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The United States Supreme Court Grants Petition for Review of a False Claims Act Case

The United States Supreme Court recently granted *certiorari*[1] to decide the scope of the "public disclosure jurisdictional bar" (the Bar) under the False Claims Act (FCA).[2] Under the FCA, a private citizen may bring a lawsuit in the name of the United States Government (called a *qui tam* action) and the government may choose to join the lawsuit. The Bar prevents a private person from bringing a *qui tam* action based upon information that is already public. The Bar does not apply if the plaintiff is "an original source" of that information.

Specifically, the Bar prevents a *qui tam* action based on "public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media…"[3] The Court granted *certiorari* to specifically address whether an audit and investigation performed **by a state or its political subdivision** constitutes an "administrative … report … audit, or investigation" within the meaning of the Bar.

The case will be closely watched because federal circuit courts have interpreted the Bar differently. In its *amicus*[4] brief, the Solicitor General urged the Court to resolve the "existing circuit conflict regarding whether state and local administrative audits and reports fall within the scope of the FCA's "public disclosure" provision."

HEAT in Action

The Health Care Fraud Prevention and Enforcement Action Team (HEAT), the joint taskforce announced last month by the Department of Justice and Department of Health and Human Services, is already achieving results. Fifty-three people were indicted in Detroit this week for allegedly submitting over $50 million in false Medicare claims. These indictments resulted in arrests across the country, including not only individuals in Detroit, but also in Miami and Denver.

On June 25, 2009, Inspector General Daniel Levinson presented testimony on efforts by the Office of Inspector General (OIG) to combat fraud, waste, and abuse in the Medicare program before the Subcommittee on Health of the House Energy and Commerce Committee. In this written testimony, Mr. Levinson noted that, in addition to focusing on fraud prevention, HEAT is building upon existing Medicare Strike Force initiatives that have been successful in South Florida and Los Angeles. Based upon the OIG's investigative and enforcement experience, Mr. Levinson reiterated in his testimony the following five-principle strategy for combating health care fraud, waste, and abuse:

- **Enrollment** – Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment in health care programs.
- **Payment** – Establish payment methodologies that are reasonable and responsive to changes in the marketplace.
- **Compliance** – Assist health care providers and suppliers in adopting practices that promote compliance with program requirements, including quality and safety standards.
- **Oversight** – Vigilantly monitor programs for evidence of fraud, waste, and abuse.
- **Response** – Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.

These five principles, additional details of which are set forth in the written testimony and in a Mintz Levin Health Care Fraud Alert from last week**,** establish the OIG's framework to protect the integrity and solvency of the Medicare program. The collaborative efforts of the OIG and other government agencies align with the Obama Administration's goal of cracking down on fraud and abuse in the health care system, as demonstrated through the recent actions of the Medicare Strike Force and HEAT taskforce.

The Health IT Policy Committee Releases Draft Recommendations on "Meaningful Use" Definition

Health care providers are one step closer to a workable definition of "meaningful use" of electronic health records (EHR). On June 16, 2009, the Health IT Policy Committee (or "Committee") released a draft definition of "meaningful use." The definition is important to health care providers because the American Recovery and Reinvestment Act of 2009 established $17 billion in Medicare and Medicaid incentive payments for hospitals and non-hospital-based physicians determined to be "meaningful users" of health information technology. The Centers for Medicare & Medicaid Services (CMS) will consider the Health IT Policy Committee's recommendations as it drafts regulations officially defining the term later this year.

The draft definition states that in 2011, a "meaningful user" of health information technology must electronically capture, report, and track key clinical conditions, and requirements for meeting the "meaningful use" definition will increase over time. For example, providers will be required to utilize EHR to guide and support care processes and care coordination by 2013 and, by 2015, to employ EHR technology to achieve and improve performance and support care processes on key health system outcomes. The draft definition includes care goals, objectives, and measures for each of the following five policy priorities:

- improve quality, safety, and efficiency and reduce health disparities
- engage patients and their families
- improve care coordination
- improve population and public health
- ensure adequate privacy and security protections for personal health information.

The Health IT Policy Committee's recommendations are set forth in the Meaningful Use Preamble and Meaningful Use Matrix. The Committee accepted public comments on the draft definition until June 26, 2009. In general, commenters stated that the objectives in the proposed definition are feasible. However, many health industry groups feel that the definition is too "aggressive" and "unrealistic" as it pertains to the implementation of Computerized Provider Order Entry. Based on the public comments, the Committee will issue a revised set of recommendations at its next meeting scheduled for July 16, 2009. In the meantime, health care providers should begin considering software implementations and other preparations to ensure that they are positioned to take full advantage of the incentive payments beginning in 2011.

Debate Rages Over Follow-on Biologics as More Parties Weigh In

On June 10, 2009, the Federal Trade Commission (FTC) released a report entitled *Follow-on Biologic Drug Competition* (the FTC Report), which adds to the contentious debate among companies that develop new biologics ("pioneer biologics"), those that seek to develop similar versions of those biologics ("follow-on biologics"), and consumers. Since the release of the FTC Report, critics, including the Biotechnology Industry Organization, have issued rebuttals disagreeing with both the FTC's premises and conclusions. More recently, President Obama endorsed the introduction of follow-on biologics as one tool to lower health care costs. In a letter dated June 24, 2009 to Representative Henry Waxman, the Office of Management and Budget endorsed a seven-year exclusivity period for pioneer biologics, which represents a compromise between the 12- to 14-year period suggested by the pioneer industry and the five-year period proposed by Representative Waxman.

The debate over biologics stems from the absence of a U.S. Food and Drug Administration (FDA) approval process for follow-on biologics. As a result, only pioneer biologics are available, and such products typically are covered by numerous patents and are costly to consumers. Three bills currently are pending in Congress that seek to close this regulatory gap and to lower the cost of biologics through generic competition.

The FTC Report addresses the likely impact of a follow-on biologics approval process on competition and pricing, and finds that the competition between pioneer and follow-on biologics will more closely resemble brand-to-brand competition than competition between branded and generic small molecule drugs. Unlike branded small molecule pharmaceuticals, which typically lose considerable market share and drop drastically in price when faced with generic competition, the FTC Report anticipates that pioneer biologics will retain as much as 70-90% market share even if competing with follow-on products, because follow-on biologics likely will not be direct substitutes for their pioneer counterparts. The FTC Report concludes, however, that the introduction of follow-on biologics will lower prices and increase access, two major goals of the pending legislation.

Further, the FTC analyzed whether an approval process for follow-on biologics should mirror the abbreviated generic approval system for small molecule pharmaceuticals created by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), which also established new patent and exclusivity protections for pioneer drugs. Congress is debating similar provisions that would apply to biologics, and the major point of contention in the current bill is the period of exclusivity that will apply to pioneer biologics. The FTC dismisses a 12- to 14-year period of exclusivity for innovative biologics as unnecessary and instead finds that patent protection and market pricing are sufficient to protect the financial interests of pioneer biologics manufacturers. The FTC Report also concludes that two provisions applicable to small molecule pharmaceuticals under the Hatch-Waxman Act—the procedure for commencing patent litigation before FDA approval of a generic and the 180-day exclusivity period for the first generic competitor—should not be included in follow-on biologics legislation.

Endnotes

[1] That is, the United States Supreme Court decided to review the decision of a lower appellate court. In this case, the Supreme Court will review a decision of the United States Court of Appeals for the Fourth Circuit.

[2] *Graham County Soil & Water Conservation District v. United States ex rel. Wilson*, No. 08-304, petition granted June 22, 2009.

[3] 31 U.S.C. § 3730(e)(4)(A).

[4] A brief *amicus curiae* is submitted to the Court to bring relevant matters to the Court's attention.

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