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NJ's next wave of health care enforcement (and preparing for it *now*)

Two statewide developments — and a third imminent development on the national level — have combined to create an environment of increased health care enforcement and litigation in New Jersey.

By Mark S. Olinsky and Gary W. Herschman

The first is the emergence of the U.S. Attorney's Office in New Jersey (NJUSAO) as a major player in national and regional health care enforcement, and the second is the recent enactment of the New Jersey False Claims Act, patterned closely on the federal government's civil False Claims Act. In addition, it appears likely new federal legislation, benignly entitled the False Claims Act Correction Act, will soon be enacted in a form diminishing defenses and expanding the universe of targets. Together, these developments should send a message to the health care industry in New Jersey to start getting ready now.

Increased federal health care enforcement

For several years, the dominant U.S. Attorney's Offices in the health care arena have been those located in Boston and Philadelphia. At the end of 2005, however, the U.S. Attorney for the District of New Jersey, Christopher J. Christie, made dramatic headlines by obtaining a Deferred Prosecution Agreement (DPA) from the University of Medicine and Dentistry of New Jersey (UMDNJ) upon threat of immediate indictment for health care fraud. In the two years after the DPA with UMDNJ, the NJUSAO entered into settlements with several major hospitals and hospital systems in New Jersey arising from the receipt of large amounts of Medicare outlier reimbursement.

In 2008, UMDNJ successfully completed the two-year period of monitorship under its DPA, but the monitor's final report noted numerous problems and the NJUSAO has continued its close scrutiny of UMDNJ. UMDNJ's cardiac surgery unit was at risk of closure because for several years the number of

cardiac procedures performed was below the minimum required by state licensure standards. The NJUSAO has alleged UMDNJ therefore undertook a program to bring in more cardiac surgery patients through part-time employment contracts with a number of community cardiologists who performed little or no genuine services, in violation of the federal Stark Law. With almost twenty cardiologists alleged to have participated in this referral scheme, the NJUSAO recently (1) obtained guilty pleas by two UMDNJ cardiologists to criminal embezzlement charges, (2) brought civil charges under the False Claims Act and the Stark Law against two others, and (3) reached civil settlements in the amount of approximately $387,000 with four more.

In September 2007, the NJUSAO reached well beyond the borders of New Jersey when it announced the landmark $311 million settlement of an investigation involving the five manufacturers responsible for 90 to 95 percent of the artificial hip and knee implants market. Unlike similar cases, this investigation was not initiated by a *qui tam* whistleblower complaint. The settlement resolved Anti-Kickback Statute allegations that the companies made payments to physicians for their use (and ordering) of the companies' products. The settlement included 18-month DPAs with four of the companies, a non-prosecution agreement with the fifth, and five-year corporate integrity agreements with all of the companies. The agreements with each company require a federal monitor to conduct a variety of oversight functions, including the requirement all new consulting agreements be disclosed to patients and that physician payments be listed on the companies' web sites. In addition, each manufacturer must prepare a detailed "Needs Assessment" to determine its commercially reasonable needs for all consultant services to fulfill medical, clinical, training, educational, and research and development requirements.

In a recent article, *The New York Times* reported that the NJUSAO has issued subpoenas to two smaller manufacturers of hip and knee implants and that the Office's "long-running investigation into the orthopedic industry's suspected kickback payments to hip and knee surgeons now has the doctors in the spotlight." U.S. Attorney Christie was quoted as having said, "I've dealt with the supply issue, now I need to deal with the demand issue."

It is virtually certain the emphasis of the NJUSAO on major health care fraud and abuse investigations will not come to an end upon the conclusion of the tenure of U.S. Attorney Christie, but instead continue during the next Presidential administration, whether Democrat or Republican. The Office has both a Criminal and a Civil Health Care Fraud Coordinator, and is increasing the resources focused on health care — it now has the equivalent of eight Assistant U.S. Attorneys working on a combination of civil and criminal health care investigations and cases.

Further, it has become common knowledge the Boston and Philadelphia U.S. Attorney Offices are backed-up with health care cases and investigations. For example, the recent agreement by Merck to pay $650 million to settle FCA charges for allegedly overcharging Medicaid and Medicare was driven by state and federal prosecutors in other jurisdictions after the case had been pending in Philadelphia for several years.

Thus, due to the continued "nationalization" of health care fraud prosecutions among U.S. Attorney Offices, and the increased prominence and resources of the NJUSAO in the health care fraud arena, there is a growing trend of both FCA plaintiffs choosing to commence cases in New Jersey and the NJUSAO initiating its own fraud and abuse investigations. The health care industry should therefore expect increasing and aggressive enforcement efforts in New Jersey.

N.J.'s new False Claims Act

The federal False Claims Act (FCA) has been the federal government's weapon of choice to enforce its antifraud initiatives, particularly in the health care industry.

New Jersey has now joined 20 other states and the District of Columbia in enacting its own version of the federal law to target alleged fraud by companies that do business with the state. On Jan. 13, 2008, Gov. Jon S. Corzine signed the New Jersey False Claims Act (NJFCA). It took effect on March 13, 2008.

The federal Deficit Reduction Act of 2005 (DRA) contained financial incentives for states to enact antifraud legislation modeled after the federal act and applicable to Medicaid claims. Federal Medicare recoveries under the FCA have dwarfed those involving Medicaid, and the DRA was intended to give states a strong incentive to pursue alleged Medicaid fraud. Any state with a law patterned sufficiently after the FCA would be entitled to have ten percent of the federal portion of Medicaid recoveries transferred to the state. To qualify, the state law must include provisions, including treble damages, that are "at least as effective" as the FCA in rewarding and facilitating *qui tam* actions for false or fraudulent Medicaid claims. While the Office of Inspector General of the Department of Health and Human Services has not yet ruled on whether the NJFCA qualifies, the NJFCA appears to satisfy the DRA standards and is not limited to Medicaid claims.

The combination of treble damages and the transfer of ten percent of the federal share of recoveries to the state creates a potent incentive for both *qui tam* plaintiffs and the New Jersey Attorney General's Office to pursue alleged Medicaid fraud. For example, consider the difference in recovery on an alleged $20 million Medicaid fraud in New Jersey, where the federal and state governments split payments and recoveries on a 50/50 basis. Without a DRA-qualifying statute — and therefore without treble damages on the state portion — the federal government would receive treble damages of $30 million and the state single damages of $10 million. With a DRA-qualifying statute (and therefore treble damages on both federal and state portions), the total recovery increases from $40 million to $60 million, and the state-federal split shifts from 50/50 to 60/40 — the state share becomes $36 million instead of $10 million before deduction of the *qui tam* plaintiff's share. Applying the federal average of approximately 17 percent, the plaintiff would collect over $10 million on the enhanced recovery: four million from the federal recovery and six million from the state.

Given the difficult economic times and New Jersey's budget woes, it is easy to see why both *qui tam* plaintiffs and state government are likely to be aggressive in pursuing recoveries and corresponding "bounties" for alleged Medicaid fraud under the NJFCA. The Attorney General's Office has instituted an affirmative litigation section within the Division of Law to oversee intake of NJFCA suits and take the lead in investigating the underlying allegations. The statute provides for ten percent of all state recoveries to be deposited in a special fund to be used only to support ongoing investigation and prosecution of alleged false claims.

The False Claims Act Correction Act of 2007

In 1986, at the initiation of Iowa Republican Senator Chuck Grassley, Congress amended the FCA to make it

easier to establish FCA liability and to increase the "bounty" for *qui tam* plaintiffs. Those amendments have been extraordinarily successful from the government's perspective, with over $20 billion in FCA recoveries since and a return of $15 for each $1 invested in health care investigations and prosecutions, with most of the investment going towards hiring of hundreds of additional investigators and prosecutors.

More recently, some judicial decisions have favored the defense on certain subjects. An example is the 2004 decision by the D.C. Circuit Court of Appeals in *United States ex rel. Totten v. Bombardier Corp.* (written by now Chief Justice John G. Roberts, Jr.) that false claims submitted to government grantees — *i.e.,* by subcontractors — are not considered to have been "presented" to the federal government under the FCA. Another example is the 2007 Supreme Court decision in *Rockwell International Corp. v. United States*, where the court ruled a *qui tam* plaintiff may not recover unless he or she was the original source for all claims brought under the FCA.

Sen. Grassley has recently stepped in again, this time to "correct" what he apparently believes to have been mistakes in the 1986 legislation or subsequent judicial rulings. The False Claims Act Correction Act (FCACA), introduced in September 2007, has bipartisan support and appears to be moving through committee and towards passage. The FCACA would make various "corrections" to the FCA, such as undoing the *Totten* and *Rockwell* decisions by repealing the requirement the allegedly false or fraudulent claim be presented directly to the government, enabling government employees to qualify as *qui tam* plaintiffs, expanding the statute of limitations from six to 10 years and loosening the level of specificity of allegations of falsity that some court decisions have required.

While it cannot be certain the FCACA will be enacted, or if enacted, what its ultimate provisions will be, a "corrected" version of the FCA is likely to lessen available defenses and widen the universe of potential targets.

Focus on prevention and compliance

With enforcement resources and incentives for whistle-blower suits both increasing, the health care industry in New Jersey will remain inviting targets for both government investigators and *qui tam* plaintiffs under the FCA and NJFCA. Companies not already having in place a comprehensive *and* effective compliance program — including training, anonymous reporting, and regular self-auditing — must make the implementation of such program a top priority. The program should include written policies and procedures, an independent compliance officer reporting to senior management and the Board, timely investigation of reported problems, self-auditing and disciplinary action and other corrective action where and to the extent appropriate. The goal should be to create an organizational culture valuing and rewarding prevention, detection and correction of compliance problems.

Many hospitals adopted corporate compliance programs in the late 1990s, and many pharmaceutical companies and other health care companies did so in the 1990s and early 2000s. In order to be truly effective — a "must" in defending health care fraud investigations and cases — compliance programs must be re-assessed, reviewed and amended as necessary each year, and comprehensively every two to three years. Doing so now must be a high priority for all members of the health care industry.

While prevention is the goal, inaccuracies will, inevitably, find their way into government submissions. Whether the government concludes errors were innocent or, at worst, negligent instead of knowingly false or fraudulent under the FCA and NJFCA may well depend on whether the company's compliance program is viewed as comprehensive and effective and its "organizational culture" as fostering compliance from the top down and bottom up. More than ever, health care companies must take the necessary steps to try to prevent allegations of fraud before they occur — not just for the sake of prevention itself, but to arm counsel to negotiate effectively with the government during an investigation and defend claims effectively in litigation.

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