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Violations of Corporate Integrity Agreement Trigger Divestiture Action by HHS OIG

In a little-noticed decision, the Office of the Inspector General of the Department of Health and Human Services (OIG) has forced a company that violated its corporate integrity agreement (CIA) to divest a subsidiary as a condition for the parent to avoid exclusion from federal health care programs. Not only is forced divestiture a relatively new enforcement approach for the OIG, this appears to be the first time the OIG has used forced divestiture as a sanction for violations of a CIA. The move signals OIG's continuing willingness to achieve program compliance through novel uses of its enforcement authority.

Top-Line Summary

- The HHS OIG recently required a company to divest a business unit in response to the parent's violation of its corporate integrity agreement — the first time the agency has taken such action.
- The divestiture action reflects two trends in OIG enforcement policy: (1) use of divestiture as a sanction for noncompliance and (2) the growing scrutiny of company compliance with CIAs.
- Companies operating under CIAs should be aware of the use of divestiture as a sanction for serious CIA violations and enhance their CIA compliance efforts accordingly.

Background: Settlement and CIA

Church Street Health Management (CSHM) (formerly FORBA Holdings, Inc.) entered into a civil settlement agreement with the U.S. Department of Justice (DOJ) on January 20, 2010. The DOJ alleged that the company engaged in a pattern of wrongdoing relating to dental services provided to low-income children, including allegations of providing services that were medically unnecessary or failed to meet professionally recognized standards of care.[1] As part of the resolution, CSHM paid more than $24 million in penalties and fines and entered into a five-year CIA with the OIG. The CIA contained standard penalty provisions for breaches of the agreement.[2]

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1 DOJ Press Release, *National Dental Management Company Pays $24 Million to Resolve Fraud Allegations*, http://www.justice.gov/opa/pr/2010/January/10-civ-052.html (Jan. 20, 2010).

2 CSHM's failure to comply with certain obligations contained within the CIA could result in the imposition of stipulated monetary penalties including, for example, a stipulated penalty of $50,000 for each false certification submitted by or on behalf of CSHM. *See* FORBA Holdings, LLC Corporate Integrity Agreement, pg. 46 (Jan. 15, 2010), *available at* http://oig.hhs.gov/fraud/cia/agreements/forba_holdings_llc_01152010.pdf.

OIG Action for Breaches of the CIA

In March 2012, OIG issued a Notice of Material Breach and Intent to Exclude (Notice) to CSHM. The Notice cited seven CIA provisions — ranging from the requirement to ensure proper and accurate documentation of dental records to management's certification of compliance — of which CSHM was in material breach. In response, CSHM informed OIG that while the company had taken measures to cure a number of identified breaches, CSHM was unable to resolve certain other breaches within the provided 30-day cure period.

Following a March 13, 2012, meeting, and in apparent recognition of CSHM's pending bankruptcy proceedings[3], OIG agreed to not commence an exclusion action in exchange for, among other things, (i) CSHM's agreement to divest, transfer or sell one of its clinics to an unrelated third party within 90 days, and (ii) a waiver of its right to appeal the exclusion.[4] On May 30, 2012, with less than two weeks remaining of OIG's mandated 90-day divesting period, the bankruptcy court overseeing CSHM's Chapter 11 petition cleared the way for the sale of the clinic.[5]

OIG's Program Exclusion Authority

Considered the death knell for careers and companies alike, the ability to exclude individuals and entities from participating in federal health care programs is perhaps OIG's most powerful enforcement tool. Excluded providers may not participate either directly or indirectly in Medicare, Medicaid or other federal health programs. Private insurers sometimes prohibit payment to excluded providers. For FY 2011 alone, OIG reported exclusions of 2,662 providers from future participation in federal programs.[6]

By statute, OIG is authorized to pursue mandatory exclusion (*i.e.*, exclusion by operation of law) (42 U.S.C. § 1320a-7(a)) or permissive exclusion (42 U.S.C. § 1320a-7(b)). For a company operating under a CIA (as in CSHM's case), exclusion may result from breach of the agreement. Specifically, CSHM's CIA provides that "[t]he parties agree that a material breach of this CIA by [CSHM] constitutes an independent basis for [CSHM's] exclusion from participation in the Federal health care programs."

Forced Divestiture as Alternative to Exclusion

While exclusion provides OIG with a powerful tool to sanction misconduct, the all-or-nothing nature of exclusion limits its use. The OIG has, understandably, been reluctant to pursue exclusion against organizations due to the potential for collateral consequences against innocent parties, including patients, employees not involved in the misconduct and others. Greg Demske, OIG's assistant inspector general for legal affairs, has stated that "we can exclude the entity that has been convicted[, but] it's not as easy to exclude a corporate affiliate." Not surprisingly, the agency has long sought alternative sanctions that reflect the seriousness of certain types of corporate misconduct but stop short of exclusion. One relatively new approach involves forced divestiture of a business unit.

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3 "We understand that CSHM is in the process of closing or transferring the Manassas Center to an unrelated third party." Amendment to CSHM CIA, pg. 3 (Mar. 14, 2012), *available at* http://oig.hhs.gov/fraud/cia/agreements/CSHM_Response_to_Material_Breach_Notice_and_CIA_Amendment_031312.pdf. On February 20, 2012, CSHM filed in United States Bankruptcy Court for the Middle District of Tennessee a petition for Chapter 11 bankruptcy. CSHM cited the combined cost of its settlement with the government, ongoing CIA compliance and follow-on litigation as the primary causes of its insolvency. *In Re: Church Street Health Management, LLC, et al.*, No. 3:12-01573, (Bankr. M.D. Tenn. Feb. 20, 2012).

4 Amendment to CSHM CIA, pg. 3 ("In the event CSHM does not close or transfer The Manassas Center as described above, CSHM agrees that the Manassas Center shall be excluded from participation in the Federal health care programs.").

5 *In Re: Church Street Health Management, LLC*, Dkt. 418 (May 30, 2012) (granting CSHM permission to sell assets free and clear of any encumbrances).

6 OIG Semiannual Report to Congress, http://oig.hhs.gov/reports-and-publications/archives/semiannual/2011/fall/HHS-OIG-SAR-Fall2011.pdf (Fall 2011).

The first case in which the OIG pursued a forced divestiture occurred in the context of the global resolution of a United States Department of Justice investigation of Synthes and its U.S. subsidiary, Norian Corporation. According to the government, Synthes and Norian conducted unauthorized clinical trials that ultimately led to several patient deaths. In addition to paying $24 million in criminal and civil penalties, Synthes entered a guilty plea to a single misdemeanor violation of the Food, Drug and Cosmetics Act (FDCA) and entered into a CIA with OIG. Norian pled guilty to various felony violations, and became subject to mandatory exclusion. In an unprecedented move for health care fraud cases, OIG, Synthes and Norian executed a divestiture agreement.[7] Under this agreement, Synthes was required to sell or dissolve Norian within seven months, or face program exclusion.[8]

Forced Divestiture in the CSHM Settlement

Much like Synthes' divestiture of Norian, OIG has called for CSHM to sell Small Smiles Dental Center of Manassas or risk federal health program exclusion.[9] The CSHM matter, however, is distinct from Synthes in three main respects. First, CSHM's forced divestiture arises from noncompliance with the terms of an existing CIA.[10] This is the first time in a health care fraud case OIG has used forced divestiture of a company subsidiary to cure deviations from CIA-imposed compliance obligations. Second, the truncated time frame required for the divestiture to occur — a mere 90 days — stands in stark contrast to the seven-month period for Norian's sale As demonstrated by the bankruptcy court's recent approval of CSHM's asset sale, operational and practical considerations make completing such a complicated transaction in a condensed time frame challenging. Third, unlike the statutorily based mandatory exclusion used in Norian, the authority for excluding Manassas Center is contractual (*i.e.* the CIA). As a basis for program exclusion, this authority is weaker and more subject to legal challenge. As a result, OIG required CSHM to waive its appeal rights by agreeing that the Manassas Center "shall be excluded" in the event CSHM does not close or transfer the center within the required period.

Future Implications for Health Care Organizations

The forced divestiture of a business unit in the context of a company's alleged breach of its CIA is yet another example of the OIG's novel use of its enforcement authorities to address perceived misconduct by a health care organization. It is not likely to be the last. Agency officials, for example, have floated the notion of forcing a company to divest a product or product line in order to avoid an exclusion action.[11] Using the threat of exclusion to force the divestiture of a business unit or product raises troubling legal and policy issues. Congress has provided the OIG with specific enforcement tools, including civil money penalties and exclusion. Forced divestiture is not among these enumerated sanctions. Perhaps more troubling, the process lacks transparency as the OIG has not issued guidance (much less regulations) as to when it might pursue divestiture. For example, it is not clear why divestiture of a specific clinic was appropriate in the CSHM case given the company's bankruptcy status and likely changes to its ownership structure. Companies involved in federal health care investigations should be aware of the OIG's evolving enforcement practices and incorporate such knowledge in developing effective defense strategies.

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7 http://www.justice.gov/usao/pae/Pharma-Device/synthes_divestagrmt.pdf.

8 For more on the Norian divestiture, see *In Forcing Subsidiary Divestiture, OIG Shakes Up Health Care Enforcement*, *available at* http://www.skadden.com/content/Publications/Publications2245_0.pdf (Oct. 6, 2010).

9 Amendment to Church Street Health Management (fka FORBA Holdings) CIA http://oig.hhs.gov/fraud/cia/agreements/CSHM_Response_to_Material_Breach_Notice_and_CIA_Amendment_031312.pdf (March 14, 2012).

10 FORBA Holdings (d/b/a Church Street Health Management) CIA http://oig.hhs.gov/fraud/cia/agreements/forba_holdings_llc_01152010.pdf (effective Jan. 15, 2010).

11 Lew Morris, OIG Chief Counsel, Interview on PBS Nightly Business Report (Mar. 18, 2010).