US v. Rockwell May Limit Speculative Qui Tam Complaints Alleging Fraud Under the False Claims Act

After the Supreme Court’s March 27, 2007, decision in *U.S. v. Rockwell International Corp.*, future whistleblowers and their attorneys will have to screen more carefully potential fraud cases regarding the Medicare Prescription Drug Benefit program (Part D) and will face a greater risk of not being paid on speculative claims under the federal False Claims Act (FCA). The Supreme Court held that a whistleblower who “predicts” fraud cannot recover in light of a public disclosure if the whistleblower did not accurately describe and have knowledge of the cause and effect. This should afford companies time to which they are entitled to self monitor and correct problems before they turn into FCA *qui tam* cases.

Even though *Rockwell* was not a Medicare or health care related case, it should have an immediate impact on potential pending and future *qui tam* lawsuits under the FCA involving Medicare Part D. Compliance and anti-fraud initiatives are among the most widely discussed aspects of Part D. The FCA is the centerpiece, with its up-to 30 percent bounty for whistleblowers. Given the notoriety of recent hundred-million-dollar FCA health care cases, whistleblowers already may have filed speculative *qui tam* complaints trying to anticipate what fraud may exist. Before *Rockwell*, a whistleblower was likely to recover a share of any settlement, regardless of what the government found. After *Rockwell*, however, whistleblowers will have to come forward with more accurate and detailed information to share in any recovery. Those who do not will face stronger opposition.

**The Rockwell Decision**

Rockwell International Corp. (RIC) contracted with the Department of Energy to dispose of nuclear waste. Whistleblower Stone worked for RIC as an engineer and predicted that Rockwell’s plan to dispose of nuclear waste would fail for certain technical reasons. Three years after he was laid off by RIC, Stone filed his *qui tam* complaint under the FCA upon learning that there was a leak with the nuclear waste system. The government intervened, the case went to trial, and the jury returned a verdict against RIC. The government argued at trial that RIC’s nuclear waste disposal system failed for reasons unrelated to what Stone had predicted and asserted in his *qui tam* complaint.

RIC filed a post verdict motion to disqualify Stone as a whistleblower, arguing that the claims were based on publicly disclosed allegations, and that Stone was not an original source under the FCA. An individual can qualify for a whistleblower share of the recovery under the FCA, even if there is a predated public disclosure, if that individual is an original source. Stone acknowledged that his claims were based on publicly disclosed allegations, but claimed he was an original source.

The Supreme Court held that Stone was not an original source under the FCA. The Court concluded that if a whistleblower predicts the wrong cause and effect in light of a public disclosure, as did Stone, then he or she could not be an original source. The Court did not reach the question of whether or not a whistleblower who predicts fraud would automatically be barred under all circumstances. Given the tenor of this decision, however, the bar certainly is set very high.

In reaching its decision, the Court noted that the whistleblower must be the original source of the allegations.
in the original complaint and all amendments thereto. This should mean that if the theory of the case shifts during the course of the government’s investigation, which is very common, then the whistleblower could loose his status under the FCA and may not share in the recovery. Rockwell will significantly alter the dynamics between the whistleblower and government, and the whistleblower’s cost/benefit analysis for determining when to bring and pursue a case.

Potential Implications of Rockwell for Alleged Fraud Under Part D

The implications of Rockwell should extend beyond its unusual fact pattern of a failed nuclear waste disposal system, and have immediate application in health care fraud cases and Part D cases, in particular. Part D includes unprecedented reporting, compliance, fraud and abuse provisions. It is important to recognize the context of these rigorous standards; at the same time the government was finalizing the Part D reporting and compliance requirements, it was engaged in an epic discovery battle in an FCA litigation with the largest pharmacy benefit manager and mail order pharmacy, which resulted in a settlement payment of $155 million and significant injunctive relief. See U.S. ex rel. Hunt et al. v. Medco Health Solutions, et al. Many Part D requirements specifically address anticipated discovery and evidentiary issues under an FCA lawsuit.

Although Part D plans have some flexibility in how they implement compliance programs, an ineffective program may be used to establish “deliberate ignorance” or “reckless disregard” under the FCA’s broad knowledge/sciencer standard. For example, Part D Prescription Drug Plans (PDPs) must have written policies and procedures, a process to report fraud, corrective action plans and internal monitoring. The PDPs are required to conduct timely and reasonable inquiries where evidence suggests there has been misconduct related to payments or prescriptions. To do this, the plan must account for its subcontractors and the reliability of the data. Failure to address these points and resolve problems could be considered evidence of an ineffective program.

Part D’s novel structure is wrought with confusion and unprecedented requirements that may lead to infractions that, if left unchecked, could turn into fraud cases. Beneficiary true out-of-pocket cost reporting, beneficiary access to negotiated pricing, formulary management, payment adjustments, and coordination of benefit programs under Parts A and B and Medicaid are just some of the key areas where federal regulators and potential whistleblowers will focus their efforts.

It would not be surprising to find that whistleblowers already have filed speculative qui tam complaints “predicting” non-compliance with Part D to preserve their status in the event the government finds something. That, according to Rockwell, is not what is intended under the FCA. Taken to its logical conclusion, Rockwell should prohibit whistleblowers from sharing in recoveries based upon vague and speculative allegations filed as place holders -- regardless of a public disclosure and original source controversy.

Because whistleblowers will not be rewarded under Rockwell for “predicting” fraud, PDPs and those receiving payments under Part D should be afforded the opportunity to identify and correct problems before they turn into federal cases. These companies should have a system in place that encourages and rewards employees for participating in an effective and constructive compliance program.

About The Author

David T. Shapiro joined Pepper in March as of counsel in the Philadelphia and Washington, DC offices. Before joining Pepper, Mr. Shapiro was a trial attorney with the U.S. Department of Justice, where he primarily prosecuted health care fraud cases under the FCA, including the Medco case cited in this article.

For more information, please contact Mr. Shapiro at 215.981.4971 or shapirod@pepperlaw.com.

RSS on www.pepperlaw.com

Subscribe to the latest Pepper articles via RSS feeds. Visit www.pepperlaw.com today and click on the RSS button to subscribe to our latest articles in your news reader.
Milk, Eggs, Bread and a Flu Shot: It’s One-Stop-Shopping at Retail Health Clinics

The past year has seen the emergence of a new business model in the health-care industry. Known as “retail clinics,” these onsite health clinics are popping up in pharmacies and retail chains across the country, and offer convenient, accessible and less-costly non-emergency health care services.

A typical retail clinic is located in the corner of a drugstore, supermarket or “big box” store, such as Target and Wal-Mart. Retail clinics are staffed by nurse practitioners or physician assistants, who are trained to diagnose and treat minor illnesses such as colds, ear infections and strep throat; treat minor injuries such as cuts, burns and sprains; perform simple diagnostic screenings for conditions such as mononucleosis, diabetes and high blood pressure; administer vaccines such as hepatitis B and chicken pox; and write non-narcotic and non-controlled substance prescriptions. Retail clinics do not treat medical emergencies or administer prescriptions that require continuity of care.

Retail clinics appear to offer tremendous incentives to patients, employers, insurance companies, hospitals and retailers alike. Patients are attracted to the clinic’s affordability and convenience – particularly since most visits take about 15 minutes and do not require an appointment. On average, services cost between $30 and $110, and many retail clinics accept health insurance.

Finding that retail clinics make it easier to contain health care costs, employers such as Bank of America and General Mills encourage employees to use the clinics. Lower health care costs have led more health insurers to offer insurance policies that include retail clinic services.

Hospitals may have an incentive to participate in the retail clinic boom, since a partnership with a retail clinic could lead to increased referrals. (Some concern exists that retail clinics can lead to discontinuity of care; however, the American Medical Association has responded to the increased number of retail clinics by publishing a number of principles for clinics to follow. One of the guidelines requires clinics to encourage patients to consult a primary care physician.)

Additionally, retail stores have tremendous financial incentive to offer clinics onsite. Patient visits not only increase store traffic, but also enhance sales of prescription drugs, over-the-counter medication and non-health care products.

The retail clinic expansion has caught the attention of the investment community. CVS acquired Minneapolis-based MinuteClinic, operator of more than 150 locations in 19 states. Two other prominent retail chains, Take Care Health Systems, which has places clinics in Walgreens, and RediClinic, which has opened clinics in Wal-Marts, have benefited from recent capital investments.

To these investors, retail clinics offer an interesting business model; because of lower payments on rent, staffing costs and malpractice premiums, the clinics face relatively low overhead costs. However, the dynamic presents many legal issues that retail clinics should evaluate, including scope of practice, Stark, HIPAA, EMTALA and accreditation.

Scope of Practice

Licensure regulations for retail clinics and the nurse practitioners and physician assistants that staff them vary from state to state. Many states have corporate practice of medicine regulations, which require the clinic to be a medical corporation owned by a physician. The ability of nurse practitioners to provide care at retail clinics may be restricted by the nurse practitioner laws of the state.

In Pennsylvania, for example, nurse practitioners are required to submit detailed collaborative agreements with physicians. Collaboration is defined as “a process in which a certified registered nurse practitioner works with one or more physicians to deliver health care services within the scope of the certified registered nurse practitioner’s expertise.” Part of this process requires physicians to be immediately available at all times to the nurse practitioner through direct communication. Other states may require a physician to be present physically for some or all of the time.

Stark

Perhaps the most interesting legal issue implicated by the CVS-MinuteClinic marriage is its relationship to the Stark regulation against physician self-referral. The Stark law prohibits a physician who has a financial relationship
Health Care Law Alert

with an entity from making a referral to that entity for furnishing a designated health service (like prescription drugs). The relationship between the retail clinic and the pharmacy in which many are located may cause concerns about over-prescribing. Parties should tread lightly when pursuing contractual arrangements between physicians and store-based health clinics.

HIPAA

The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) regulates the use and disclosure of a patient’s protected health information (PHI), which includes written documents, electronic files and verbal information. Retail clinics must be certain that patients’ PHI is secured in accordance with HIPAA’s privacy regulations. The small size, public location and relative informality of retail clinics make privacy concerns especially relevant.

EMTALA

Because retail clinics are designed to treat non-emergency conditions, some hospitals may see a partnership with a local retail clinic as a way to lessen the strain on their overcrowded emergency rooms. These hospitals should take care not to run afoul of the Emergency Medical Treatment and Labor Act (EMTALA), which requires all hospitals that participate in Medicare and Medicaid and have emergency rooms to provide appropriate medical screenings to any patient who comes to the emergency department requesting examination or treatment for a medical condition.

Accreditation

Among the obstacles retail clinics face is establishing organizational quality and safety-of-care standards similar to those of traditional hospitals, which typically undergo voluntary accreditation with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Last year, MinuteClinic became the first retail clinic to earn JCAHO accreditation. However, accreditation with JCAHO can be time-consuming and costly, and some retail clinics may choose to forego the process entirely.

As a possible alternative to accreditation, the Convenient Care Association (CCA), a recently formed trade association for retail clinics, issued 10 mandatory standards for its members. The standards include monitoring quality through peer review and collaborating physician review, encouraging patients to establish relationships with primary care providers and complying with OSHA, CLIA, HIPAA and ADA standards. The CCA’s approach is an important step towards establishing standards of care for members of the emerging retail clinic community.

The emergence of retail clinics is an exciting, evolving model, and one that’s worth keeping an eye on. The clinics’ acceptance as a viable provider of health care services depends on a number of factors, including the response of the regulatory and medical community. We’ll certainly be watching.

Author:
Andrew J. Siegel
215.981.4043
siegela@pepperlaw.com

The material in this publication is based on laws, court decisions, administrative rulings and congressional materials, and should not be construed as legal advice or legal opinions on specific facts.