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DOJ's Important Message to Health System Leadership

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Health system leadership should recognize, and respond to, the dramatically increasing emphasis of the Department of Justice (DOJ) on health care fraud enforcement, and on related issues of corporate cooperation and individual accountability.

Over the last several months, the DOJ's Criminal Division has been engaged in a focused public discussion of health care fraud enforcement, and the process DOJ applies when making a decision with respect to corporate prosecutions. This isn't a "same old, same old" deal. Rather, it reflects a new and notable intensity with which the DOJ is publicly making its point—emphasizing not only its focus on enforcement, but also on issues of executive accountability, corporate cooperation, and compliance plan effectiveness. These are concepts that both the board and executive leadership should closely consider. The system general counsel is well suited to frame the related internal discussion.

As to Enforcement. The DOJ's Criminal Division has been active this spring with efforts to increase public transparency concerning the process it applies when making corporate prosecution decisions. DOJ's goal is to clarify the parameters it considers in deciding how to proceed, once it is made aware of alleged corporate wrongdoing. This goal includes making the value of cooperation, and the consequences of noncooperation, more clearly apparent to corporations and their advisors.^[1]

More specifically, DOJ's Criminal Division is sending a clear signal that its enforcement focus in health care has shifted from being "re-active" to being "proactive." This is manifested most notably in the nationwide activities of the Medicare Fraud Strike Force, which is now expanding its attention to emerging frauds arising from Medicare Part D, laboratory services, hospital-based services, and hospice care.^[2]

This proactive emphasis also is reflected in coordinated investigative efforts of the DOJ's Civil and Criminal Divisions. The criminal prosecution of American Therapeutic Corporation and its executives is cited by DOJ as an example of such coordination. The criminal case started with a False Claims Act qui tam filing but expanded to a kickback case in which over 20 individuals ultimately were convicted.^[3] The Criminal Division will review qui tam complaints early in the process, to determine whether there is, or is likely to be, evidence of criminal conduct (and if so the Criminal Division will open a parallel investigation).^[4] This may be noteworthy for health system leaders who are prone to dismiss FCA qui tam filings actions as merely "the cost of doing business."

Of course, the recent, successful criminal prosecution of several executives of Sacred Heart Hospital in Chicago serves as an example of the enforcement efforts of individual U.S. Attorney offices.^[5]

As to Corporate Cooperation. The concept of "corporate cooperation" with the government in the context of an investigation has been emphasized in a series of recent speeches by Leslie Caldwell, the head of DOJ's Criminal Division. While government policy has long spoken to the benefits of corporate cooperation, it is likely to be a foreign concept to most health care systems and their

leadership teams—for understandable reasons. Yet the repeated recent references by Criminal Division leadership to the benefits of cooperation (and the “real and sometime severe consequences for non-cooperation and foot-dragging”)[6] should be closely noted by system leadership—and especially by their board audit and compliance committees. What does “corporate cooperation” really mean to a health system?

The basic principles of corporate cooperation as they relate to a prosecution decision are set forth within DOJ’s Principles of Federal Prosecution of Business Organizations (the so-called “Filip Memo”).[7] The Principles document makes clear that two of the many factors DOJ will consider in making a prosecution decision are “the corporation’s timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents.”[8] As the Filip Memo makes clear, “cooperation” in the context of a government investigation is a potential mitigating factor, by which a corporation “can gain credit in a case that otherwise is appropriate for indictment and prosecution.”[9] Certainly, a decision by the corporation not to cooperate doesn’t in and of itself constitute evidence of misconduct—at least in circumstances in which the absence of cooperation “does not involve criminal misconduct or demonstrate consciousness of guilt (e.g., suborning perjury or false statements, or refusing to comply with lawful discovery requests).”[10] Thus, a corporation’s decision not to cooperate, “in and of itself, does not support or require the filing of charges with respect to a corporation any more than with respect to an individual.”[11] As DOJ also points out, most corporations are not obligated to cooperate with the government and it is clearly the corporation’s decision to do so.[12] But certainly the whole question of whether to cooperate will be a momentous one for the board and executive leadership, and should only be made upon the advice of qualified counsel.

In addition, Ms. Caldwell’s recent speeches have sought to add clarity on both the value of cooperation, and the government’s expectations regarding cooperation; i.e., that it “be candid, complete and timely.”[13] The form and structure of a corporation’s internal investigation may bear heavily on the question of whether there has been bona fide corporate cooperation. In her several speeches, Ms. Caldwell has provided prominent examples of what constitutes satisfactory corporate cooperation (and the resulting benefits), and what constitutes insufficient cooperation (and the resulting consequences).[14] For while there is certainly no “one size fits all” form of internal investigation, DOJ’s expectation is that the investigation will focus on learning the relevant facts—including those about individuals allegedly responsible for the misconduct; making relevant documents available where DOJ might otherwise have difficulty obtaining them; and the timely provision of evidence to the government; i.e., no delay in providing them once the facts have been determined.[15]

In other words, “cooperation” is all about helping to remove and overcome barriers to identifying and producing the information the government needs to conduct a meaningful investigation[16] and does not mean doing things that most corporations would ordinarily do under any investigative circumstances. Rather, it involves a much more significant and substantive level of interaction with the government—which may come as something of a “reality check” for some health system leaders.

As to Individual Accountability. Eyebrows are likely to be raised—at least among the “uninitiated”—by Ms. Caldwell’s repeated reference to evidence of individual culpability. This isn’t new—the Filip Memo has always made clear the linkage between corporate cooperation and individual accountability. The Strike Force also will focus on individual prosecution, and has made fraud by health care executives a clear priority.[17] And it shouldn’t be all that surprising, given broader Justice Department emphasis in the financial sector on holding culpable executives responsible for corporate wrongdoing; i.e., that ‘the buck has to stop somewhere.’

Yet there is something fundamentally jarring about the government’s expectation that cooperating companies will identify culpable individuals—including senior executives if they were involved—and

turn over evidence of such alleged wrongdoing. Government policy or not, it has the potential for significantly altering the board/management dynamic. Traditional loyalties may be strained when executive leadership is aware that, in a pinch, the board may be motivated/have no choice but to provide the government with internal investigation-produced evidence about potentially culpable executives. It also may affect the extent to which the board is involved in the structure and direction of internal investigations and in the development of defense strategies—including but not limited to the reporting relationships of outside counsel.

As to the Compliance Program. Notably, Ms. Caldwell devoted the entirety of one of her May speeches to the subject of compliance plans, and to how corporations should hold themselves accountable for developing substantive compliance programs and structures.^[18] Her emphasis on this important topic is a reminder to the Audit & Compliance Committee (and to the Chief Compliance Officer and General Counsel) that the Department of Health and Human Services (HHS)/Office of Inspector General (OIG) is not the only health care fraud enforcement agency with something to say about compliance plan effectiveness.

Like HHS/OIG, DOJ recognizes that there is no “one size fits all” compliance program.^[19] The Filip Memorandum contains basic expectations for an organization’s compliance program.^[20] It mirrors the HHS/OIG guidance and the Federal Sentencing Guidelines with respect to many individual elements of effectiveness. Yet it is unique in several important areas.

One such area is its specific focus on practical aspects of effectiveness; i.e., on whether the plan is “real” or merely “paper.” The Filip factors place great emphasis on the importance of “tone at the top” considerations; on evidence of leadership’s “strong, explicit and visible support” for the compliance program. They also address practical aspects of management-employee interaction; i.e., whether employees are tacitly encouraged or pressured to engage in misconduct, or whether employees are encouraged to place ‘profits over compliance.’^[21]

The Filip Memo is consistent with the HHS/OIG view to the extent that it supports the ability of compliance officers to have the authority to report to independent monitoring bodies; e.g. internal auditors or the governing board.^[22] This is the position taken in the Federal Sentencing Guidelines. But the Filip Memorandum does not contain an explicit recommendation against a compliance officer-to-general counsel reporting relationship.

Ms. Caldwell’s remarks on the “hallmarks” of an effective compliance plan should prompt the general counsel and compliance officer to consider whether the organization’s existing plan should be amended to incorporate any unique DOJ elements of effectiveness.

So What’s the Message?

Well, the direct message is that DOJ will continue to be a real force in health care fraud enforcement on both civil and criminal bases, depending upon the circumstances. The health system board will need to recalibrate its legal compliance oversight practices accordingly.

But it’s the indirect message that’s more significant. There’s a certain “whoa” moment associated with all the “hardball” talk about corporate cooperation and individual accountability. A sense that this is real serious stuff; a place where no health system ever wants to be. It’s a sharp jab of a reminder that the board needs to take its *Caremark* obligations very, very seriously.

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[1] Leslie R. Caldwell, Assistant Att’y Gen., U.S. Dept. of Justice, Remarks at the New York City Bar Association’s Fourth Annual White Collar Crime Institute (May 12, 2015) [hereinafter *Caldwell, May 12th Remarks*].

[2] Leslie R. Caldwell, Assistant Att’y Gen., U.S. Dept. of Justice, Remarks at the American Bar Association’s 25th Annual National Institute on Health Care Fraud (May 14, 2015) [hereinafter *Caldwell, May 14th Remarks*].

[3] *Id.*

[4] *Id.*

[5] Press Release, U.S. Dept. of Justice, Owner and Executives Convicted in Medicare Referral Kickback Conspiracy at Closed Sacred Heart Hospital (Mar. 19, 2015); *see also* Tony Maida & Michael W. Peregrine, *Health Care Executive Liability Exposure Post-Sacred Heart*, Law360 (Apr. 14, 2015), available at <http://www.law360.com/articles/642441/health-care-executive-liability-exposure-post-sacred-heart>. (Subscription required)

[6] *Caldwell, May 12th Remarks, supra* note 1.

[7] Memorandum from Mark Filip, Deputy Att’y Gen., U.S. Dept. of Justice, to Heads of Department Components, United States Attorneys (Aug. 28, 2008).

[8] United States Attorneys’ Manual, § 9-28.300(A)(4).

[9] United States Attorneys’ Manual, § 9-28.700.

[10] *Id.*

[11] *Id.*

[12] *Caldwell, May 12th Remarks, supra* note 1.

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Caldwell, May 14th Remarks, supra* note 2.

[18] Leslie R. Caldwell, Assistant Att’y Gen., U.S. Dept. of Justice, Remarks at the Compliance Week Conference (May 19, 2015).

[19] *Id.*

[20] United States Attorneys’ Manual, § 9-28.800.

[21] United States Attorneys’ Manual, § 9-28.800(B).

[22] Office of Inspector General, U.S. Department of Health and Human Services; Association of Healthcare Internal Auditors; American Health Lawyers Association; Health Care Compliance Association, *Practical Guidance for Health Care Governing Boards on Compliance Oversight* (Apr. 20, 2015), available at <https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>.

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