HHS OIG Releases New Guidance on Exclusion of Officers and Managers Following Corporate Pleas

The Office of the Inspector General of the Department of Health and Human Services (OIG) has released a pathbreaking guidance document describing its approach to excluding individuals from participation in federal health care programs for controlling a sanctioned entity under 42 U.S.C. § 1320a-7(b)(15) ((b)(15)). This guidance finds OIG asserting the breadth of its authority by creating a presumption in favor of exclusion in certain cases and endorsing a new strict liability exclusion standard in other cases. These enforcement positions appear likely to accelerate the government’s recent efforts to hold individuals accountable for corporate wrongdoing.

Background on Exclusion and (b)(15)

Exclusion is the process by which OIG prohibits individuals from participating in federal health care programs. When an individual is excluded, federal health care programs like Medicare and Medicaid will not pay for any item or service furnished, ordered, or prescribed by that individual. Moreover, entities that employ an excluded individual for the provision of items or services to federal program beneficiaries are subject to monetary penalties, making exclusion a *de facto* ban on working in the health care industry.

The (b)(15) exclusion authority authorizes permissive exclusion, at the discretion of OIG, of individuals who control a sanctioned entity. An entity is considered “sanctioned” for purposes of (b)(15) if it has been convicted of a criminal offense requiring mandatory exclusion or exclusion under one of three specified permissive authorities. Any individual with a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know of the action constituting the basis for the conviction or exclusion is subject to (b)(15) exclusion. Also, any officer or managing employee of a sanctioned entity may be excluded, regardless of their knowledge of the conduct giving rise to the sanction.

New Exclusion Guidance

As written, (b)(15) is potentially sweeping, and the OIG’s new guidance suggests that the agency is eager to interpret the statute broadly. The guidance sets forth OIG’s *presumption* that an owner, controller, officer or managing employee of a sanctioned entity who knows or should know of the conduct giving rise to the sanction will be excluded. This presumption “may” be overcome only if OIG finds that “significant factors” weigh against exclusion. These factors are left undefined.

For an officer or managing employee who neither knows nor should know about the conduct giving rise to the sanction, the agency outlines a separate set of factors that OIG may use to inform its exclusion decision. The guidance notes that the factors are informal and nonbinding, meaning that OIG may use them, or not, at its discretion. The four factors are:

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2. Conviction of any of the criminal offenses that form the respective predicates for all of the mandatory and three of the permissive exclusion authorities make an entity “sanctioned.” Generally, this means any entity is considered “sanctioned” once it is convicted of a crime relating to delivery of an item or service under federal or state health care programs, patient abuse or neglect, health care fraud, government program fraud, controlled substances, or obstruction of an investigation. 42 U.S.C. § 1320a-7(a)(1)-(b)(3).
the circumstances of the misconduct and seriousness of the offense, the individual’s role in the sanctioned entity, the individual’s action in response to the misconduct and information about the entity. All of these factors are briefly explained in the guidance document.

**The More Things Change . . .**

With this guidance, OIG has taken two extraordinary steps. First, it appears to have elevated (b)(15) from a permissive exclusion authority to a quasi-mandatory one by creating the presumption that owners, controllers, officers and managing employees of a sanctioned entity who know or should know of underlying conduct will be excluded. Generally, until this guidance, permissive exclusions have been made on a case-by-case basis. It is unclear how rigid the presumption will be, particularly since OIG does not define the “significant factors” that may overcome the presumption. It is particularly noteworthy that the first quasi-mandatory permissive exclusion authority is (b)(15), a seldom-used authority which has been the basis for no administrative appeals or court cases since it became effective in 1997.

Second, OIG has affirmed that it may, in some circumstances, exclude officers and managing employees on a strict liability basis for conduct that takes place at their company, even if the conduct is far removed from the individuals’ oversight and even if the individuals could not be expected to know about the conduct. This strict liability standard echoes the responsible corporate officer (RCO) doctrine used in misdemeanor prosecutions under the federal Food, Drug, and Cosmetic Act (FDCA) and other public welfare acts whereby the government may make a *prima facie* case by showing that an individual had, by reason of his or her position in the corporation, responsibility and authority to prevent in the first instance, or promptly to correct, the wrongdoing and that he or she failed to do so. Just as the RCO doctrine has shown signs of awakening after years of near-dormancy, OIG’s statement of these factors for strict liability exclusions suggests its newfound focus on a provision that has rarely, if ever, been used to exclude such individuals in the past.

OIG’s more aggressive posture vis-a-vis exclusion has been seen most recently in the Synthes/Norian case, where the agency required Synthes (a global medical device maker) to divest its U.S. subsidiary, Norian Corporation, as part of a criminal and civil settlement.

. . . *The More They Stay the Same*

Despite the unusual nature of this guidance, it is in step with the federal government’s recent focus on holding individuals accountable when wrongdoing takes place in the health care context. In March, Food and Drug Administration (FDA) Commissioner Margaret Hamburg revealed an FDA internal committee’s recommendation to increase RCO prosecutions and her agency’s intention to integrate newly developed criteria for such prosecutions into FDA’s revised policies and procedures. U.S. Attorney’s Offices have increased rates of individual prosecutions in pharmaceutical and device cases, with 25 individuals charged in conjunction with major pharmaceutical and device cases from 2006 to 2009, including seven employees of one device company — from sales representative to president — facing charges in relation to a single 2009 case. OIG has been no exception to this multi-agency trend, exercising its permissive exclusion authority with greater frequency in recent years.

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Implications for Health Care Companies and Executives

Working in the health care industry has become a riskier proposition over the last several years, and OIG’s new guidance has created yet another pitfall. Individuals who are particularly susceptible to (b)(15) exclusion are those covered by the new presumption, i.e., owners, controllers, officers and managing employees who know or should know of conduct that gives rise to a sanction. Managing employees are defined as general managers, business managers, administrators and directors who exercise operational or managerial control over the entity or who directly or indirectly conduct the day-to-day operations of the entity. 42 U.S.C. § 1320a-5(b).

Officers and managing employees of a sanctioned entity face risk even when they do not know and are not expected to know of conduct forming the basis for a sanction. Such individuals would be wise to position themselves as positively as possible within the four-factor analysis expressed in OIG’s guidance document. However, of the four factors, the only one that provides an individual with an opportunity to position himself or herself positively is the third factor, which accounts for the individual’s actions in response to the misconduct:

Did the individual take steps to stop the underlying misconduct or mitigate the ill effects of the misconduct (e.g., appropriate disciplinary action against the individuals responsible for the activity that constitutes cause for the sanction or other corrective action)? Did these actions take place before or after the individual had reason to know of an investigation? If the individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.

Guidance, at 4. However, efforts to curry positive favor through this factor may conflict with advice an officer may receive from counsel during the investigation (for a variety of reasons, including the uncertain atmosphere at present regarding the application of the RCO doctrine, counsel for the individual may advise him/her to assert his/her Fifth Amendment privilege against self-incrimination). An officer could succeed in fending off RCO charges, in part by refusing to cooperate and provide potentially incriminating evidence on the scope of his/her job responsibilities, only to have that “victory” prove Pyrrhic through an OIG imposed exclusion premised in part on the officer’s successful defense against criminal charges.

The other factors address the nature of the offense, the individual’s position in the company and the nature of the company. Other than generally promoting a company culture of compliance and taking whatever steps possible to minimize the risk of misconduct, there is little that an officer or managing employee can do to mitigate the prospect of exclusion for a strict liability offense.

More broadly, OIG’s exercise of (b)(15) authority may fundamentally alter a company’s defense strategy in cases involving criminal charges. The traditional approach of engaging OIG relatively late in the process – e.g., once the basic parameters with the Department of Justice (DOJ) have been negotiated – may not work for companies since almost any criminal resolution will subject officers and managing employees to strict-liability exclusion upon entry of a guilty plea. Early engagement with OIG may be the best approach; and in some cases, companies may seek to resolve potential (b)(15) issues prior to any corporate criminal plea agreement with DOJ. Of course, such early engagement with the OIG creates new risks, since legal and factual positions taken to resolve (b)(15) issues could disadvantage the company in resolving criminal charges with the DOJ. At a minimum, companies and their counsel need to be aware of OIG’s stepped-up use of exclusion against companies and individuals, and incorporate such risks in the early stages of an investigation.