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May 1, 2014

Halifax Case Signals Greater Stark Law Enforcement
By Ben A. Durie

In March, Florida nonprofit Halifax Health Medical Center agreed to an $85 million settlement with the United States Department of Justice (DOJ) to resolve allegations that certain of its agreements with physicians violated the False Claims Act (FCA)[1] because the hospital submitted claims to the Medicare Program that did not comply with the federal physician self-referral statute (commonly known as the Stark Law).[2] This case is important not only because it highlights the increased enforcement of the Stark Law, but also because it helps to define what increased enforcement looks like in the post Affordable Care Act (ACA) landscape. Halifax underlines how critical it is for hospitals to maintain a robust compliance program for physician contracts, including weighing the risks associated with actual or potential Stark Law violations in the context of both FCA enforcement cases and the Self-Referral Disclosure Protocol (SRDP) established by CMS.

Government Enforcement of the Stark Law

Halifax is just the most recent FCA whistleblower Stark Law case where the DOJ intervened. It joins other instructive cases such as Tuomey Healthcare System[3] and Bradford Regional Medical Center.[4] Future high-profile cases on the horizon that are still pending include a case against Infirmary Health System in Alabama and a series of cases against Health Management Associates.

Taken together, these cases provide anecdotal evidence that the number of cases being brought by whistleblowers appears to be increasing, and in fact the actual number has almost doubled over the last five years.[5] As described in more detail below, these cases also highlight the different postures taken by the DOJ in qui tam cases versus CMS in SRDP settlements.

Overview and Origins of Halifax

- 568-bed hospital located in Daytona Beach, Florida.
- Whistleblower was hospital's compliance officer and physician services director (who is still employed by the hospital). She will receive $20.8 million of the settlement.
- Complaint alleged noncompliant physician employment arrangements with neurosurgeons and medical oncologists included incentive payments that varied based on the value and volume of services referred by the physicians to the hospital.
- $85 million settlement is eight times hospital's annual operating margin.

CMS is the government agency with primary enforcement responsibility for the Stark Law, however, the DOJ, in collaboration with the FBI, has authority to investigate alleged violations if complaints include alleged violations of the federal Anti-kickback Statute[6] and/or the FCA. That said, neither CMS nor the DOJ has significant history of independent investigation of potential Stark Law violations. Instead, the overwhelming

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majority of Stark Law violations are resolved either through self-disclosures submitted by health care entities (either to CMS or the OIG) or through cases referred to the government by whistleblowers. Of approximately 100 published cases alleging Stark Law violations, only two cases were brought by the United States without whistleblower involvement.[7]

False Claims Act Qui Tam Actions

The FCA is now the primary vehicle used by the government to combat perceived health care fraud and abuse, including alleged violations of the Stark Law. Importantly, not only does the FCA allow for cases to be brought by whistleblowers through qui tam actions, but also makes available huge civil penalties of as much as $5,500 to $11,000 per claim along with potential treble damages. Whistleblowers personally benefit from any final settlement. The relator in the Halifax case, for example, is on pace to receive roughly $20.8 million.

Both the Fraud Enforcement and Recovery Act (FERA) passed in 2009 and the ACA passed in 2010, include provisions that directly impact the enforcement of the Stark Law under the FCA. Specifically, FERA expanded the reach of the FCA to include knowing retention of overpayments even when the overpayment did not result from the submission of any false record or statement. The practical consequences of this amendment, when combined with the ACA's requirements regarding obligations to return known overpayments within sixty (60) days of "identification," is that the FCA has now become a particularly potent source of potential Stark Law liability. In the event that a hospital discovers an actual or potential Stark Law violation, failure to return overpayments received from prohibited claims billed to the Medicare program within sixty (60) days of discovery creates potential FCA liability in addition to the underlying Stark Law liability.

Not only did FERA and the ACA expand the scope of liability of the Stark Law through the FCA, but as illustrated by Halifax and other recent FCA cases, the DOJ appears to be taking aggressive interpretations of the enumerated requirements contained in applicable Stark Law exceptions (e.g., alleging that, if a physician's compensation from a hospital or other facility, in exchange for providing professional services, exceeds the amount the hospital or facility is able to collect from patients and third party payors for the physician's professional services, then this "must" mean the physician's compensation is also, in part, for referrals to the hospital or facility). These types of positions are creating additional ambiguity for providers regarding how exactly to comply with relevant Stark Law exceptions.

CMS Stark Self-Disclosure Protocol

As mandated by the ACA, in late 2010 CMS established the SRDP, which created a new pathway for providers to self-disclose actual or potential violations of the Stark Law.[8]
Since the creation of the SRDP, CMS has publically settled forty-one self-disclosures, the largest of which was for $579,000.[9] Currently, settlements average a little over $100,000 per disclosure and in many instances there is more than one physician arrangement

involved the self-disclosures at issue. CMS has not publically revealed the specific criteria used to evaluate and ultimately settle claims; however, anecdotal evidence and review of the public summaries published on the CMS website appears to reveal settlement amounts that are a fraction of potential Medicare collections subject to recoupment, rather than the multiples of Medicare collections available in qui tam FCA actions.

Key Take Aways:

- ***Internal Compliance Program:*** Halifax serves as a reminder of the importance of having a robust internal compliance program. The OIG has published sample program guidance for hospitals, which provides specific details of how programs can be structured.

- ***Formalities – Signatures and Expiration Dates:*** In the heightened enforcement landscape, establishing consistent and realistic policies and procedures for negotiating, drafting, executing and implementing physician contracts is of paramount importance.

- ***Document Fair Market Value:*** One alternative interpretation for the increased enforcement of the Stark Law is that providers are simply entering into more agreements due to the renewed focus on integration across the health care delivery spectrum. Fair market value and commercial reasonableness standards, and whether compensation takes referrals into account, have been an area of interest for the DOJ in recent FCA cases and should be carefully considered by providers in transactions where the Stark Law is implicated.

- ***Periodically Monitor Performance:*** Consistent polices are critical not only at the start of referral source arrangements, but also over the term of relevant agreements. Recent FCA cases highlight the potential for parties' performance to drift away from the written terms of agreements over time. This is especially true in real property leases, as well as other arrangements with long or potentially complex terms.

For additional information, please contact Charles Oppenheim, Lloyd Bookman, or Brad Tully in Los Angeles at 310.551.8111; or Paul Smith or Ben Durie in San Francisco at 415.875.8500.

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[1] 31 U.S.C. 3729 *et seq*.
[2] *See* http://www.justice.gov/opa/pr/2014/March/14-civ-252.html. Announcing proposed settlement of *U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Med. Ctr.* (Middle Dist. of FL, Orlando Div., Pending).
[3] *U.S. ex rel. Drakeford v. Tuomey Healthcare System* (4th Cir., Mar. 30, 2012).
[4] *U.S. ex rel. Singh v. Bradford Regional Med. Ctr*.,752 F.Supp.2d 602 (W.D. PA, Nov. 10, 2010).
[5] http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html
[6] 42 U.S.C. § 1320a-7B

[7] *See* http://www.taf.org/DoJ-fraud-stats-FY2011.pdf.

[8] http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf . Prior to the SRDP the OIG had made a self-disclosure process available for potential and actual Stark Law violations. However, that program no longer accepts disclosures unless the underlying conduct includes at least a colorable anti-kickback violation.

[9] http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html