Health Care Executive Liability Exposure Post-Sacred Heart

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Let's get something straight, up front. The sky is not falling. No new enforcement wave is coming. Health care executives need not start contacting personal defense counsel.

But in the wake of the March 19 verdict[1] in the Sacred Heart anti-kickback case, it's reasonable for general counsel to expect a question or two about personal liability from senior leadership team members. And that's a great teaching moment for the general counsel. Indeed, Sacred Heart involved highly unique facts, and individual executive prosecutions under the federal Anti-Kickback Statute[2] remain extremely rare. But the federal government has a wide variety of enforcement tools from which to pursue health care executives that it regularly considers using. So Sacred Heart provides an opportunity for general counsel to brief executives on the scope of the government's power and discretion related to individual executives.

The Government's Toolbox

The government's primary strategy in pursuing health care fraud has been through monetary recoveries and corporate integrity agreements. Yet, as most general counsel are aware, the federal government is under increasing pressure to hold individual executives accountable who knowingly contributed to corporate malfeasance. As Attorney General Eric Holder has publicly stated, "the buck needs to stop somewhere [emphasis added] where corporate misconduct is concerned."[3]

The Office of Inspector General of the U.S. Department of Health and Human Services has joined in scrutinizing health care executives to change the perceived "cost-benefit calculus" beyond the potential for the company paying a fine to the potential for personal liability.[4] In significant cases, OIG lawyers regularly evaluate whether to pursue administrative "spin-off" cases against key executives. While the number of actual cases pursued may be small now, the number of nonpublic investigations following a settlement, verdict or judgment is a little larger, and the number of cases in which OIG thinks about pursuing an executive exclusion action is larger than outsiders might imagine.

The federal government's fraud enforcement paradigm has three main subsets: criminal, civil and administrative monetary actions, and exclusion — with various statutes potentially in play. Individual liability is possible in all three areas.

1. Criminal Health Care Fraud Statutes

The AKS will be the most familiar to health care lawyers due to its impact on a wide range of business relationships. Much ink has been spilt discussing the AKS, its safe harbors and nuances of compliance; our intent is not to add to that body here. The important points for this purpose are: (1) the government can, and does, enforce the AKS criminally, civilly and administratively, and (2) government investigators and prosecutors hunt for the "smoking gun" evidence showing improper intent. In Sacred Heart, the government wired cooperating witnesses to record conversations with executives to build their case.

A variety of other federal criminal statutes exist, including health care fraud,[5] mail[6] or wire[7] fraud, and conspiracy.[8] The essence of these authorities is to capture knowingly making false or fraudulent claims to the government. The Medicare Strikeforce initiative by HHS and the U.S. Department of Justice has been successful in streamlining investigations and prosecutions to achieve greater and faster results. Reviewing the list of recent convictions and indictments shows that a large number of Strikeforce cases are brought against individual owners and managers, including Sacred Heart.[9]

Life sciences entities are familiar with the Food Drug and Cosmetic Act misdemeanor penalties for selling mislabeled or adulterated products.[10] The "responsible corporate officer" (RCO or "Park[11] doctrine"), flows out of the FDCA. While Park prosecutions are rare, they have occurred in the pharmaceutical and medical device industry on occasion. Executives from Purdue Pharma and Synthes pled to misdemeanor misbranding charges, which also resulted in their exclusion by OIG.

2. False Claims Act and Civil Monetary Penalty Law (CMPL)

The FCA[12] has been a powerful tool for the government in pursuing corporations and recovering over $27.8 billion since 1997.[13] As the FCA's administrative allegory, the CMPL[14] similarly applies to false or fraudulent claims or AKS conduct. However, lawsuits against executives under either statute have been few. The FCA settlement generally releases officers and directors from civil and administrative monetary liability, including the FCA and CMPL. However, OIG's practice has been to only provide the entity that is the party to the corporate integrity agreement, and not categories of individuals, with the exclusion release in exchange for entering into the CIA. When there is no CIA, or in particularly noteworthy cases, OIG has begun to be more active in bringing, or at least continuing an investigation post-settlement, of spin-off cases of potentially culpable individuals for exclusion.

3. Exclusion Statute

OIG's exclusion authorities[15] also cover false claims and AKS conduct. A specific exclusion authority permits excluding officers or managing employees of a convicted or excluded entity without proving the individual's knowledge of the misconduct, although this authority is seldom used because it is rare that there is an excluded or convicted entity in a civil resolution outside of the FDCA context.[16]

A recent example of a spin-off enforcement action following an FCA settlement is OIG's exclusion of Michael Dinkel, the owner and president of Drew Medical Inc., a diagnostic imaging services provider. Drew Medical entered into a FCA settlement for $1,147,564 resolving allegations of submitting false claims for certain radiology procedures that were not provided as claimed. Prior to the civil settlement, OIG notified Dinkel that OIG intended to exclude him, and following the settlement, proposed an eight-year exclusion term, which was upheld on appeal.[17]

What Does the Government Look For?

A key question for a health care executive is how will the government judge executive conduct and decide which conduct to pursue more aggressively? The following is a nonexhaustive list of red flags that may lead a government investigator to take a serious look at individual executive liability:

Allegations of Patient Harm

One of the surest ways to prompt an investigator's interest in pursuing a case is allegations of potential patient harm. Many times, however, the patient harm allegations fall away from the case because of the inherent difficulty in proving harm. But in the process of scouring for patient harm evidence, the government will build its case supporting a false claims or AKS theory.

That certainly appears to be what may have happened in Sacred Heart. The original search warrant from April 2013 included not only the kickback allegations but also allegations of emergency room evaluation, testing and observation services that were not medically necessary, as well as medically unnecessary sedation, intubation and tracheotomy procedures.[18] Some of the allegations were certainly eye-catching: the warrant cited to a recorded conversation in which a physician allegedly told the wired witness that he used to make the hospital "so much money" performing almost daily penile implant procedures on patients, but that he no longer performed as many of those procedures because Medicare had decreased its rates of reimbursement for the procedure. The physician did not comment on whether the patient need for the procedure had somehow changed, according to the affidavit. These patient harm allegations were ultimately not included in the indictment or trial, but they may explain why the investigation moved from arrest to indictment within six months.[19]

Corruption of Medical Decision-Making

Trying to influence physician decision-making away from the best interests of patients and towards personal financial gain is another hot topic for government investigators. This theme has underpinned concerns about physician relationships expressed in various OIG guidance and advisory opinions. According to Sacred Heart prosecutors, the kickback scheme resulted in questionable care for patients, many of them elderly nursing home residents, to the financial benefit of those involved.[20]

Personal Involvement in Clear Conduct and/or Cover-Up

Proving the intent element in a kickback case is often challenging. However, proving intent becomes easier for the government when (1) the conduct at issue is relatively straight-forward or (2) the executives were involved in the attempts to make illegitimate payments appear legitimate. The scheme at Sacred Heart was not very sophisticated. Juries will understand that bogus office leases, paying for teaching medical residents that does not in fact occur, or lending hospital employees to the doctors for free are a problem. Harder cases are more complex business deals that had legal counsel and other expert advice.

Tone From the Top

The government expects that executives will set the right tone about their commitment to fostering a culture of compliance in their organization. While no compliance program is expected to prevent all misconduct, the government will look at whether the program is "right-sized" for the organization as a positive sign of commitment. And acting consistent with that commitment is key. Witnesses are too happy to share conversations, emails, texts, or videos of a CEO disparaging or complaining about the unnecessary burdens of compliance, which can shape the government's view of the responsibility that the CEO had in creating the environment for the conduct to occur.

As Holder said, responsibility for corporate misconduct has to rest with someone. "I'm the owner of Drew Medical. The buck stops with me," Dinkel acknowledged in his exclusion hearing.[21]

The Sacred Heart verdict arose out of extraordinary facts, and on its own does not reflect a new emphasis on criminal prosecution under the AKS. However, the government's focus on personal accountability for corporate malfeasance is real. The government has several enforcement mechanisms available from which it can pursue health care executives, including civil or administrative remedies. The Sacred Heart verdict provides a good opportunity for health care counsel to discuss these enforcement mechanisms with the senior executive team, as well as examples of individual conduct that should materially lessen exposure to individual liability. This information should also be shared with the board's audit and compliance committee to the extent it enhances awareness of regulatory risks.

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[1] Jury Finds Chicago Hospital Execs Guilty In Kickbacks Case; http://www.law360.com/health/articles/633673?nl_pk=dddb0bf2-ae6c-428e-b972-ff8a32705342&utm_source=newsletter&utm_medium=email&utm_campaign=health; http://www.justice.gov/usao/iln/pr/chicago/2015/pr0319_02.html

[2] 42 U.S.C. 1320a-7b(b).

[3] http://www.justice.gov/opa/speech/attorney-general-holder-remarks-financial-fraud-prosecutions-nyu-school-law

[4] See, e.g., Testimony of Daniel R. Levinson, Inspector General, HHS, United States Senate Committee on Homeland Security & Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security (March 9, 2011), at http://oig.hhs.gov/testimony/docs/2011/levinson_testimony_03092011.pdf (One way to address the "too big to fire" issue discussed above is to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.).

[5] 18 U.S.C. § 1347.

[6] 18 U.S.C. § 1341.

[7] 18 U.S.C. § 1343

[8] 18 U.S.C. §§ 286, 371.

[9] http://oig.hhs.gov/fraud/enforcement/criminal/index.asp.

[10] 21 U.S.C. § 331.

[11] United States v. Park, 421 U.S. 658, 670, 95 S.Ct. 1903, 44 L.Ed.2d 489 (1975). Criminal liability under the Park doctrine includes individuals who, by virtue of their managerial positions, had the authority and responsibility to prevent or correct violations and failed to do so. This can result in subjecting a corporate officer to misdemeanor misbranding liability without knowledge of, or personal participation in, the underlying fraudulent conduct.

[12] 31 U.S.C. §§ 3729-3733.

[13] Health Care Fraud and Abuse Control Program FY 2014 Report, at http://oig.hhs.gov/publications/docs/hcfac/FY2014-hcfac.pdf.

[14] 42 U.S.C. § 1320a-7a.

[15] 42 U.S.C. § 1320a-7.

[16] 42 U.S.C. § 1320a-7(b)(15). OIG published guidance on the factors it will consider when evaluating whether a section (b)(15) exclusion should be imposed. http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf. The best known attempt by OIG to use this authority was against former Forrest Laboratories' CEO Howard Solomon following Forest Lab's FCA settlement in April 2011. But by August, OIG decided to close the case without taking action. http://www.law360.com/articles/262985/us-ends-bid-to-oust-forest-labs-ceo-solomon.

[17] http://www.hhs.gov/dab/decisions/dabdecisions/dab2445.pdf.

[18] http://www.justice.gov/usao/iln/pr/chicago/2013/pr0416_01.html.

[19] http://www.fbi.gov/chicago/press-releases/2013/owner-executives-and-physicians-at-closed-sacred-heart-hospital-indicted-in-alleged-medicare-referral-kickback-conspiracy.

[20] http://www.law360.com/health/articles/633673?nl_pk=dddb0bf2-ae6c-428e-b972-ff8a32705342&utm_source=newsletter&utm_medium=email&utm_campaign=health.

[21] http://www.hhs.gov/dab/decisions/civildecisions/2011/cr2396.pdf.