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Updated OIG Guidance on Health Care Program Exclusions – More Trouble for Health Care Entities Owned or Controlled by Excluded Persons?

On May 8, 2013, the United States Department of Health & Human Services (HHS) Office of Inspector General (OIG) issued an updated advisory bulletin on the impacts of exclusion from federal health care programs.[1] This guidance updated the previous 1999 OIG advisory on exclusions. The new guidance provides significantly more detail on conduct that might trigger exclusion or sanction, as well as the affirmative duties imposed on entities to ensure they are not impermissibly interacting with an excluded person. What is of particular interest, however, is the OIG guidance's discussion on permissive exclusion of a health care provider[2] because it is controlled or owned in part by an excluded individual. The previous guidance contained no similar discussion, and it is of note that OIG chose to present guidance on the issue considering this type of exclusion is infrequent—it represents less than three percent of current exclusions.[3] Does this possibly suggest a new level of scrutiny for entities that are controlled or owned in part by an excluded individual? The "owned in part" provision is especially concerning because, as discussed below, a relatively modest nexus can trigger review by OIG for potential exclusion. In this advisory, we provide a summary of the legal framework and new OIG guidance on this discretionary exclusion.

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1 U.S. Dep't Health & Human Servs., Office of Inspector Gen., Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013), *available at* http://oig.hhs.gov/exclusions/files/sab-05092013.pdf [hereinafter "OIG Guidance"].

2 Throughout this advisory, the terms "health care provider," "provider" and "entity" are synonymous with each other and are used broadly to encompass manufacturers, suppliers, health care entities and other individuals involved with providing health care in connection with a federal health care program.

3 Based on OIG posted data, there are 54,553 current exclusions, of which 1,471 are related to exclusion of an entity due to ownership or control by an excluded individual. *List by Exclusion Type*, Office of Inspector General, http://exclusions.oig.hhs.gov/ExclusionTypeCounts.aspx (last visited on May 16, 2013).

Background and Scope of Entity Exclusion Based on Ownership or Control Interest

The Medicare and Medicaid Patient and Program Protection Act of 1987 provided OIG with authority to impose a variety of sanctions, including the authority to exclude individuals from participation from federal health care programs.[4] Proscribed conduct can trigger either mandatory or permissive exclusion.[5] The permissive exclusion of an entity controlled or owned in part by an excluded individual[6] applies, with respect to an entity, if the individual is an "officer, director, agent, or managing employee" or if he has "a direct or indirect ownership or control interest of 5 percent or more" in the entity.[7] Regulations have been issued under this provision, which provide clarifying definitions.[8] For example, indirect ownership includes an "interest through any other entities that ultimately have an ownership interest."[9] This definition provides an example of how a person may have a 10-percent indirect ownership interest in an entity. Essentially, the regulation states that if a person owned 20 percent of "Corporation X" and that corporation had 100-percent ownership of "Subsidiary Y," which was a 50-percent owner of "Entity Z," then that person would have a 10-percent indirect ownership in Entity Z.[10] Needless to say, under this exclusion regulation, a covered ownership interest can be rather attenuated.

HHS stated that the broad purpose of this exclusion is to "ensure that the [federal health care] programs do not indirectly reimburse excluded individuals through payments to entities they control or own or...have a significant relationship."[11] Based on the text of the regulation and OIG's interpretation, such ownership or control includes a five-percent or greater interest even if such an interest is attenuated or otherwise passive. Indeed, this interpretation is supported in ***Florida Medical Center of Clearwater, Inc. v. Sebelius***.[12] In that case, the Eleventh Circuit suggested that permissive exclusion is appropriate with respect to an entity in which an excluded individual had a 51-percent ownership, even though the individual "was never involved in its daily operations, was not an employee, and did not provide any services to [the entity] or any of its patients."[13]

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4 The Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. Law 100-93 (1987).

5 *Id*. § 2 (codified at 42 U.S.C. § 1320a-7).

6 The actual provision covers both "excluded" and "sanctioned" individuals; however, the discussion here is limited to exclusions.

7 42 U.S.C. § 1320a-7(b)(8). This provision further defines "ownership or control interest" by reference to Section 1124(a)(3) of the Social Security Act, which states that ownership includes interest in a mortgage, deed or other obligation. 42 U.S.C. § 1320a-3(a)(3).

8 *See* 42 C.F.R. § 1001.1001.

9 *Id*. § 1001.1001(a)(2).

10 *See id*.

11 Health Care Programs: Fraud and Abuse; Amendments to OIG Exclusion and CMP Authorities Resulting From Public Law 100-93, 57 Fed. Reg. 3296, 3309 (Jan. 29, 1992) (codified at 42 C.F.R. pts. 1001, 1002, 1003, 1004, 1005, 1006,and 1007).

12 *Florida Medical Center of Clearwater, Inc. v. Sebelius*, 614 F.3d 1276 (11th Cir. 2010).

13 *Id*. at 1279-80.

OIG enforcement under this provision has been relatively sparse. A review of HHS Departmental Appeals Board (DAB) decisions does, however, provide some insights. In cases where the excluded individual was an owner, he often also exercised significant managerial control.[14] It would appear that OIG typically has not sought exclusion for providers that are only passively owned by excluded individuals, even though the applicable regulation is broad and covers attenuated ownership. In one DAB case, the administrative law judge stated that an entity's exclusion was based on the showing that an excluded individual "bears a relationship of responsibility" to that entity.[15] Thus, it would appear that OIG has not regularly excluded entities as a result of the exclusion of an individual within the entity absent other factors, such as having active control over the entity's operations.

New OIG Guidance and What May Be on the Horizon

The updated guidance states that while an individual's exclusion does not directly prohibit ownership—by that individual—in a provider that participates in federal health care programs, such ownership may be subject to OIG enforcement.[16] The guidance does not limit the five-percent ownership trigger in any way, suggesting that OIG is leaving open possible enforcement actions against health care providers that have excluded individuals with arguably passive (i.e., non-managerial) or minor ownership interest. In addition, the guidance discusses at length the liability risks that arise if an excluded owner provides services, including certain administrative services, for the entity that are in anyway payable under a federal health care program.[17] This suggests that there will be additional scrutiny of these types of relationships. It would seem, therefore, that a provider should be cautious regarding the status of its owners.

Indeed, even the possibility of an entity's exclusion has been enough to unnerve some companies. For example, OIG announced in 2010 that it was excluding the chief executive officer (CEO) of KV Pharmaceuticals due to drug manufacturing sanctions against the corporation.[18] For KV Pharmaceuticals, significant action was needed to remove both *ownership* and *control* of the excluded CEO in order to effectively eliminate the possibility that KV Pharmaceuticals could be subject to permissive entity exclusion.

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14 *See*, e.g., *Buena Vista Pharmacy, Inc. v. Inspector Gen*., Decision No. CR838 (Nov. 13, 2001), http://www.hhs.gov/dab/decisions/cr838.html (sanctioned individual was vice president and held a 33-percent ownership interest in entity at issue); *Donald R. Hamlin and Burnside Pharmacy v. Inspector Gen.*, Decision No. CR870 (Feb. 8, 2002), http://www.hhs.gov/dab/decisions/cr870.html (sanctioned individual was the principal stockholder and sole officer of entity at issue); *Paul W. Williams, Jr. and Grand Coteau Prescription v. Inspector Gen.*, Decision No. CR787 (June 27, 2001), http://www.hhs.gov/dab/decisions/cr787.html (sanctioned individual was owner and the registered pharmacist of the entity at issue).

15 *Bethany Anne Winther-Gailmore and the Winther Family Chiropractic Center, LLC v. Inspector Gen*., Decision No. CR2501 (Feb. 13, 2012), http://www.hhs.gov/dab/decisions/civildecisions/cr2501.pdf.

16 OIG Guidance, *supra note* 1 at 9-10.

17 *Id*. at 10.

18 Press Release, U.S. Dep't of Justice, "Marc S. Hermelin, Former CEO of KV Pharmaceutical, Pleads Guilty to Misbranding Drugs and Agrees to Pay United states $1.9 Million as Fines and Forfeiture" (Mar. 10, 2011), *available at* http://www.fda.gov/ICECI/CriminalInvestigations/ucm246881.htm. The exclusion was based on Section 1128(b)(15) of the SSA, which permits permissive exclusion against individuals controlling a sanctioned entity. 42 U.S.C. § 1320a-7(b)(15) . This exclusion is essentially the converse of the permissive entity exclusion discussed in this advisory.

According to KV Pharmaceuticals, the CEO agreed to divest himself not only of all ownership interest in the company, but also to divest himself of control of the family trusts (which also owned voting shares in the company), and thus of voting interest in the corporation, in order to eliminate the potential of exclusion of the corporation because of his potential control of the company through these mechanisms.[19] Therefore, this exclusion has the potential to require significant divestments or other changes in corporate ownership and structure due to the exclusion of an individual within an entity.

Ultimately, the updated guidance may not represent any dramatic change in OIG enforcement policy. However, assuming the new guidance commentary signals increased interest in this permissive exclusion, applicable health care providers may find themselves at increased risk. OIG has interpreted its exclusion authority broadly. As such, the agency maintains considerable enforcement discretion. It may be that the OIG had historically not used this exclusion due to other enforcement priorities (e.g., exclusion for a health care program related conviction). However, OIG may now be looking to broaden its enforcement focus and help generate deterrence and compliance.

For an applicable health care provider, the highest risk scenario is likely where the excluded individual has some direct control or active involvement with the entity or provides services on behalf of the entity. Nevertheless, given recent enforcement actions and the updated OIG guidance, it may be advisable for providers to review their organizational structures and whether there is a risk that an excluded individual, regardless of his degree of ownership or control, may have or take an applicable ownership or control interest in the entity. Furthermore, a provider should take appropriate action to preclude the possibility of an OIG enforcement action if the provider becomes aware of an excluded individual's ownership or control of the entity. Such actions would include monthly screenings, as recommended by the OIG guidance, to see whether individuals associated with a provider have been excluded.[20]

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[19] Press Release, "K-V Pharmaceutical, K-V Pharmaceutical Secures Financing Commitments Establishing Path Forward For Specialty Pharmaceutical Business" (Nov. 17, 2010), *available at* http://www.kvpharmaceutical.com/news_center_article.aspx?articleid=329.

[20] OIG Guidance, *supra* note 1, at 15.

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