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OIG Updates Guidance on Effect of Exclusion from Federal Health Care Programs

On May 8, 2013, the Department of Health and Human Services Office of Inspector General (OIG) issued an "Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs." This updated Bulletin replaces and supersedes a Special Advisory Bulletin on the same subject which was issued by OIG in September 1999. The 19-page advisory answers numerous questions on the effect of exclusion, gives some helpful factual examples and suggests best practices for avoiding violations, including recommendations on the frequency of exclusion checks.

In 1977, Congress first mandated exclusion from participation in Medicare and Medicaid for practitioners convicted of program-related crimes. Since that date, the federal government's exclusionary authority has steadily expanded. An OIG exclusion, which can be imposed for fraudulent Medicare claims or for student loan defaults, prohibits federal health care program payments for any items or services "furnished" by an excluded person, or at the medical direction or on the prescription of an excluded person. The Balanced Budget Act of 1997, Public Law 105-33, authorized civil monetary penalties (CMPs) against providers or entities that employ or enter into contracts with a person or entity that has been excluded from providing items or services for which payment may be made under a federal health care program.

Previous guidance made clear that the "furnished by" prohibition includes items and services beyond direct patient care if the item or service is necessary and integral to the delivery of patient care. However, where to draw that line was not always clear. Previous guidance did generally clarify that using an excluded person for administrative or management services payable by federal health care programs is prohibited. Providers who furnish items based on an order or prescription by an excluded physician are subject to CMPs as well. Companies that violate the exclusion rules can be subject to treble damages plus \$10,000 per false claim, and can themselves be excluded from federal health care programs.

The OIG's updated Bulletin now offers answers to the following questions:

- **May an excluded person provide an item or a service that a healthcare provider needs but that is not for direct patient care and billing?** Per the updated guidance, if federal health care programs do not pay, directly or indirectly, for the items or services

being provided by the excluded individual, then the provider may employ or contract with the excluded person for such items or services. Examples given by OIG of indirect tasks by excluded individuals that would trigger sanctions include: preparation of surgical trays; review of treatment plans; inputting prescription information for pharmacy billings; transportation services such as ambulance drivers and dispatchers; CEO; CFO; general counsel; directors of IT management or human resources; and physician office administrator. Consequently, the scope of permitted employment now appears quite narrow. Moreover, providers should be wary of employing an excluded person in any capacity because private payors frequently follow OIG's lead and prohibit such person's employment.

- **Is a provider that employs or contracts with an excluded person to provide an item or service that a healthcare provider needs but that is not for direct patient care and billing subject to CMP liability?** Such a provider would not be subject to CMP liability, and the provider is not required to maintain a separate account from which to pay the excluded individual.
- **What is the scope of the obligation to screen current and potential employees and contractors against OIG's List of Excluded Individuals and Entities (LEIE) to determine whether they are excluded? How frequently should providers screen against the LEIE? How far downstream do they need to screen (e.g., do they have an obligation to screen the employees of contractors and subcontractors in addition to screening contractors?)** The OIG advisory notes that no federal statute or regulation actually mandates that a provider check the LEIE, but of course CMP liability attaches if a provider employs or contracts with an excluded individual or entity and that individual or entity participates in any way in the furnishing of items or services payable by a federal health care program. Using a volunteer who has been excluded can also trigger penalties. Moreover, the exclusion "follows the person" – if an individual is excluded while a pharmacist and subsequently earns a medical degree, exclusion continues to apply. Providers may choose to rely on screening conducted by a contractor, such as a staffing agency or billing company, but the OIG recommends that the provider verify the screening by requesting and maintaining screening documentation from the contractor. As to frequency, the OIG states that checks of the exclusion databases should be done prior to hire and periodically on current employees and contractors, and OIG recommends that providers maintain documentation of their checks. Because the OIG updates the LEIE monthly, checking the LEIE monthly is a "best practice" and minimizes potential overpayment and CMP liability. Additionally, many Medicaid programs now require monthly checks, and in 2011, CMS issued regulations requiring states to screen all providers on a monthly basis.
- **How should a provider disclose to OIG that it has employed or contracted with an excluded person?** OIG directs providers to use OIG's Self-Disclosure Protocol (SDP) to self-disclose the employment of or contracting with an excluded person. (For more information on the recently revised SDP, see AGG's Client Alert titled "OIG Revises Self-Disclosure Protocol (SDP)," at <http://www.agg.com/OIG-Revises-Self-Disclosure-Protocol-SDP-04-24-2013>.)

- **What is the distinction between the information that appears on the LEIE and the information that appears on the General Services Administration (GSA) System for Award Management (SAM) and other systems that report sanctions or adverse actions taken with respect to health care practitioners (e.g., the National Practitioner Data Bank (NPDB))?** The GSA's Excluded Parties List System was recently merged into SAM. SAM includes OIG's exclusions as well as disbarment actions by other federal agencies, while the LEIE only lists OIG exclusions. OIG recommends that the LEIE be the primary source for checking exclusion status because it is updated monthly and its database provides more details, such as the statutory basis for exclusion, occupation at time of exclusion, date of birth and address. Additional information about SAM and debarment is available at <https://www.sam.gov>. Other sources such as the National Practitioner Data Bank and the Health Care Integrity and Protection Databank provide information on other types of sanctions, such as medical malpractice payments and adverse licensing actions, but are not a replacement or alternative to LEIE checks.

Another helpful clarification relates to referrals by excluded providers: an excluded provider may refer a patient to a non-excluded provider as long as the referring excluded provider does not furnish, order, or prescribe any services for the referred patient.

Finally, the OIG notes that the OIG Advisory Opinion process is available to offer formal binding guidance on whether any particular employment or contractual arrangement would be grounds for the imposition of sanctions under OIG's exclusion and CMP authority.

To access the entire updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, as well as the LEIE and detailed instructions its use in checking for excluded individuals and entities, go to <http://oig.hhs.gov/exclusions/advisories.asp>.

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