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OIG's Special Advisory Bulletin on the Effect of Exclusion—Continuing the Focus on Individual Accountability

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On May 8, 2013, the U.S. Department of Health and Human Services' Office of Inspector General ("OIG") released an *Updated Special Advisory Bulletin on the Effect of Exclusion from the Participation in Federal Health Care Programs* ("2013 Exclusion Update"),[1] which supersedes the original bulletin released in September 1999 ("1999 Exclusion Update").

For several years, OIG has evidenced an intent to increase its use of its authority to exclude—a potentially career-debilitating penalty—to combat fraud and abuse in the health care industry. The 2013 Exclusion Update reiterates OIG's earlier guidance regarding the scope and effect of an exclusion, and serves as yet another signal of OIG's ongoing intention to hold accountable both excluded persons as well as the health care entities that employ or contract with them. Also, the 2013 Exclusion Update provides additional guidance on civil monetary penalty ("CMP") liability, OIG's Provider Self-Disclosure Protocol, and best practices for screening employees and contractors against OIG's List of Excluded Individuals and Entities ("LEIE"). This Client Alert summarizes the 2013 Exclusion Update and concludes by identifying several key takeaways for those entities that wish to avoid liability from employing or contracting with excluded persons.

Brief Background on Exclusion

Through the 1977 Medicare-Medicaid Fraud and Abuse Amendments, Congress established OIG's authority to exclude individuals and entities from participation in federal health care programs. Since that time, OIG's exclusion authority has expanded through the enactment of various laws, including the Civil Monetary Penalties Law ("CMPL") in 1981.[2] Among other things, these subsequent enactments have

[1] U.S. Dep't of Health and Human Servs., Office of the Inspector General, *Updated Special Advisory Bulletin on the Effect of Exclusion from the Participation in Federal Health Care Programs*, *available at* http://oig.hhs.gov/exclusions/files/sab-05092013.pdf (hereinafter "2013 Exclusion Update").
[2] *See* Social Security Act, 42 U.S.C. § 1128.

established additional mandatory and discretional exclusions, expanded OIG's sanction authority to cover all federal health care programs, and authorized the imposition of CMPs against providers that employ or contract with excluded persons.

In September 1999, OIG released the 1999 Exclusion Update, which was designed to help providers understand the scope and effect of OIG exclusions. The 1999 Exclusion Update provided broad guidance to providers and entities that employ or contract with excluded persons. Also, the 1999 Exclusion Update provided very broad guidance to providers on the scope of the prohibition on employing or contracting with excluded persons, when a provider might be subject to CMPs for violating that prohibition, and how to determine whether a potential employee or contractor is excluded. For example, OIG recommended that providers "periodically" check the OIG website to determine the exclusion status of employees and contractors but never defined "periodically" or the impact that "periodic" checks have on CMP liability. Since the publication of the 1999 Exclusion Update, several statutory amendments, such as those included in the Affordable Care Act, have further strengthened OIG's authority to exclude individuals from federal health care programs.

Key Differences Between the 1999 and 2013 Exclusion Updates

Though the 2013 Exclusion Update reiterates much of OIG's previous guidance, it also addresses issues brought to OIG's attention since the release of the 1999 Exclusion Update, including: (i) whether an excluded person may provide an item or service to a non-excluded health care provider that is not for direct patient care or billing;[3] (ii) the obligation of a provider or entity to screen employees against the LEIE, and the distinction between information on the LEIE and other systems that report sanctions and adverse actions taken with respect to health care practitioners;[4] (iii) whether a provider that employs or contracts with an excluded person is subject to CMP liability;[5] and (iv) the protocol for an employer to disclose when it employs, or contracts with, an excluded person.[6]

Set forth below is a summary of the information included in the 2013 Exclusion Update.

1. Details on the Scope of Exclusions

An OIG exclusion prohibits federal health care program payment for any item or service furnished by an excluded person, or at the medical direction or on the prescription of an excluded person.[7] The 2013 Exclusion Update further details that prohibitions on federal health care program payments for excluded persons apply even if the excluded person changes from one health care profession to another while excluded, regardless of whether the person is an employee, a contractor, or a volunteer or has any other relationship with the provider. Additionally, the 2013 Exclusion Update explains that prohibitions under an exclusion go beyond direct patient care. Consistent with the 1999

[3] *See* 2013 Exclusion Update, at 6-10.
[4] *Id.* at 13-19.
[5] *Id.* at 10-13.
[6] *Id.* at 13.
[7] 42 C.F.R. § 1001.1901.

Exclusion Update, OIG emphasizes that excluded persons are prohibited from furnishing administrative and management services payable by federal health care programs. Such services include serving as an executive or in a leadership role (e.g., CEO, CFO, general counsel, physician practice office manager, etc.) for a provider that furnishes items and services payable by federal health care programs. OIG also explains that the scope of prohibited administrative and management services extends to health information technology service support, strategic planning, billing and accounting, staff training, and human resources, unless any of these roles are wholly unrelated to federal health care programs.

The 2013 Exclusion Update also provides that an exclusion prohibits any items and services furnished at the medical direction or on the prescription of an excluded person. For example, if a provider furnishes services on the basis of an order or prescription (e.g., laboratory, pharmacy, x-ray, etc.) from an excluded person, the item or service is prohibited if it is for a federal health care program beneficiary, and the provider furnishing the service would be subject to liability for furnishing the prohibited service or item.[8] OIG cautions providers that take orders and prescriptions from other providers, stating, "Some excluded practitioners will have valid licenses or Drug Enforcement (DEA) numbers. Therefore, it is important not to assume that because a prescription contains a valid license number or DEA number, the practitioner is not excluded."[9]

2. Screening Guidance

In the 2013 Exclusion Update, OIG recommends that providers screen employees and contractors utilizing the LEIE in order to minimize CMPL liability. OIG recommends that providers use the LEIE as a primary source of screening employees and contractors rather than using the General Services Administration's System for Award Management ("SAM") or the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.[10] Unlike the SAM and the National Practitioner Data Bank, the LEIE is updated monthly by OIG and provides more information regarding excluded persons. OIG also recommends that, each month, providers screen employees and contractors, including nurses provided by a staffing agency, physician groups that contract with hospitals to provide patient care coverage, and billing and coding contractors.

In 2011, the Centers for Medicare & Medicaid Services ("CMS") also issued final regulations requiring Medicaid agencies to screen all providers' exclusion status each month.[11] OIG's recommendation in the 2013 Exclusion Update that health care providers should screen employees and contractors each month is consistent with CMS's monthly screening requirement, but it is noticeably more specific than the 1999 Exclusion Update, which indicates only that "periodic" screening is necessary. The

[8] *See* Social Security Act, 42 U.S.C. § 1862(e)(1)(B).
[9] *See* 2013 Exclusion Update, at 8 n.10.
[10] The SAM includes information on debarred persons. OIG has no authority to impose CMPs on the basis of employment with a debarred person. Additionally, OIG exclusion does not preclude payment in other government procurement or non-procurement transactions.
[11] CMS then uses the updates to populate the Medicare Exclusions Database, which is available to state Medicaid agencies and other stakeholders.

2013 Exclusion Update is also stricter than the screening provisions of recent Corporate Integrity Agreements, which only require annual exclusion checks.

3. CMPL Liability Guidance

OIG has the authority to impose CMPs against providers that employ or contract with excluded persons that provide items and services payable by federal health care programs.[12] OIG may impose CMPs up to $10,000 for each item or service furnished by the excluded person, as well as treble damages. Exclusion violations may also lead to additional criminal prosecutions or civil actions. However, it should be noted that, in cases when an exclusion violation occurs in the context of staff (i.e., non-direct billers), OIG will often settle the case for an amount equal to the salary of the staff member at issue without additional fines and penalties.

Furthermore, there are limited circumstances in which a provider may employ or contract with an excluded person, and OIG has issued several Advisory Opinions on the subject. In these limited circumstances, providers are shielded from CMP liability as the excluded person is neither providing items or services to federal health care program beneficiaries nor billing for such services. In the 2013 Exclusion Update, OIG reiterates that a provider that participates in federal health care programs may employ or contract with an excluded person to provide items and services if:

- federal health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual; or
- the excluded person furnishes items and services solely to non-federal health care program beneficiaries.

4. Provider Self-Disclosure Protocol

For those providers that identify potential or actual CMP liability due to the employment of, or contracting with, an excluded person, OIG recommends the use of its Provider Self-Disclosure Protocol.[13] A decision about whether or not to use the Provider Self-Disclosure Protocol is a significant one and should be made only after a full understanding of the process and potential outcomes. For more information on the Provider Self-Disclosure Protocol, see the Epstein Becker Green Client Alert entitled "OIG Unveils Updated Self-Disclosure Protocol."

Key Takeaways

With the 2013 Exclusion Update, OIG continues to alert the health care industry that it remains committed to aggressively wielding its exclusion authority. The 2013 Exclusion Update details the substantial impact that exclusions have not only on excluded persons but also on health care entities employing or contracting with excluded persons. Providers and those responsible for making contracting and employment decisions at

[12] *See* 42 C.F.R. § 1003.102(a)(2).
[13] *See* U.S. Dep't of Health and Human Servs., Office of the Inspector General, *OIG's Provider Self-Disclosure Protocol*, *available at* http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.

entities that participate in federal health care programs must be aware that the government will take the position that, if a person appears on an exclusion list, the employer should have known of his or her exclusion status. Therefore, providers and entities that participate in federal health care programs should take the following steps to minimize liability for hiring or contracting with excluded persons:

- Be cognizant of the fact that the use of a vendor does not shield completely an individual or entity from liability in the context of the improper hiring/contracting of excluded individuals.

- When negotiating employment and vendor agreements, consider including contractual language requiring (i) express warranties that the individual or entity (and any individuals employed thereby) are not excluded, (ii) monthly exclusion checks by vendors, and (iii) indemnification provisions with regard to any claim relating to, or liability resulting from, the exclusion of the employee, vendor, or vendor's personnel.

- Review vendor agreements with the signing vendor, ensuring the degree to which the vendor conducts exclusion checks in relevant federal and state databases.

- Be cognizant of the fact that OIG's screening guidance addresses only federal exclusions; therefore, remain diligent and cross-check employees and contractors against relevant state exclusion databases since the LEIE and state exclusion databases are not always consistent.

- Perform exclusion checks on employees and contractors (to include sub-contractors) on a **monthly** basis.

- Retain copies of all exclusion checks and screening results, and use a log that indicates the date of the check and any significant findings.

- Inquire into the exclusion status of potential employees and contractors during employment interviews and when negotiating vendor agreements.

- To the extent that an excluded person is an employee or a contractor, ensure that the excluded person furnishes items and services solely to non-federal health care program beneficiaries or ensure that federal health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual.

- If an employee or contractor is discovered to be an excluded person, terminate the relationship and stop billing federal health care programs for items or services provided by the excluded person. Seek legal counsel to navigate possible corrective action, including self-disclosure.

The 2013 Exclusion Update is a clear indication that items or services provided by excluded persons are a continuing concern for OIG. Health care entities must remain diligent to protect against the consequences of employing or contracting with excluded persons.

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This Client Alert was authored by **George B. Breen, Carrie Valiant,** *and* **Jonah D. Retzinger**. **Marshall E. Jackson, Jr.,** *a Law Clerk in Epstein Becker Green's Washington, DC, office, contributed significantly to the preparation of this Client Alert. For additional information about the issues discussed in this Client Alert or if you have questions on how to operationalize this guidance, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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