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Unintended Consequences: Ex-U.S. Activities Impacting U.S. Federal Health Care Business

Given the uptick in global awareness and enforcement of anti-bribery and corruption laws, most health care companies are attuned to the risks associated with legal infractions caused by ex-U.S. activities. However, ex-U.S. activities may also impact health care companies' ability to conduct business within the U.S. For example, overseas conduct could trigger exclusion, debarment or suspension from federal procurement or health care programs, such as Medicare and Medicaid, even if the alleged wrongdoing (*e.g.*, conduct relating to bribery or corruption) occurs entirely outside of the U.S. and has no tie to any federal program. Further, quasi-government entities, such as the World Bank, also have debarment policies which can impact U.S. health care companies. This alert first explores the interaction between the OIG exclusion statute and the Foreign Corrupt Practices Act ("FCPA"). Second, it discusses how debarment of federal contractors participating in development programs run by quasi-governmental organizations (such as the World Bank) could lead to unexpected scrutiny by U.S. federal agencies.

I. The FCPA and Mandatory Exclusion

A felony FCPA plea or conviction triggers fines and penalties under U.S. securities laws, and could also impact a company's ability to participate in U.S. federal health care programs. The Office of Inspector General of the Department of Health and Human Services ("OIG") has the authority to exclude individuals and entities from all federally funded health care programs as required by statute ("Mandatory Exclusion")[1], or based on OIG's discretion ("Permissive Exclusion").[2] A company charged with a violation of the FCPA books and records and internal controls provisions,[3] a felony under federal law[4] could be excluded based on: (i) a guilty plea or conviction in a court with competent jurisdiction; and (ii) OIG's determination that the underlying conduct meets the language of the Mandatory Exclusion statute. Mandatory Exclusion compels OIG to exclude individuals and entities convicted of certain offenses, including felony convictions relating to health care fraud, from participation in all federal health care programs for a minimum of five years.[5] The consequences of exclusion, either mandatory or permissive, are severe: exclusion prevents items or equipment sold by an excluded manufacturer that are used in the care or treatment of federal health care program beneficiaries from being reimbursed, directly or indirectly, by any federal health care program. Although OIG has not yet excluded a company for an FCPA violation, the self-executing nature of the statute and OIG's lack of discretion leave open the real possibility that such an exclusion could happen in the future,[6] a fact which the Department of Justice has acknowledged.[7] This threat of exclusion has doubtless impacted

[1] 42 U.S.C. § 1320a-7(a).
[2] 42 U.S.C. § 1320a-7(b).
[3] *See* 15 U.S.C. § 78m(b)(2)(A)–(B).
[4] *See* 15 U.S.C. § 78m(b)(5); 15 U.S.C. § 78ff(a).
[5] 42 U.S.C. § 1320a-7(c)(3)(B).
[6] *See* Travers v. Sullivan, 791 F. Supp. 1471, 1480–81 (E.D. Wash. 1992), *aff'd sub nom.Travers v. Shalala*, 20 F.3d 993 (9th Cir. 1994); Diane Amicucci, DAB No. CR540, 1998 WL 479299 (H.H.S. June 29, 1998); *see also Harkonen v. Sebelius*, No. C 13-0071 PJH, 2013 WL 5734918, at *2 (N.D. Cal. Oct. 22, 2013).
[7] *See, e.g.*, Deferred Prosecution Agreement with Johnson & Johnson, *United States v. DePuy, Inc.*, ¶ 4.j (D.D.C. filed Apr. 8, 2011); *see also* U.S. Dep't of Justice & U.S. Sec. Exch. Comm'n, A Resource Guide to the U.S. Foreign Corrupt Practices Act 69-70 (2012); Lanny A. Breuer, Assistant Attorney Gen., Criminal Div., U.S. Dep't of Justice, Keynote Address to the

numerous companies facing prosecution in their decisions to cooperate and enter into Deferred Prosecution Agreement, despite the high associated costs of compliance.

To determine whether a violation triggers Mandatory Exclusion, OIG evaluates the *conduct* underlying the guilty plea or conviction. For an FCPA books and records and internal controls violation, OIG would consider whether the misconduct was undertaken: (1) "in connection with the delivery of a health care item or service"; and (2) "relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct."[8] Unlike other parts of the statute governing Mandatory Exclusion, a violation under § 1320a-7(a)(3) does not require any nexus to a government health care item or service, but broadly covers "any felony conviction under Federal, State, or local law related to health care fraud, even if governmental programs are not involved."[9]

OIG has wide latitude in determining whether an offense was carried out "in connection with . . . a health care item or service" and "relat[ed] to fraud . . . or other financial misconduct"—which could be interpreted to incorporate a broad range of conduct.[10] For the first prong, OIG need only determine that the conduct underlying the FCPA violation was carried out "in connection with . . . a health care item or service," which just requires a "common sense connection" or "nexus" between the "underlying facts and circumstances of the offense and the delivery of health care items or services to individuals for their health care needs."[11] As to the second prong, OIG may look to the conduct as plead and courts have consistently held—both in the context of exclusion jurisprudence and more broadly—that the terms "in connection with" and "relates to" are "generally interpreted expansively."[12] In this case, whether a failure to satisfy the accounting provisions would be "relat[ed] to fraud . . . or other financial misconduct" likely would turn on the facts underlying the company's conduct. Courts have noted, however, that the statute does not require a felony *for* health care fraud, but only a felony *relating to* health care fraud—a distinction that is bound to encompass more conduct rather than narrow the potential applicability of 42 U.S.C. § 1320a-7(a)(3).[13]

Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009) (warning that FCPA conviction could lead to "possible exclusion from Medicare and Medicaid").

[8] 42 U.S.C. § 1320a-7(a)(3).

[9] *See* Health Care Programs: Fraud and Abuse, 63 Fed. Reg. 46,676, 46,676 (to be codified at 42 C.F.R. pt. 1001); *Harkonen*, 2013 WL 5734918, at *2, 8-9; *see also* Medicare and State Health Care Programs: Fraud and Abuse, 79 Fed. Reg. 26,810, 26,810.

[10] *See Friedman v. Sebelius*, 686 F.3d 813, 821 (D.C. Cir. 2012). Under *Friedman*, even if the text of the FCPA accounting provisions itself does not require proof of fraud, misrepresentation, or other direct showing of financial misconduct as an element of the criminal offense, OIG can look beyond the "technical components" of the law to determine whether the statutory criteria for Mandatory Exclusion are met.

[11] *Harkonen*, 2013 WL 5734918, at *4.

[12] *Id.* at 7 (citing *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 739 (1985) ("relate to" has a "broad common-sense meaning" and a statutory provision containing the phrase therefore has "broad scope"); *see also* Ellen L. Morand, DAB No. 2436, 2012 WL 369634, at *8-9 (H.H.S. Jan. 17, 2012); Charice D. Curtis, DAB No. 2430, 2011 WL 7444589, at *2-5 (H.H.S. Dec. 21, 2011); Kenneth M. Behr, DAB No. 1997, 2005 WL 2835001, at *4 & n.5 (H.H.S. Sept. 28, 2005) (all applying "common sense connection" or "nexus" interpretation of phrase "in connection with" together with "delivery" in context of § 1320a-7(a)(3)).

[13] *See, e.g.*, *Morand*, 2012 WL 369634, at *7 (finding that 42 U.S.C. § 1320a-7(a)(3) "does not require a 'felony conviction *for* health care fraud,' but rather a '[f]elony conviction *relating to*health care fraud'" (emphasis and brackets in original)); *Curtis*, 2011 WL 7444589, at *4 (finding that 42 U.S.C. § 1320a-7(a)(3) "does not require that the felony conviction be for an offense specified as 'health care fraud,'" that the plain language "encompasses felonies 'relating to' fraud," and, by including the term "other financial misconduct" within the scope of offenses, "Congress clearly intended to broadly encompass financially-related offenses").

If OIG does determine that the requirements for Mandatory Exclusion have been met, it has *no discretion* pursuant to statute and exclusion must follow. In light of the above, U.S. health care companies should carefully consider all potential applicable laws, including the OIG exclusion statute, when resolving FCPA matters.

II. Development Bank Debarments and Their Domestic Consequences

Health care companies with federal procurement arrangements may also face unexpected consequences from ex-U.S. activities if they find themselves debarred by an international development bank, such as the World Bank. In 2016, the World Bank alone invested over $64 billion in both private and public sector organizations.[14] In order to protect current investments and deter bad actors, development banks employ sanctioning regimes that rely heavily on debarments, which exclude entities from eligibility for World Bank financing for a period of time. The World Bank identifies five forms of misconduct subject to sanctions: corrupt practices, fraudulent practices, coercive practices, collusive practices and obstructive practices,[15] covering activities such as bribes, misrepresentations, collusive pricing, threats of force, as well as interfering with World Bank investigations.[16]

Development bank debarment actions are public and may be highly publicized depending on the situation and underlying conduct in order to deter future misconduct.[17] Further, in 2010, a consortium of major development banks, including the World Bank, executed a cross-debarment agreement, which provides that debarment of an entity by one bank triggers exclusion by all.[18] Additionally, the World Bank at times refers the results of its investigations directly to state authorities.[19] Given the broad scope of development banks' public and private sector activities, companies with any type of federal contract should be aware of the potential effects of debarment. This quasi-governmental debarment action could cause a U.S. federal agency to view the debarred contractor as an unreliable partner, leading to a potential investigation or debarment action in accordance with General Services Administration ("GSA") regulations.

GSA regulations give broad discretion to agency officials to determine whether to debar a firm with a federal contract, including for "[c]ommission of any . . . offense indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a Government contractor or subcontractor."[20] While this provision only *permits* agencies to issue debarments, rather than mandating they do so, it captures a wide range of misconduct, similar to the activities identified in the debarment provisions of development banks.

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[14] *See* World Bank, *Annual Report 2016* 3.
[15] *See* International Finance Corporation, World Bank Group, *Definitions and Interpretive Guidelines (2009)*.
[16] *See* Sope Williams, *The Debarment of Corrupt Contractors from World Bank-Financed Contracts*, 36.3 Pub. Cont. L. J. 277, 287–88 (Spring 2007); World Bank, *Guidelines on Preventing and Combating Fraud and Corruption in Projects Financed by IBRD Loans and IDA Credits and Grants* (Oct. 15, 2006).
[17] *See* Anne-Marie Leroy & Frank Fariello, *The World Bank Group Sanctions Process and Its Recent Reforms*, The World Bank 15 (2012) ("The Bank Group's sanctions regime has the dual purpose of protecting Bank Group funds and also promoting both specific and general deterrence.").
[18] Agreement for Mutual Enforcement of Debarment Decisions, dated as of April 9, 2010, by and among the African Development Bank Group, Asian Development Bank, European Bank for Reconstruction and Development, Inter-American Development Bank Group and World Bank Group.
[19] *See, e.g.* Integrity Vice Presidency, The World Bank Group, *Annual Update, Fiscal Year 2016*40 (2016) (listing referrals made to state governments during fiscal year 2016).
[20] F.A.R. § 9.406-2(a)(5).

In assessing whether to debar, the government agency will decide whether the firm's conduct "indicate[s] a lack of business integrity" and whether that lack of integrity is closely enough related to the firm's "present responsibility."[21] Triggering conduct need not directly arise from the firm's conduct related to a government contract, nor must it take place under U.S. jurisdiction. Debarment from U.S. government contracts is meant only to protect the public interest, not to punish supposed wrongdoers, and GSA regulations provide agencies with broad discretion to decide what facts to consider in judging a firm's integrity.[22]

Health care companies with federal contracts should proceed carefully when faced with a quasi-governmental debarment, given the possible impact on their U.S. government business. GSA regulations do weigh timely disclosure of misconduct as a mitigating factor in an agency's determination of whether to debar a firm, and as a result, proactive disclosure to the applicable federal agency, particularly in the event of highly publicized misconduct, may be a course worth considering.[23]

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[21] If a contracting agency initiates an investigation, those questions are answered pursuant to a formal process mandated by GSA regulations. For example, the Veterans Administration requires an extensive reporting process for complainants, after which notice is given to the accused firm along with an opportunity to respond. Depending on an informal review of that response, the accusation is dismissed or a formal hearing resembling a lawsuit begins. *See*F.A.R. § 809.406-3.

[22] *See* F.A.R. § 9.402 (setting out the policy that debarment and suspension from U.S. government contracts shall be imposed "only in the public interest for the Government's protection and not for purposes of punishment"); Federal Acquisition Institute, *Transcript: Suspension and Debarment*, last accessed September 13, 2017, (noting that this "broad" mandate encompasses behavior that does "not . . . relate to work on a federal government contract").

[23] *See* F.A.R. § 9.406-1 ("Before arriving at any debarment decision, the debarring official should consider factors such as . . . [whether] the contractor brought the activity cited as a case for debarment to the attention of the appropriate Government agency in a timely manner.").