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Targeting Health Care Execs And Managers

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Law360, New York (October 28, 2010) -- For the first time in over a decade, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued new guidance on the implementation of its permissive exclusion authority. See OIG, Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act (Oct. 20, 2010).

The new guidance sets forth nonbinding factors the OIG says it will consider in deciding whether to impose permissive exclusion on an officer or a managing employee of an excluded or convicted entity — regardless of whether they themselves have been convicted or even charged in the underlying case.

The breadth of the authority asserted in the guidance emphasizes the OIG's recent commitment to pursuing not just corporate entities, but also the health care industry executives and managers it deems responsible for the actions of those entities. See Hogan & Hartson LLP Health Update, "OIG Predicts Increased Scrutiny and Actions Against Individuals for Wrongdoing" (March 17, 2010).

Even absent passage of legislation pending in Congress to expand the OIG's exclusion authority, the OIG's new guidance effectively announces its intention to make greater use of its existing authority to exclude uncharged individuals based on their relationship to corporations convicted of health care offenses.

OIG's new declaration of its existing authority may contribute to a paradigm shift in how companies approach settlement negotiations with the U.S. Department of Justice and the OIG. At the same time, officials from the U.S. Food and Drug Administration are stressing that they intend to increase the number of cases in which they pursue misdemeanor

misbranding charges against individuals under the responsible corporate officer doctrine of United States v. Park, 421 U.S. 658 (1975).

Going forward, resolution of any investigation involving alleged health care fraud or regulatory offenses will necessarily include assessment of the impact on key officers and managing employees.

Permissive Exclusion Authority

Under Section 1128 of the Social Security Act, the OIG has authority to exclude individuals and entities from participation in federal health care programs. The act identifies certain types of criminal convictions and other derivative grounds upon which the OIG, in its discretion, may base an exclusion. Section 1128(b)(15) articulates one such ground for permissive exclusion by authorizing the OIG to exclude an individual based upon the individual's role or interest in an entity that has been convicted of certain offenses or excluded.

The new OIG guidance focuses on how it will use that authority to decide whether to exclude officers and managing employees. Both the statements of purpose and rationale, as well as the description of the factors themselves, demonstrate the OIG's determination to interpret and assert its exclusion authority broadly.

The Scope of the (b)(15) Exclusion Provision

The exclusion described in the OIG's guidance will likely reach a wide swath of the health care industry. Section 1128(b)(15) authorizes the OIG to exclude officers or managers of any entity that is excluded, convicted of or pleads to particular health care offenses.

Among the relevant health care offenses is the increasingly common plea to a misdemeanor misbranding violation of the Food, Drug and Cosmetic Act. Accordingly, the guidance will apply to officers and managing employees of many companies in criminal settlement negotiations with the DOJ irrespective of whether their company is facing OIG exclusion.

Within a company, the new guidance claims OIG has the authority to exclude all "officers" as well as any "managing employees" — defined as individuals with operational or managerial control over the entity or who directly or indirectly conduct day-to-day operations.

Under its newly articulated standard, the OIG will apply a presumption in favor of exclusion if the OIG determines there is evidence that the officer or managing employee knew "or should have known" of the conduct that formed the basis for the corporate sanction. The presumption may be overcome if the OIG determines that unidentified "significant factors weigh against exclusion."

The new guidance also describes a second basis for exclusion of officers and managers in the absence of evidence triggering the presumption of exclusion and identifies the set of factors the OIG will consider to determine whether to exclude such individuals.

Exclusion Criteria for Officers and Managing Employees

The OIG guidance explains that when assessing whether to impose a derivative permissive exclusion on an officer or managing employee where there is no evidence that the individual knew or should have known of the misconduct, the OIG will consider four categories of factors: 1) information about the entity; 2) individual's role in entity; 3) circumstances of the misconduct and seriousness of the offense; and 4) individual's actions in response to the misconduct.

While exclusion is intended to be a prophylactic remedy protecting federal health care programs and beneficiaries from harm the excluded person could cause, the OIG's categories focus primarily on the conduct and character of the convicted corporation and not the individual who may be excluded — the first two categories look at the company and the individual's position in the organization, and the third focuses on the company's misconduct and the resolution.

Notably, the OIG has interpreted misconduct to include not only the factual basis for the corporate sanction, but also "any other conduct OIG considers relevant." The OIG specifically identifies allegations in criminal, civil or administrative matters, as well as

conduct that formed the basis for any criminal, civil or administrative investigation, to be relevant in its consideration.

In the end, it is only the fourth category that looks at the individual's relationship to the company's misconduct.

Implications

The issuance of the new guidance is the latest step in the progression of the OIG's efforts to interpret expansively who and what is subject to its exclusion authority.

If enacted, pending federal legislation (H.R. 6130) would amend Section 1128(b)(15) to reach further to individuals that have no current relationship with the sanctioned entity, as well as individuals and entities in the same corporate structure as the sanctioned entity. The bill passed the U.S. House of Representatives by unanimous consent on Sept. 22, 2010.

Although the outlook for this legislation in the Senate remains unclear, this and other congressional activity suggests growing support for broad OIG exclusion authority.

The OIG's guidance is also part of a broader and increasing focus on seeking sanctions against health care industry executives by other divisions within the HHS.

In a March 4, 2010 letter, FDA Commissioner Margaret Hamburg told Senator Chuck Grassley, R-Iowa, that the agency has developed criteria for use in selecting appropriate cases for the misdemeanor misbranding prosecution of executives. In recent weeks, Eric Blumberg, deputy chief for litigation, office of the chief counsel FDA, reiterated the agency's intention to pursue Park doctrine misdemeanor prosecutions against industry executives.

In one notable recent case in which Hogan Lovells represents the individuals involved, the OIG extended its exclusion authority to executives convicted of strict liability misdemeanors under that doctrine.

The new OIG guidance on permissive exclusions of individuals pursuant to Section 1128(b)(15) strongly suggests the OIG is no longer content to wait for the FDA and DOJ to

obtain such convictions — laying out instead factors the OIG will consider in determining whether to pursue exclusion of officers and other executives working for companies that have been convicted of such offenses, regardless of whether the executives have been charged with crimes themselves.

In sum, it appears that the OIG and FDA are committed to increased enforcement and sanctions against individuals and that the OIG will continue to expand its authority to reach executives and managers whether or not those individuals are charged in criminal investigations. Health care entities and their leadership need to carefully consider the potential exposure arising from these efforts in any ongoing and future corporate plea agreement or settlement negotiation.

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