PUBLICATION

OIG Updates Special Advisory Bulletin on the Effect of Exclusion from Federal Health Programs [Ober|Kaler]

May 10, 2013

This article appeared in the May 10, 2013 issue of* Health Lawyers Weekly*, a publication of the American Health Law Association.

On May 8, 2013, the OIG issued an update that supersedes and replaces its 1999 Special Advisory Bulletin, The Effect of Exclusion from Participation in Federal Health Care Programs. The updated bulletin [PDF] continues to stress the importance of health care providers determining whether potential and current employees and contractors have been excluded from federal health care programs and seeks to answer questions that have arisen since the original 1999 publication.

The effects of an OIG exclusion from federal health care programs are far reaching. No payment may be made by a federal health care program, either directly or indirectly, for any item or service that has been (1) furnished by an excluded entity or individual or (2) directed or prescribed by an excluded physician.1 *Federal health care program payments* are defined to include amounts based on a cost report, fee schedule, prospective payment system, capitated rate, or other payment methodology. Thus, for example, no federal program payment may be made to cover an excluded individual's salary, expenses, or fringe benefits, regardless of whether the individual provides direct patient care (i.e., a nurse or a practice administrator).

The OIG sets forth a number of questions that have been presented since publication of the 1999 bulletin. The updated bulletin incorporates new guidance, including examples, designed to satisfy those questions. The questions and the answering guidance found in the updated bulletin are discussed in turn below.

Is an excluded person permitted to provide an item or service to a health care provider that is necessary, but is not part of direct patient care or billing? Will there be CMP liability if a provider employs or contracts with an excluded person to provide such items or services?
The updated guidance is consistent with the OIG's original guidance on this question. However, seeking to further explain the impact of exclusion, the OIG provides the following examples of services that would be problematic if provided by an excluded person: preparation of surgical trays; review of treatment plans; prescription information input for pharmacy billing; filling prescriptions for drugs that are billed to a federal health care program; driving an ambulance; and providing ambulance dispatch services.

The updated bulletin also specifically addresses administrative and management services paid for by federal health care programs, including management roles as well as administrative and management duties. The OIG notes that excluded individuals cannot hold roles such as CEO, General Counsel, Director of Health Information Management, or Director of Human Resources. Additionally, excluded individuals cannot provide other types of administrative and management services, such as health information technology services and support, strategic planning, billing and accounting, staff training, or human resources.

The bulletin states that excluded individuals may provide services to entities that receive federal health care funds if the individual is not providing any services for which federal health care programs pay directly or indirectly. Additionally, a provider that contracts with an excluded individual to provide services to non-federal

health care patients only is not subject to CMP liability. Notably, the OIG does not provide specific examples of services that would not be directly or indirectly paid for by federal health care funds.

Finally, the bulletin notes that excluded individuals are not banned from owning health care providers. However, the OIG has the authority to exclude, at its discretion, a provider owned by an excluded individual holding at least 5 percent interest. Additionally, the owner may be subject to CMP liability if the business provides services to federal health care program beneficiaries or if the provider seeks payment (direct or indirect) for administrative and management services provided by the owner.

When a health care provider employs or contracts (directly or indirectly) with a person that the provider knows or should know is excluded by the OIG, the provider may be subject to CMP liability. The OIG may impose CMPs of up to $10,000 for each item or service furnished by the excluded person for which federal program payment is sought, as well as an assessment of up to three times the amount claimed, and program exclusion.

The excluded individual may be subject to a CMP of $10,000 for each claimed item or service furnished during the period of exclusion. The OIG may also subject the individual to an assessment of up to three times the amount claimed for each item or service. Violation of an exclusion is also grounds for denial of reinstatement to federal health care programs at the end of the term of the exclusion. Furthermore, according to the OIG, exclusion violations may lead to additional criminal prosecutions or civil actions.

The bulletin states that individuals who order or prescribe items or services while excluded are subject to CMP liability when the excluded person knows or should know that a claim for the item or service may be made to a federal health care program. However, the OIG clarifies that where an excluded individual treats a patient, but does not submit a claim, and refers a patient to another non-excluded physician, who makes an independent judgment upon which additional items or services are ordered, and who bills for those services independently of the excluded provider the claims do not violate the exclusion provisions.

What obligations do providers have to screen current and potential employees and contractors against the OIG's List of Excluded Individuals and Entities (LEIE) to determine whether they are excluded? How frequently should providers screen against the LEIE? Do providers need to screen downstream contractors?
While acknowledging that there is no statutory or regulatory federal requirement to screen individuals for exclusion, the OIG recommends that best practice is for providers to screen individuals for exclusion when they are hired and thereafter monthly. Notably, in 2011, CMS issued final regulations requiring state Medicaid agencies to screen all providers monthly, and several states have adopted similar requirements for their Medicaid providers to perform monthly screenings.

The OIG states that screening should be performed through the use of the OIG's *List of Excluded Individuals and Entities (LEIE)*. The LEIE is accessible through a searchable online database and downloadable data files. The OIG also advises that providers should maintain documentation of the initial name search performed (such as a printed screen-shot) and any additional searches conducted, in order to verify results of potential name matches. The OIG acknowledges that providers may contract with an outside entity to perform the searches, but cautions that the provider remains liable for any CMP if the search is inadequate.

With respect to which individuals to screen, the OIG suggests that providers screen those individuals who provide services that are directly or indirectly payable by a federal health care program. This applies whether the individuals are employees or are independent contractors or subcontractors. A provider can rely on a contractor or subcontractor to perform the service, but if there is an error and the provider bills for services provided by an excluded individual, liability remains with the provider. The OIG does not address that the provider could seek indemnification from the contractor, if the contract allows.

What database should providers review to determine if an individual is excluded (i.e., LEIE, the General Services Administration's (GSA) System for Award Management (SAM) and/or the National Practitioner Data Bank (NPDB)?
Interestingly, the bulletin describes other government databases, such as GSA's SAM and the NPDB, and concludes that searches of those databases are unnecessary for purposes of the OIG's exclusion CMPs. Further, the bulletin states that OIG has no authority to impose a CMP on an individual listed as debarred on the GSA website if that individual has not also been explicitly excluded by the OIG.

What is the process to disclose the employment or independent contractor relationship with an excluded individual if a provider learns of it?
Providers who learn that they have employed or contracted with an excluded individual should use the OIG's Self-Disclosure Protocol. Notably, the disclosure protocol, which was recently revised on April 17, 2013, contains a section dedicated to the disclosure of excluded individuals, including how to calculate potential repayment to the government.

Ober|Kaler's Comments

The updated bulletin is consistent with the OIG's 1999 bulletin. This new document provides additional examples and further insight into how the OIG views its exclusion authority. Perhaps most importantly, the issuance of the updated bulletin makes clear that items and services provided by excluded individuals are a continuing concern and area of inquiry for the OIG.

Notes

1 See 42 C.F.R. § 1001.1901.