KING & SPALDING

# Health Headlines

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**OIG Audits Attribute Approximately $29 Million in Overpayments to Incorrect "Place-of-Service" Coding** – Two recent reports from the U.S. Department of Health and Human Services Office of Inspector General (OIG) estimate that Medicare Part B contractors may have overpaid $29 million for claims submitted in 2008 and 2009 due to incorrect "place-of-service" coding based on the OIG's review of 100 sample claims in each of 2008 and 2009. Physicians are required to identify the place of service on the health insurance claims forms they submit to Medicare contractors. The reimbursement rate is lower for physician services provided in an ambulatory surgical center (ASC) or hospital outpatient setting because Medicare reimburses the overhead expenses to the facility rather than to the physician. Thus, inappropriate use of the office place-of-service code results in physician overpayments for services actually provided in an ASC or outpatient center.

Physician claims correctly coded non-facility place-of-service for only 11 out of the 100 claims sampled for 2008 and only 17 of the 100 claims sampled for 2009. The incorrect coding of the remaining 89 claims in 2008 resulted in approximately $4,600 in overpayments, and the incorrect coding of the remaining 83 claims in 2009 resulted in approximately and $3,000 in overpayments. Based on these sample results, the OIG estimated that Medicare contractors nationwide overpaid physicians $19.3 million in 2008 and $9.5 million in 2009.

In both reports, the OIG attributed the overpayments to internal control weaknesses at the physician billing level and insufficient post-payment reviews by Medicare contractors. The OIG recommended in both reports that the Centers for Medicare and Medicaid Services (CMS): (1) recover the overpayments for the sampled services; (2) immediately reopen the claims associated with the non-sampled services, review information on these claims and work with physicians to recover any overpayments; (3) strengthen physician and billing agent education on correctly coding place of service; and (4) continue to work with contractors to identify physicians who are at a high risk of place-of-service miscoding. CMS agreed with the OIG's recommendations and stated that it was working to recover the overpayments.

The 2008 OIG report is available by clicking **here**, and the 2009 report is available by clicking **here**.

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**President Proposes Health Savings as Part of Deficit Reduction Plan –** On September 19, 2011, President Obama announced proposals to create more than $320 billion in health savings over the next 10 years as part of the White House's deficit reduction plan entitled "Living Within Our Means and Investing in the Future" (the President's Plan). The Office of Management and Budget also estimated that the health savings from these proposals would grow to over $1 trillion in the second decade. These savings are in addition to savings that are anticipated to occur through implementation of the Affordable Care Act.

The following are several of the President's proposals along with the estimated cumulative savings over a ten-year period:

- Allowing Medicare to receive the same rebates and prices as Medicaid for brand name and generic prescription drugs ($135 billion);
- Limiting the use of provider taxes by states to draw federal matching funds for Medicaid ($26.3 billion);
- Streamlining current multiple Medicaid and Children's Health Insurance Program federal payment formulas into a single blended rate starting in 2017 ($14.9 billion);
- Reducing waste, fraud, abuse and improper payments in Medicare and Medicaid, including adjustments to payments for advanced imaging services, strengthening third-party liability in Medicaid, and making changes related to Medicaid prescription drug coverage ($6.4 billion);
- Incentivizing "high-value services" for new Medicare beneficiaries starting in FY 2017, including changes to Part B and Medigap deductibles and premiums and additional cost-sharing for home health services ($3.9 billion);
- Reducing special payments in the Medicare program for bad debts, rural providers, and implementing a 10 percent cut in Indirect Medical Education add-on payments ($35 billion);
- Changing payments to encourage more efficient post-acute care, including adjusting payments for inpatient rehabilitation facilities, skilled nursing facilities, and other post-acute care providers ($42 billion); and
- Increasing means-tested Medicare Parts B and D premiums for higher-income beneficiaries ($20 billion).

In addition, the President's Plan proposes to make further adjustments to health system reforms enacted through the Affordable Care Act, including:

- Reducing the health expenditure growth rate target of the Independent Payment Advisory Board to GDP plus 0.5 percent (from GDP plus 1 percent); and
- Cutting the Prevention and Public Health Fund by $3.5 billion.

The President's Plan contains numerous other proposed reforms related to the health care sector and federal health care programs. The complete President's Plan is available by clicking **here**.

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

**District Court Dismisses FCA Case, Rejecting Whistleblower's Attempt to Plead Off-Label Marketing Allegations Through Statistics** – On September 6, 2011, the District Court for the Eastern District of Virginia dismissed a *qui tam* whistleblower's False Claims Act (FCA) allegations of off-label promotion because the relator could not plead facts sufficient to state a claim. *See United States ex rel. Nathan v. Takeda Pharms. N. Am., Inc.*, No. 1:09-cv-1086 (AJT), 2011 WL 3911095 (E.D. Va. Sept. 6, 2011). The Court rejected the relator's attempt to buttress his third amended complaint with statistical evidence, finding the complaint failed to plead fraud with particularity and failed to state a claim.

The relator, Noah Nathan, alleged that Takeda Pharmaceuticals North America, Inc. and Takeda Pharmaceuticals America, Inc. (Takeda) engaged in a scheme to market its drug, Kapidex, in a manner that resulted in physicians prescribing the drug for "off-label" uses in violation of the Food, Drug and Cosmetics Act. This promotion allegedly caused the submission of false claims to federal healthcare programs, including Medicare and Medicaid. The relator's operative complaint "fail[ed] to identify any specific false claims or any specific prescriptions, physicians, pharmacies, payments or reimbursements that caused such a false claim to be filed." Instead of pleading these facts, the relator argued that he could satisfy the specificity requirements for a fraud claim under the FCA by pleading, among other details, statistics concerning the distribution of Kapidex sales and patient populations served by the specialists who received samples in certain doses.

The Court found that the relator failed to plead the facts of any specific claims that were presented to the Government for payment or that Takeda caused any such presentment in violation of 31 U.S.C. § 3729(a)(1)(A). The relator also failed to allege affirmative misrepresentations with the specificity required by Rule 9(b) to plead a violation of 31 U.S.C. § 3729(a)(1)(B). Among other claims, the relator asserted that rheumatologists do not treat conditions that are on-label for Kapidex, so all prescriptions written by rheumatologists must be off-label. He then sought to establish that some of these prescriptions must have been reimbursed by Government payers, given that "a significant percentage of prescriptions

from his territory and his district were submitted for reimbursement to government programs." The court rejected this contention, finding "there is nothing that establishes beyond a possibility that 'tens of thousands of prescriptions' of Kapidex were written by rheumatologists" or that the Government paid for some of them.

Additionally, the relator pled no facts to support his theory that primary care physicians in his district prescribed Kapidex at a 60 milligram dose, which he contended was off-label for the conditions treated by primary care physicians. He claimed that more than 90 percent of the company's overall sales were at 60 milligrams, so it was reasonable to infer that over 90 percent of the primary care physicians' prescriptions would have been for the 60 milligram dose. The Court, nevertheless, found no factual evidence to allow it to conclude the same ratio of overall Kapidex sales would apply to prescriptions that were actually written by the primary care physicians at issue.

The Court also found the relator failed to plead facts sufficient to make a plausible claim that Takeda "caused" the submission of any false claims. It explained that "physicians are not unsophisticated lay persons and it is reasonable to assume that they are familiar with relevant medical literature" and that "off-label FCA cases generally involve allegations that the judgment of a physician was altered or affected by the defendant's fraudulent activities, which also typically involve improper payments, benefits or inducements, or misrepresentations." In this case, the "[r]elator [did not make] any allegations regarding kickbacks or other improper incentives or attempts to distort otherwise objective medical literature."

The Court found additional amendments would be futile, and it dismissed the FCA claims without leave to amend. It declined to exercise supplemental jurisdiction over state law claims and dismissed these without prejudice. The Court's decision is available by clicking **here.**

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**King & Spalding LLP Co-Sponsoring 4th Annual Healthcare Deal Making Summit** – King & Spalding is co-sponsoring the 4th Annual Healthcare Deal Making Summit—dedicated to M&A deal making activity for non-profit and for-profit providers. The summit will be held at the Union Station Hotel in Nashville, Tennessee on October 3-5, 2011. Topics of the summit include:

- Implications of healthcare reform and industry consolidation of healthcare provider M&A transactions;
- Market intelligence on deal making activity and pricing from the leading equity investors, financiers, and investment bankers; and
- Opportunities for non-profit and for-profit providers to facilitate deal making in a strategic business environment with the gathering of financiers and dealmakers under one roof.

For more information, please visit: **4th Annual Deal Making Summit**.

To register, please visit **Healthcare Deal Making Summit Registration**. Please contact **Jay Harris**, **Paul Quiros**, or **Bill Spalding** at +1 404 572 4600 for more information on this event.

**King & Spalding Starts New Distribution List for CMS's Bundled Payment Demonstration Project –** King & Spalding's Healthcare Industry Group is creating a distribution list of clients and others who would like to receive updates from us on CMS's Bundling Demonstration project. We will include on this list all those who were signed up for our September 12 Roundtable (subject, of course, to opt out) and others who request to be included. Please respond by e-mail to healthcare@kslaw.com if you would like to be on our Bundling Distribution List. We will distribute the slides we used for our Roundtable presentation, and also will distribute the list of questions that we are submitting to CMS on the Bundling Demonstration.

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