KING & SPALDING

Health Headlines

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Supreme Court Considering Providers' Right to Enforce Drug Discount Law – On January 19, 2011, the U.S. Supreme Court heard arguments in *Astra USA, Inc. v. Santa Clara County*, a case concerning whether hospitals have a private right of action against drug manufacturers to enforce the requirements of the 340B drug discount program. Under the 340B program, manufacturers are required to provide outpatient drugs at a discount to certain providers, called "covered entities." More than 15,000 hospitals and clinics currently purchase more than $3.4 billion in drugs at a 30 to 50 percent discount under the program. The Secretary of the U.S. Department of Health and Human Services (HHS) signs agreements with pharmaceutical companies creating binding maximum prices for drugs sold to covered entities, including a public hospital and several clinics operated by Santa Clara County, California.

In a 2005 report entitled "Review of 340B Prices," the HHS Office of Inspector General (OIG) estimated that 14 percent of total purchases made under the 340B program exceeded the 340B program's ceiling prices. At issue in the case is whether providers like Santa Clara County have a private right of action to force the drug manufacturers to provide the required discounts. The Ninth Circuit ruled in favor of Santa Clara County in December 2009.

The Obama administration submitted an amicus brief on behalf of the pharmaceutical companies, contending that there is no such right of action. The U.S. Justice Department states that allowing Santa Clara County the right to sue would bring about a plethora of provider lawsuits, while the statute confers enforcement responsibilities solely on the government. Other entities, including the U.S. Chamber of Commerce, filed similar briefs in support of the drug makers.

Notwithstanding the outcome of this particular case, last year's health care reform law contains provisions that have the potential to strengthen enforcement with 340B drug discount program requirements. Indeed, on September 20, 2010, HHS issued a notice of proposed rulemaking and request for comments outlining its plan to implement section 7102(a) of the Affordable Care Act, which requires the Secretary of HHS to impose civil monetary penalties against manufacturers who overcharge covered providers for 340B program drugs. Individual penalties would reach as high as $5,000 per instance and would apply to any manufacturer that "knowingly and intentionally" charges a price above the 340B program ceiling. A copy of the Federal Register notice is available by clicking here.

Also on September 20, 2010, HHS issued a separate advance notice of proposed rulemaking and request for comments outlining its plan to implement a provision of the same section of the Affordable Care Act, which requires the Secretary to develop an administrative dispute resolution process for providers to use when they believe that a manufacturer has overcharged. HHS did not propose a specific model. A copy of the Federal Register notice is available by clicking here.

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District Court Rejects Whistleblower's False Claims Act Allegations, Finding Certain Regulatory Violations Are not Conditions of Payment – On January 19, 2011, in *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 5:09-cv-710-NAM-DEP, the District Court for the Northern District of New York dismissed with prejudice a Complaint by a whistleblower and former staff nurse against Dialysis Clinic, Inc., alleging that the company submitted false claims by billing for dialysis services rendered at times when the company failed to comply with federal regulations set forth in 42 C.F.R. § 494 ("Conditions for Coverage for End-Stage Renal Disease Facilities"), resulting in what the Relator described as "compromised care." *Id.* at 4-5. The Court rejected theories of both express and implied false certification and found the Relator could not plead details of any alleged false billing to survive Federal Rule of Civil Procedure 9(b)'s specificity requirement.

The False Claims Act generally requires the submission or use of a "false claim." A claim may either be factually false (*e.g.* a claim for a service never provided) or legally false (*e.g.* a claim either expressly or by implication states that certain legal prerequisites to payment have been complied with in submitting the claim). In this case, Relator claimed that the services failed to comply with regulatory requirements—and thus were legally false claims. The Court rejected these arguments, making two important rulings.

First, the Court rejected the Relator's claim that the Defendant's certification in its Medicare Enrollment Form CMS 855A that it would comply with Medicare laws, regulations, and instructions constituted an express certification such that later failures to comply with Medicare regulations constituted false certifications. Form CMS 855A includes the following certification:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all application conditions of participation in Medicare.

Id. at 25. The Court adopted the reasoning of another district court, finding that "'there is no reason why such an explicit certification of future compliance cannot be the basis of False Claims Act liability if the provider makes such a certification *knowing it will violate the statute*, and later submits claims which are not in compliance with the statute.'" *Id.* at 26 (citation omitted) (emphasis added). Nevertheless, in this case, the Relator failed to allege that when the Defendant signed the enrollment form it knew it would be submitting false claims. *Id.* at 27.

Second, the Court rejected Relator's claims based on implied certification and highlighted the long-standing line of FCA case law distinguishing between conditions of participation and conditions of payment. The Court explained, "[c]onditions of participation, as well as a provider's certification that it has complied with those conditions, are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program. Conditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *Id.* (citations and quotation marks omitted). In this case, the Court found that operative provisions of the regulation at issue applied to "'conditions' relating to, *inter alia*: infection control, . . . quality assessment, physical environment, patients rights, patient assessment, personnel qualifications and medical records." *Id.* at 34. Related regulations provide for the ultimate sanction of termination from the Medicare program if a provider is non-compliant with these conditions of participation. Nevertheless, a provider may continue to receive Medicare payments during periods of non-compliance. *Id.* Accordingly, the Court found that the regulations at issue imposed conditions of participation, but not conditions of payment that triggered FCA liability. *Id.* at 36.

In addition to the rulings on express and implied false certification, the Court addressed Defendant's public disclosure bar challenge under Federal Rule of Civil Procedure 12(b)(1) and a motion to dismiss based upon the failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b). As to the first, the Court found the Relator's operative complaint was not "based upon" a public disclosure and survived operation of the FCA's public discourse bar. *Id.* at 16. On the other hand, the Court found that Defendant's 9(b) motion provided an alternative ground to dismiss the complaint. It held that Relator "has not identified a single bill submitted in relation to any of the examples [of compromised patient care] outlined in the second amended complaint." *Id.* at 21. The Court went on to state that "Plaintiff summarily asserts that, 'any bill submitted to the government is . . . a fraudulent claim.' This is exactly the type of vague and generalized

allegation that is impermissible under Rule 9(b)." *Id.* at 22.

The Court's decision is available by clicking here.

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Upcoming PPACA Regulations – The Congressional Research Service (CRS) published a January 13, 2011 report which identifies the upcoming proposed and final rules that are expected to be issued pursuant to the Patient Protection and Affordable Care Act (PPACA, P.L. 11-148).

The report is based on the most recent edition of the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, which was published on December 20, 2010. The *Unified Agenda* identified 29 PPACA-related upcoming proposed rules, and 18 PPACA-related actions that are in final rule stage. CMS is issuing 15 of the 29 proposed rules. The CMS rules expected to be published in the first quarter of 2011 include:

- "Medicare Shared Savings Program: Accountable Care Organizations" - expected to be published in January 2011;
- "Federal Funding for Medicaid Eligibility Determination and Enrollment Activities" - expected to be published in January 2011 but note that it was published on November 8, 2010, with comments due by January 7, 2011;
- "Community First Choice" - expected to be published in February 2011; and
- "Requirements for Long-Term Care Facilities: Notification of Facility Closure" - expected to be published in February 2011.

The report also addresses options for congressional oversight of the forthcoming regulations and long-term actions that are expected to be issued pursuant to PPACA.

The report is available by clicking here.

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Client Alert on Executive Order Directing Regulatory Reform – In a January 18 *Wall Street Journal* op-ed entitled, "Toward a 21st Century Regulatory System," President Obama announced provisions of a new Executive Order aimed at "addressing burdens that have stifled innovation and have had a chilling effect on growth and jobs." The Executive Order, signed by the President that same day, requires federal agencies to assess the necessity and effectiveness of existing "significant" regulations and to consider certain "principles" when drafting rules. Adherence to these principles would ensure that regulations "protect public health, welfare, safety and our environment while promoting economic growth, innovation, competitiveness and job creation." Supplementing the Executive Order, the President issued two memoranda containing directives on regulatory flexibility for small businesses, as well as increased accessibility to "publicly-available compliance information." A copy of the complete Client Alert is available by clicking here.

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King & Spalding 20th Annual Health Law and Policy Forum – Our 20th annual Health Law and Policy Forum will be held this year on March 14 at the Four Seasons Hotel in Atlanta. Please be on the lookout for additional communications from us soon that will provide details on the specific content of the program.

Health Headlines – Editor:

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