Congressional Hearings Offer Insight Into Government's Intention to Target Corporate Healthcare Executives

During the first week of March 2011, Congress held three hearings to address healthcare fraud and abuse enforcement. The hearings occurred before the Senate Finance Committee, the House Ways and Means Committee, Subcommittee on Oversight, and the House Energy & Commerce Committee, Subcommittee on Oversight and Investigations. Each offered insight into the intentions of the Obama administration in healthcare fraud enforcement, as well as legislative priorities in the area.

A continued refrain within the hearings was that, while billions of dollars continue to be collected in civil and criminal penalties, there is a congressional perception that corporate noncompliance is slow to change absent individual executives being held personally accountable. This advisory addresses what the US Department of Health and Human Services (HHS), Office of Inspector General (OIG), and Centers for Medicare and Medicaid Services (CMS) say they intend to do to address congressional concerns.

Message from Administration

On March 2, 2011, OIG and CMS leaders testified that the Patient Protection and Affordable Care Act (the Affordable Care Act or ACA), as signed into law on March 23, 2010, provided "unprecedented new tools" for waging the fight against fraud and abuse. OIG, however, asked Congress to go further by enacting the Strengthening Medicare Anti-Fraud Measures Act of 2011,[1] which would expand the reach of OIG exclusion authority.

In testifying before the House Ways and Means Committee, OIG's Chief Counsel Lewis Morris called exclusion from participation in federal health care programs "one of the most powerful tools in our arsenal," noting that exclusions "bolster our fraud fighting efforts by removing from the federal health care programs those who pose the greatest risk to programs and beneficiaries."[2] Morris stated that his office intends to exercise its exclusion authority "in a broader range of circumstances."[3] He added that his office will use exclusion "once we determine that an individual

1 H.R. 675, 112th Cong. (2011).

2 *See* Testimony of Lewis Morris, Chief Counsel, Office of Inspector General, before the House Ways and Means Committee, Oversight Subcommittee, *Hearing on Improving Efforts to Combat Health Care Fraud* (March 2, 2011).

3 *Id.*

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Healthcare Reform Chart

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or entity is engaged in fraud, waste, abuse, or the provision of substandard care."[4]

HHS Inspector General Daniel Levinson testified before the Senate Finance Committee that congressional action was required to eliminate exclusion loopholes.[5] Levinson asked that OIG be given authority to exclude corporate executives who are no longer working for sanctioned companies, including corporate heads of excluded subsidiaries.[6]

Legislative Movement

Levinson requested that Congress strengthen OIG's exclusion authority by passing the provisions originally proposed in the Strengthening Medicare Anti-Fraud Measures Act of 2010.[7] The House passed the bill on September 22, 2010, but the legislation died after the Senate failed to act before the expiration of the 111th Congress. The bipartisan legislation, however, was reintroduced on February 11, 2011, co-sponsored by Rep. Pete Stark (D-CA) and Rep. Wally Herger (R-CA).[8]

The proposed legislation would permit the exclusion of individuals or entities who were affiliated with a sanctioned entity at the time the conduct underlying the sanction occurred, regardless of whether the individual or entity is affiliated with the sanctioned entity. The term "affiliated entity" is defined as "(I) an entity affiliated with such sanctioned entity; and (II) an entity that was so affiliated at the time of any of the conduct that formed the basis for the conviction or exclusion."[9] An entity could be "affiliated with" another entity if one entity owns or controls the other entity, through a person with an ownership or control interest in both entities, or through a person who is an officer or managing employee of both entities. If the bill becomes law, OIG's exclusion authority will extend to executives who have long since parted ways with the subsequently sanctioned company.

According to Rep. Herger, the bill is designed to close two loopholes in the existing provision that have permitted individuals and entities responsible for program violations to continue to receive federal funding. As the law now stands, the Secretary may not exclude an individual or entity who is not affiliated with a sanctioned entity when the penalty is imposed. Second, companies operating convicted or excluded subsidiaries may effectively insulate themselves from the exclusion penalty by divesting or dissolving the offending company prior to notice of exclusion.[10]

One enforcement directive of the Affordable Care Act was already repealed after the US Department of Justice (DOJ) alerted Congress that implementation would harm resolution of existing matters.[11] That repealed provision had directed Medicaid agencies to exclude entities from Medicaid participation if any affiliated entity had been excluded from participation in a federal health care program.[12] While ACA did not define the term "affiliated," even a narrow construction would have significantly hindered the resolution of pending cases.

Historical Exclusion Enforcement

Notwithstanding its tough talk, OIG has rarely exercised its current permissive exclusion authority. Two recent exclusion cases, however, demonstrate that the OIG may be changing course.[13] At the March 2, 2011 hearings, Morris cited the OIG's 20-year exclusion of the former CEO of KV Pharmaceutical Company as an example of his agency's stepped-up program to utilize exclusion.

On November 18, 2010, OIG issued its notice to exclude the former KV CEO for allegedly failing to take action to correct manufacturing violations that resulted in distribution of irregular drug tablets. OIG's decision to exclude the KV CEO is notable because it appears to be the first action under the agency's published statement of its intent to more aggresively use its permissive exclusion authority to target responsible corporate executives that "knew or should have known" of the offending conduct.[14]

4 *Id.*

5 *See* Testimony of Daniel Levinson, Inspector General, Office of Inspector General (OIG), US Department of Health and Human Services, before the Senate Finance Committee, *Hearing on Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges* (March 2, 2011).

6 *Id.*

7 H.R. 6130, 111th Cong. (2010).

8 *See* Strengthening Medicare Anti-Fraud Measures Act of 2011, H.R. 675, 112th Cong. (2011).

9 *Id.*

10 *See* Press Release, *Stark, Herger Reintroduce Bipartisan Bill to Fight Medicare Fraud* (Feb. 11, 2011).

11 *See* Medicare and Medicaid Extenders Act of 2010 (December 15, 2010).

12 *See* PPACA, Pub. L. 111-148, 125 Stat. 119, 776. 6502 (amending section1902(a) of the Social Security Act (42 U.S.C. 1396a(a)).

13 *See* Ogrosky, *Law Enforcement Targets Pharmaceutical and Medical Device Executives,* Bloomberg's Health Law Reporter (February 7, 2011).

14 See HHS Office of Inspector General, Guidance for Implementing Permissive Exclusion Authority (October 20, 2010).

In December of 2010, the US District Court for the District of Columbia affirmed the OIG's decision to exclude three executives from Purdue Pharma for a period of twelve years.[15] The executives were excluded under 42 U.S.C. 1128(b)(1), which authorizes the OIG to exclude individuals convicted of a misdemeanor related to health care fraud, and 42 U.S.C. 1128(b)(3), which permits the OIG to exclude individuals convicted of a misdemeanor related to the manufacture, distribution, prescription, or dispensing of a controlled substance. In reaching its decision, the court noted that one purpose of the permissive exclusion statute is "to provide a clear and strong deterrent against the commission of criminal acts," a declaration that appears inconsistent with the government's historical use of its authority in this area.

Additional Activity

In recent years, the government has stepped up its program integrity activities in response to mounting fraud and abuse concerns. The ACA included a number of provisions aimed at strengthening the integrity of Medicare, Medicaid, and other federal health programs. A final regulation coauthored by CMS and OIG was issued earlier this year and will become effective on March 25, 2011.[16] The regulation gives the government greater authority to screen providers before allowing them to enroll, as well as the ability to suspend payments and investigate claims before paying them in the event of a credible allegation of fraud, to impose temporary moratoria on new providers or specific provider types if necessary, and to pursue other activities to combat fraud, waste, and abuse. The regulation also provides guidance for states regarding the termination or exclusion of providers from Medicaid if they are terminated by Medicare or by another Medicaid state agency.[17]

Conclusion

Exclusion from participation in federally funded health care programs can be the death knell for corporations and individual careers. The Stark-Herger bill is yet another attempt to expand the extraordinary tools available to federal enforcement agencies. While inactive in the past, OIG has made clear its intention to use its existing permissive exclusion authority to aggressively deter and prevent program fraud and abuse. In such a heated regulatory climate, senior executives at healthcare companies, including in-house counsel, will want to make sure that their compliance programs and internal reporting policies are updated and that meaningful resources are dedicated to implementing and enforcing these programs. Exclusion screening procedures should also be revisited to ensure that they capture the broader universe of relationships anticipated by the legislation noted above.

We hope that you have found this advisory useful. If you have questions about the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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15 *See* Friedman, *et al.,* v. *Sebelius*, Civil Action No. 09-2028 (ESH) (D.C. Dec. 13, 2010).

16 *See* Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5862 (February 2, 2011).

17 *Id.*