houston, +1 713 276 7400, alaughton@kslaw.com.

Washington District Court OKs FCA Claims, Dismisses Stark Law Claims – On August 12, 2011, a Washington federal judge in Seattle ruled that plaintiffs in a qui tam lawsuit filed in 2005 could proceed with their False Claims Act (FCA) claims against a national provider of outpatient imaging services but dismissed plaintiffs' Stark Law claims against the provider.

The case, *United States ex rel., et al. v. Center For Diagnostic Imagining, Inc., et al.*, No. 2:05-cv-000058-RSL, is currently pending in the U.S. District Court for the Western District of Washington and involves various allegations against defendant Center for Diagnostic Imaging, Inc. (CDI) by a former CDI vice president and a Seattle radiologist. Specifically before district judge Robert Lasnik was CDI's motion to dismiss two counts of plaintiffs/relators' fourth amended complaint: one arising under the FCA for CDI's alleged failure to obtain written physician orders for radiological exams before submitting "thousands" of claims to Medicare; and the other, under the Stark Law, for CDI's alleged illegal payments to doctors for Medicare and Medicaid referrals. CDI did not seek to dismiss other counts in plaintiffs' amended complaint.

With respect to the FCA claims, plaintiffs advanced an implied false certification theory of liability. Plaintiffs contended that while CDI did not expressly certify compliance when it submitted the claims at issue, it had nevertheless previously agreed to comply with Medicare's mandatory written order requirement when it entered into its provider agreement with the Centers for Medicare and Medicaid Services (CMS). Pursuant to 42 U.S.C. § 1395y(a)(1)(A), and other federal regulations, Medicare reimbursement is conditioned upon a provider's showing that certain diagnostic tests were ordered by a physician and therefore were reasonable and medically necessary.

CDI argued that plaintiffs' FCA claims should be thrown out because its alleged regulatory violations—*i.e.*, failing to obtain written orders—were immaterial and could not, by themselves, provide the basis for liability. A theory of implied false certification, CDI further argued, did not apply where the statute at issue did not expressly require provider compliance for reimbursement. Judge Lasnik disagreed, first noting that "it is the false certification, not just the absence of medical necessity, that creates liability." Judge Lasnik next noted that the Ninth Circuit had considered whether to adopt an express compliance requirement under an implied false certification theory, but declined to do so. Therefore, because CDI entered into a provider agreement with CMS whereby it acknowledged that claim reimbursement was

conditioned upon its compliance with applicable laws and regulations, and because "in submitting a Medicare reimbursement form, a defendant implicitly certifies compliance with § 1395y(a)(1)(A)," CDI's failure to comply with the regulation was indeed material. For this and other reasons, the district court ruled that plaintiffs' FCA count withstood CDI's motion to dismiss.

With respect to plaintiffs' Stark Law claims, the district court's reasoning turned on what was missing from plaintiffs' fourth amended complaint. Specifically, Judge Lasnik ruled that plaintiffs failed to allege with sufficient specificity a "financial arrangement" for purposes of the Stark Law between CDI and certain of the referring physicians. For certain other physicians, although plaintiffs sufficiently alleged a particular financial arrangement, they failed to allege sufficient facts with respect to the "who, what, where and how" of their referrals (e.g., when the referrals occurred, how many were made, the patients involved or what services the referrals involved). The order noted that the latter point was especially problematic because the Stark Law prohibits only referrals of designated health services. Plaintiffs' claims of improper payments therefore amounted only to "general allegations and speculation." Because plaintiffs failed to satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b), the district court dismissed their Stark Act claims.

A copy of the court's decision in this case is available by clicking **here**.

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King & Spalding Client Alert Issued Concerning FDA's Issuance of Recommendation Regarding the Design of Pivotal Clinical Investigations of Medical Devices – King & Spalding's FDA & Life Sciences Practice Group recently issued a Client Alert entitled "FDA Issues Draft Guidance Regarding the Design of Pivotal Clinical Investigations of Medical Devices." The Client Alert, issued on August 19, 2011, describes the FDA's recently released recommendations regarding the design of pivotal clinical investigations of medical devices. The recommendations are intended to assist manufacturers and researchers in the design of clinical investigations that satisfy premarket clinical data requirements. The Client Alert is available in its entirety by clicking **here**.

King & Spalding Attorney Ross Nadel to Moderate Panel of Government Attorneys on Trends in U.S. Enforcement – On November 15, 2011, from 8:15 to 9:15 Pacific Time, Ross Nadel will moderate a panel of U.S. Attorneys who will discuss trends in U.S. enforcement, with areas of focus including:

- Individual corporate criminal liability
- Off-label promotion
- False Claims Act (FCA)
- FCA qui tam actions
- Fraud Enforcement and Recovery Act (FERA)
- Debarment/exclusion

The panel presentation will take place at the 2nd Annual Life Sciences West Coast Compliance Congress in Burlingame, California.

Registration and program information are available by clicking **here**.

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