

A “Responsible Corporate Officer” Defense Plan

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It’s controversial. It’s severe. It’s aggressive. It targets individuals, not corporations. It’s the Responsible Corporate Officer Doctrine (RCOD), and new developments make it a credible, personal, compliance risk for the officers and key employees of hospitals and health systems. It is thus incumbent on the board—working through the general counsel—to develop a defensive strategy that will reduce executive exposure to the RCOD. That will be no easy task, given the fundamental vagaries of the doctrine and the amorphous nature of possible defenses. But, for the sake of dedicated executives, it is important to try.

The RCOD is a Supreme Court-grounded strict liability theory interpreted by the government as permitting (in certain circumstances) the prosecution of officers and directors for misdemeanor criminal offenses—without the need to establish their intent or personal involvement in wrongful conduct. Federal healthcare fraud enforcement has, for the past two years, focused not only on corporate actors, but also on holding individuals accountable for corporate noncompliance—either through direct proof of their knowledge of noncompliant practices or through strict liability under the RCOD. Prosecutors believe that attributing responsibility to individuals at the highest corporate levels will have a strong deterrent effect and thus enhance compliance with federal healthcare laws.

RCOD prosecutions have until recently been concentrated in the pharmaceutical and medical device industries, pursuant to the federal Food, Drug and Cosmetic Act (FDCA).¹ The primary health provider anti-fraud statutes are an awkward fit for RCOD application given that they require proof of intent as an element of a violation. However, the new expansion of the Department of Health and Human Services (HHS) Office of Inspector General’s (OIG’s) civil permissive exclusion authority regarding key individuals brings RCOD exposure to the doorstep of the hospital/health system board room and executive suite. Responsive board action is called for.

RCOD Foundations

In two cases, the Supreme Court has articulated a standard under which criminal liability could be attributed to a corporate officer for the actions of subordinates in the absence of knowledge or involvement in such actions. Both *United States v. Dotterweich* and *United States v. Park*² involved FDCA violations. *Dotterweich* addressed the conviction of a pharmaceutical company executive charged with interstate shipment of misbranded drugs. While there was no evidence that the executive was aware that the shipments were indeed misbranded or adulterated, the Supreme Court upheld his

conviction. In doing so, it held that criminal liability for violation of a public welfare-based statute (e.g., the FDCA) could be established where the officer possessed the authority to prevent the violation, and failed to take action to do so. Critical to the Court’s conclusion was the extent to which violations of public welfare statutes (the risk of endangering public health) support an exception to traditional rules of liability.

The *Park* court, which involved the same FDCA misdemeanor provisions, clarified the RCOD by articulating a standard under which criminal liability could be attributed to a corporate officer for the actions of subordinates in the absence of knowledge or involvement in such actions:

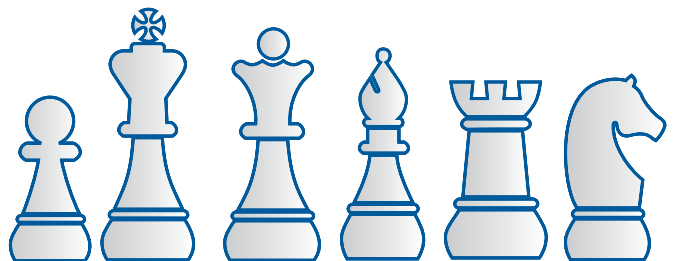
- » By virtue of his position in the corporation, the officer both:
- Had “the responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of”; and
 - Failed to prevent or correct the violation.³

According to the Supreme Court, corporate officers are subject to prosecution under the RCOD only if they stand in some “responsible relationship” to a specific violation of the relevant law, such that their failure to exercise the authority and supervisory responsibility assigned to them resulted in the violation.⁴ This obviously serves to place a high duty of care on corporate officials in industries subject to RCOD exposure.

It should be noted that prosecutors have, with judicial approval, successfully applied RCOD-type theories to several different types of state and federal statutes, including but not limited to criminal violations of the Sherman Act, the federal securities laws, and state/federal environmental laws. A common thread is that the statute under which liability is sought to be imposed is a public welfare statute.⁵

Recent Health Sector Application

In recent years, Department of Justice (DOJ) prosecutions of pharma and medical device companies for FDCA violations⁶ have led to misdemeanor guilty pleas by (and significant penalties against) senior corporate executives—including a general counsel. One case involved three senior executives of Purdue Frederick Company (including the chief executive officer and the general counsel), who in 2007 pled guilty to violations



of the FDCA associated with the misbranding of the drug OxyContin. DOJ did not allege that the three officers participated in or were even aware of the misbranding, but rather that they were responsible corporate officers during the time the conduct occurred. Another case resulted in the 2009 guilty pleas of four executives of Synthes, Inc. and its Spine Division to misdemeanor charges associated with shipping adulterated and misbranded medical devices in interstate commerce. In their guilty pleas, the executives stipulated that they were responsible corporate officers at the time the misbranding occurred. These prosecutions were followed by a series of public comments by DOJ officials predicting additional prosecutions based on RCOB theories, illustrating the government's interest in "following the conduct" to identify individuals who can be held responsible for healthcare fraud—whether they are "in the field," executive suite, or the board room.⁷

A series of developments over the last 18 months has continued RCOB-based health industry enforcement and, in some instances, tilted it closer to the provider sector. One notable event was the July 2009 program exclusion of Emmanuel Bernabe, following an investigation of standard care at nursing homes operated by a company managed by Bernabe. The exclusion was carried out pursuant to HHS OIG's existing permissive exclusion authority (under Section 1128(b)(15) of the Social Security Act) to exclude owners, officers, or managing employees of an entity that has been excluded or convicted of certain offenses (Permissive Exclusion Authority).⁸

Another noteworthy development was the 2010 congressional testimony of OIG Inspector General Daniel Levinson and OIG Chief Counsel Lewis Morris, both addressing new tools necessary to combat healthcare fraud and abuse. Both Messrs. Morris and Levinson spoke to the importance for fraud enforcement purposes of determining responsibility within an organization's management structure. Their testimony placed particular emphasis on the need to establish accountability in situations where corporations intentionally "construct byzantine structures that obscure responsible parties from view."⁹

Their testimony contributed to the introduction by Representatives Herger and Stark of the Strengthening Medicare Anti-Fraud Measures Act.¹⁰ This legislation is intended to address two perceived gaps in the context of Medicare/Medicaid enforcement: the need to (1) expand the Permissive Exclusion Authority of HHS OIG to include the ability to exclude executives of companies convicted of healthcare fraud where the executives had left the company at the time of the conviction; and (2) exclude parent companies of certain types of organizations (e.g., shell companies) convicted of healthcare fraud. The future of this legislative proposal should be closely monitored by health lawyers; query the unintended consequences on healthcare system parent corporations, their officers, and board members.

New expansion of the HHS OIG's civil permissive exclusion authority regarding key individuals brings RCOB exposure to the doorstep of the hospital/health system board room and executive suite.

Also noteworthy was the December 13, 2010 decision of the U.S. District Court for the District of Columbia affirming the federal healthcare program exclusion of the three Purdue Frederick executives who had initially pled guilty to FDCA misdemeanors.¹¹ These executives sought to set aside their exclusions, arguing in part that their RCOB convictions did not constitute fraud because the record lacked any evidence that they possessed personal knowledge of the wrongful corporate conduct. In a strongly-worded decision, the district court upheld the OIG's twelve-year exclusion. This ruling was consistent with the government's theory that the executives were responsible for the underlying criminal conduct regardless of whether they were aware of it.

The OIG and RCOB

RCOB-based misdemeanor prosecution is perceived as a valuable enforcement tool in healthcare. A new development directly exposes hospitals and health systems to RCOB-based exclusion penalties. HHS OIG's new guidance document (Exclusion Guidance), released last October, sets forth a series of non-binding factors OIG will consider in deciding whether to impose its Permissive Exclusion Authority.¹² This Authority provides two different bases for exclusion.

At one level, the new Exclusion Guidance provides that in circumstances where the facts indicate that an owner, officer, or managing employee of a sanctioned entity *knew or should have known* of the prohibited conduct that led to the entity sanction, the OIG will operate with a presumption in favor of excluding the individual from federal healthcare programs. This presumption may be overcome if OIG finds that significant factors weigh against exclusion. The Exclusion Guidance does not define these factors.

At another level, officers and managing employees may in certain circumstances be held to a higher, RCOB-style, standard of conduct than owners. The Exclusion Guidance provides that officers and managing employees may also be subject to exclusion *in the absence of evidence that they knew or should have known of the corporate misconduct*. In so doing, the Exclusion Guidance authorizes a strict liability

basis for excluding officers and managing employees; one that does not require satisfaction of the “known or should have known” element. In other words, officers and managing employees may be subject to exclusion on a strict liability basis due solely to their position with the entity. The application of such an RCOD-based grounds for exclusion places officers and managing employees at far greater risk of exposure than owners, who are subject to a knowledge standard. In this regard, it is important to note that a “managing employee” is defined as an individual (including a general manager, a business manager, an administrator, or a director) who exercises operational or managerial control over the entity or who directly or indirectly conducts the day to day business of the entity. While this definition *excludes* governing board members, it nevertheless cuts a wide swath through an organization’s management roster.

The Exclusion Guidance sets forth four factors OIG will consider in deciding whether to exclude an officer or managing employee in the absence of evidence that the person knew or should have known of the misconduct: (1) the circumstances of the misconduct and the seriousness of the offense; (2) the individual’s role in the sanctioned entity; (3) the individual’s action in response to the misconduct; and (4) certain information about the sanctioned entity. In other words, OIG will ask the following questions: *What was your job within the organization? Were you in a position to prevent the wrongdoing? Was there a reasonable relationship between your position and the nature of the activity that led to the violation? Once it was identified, were you in a position to correct the wrongdoing? And did you?* The Exclusion Guidance acknowledges that these factors were drawn from the RCOD as established in case law, including the Supreme Court’s decision in *Park*.

An early example of the use of this authority was the November 17, 2010 action by HHS OIG to exclude a member of the board of directors of a pharmaceutical company from federal health program participation. The action followed a series of controversies involving the company and FDA manufacturing compliance issues at the company. This exclusion was described as a “preview of things to come” by Gregory E. Demske, assistant HHS inspector general.¹³

Where is This Headed?

Under this administration, the government appears committed to a healthcare sector enforcement strategy of focusing on the conduct, culpability, and accountability of individuals as well as organizations, including application of the RCOD and similar strict-liability theories. The recent judicial approval of the Purdue executives’ exclusion sets aside, for the moment at least, any suggestion that RCOD theories should not be applied to penalize individuals solely on the basis of their positions within the corporate hierarchy.

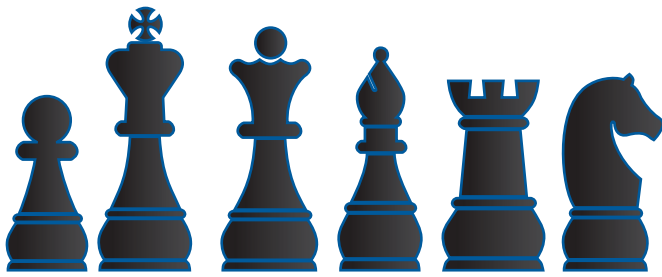
The authors believe that the traditional healthcare anti-fraud statutes do not lend themselves to easy application of

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RCOD principles because they require proof of intent as an element of violation. Similarly, extension of the RCOD to the Stark law—which has no intent requirement—would seem to be a prosecutorial “long shot” unless it was aggressively styled as a public welfare-type statute. That notwithstanding, there is no question that the release of the Exclusion Guidance on its own subjects hospitals and health systems to a responsible corporate officer-type exposure (although one with exclusion rather than criminal penalties).

Time will tell whether HHS OIG will aggressively apply its RCOD-based Permissive Exclusion Authority to hospitals and health systems. Where the evidence suggests that officers and managing employees *neither knew nor should have known* of the misconduct, it is likely that exclusion will be sought only in aggravated fact patterns. This could include circumstances involving egregious Bernabe-like quality of care deficiencies; systemic organizational compliance violations suggestive of a lack of institutional control; the intentional refusal by executives to respond through corrective action to material compliance misconduct; evidence of obstruction of justice; recidivist corporate behavior; where senior management and/or the board otherwise acted in bad faith with respect to their compliance oversight obligations (i.e., failed to act in the face of a known duty to act, thus demonstrating a conscious disregard for their compliance obligations); or consciously disregarding the obligation to be reasonably informed about the compliance risks of the organization. The authors do not believe OIG intends to use RCOD-like principles against volunteer directors of not-for-profit healthcare companies, as a matter of public policy (except, perhaps, in the most egregious of circumstances). Experience suggests that OIG’s preferred approach is dealing with director conduct through education and guidance (and the occasional corporate integrity agreement (CIA) provisions), deferring to the state attorney general matters relating to possible breach of fiduciary duty.

In any event, the ultimate persuasive effect of the new Permissive Exclusion Authority as it relates to leveraging compliant conduct and effecting settlements with the government cannot be understated.



Developing A Strategy

These are developments that healthcare executives—and boards—should take seriously. Fairness requires that management and key employees be informed of the risk and at the same time provided with specific board-supported recommendations on how to mitigate the risk. This is not a simple task as RCOD risk is exacerbated by the absence of any clearly articulated guideposts from which officers and managing employees may appropriately structure their conduct.

For example, the factors OIG will consider in determining whether to exercise its Permissive Exclusion Authority are helpful in risk mitigation only to a very limited extent, particularly in circumstances where the officer or managing employee neither knew, nor should have known, of the problematic conduct. Only the third factor (Individual's Actions in Response to the Misconduct) serves to provide an officer or key employee with *any* guidance on a proper defensive position. However, it should be noted that responsive conduct that involves disclosure to, or cooperation with, law enforcement agencies should be based upon the advice of legal counsel.

The third factor does recognize the “Impossibility Defense” to RCOD allegations (as originally set forth by the *Park* court): if “the individual... can demonstrate either that preventing the misconduct was impossible or that the individual *exercised extraordinary care* [emphasis added] but still could not prevent the conduct,” OIG may consider such evidence as a factor weighing against exclusion. In essence, the Impossibility Defense provides that a corporate officer who exercises “extraordinary care” and still is unable to prevent the underlying illegal conduct will not be held personally responsible.¹⁴ However, the availability of such a defense is elusive to the point of frustration. There simply is no reliable definition of conduct constituting “extraordinary care” or “the utmost care.” None of the courts, administrative proceedings, DOJ, nor OIG has provided useful guidance on how the elements of this defense can be satisfied.

Specific Action Plan

In the absence of such reliable guidance, hospitals and health systems should consider a three-pronged approach to mitigating RCOD risk in general and permissive exclusion risk in particular.

The *first prong* of this approach is fairly simple—educating all persons fairly falling within the definition of “officer” and “managing employee” of the relevant permissive exclusion risks. The threat of a health sector “death sentence” is likely to be an effective compliance motivation technique, as the OIG clearly intends. The board and compliance committee should similarly be informed.

The *second prong* would be advising on an appropriate response to be taken once the officer or key employee becomes aware of the alleged misconduct, as contemplated by the third Exclusion Guidance factor. This advice would relate to steps that could be taken to stop the misconduct or to mitigate its ill-effects (e.g., appropriate disciplinary action). The advice would distinguish between responses that occurred before, or after, the officer learned of an investigation into the alleged misconduct.

The *third prong* would be efforts by officers and directors to adopt a comprehensive, “state of the art” compliance program in every respect, even in situations where no previous concern with the effectiveness of the compliance program had been identified. Specific enhancements should be designed to emphasize the good faith/“extraordinary care” of the officers and managing employees, and could include:

- » Materially increased compliance training and education, especially for individuals meeting the definition of “officers and managing employees”;
- » Enhanced reporting mechanisms that provide the board and senior management with a more acute awareness of the organization’s compliance profile and position them to be more responsive in taking corrective action where warranted, including increased “face time” between the compliance officer, the general counsel, and both the CEO and board leadership;
- » Emphasis on close management and compliance committee monitoring of potential compliance risk areas;
- » Senior management support for expanding the compliance department budget and for hiring compliance officers and in-house counsel with qualifications appropriate for the size and sophistication of the organization.
- » Significant expansion of employee and vendor accessibility to confidential reporting mechanisms and to organizational responses to individual reports (e.g., “here’s how we reacted”);
- » Effective, conflict-free vertical and horizontal reporting and other communication relationships among the compliance officer, the general counsel, senior management, the compliance committee, and the board;
- » Evidence of material board attentiveness to compliance-related comments contained in the “management letter” from the external auditor;
- » Internal controls intended to reduce obstruction of justice-related risks in responding to government inquiries;
- » Clarification of officer and key manager operational oversight responsibilities;

- » Financial incentives for officer/managing employee conduct consistent with support of the compliance plan, and harsh remediation of conduct inconsistent with the plan;
- » Increased organizational commitment to periodic auditing of compliance plan effectiveness;
- » Advising the board of the perils of “microgovernance” (as opposed to traditional oversight) with respect to operational matters; and
- » Educating executives and key employees (and board leadership) about establishing an organizational commitment to compliance (a/k/a “Tone at the Top”).

However, there can be no assurance that such enhancements or similar efforts will reduce exposure to RCOB-based sanctions. Furthermore, a decision not to implement such enhancements should not be interpreted as evidence of bad faith (or anything else, for that matter). Nevertheless, the more that corporate officers and managing employees are made aware of RCOB risks, the more likely they are to support measures intended to enhance the effectiveness of the compliance plan, which clearly is a goal of the OIG’s Exclusion Guidance. Given these circumstances, it should be the obligation of the board to support an enhanced defensive plan for its valued employees. ☐

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Endnotes

- 1 Now codified at 21 U.S.C. §§ 301 *et seq.* This statute contains a strict liability provision for misdemeanor misbranding and adulteration violations.
- 2 *United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Park*, 421 U.S. 658 (1975).
- 3 See *Park*, 421 U.S. at 673-74. Mr. Park was the president of a retail food company who had no meaningful oversight over company practices at the core of the FDCA violation (rodent infestation).
- 4 *Park*, 421 U.S. at 671.
- 5 *Blue Sky* § 9:117.5 (SEC BLUE § 9:117.5); Berman and Donath, *When No Knowledge Can Still Be a Dangerous Thing: The Potential Criminal Liability of Officers and Directors of Healthcare Companies for the Acts of Their Subordinates*, American Health Lawyers Association Business Law and Governance Practice Group, Business Law and Governance, Vol. 1, Issue 1, Dec. 2008.
- 6 21 U.S.C. § 331(a) prohibits the introduction or delivery for introduction into interstate commerce of a misbranded drug.
- 7 See, e.g., *DOJ Officials Outline Enforcement, Prevention Initiatives to Tackle Fraud*, HEALTH CARE DAILY REP. (BNA) (Nov. 16, 2009) (Comments attributed to Tony West, head of Civil Division, DOJ); *Government Attorneys Discuss Conduct That Gives Rise to Fraud Investigations*, HEALTH CARE DAILY REP. (BNA) (Nov. 12, 2009) (Comments attributed to Gerald Sullivan, of the U.S. Attorney’s Office for the Eastern District of Pennsylvania).
- 8 See http://oig.hhs.gov/publications/docs/press/2009/hhs_oig_bernabe_exclusion_release.pdf.
- 9 The testimony is available at <http://oig.hhs.gov/testimony.asp>.
- 10 See <http://herger.house.gov>; originally introduced in 2010 as H.R. 6130 when it passed the House but the Senate failed to act.
- 11 *Friedman v. Sebelius*, No. 09-cv-02028, 2010 U.S. Dist. LEXIS 131465 (D.D.C. Dec. 13, 2010).
- 12 “Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act” (October 20, 2010), available at <http://oig.hhs.gov/fraud/exclusions/asp>.
- 13 “OIG Excludes Drug Company Executive from Federal Health Program Participation,” HEALTH LAW REPORTER (BNA) (Nov. 24, 2010).
- 14 See, e.g., *Park*, 41 U.S. at 673; *U.S. v. Wiesenfeld Warehouse Co.*, 376 U.S. 86, 91 (1964). Yet, case law suggests that the Supreme Court intended the use of the defense to be narrow.