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Beware Excluded Individuals and Entities

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Federal laws generally prohibit providers from billing for services ordered by, or contracting with, persons or entities that have been excluded from participating in Medicare, Medicaid, or other federal health care programs. Violations may result in significant penalties, including repayment of amounts improperly received. To avoid penalties, providers should check the OIG's List of Excluded Individuals and Entities ("LEIE") before hiring, contracting with, or granting privileges to employees, contractors, or practitioners, and should periodically re-check the LEIE thereafter.

Effect on Excluded Entities. Federal statutes such as the Civil Monetary Penalties ("CMP") law allows HHS to exclude individuals and entities from participating in federal health care programs if they have been convicted of fraud or abuse or engaged in certain other misconduct. (*See*, *e.g.*, 42 USC §§ 1320a-7 and 1320c-5). States are required to exclude from Medicaid any person or entity that has been excluded by HHS. (*Id.*). An excluded individual or entity generally may not do the following:

1. Submit or cause claims to be submitted for items or services covered by federal health care programs. No federal payment may be made for items or services furnished, ordered, prescribed, or provided under the direction of an excluded person or entity. (42 CFR § 1001.1902(b)). Consequently, excluded persons or entities may not submit claims for such items for payment themselves, nor may they cause such claims to be submitted on their behalf or perform services knowing the claims will be submitted. (OIG, *Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* (8/13), hereafter "OIG Bulletin (8/13)).

2. Providing administrative or managerial services to program participants. The prohibition extends beyond direct patient care. Excluded persons and entities are prohibited from furnishing administrative and management services that are payable by federal health care programs. According to the OIG, an excluded individual may not serve in an executive leadership role (*e.g.*, CEO, CFO, general counsel, HR director, HIM director, office manager, etc.) at a provider that furnishes items or services payable by federal health care programs. (OIG Bulletin (8/13)). Furthermore, the OIG maintains that an excluded individual may not provide other types of administrative and management services (*e.g.*, HIM services, HR, billing, accounting, strategic planning, etc.) unless wholly unrelated to federal health care programs. (*Id.*).

3. Owning an entity that participates in federal programs. Although the federal laws do not categorically prohibit excluded persons or entities from

owning a provider who participates in federal health care programs, the OIG may use its permissive authority to exclude the owned entity unless certain conditions are satisfied. (OIG Bulletin (8/13)). In addition, an excluded individual may be subject to CMP liability if he or she has an ownership or control interest in a provider participating in Medicare or state health care programs of if he or she is an officer or managing employee of such an entity. (42 CFR § 1003.102(a)(12)). Further, the provider may not seek federal health care program payments for services furnished by the excluded owner. (*Id.* at § 1003.102(a)(2)). As a practical matter, this means that an excluded person may own a provider, but may not provide any items or services, including administrative and management services, that are payable by federal health care programs. (OIG Bulletin (8/13)).

Effect on Third Parties. The laws extend beyond the excluded individuals to third parties. They generally prohibit the third parties from doing the following:

1. Billing for items or services furnished or ordered by an excluded person or entity. Providers who furnish items or services rendered, ordered, prescribed, or directed by an excluded individual or entity may not submit claims for such items or services to Medicare, Medicaid or other federal health care programs if the provider “knew or had reason to know” of the exclusion. (42 CFR §§ 1001.1902(b)(1) and 1003.102(a)(3)). For example, no federal program payment may be made to a hospital for the items or services furnished by an excluded nurse to federal health care program beneficiaries even if the nurse's services would be covered under the hospital's DRG payment and not separately billed. (OIG Bulletin (8/13)). Limited exceptions exist for emergencies and certain other services. (*Id.* at § 1001.1902(b)(c)). To avoid liability, the OIG cautions providers to ensure, at the point of service, that the ordering or prescribing practitioner is not excluded. (OIGr Bulletin (8/13)).

2. Employing or contracting with an excluded individual or entity. Providers may not employ, contract with, or arrange for an excluded individual or entity to provide items or services payable in whole or in part, directly or indirectly, by federal programs if such provider knew or should have known of the exclusion. (42 CFR § 1003.102(a)(2)). As interpreted by the OIG, the law prohibits hiring, contracting with, or arranging for excluded individuals or entities to perform administrative, managerial, or volunteer services related to items or services payable by federal health programs. (OIG Bulletin (8/13)). For example, if a hospital contracts with a staffing agency for temporary or per diem services provided by an excluded nurse and paid by federal health care programs, the hospital will be subject to repayment and CMP liability. (OIG Bulletin (8/13)). The prohibition applies even if the excluded individual or entity providing the items or services is paid with non-federal funds, is paid by an unrelated party, or provides items or services as a volunteer. (Adv. Op. 03-01). Providers and facilities may not use federal program payments to pay an excluded individual's salary, expenses, or fringe benefits, regardless of whether the individual provides direct patient care. (OIG Special Advisory Bulletin, *The Effect of Exclusion from Participation in Federal Health Care Programs* (9/99)). To avoid violating the exclusion laws, a provider or facility that employs or contracts with an excluded individual would have to establish that federal

health care programs do not pay, directly or indirectly, for the items or services being provided by the excluded individual, or that the excluded individual furnished items or services solely to non-federal health care program beneficiaries. (OIG Bulletin (8/13)). If the employee or contractor provides general administrative or management services, the OIG has previously suggested that the provider would have to establish that it paid the excluded individual's salary, expenses and benefits exclusively from private funds or from other non-federal funding sources, and (2) the services furnished by the excluded individual relate solely to non-federal program patients. (*Id.*; see also Adv. Op. 03-01). That is impractical if not impossible in most health care settings.

Penalties. Violations of the exclusion laws may result in serious penalties, including:

1. Denial of payment for items or services provided in violation of the exclusion laws.

2. Repayment of amounts improperly received in violation of the exclusion laws. Under the Affordable Care Act, providers must generally report and repay overpayments within 60 days or risk False Claims Act penalties, which include fines of $5,500 to $11,000 per claim, treble damages, and program exclusion. (31 USC § 3729; 42 USC § 1320a-7k(d))

3. Civil monetary penalties of $10,000 for each item or service provided by the excluded entity or individual for which payment is submitted to government payers, and an assessment of up to three times the amount claimed for such items or services. (42 CFR §§ 1001.1901(b)(3) and 1003.102(a)(2)-(3)). Improperly submitted claims may also trigger False Claims Act penalties. (OIG Bulletin (8/13)).

4. Criminal penalties if an excluded entity or provider knowingly conceals or fails to disclose any action affecting the ability to receive any benefit or payment with the intent to fraudulently receive such benefit or payment. (OIG Bulletin (8/13)).

5. Exclusion of the entity that improperly submitted or failed to repay amounts received for federal program claims. (42 USC §1320a-7a(a)(10))

The penalties can add up rapidly. In July 2014, for example, the OIG reported that the University of Utah agreed to pay $197,839.94 for hiring three excluded individuals. (*See* OIG Report, available at http://oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp#CMP2014071101). The OIG may reduce penalties where an entity self-reports violations, but the OIG generally insists on a repayment based on certain pre-determined formulas. The result is that even innocent violations may result in penalties of tens of thousands if not hundreds of thousands of dollars.

Check the LEIE. The exclusion law generally applies if the provider “knew or had reason to know” of the exclusion. (*See* 42 CFR § 1001.1901(b)(1)). CMS will usually notify providers if a claim has been submitted with the provider number of an excluded practitioner. In addition, the OIG maintains the LEIE, its database of excluded providers, which is available at

https://oig.hhs.gov/exclusions/exclusions_list.asp. Providers may be deemed to have knowledge of information contained on the LEIE, and, therefore, providers should check the LEIE regularly. In last year's Special Advisory Bulletin, the OIG stated:

> To avoid potential CMP liability, providers should check the LEIE prior to employing or contracting with persons and periodically check the LEIE to determine exclusion status of current employees and contractors….
> [P]roviders may decide how frequently to check the LEIE. OIG updates the LEIE monthly, so screening employees and contractors each month best minimizes potential overpayment and CMP liability.

(OIG Bulletin (8/13)). In 2009, CMS recommended that state Medicaid directors require providers to screen all employees and contractors monthly. (Letter from H. Kuhn, Deputy Administrator, Center for Medicaid and State Operations (1/16/09)).

Which Persons and Entities to Check. The OIG recommends that providers check all employees or contractors who provide items or services that are payable, directly or indirectly, in whole or in part, by federal health care programs. (OIG Bulletin (8/13)). In the case of contractors, the more closely the services relate to federal program business, the greater the need to check the LEIE. For example, the OIG recommends screening clinical personnel provided by staffing agencies, physician groups that contract with hospitals for services, and billing or coding contractors. (*Id.*). As for non-employed or non-contracted practitioners, the OIG previously suggested that providers check the LEIE "routinely (*e.g.*, at least annually)" for "medical and clinical staff members." (OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4876 (1/31/05)).

Practical Suggestions. Given the penalties, potential repayments, and recent government warnings, providers should do the following to protect against liability for doing business with an excluded individual or entity:

1. Check the LEIE before hiring employees; contracting with practitioners, vendors or suppliers; credentialing physicians and other practitioners; or engaging temporary staff, locum tenens personnel, volunteers, or other workforce members. LEIE checks should be part of the normal human resources, credentialing, and contracting processes.

2. Check the LEIE on a regular basis thereafter. If possible, check the LEIE monthly. Providers may download the LEIE and run an electronic search against employees, contractors, vendors and medical staff. If you cannot check monthly, then check the LEIE as frequently as possible. The more often you check it, the safer you will be and the lower the potential penalties if an excluded entity does show up in your organization. Providers should print screen-shots to document their search.

3. When checking the LEIE, beware of name changes. If possible, cross check the LEIE with birthdates, social security numbers, employee identification numbers, or other available data using the OIG's online

searchable database. Ensure your employment and credentialing applications require disclosure of other names by which the applicant has been known, and include such names in your LEIE searches.

4. Include questions in your applications and terms in your contracts that require the applicant, provider, employee, or contractor to confirm that they are not excluded and indemnify you for any misrepresentation. Ensure your relevant agreements, contracts, bylaws, and policies condition any arrangement on the party's eligibility to participate in federal programs.

5. Ensure temporary agencies, locum tenens companies, and contractors who provide services through individuals have performed an adequate background check that includes an LEIE search. The OIG has suggested that a provider may be able to reduce or minimize its CMP liability if it is able to confirm that it reasonably relied on a staffing agency to check the LEIE and the hospital exercised due diligence to confirm the agency was doing so (OIG Bulletin (8/13) at fn. 21); nevertheless, to be safe, the provider may want to conduct its own check of the LEIE.

6. Require any applicant, provider, employee, or contractor to notify you immediately if they are excluded from federal programs. Ensure that your bylaws, contracts and other agreements allow you to immediately terminate the relationship in the event of program exclusion. Consider requiring the applicant, provider, employee or contractor to defend, indemnify, and hold you harmless from any costs or damages incurred due to program exclusion.

7. If you discover that you have an excluded provider, you should carefully consider your options. Under the ACA, entities generally have an obligation to report and repay overpayments within 60 days. Providers may want to consider using the OIG's Self-Disclosure Protocol. The timing, method and manner of self-disclosure may impact the penalties and repayment obligation that may be imposed. You may want to consult with an experienced health law attorney.

Conclusion. The government's focus on fraud and abuse enforcement has increased the chances that you may, at some point, deal with an excluded individual or entity. In addition, the government has recently proposed changes to expand its exclusion authority. Given the potential penalties, it is better to be safe than sorry; providers should ensure they check the LEIE and take other reasonable steps to avoid dealing with excluded persons and entities.

For more information about excluded entities, see the OIG's website, https://oig.hhs.gov/exclusions/index.asp.

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