OIG Updates its Special Advisory Bulletin on Exclusions: Its Broad View of the Payment Prohibition and Ongoing Interest in Exclusion Screening Warn of Potential Increasing Enforcement Efforts

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The OIG continued to focus on exclusion screening issues with its update to the *Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs*.[1] On May 8, 2013, less than a month after specifically amending its Self-Disclosure[2] protocol to include exclusion violations, OIG described the "scope and effect" of exclusions, emphasizing conduct that could violate the payment prohibition to excluded persons and the potential administrative sanctions for employing excluded persons or contractors. While it also provided some guidance on the screening of employees and contractors, the timing of the advisory and its emphasis on enforcement strongly suggested that OIG would expand its efforts. Subsequent events have shown this to be true.

I. The Regulations on Payment and Penalties

The regulation prohibiting payment for services furnished or provided by excluded persons, 42 CFR § 1001.1901(b), states that payments should not be made for items or services furnished "by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion." As the regulation's language makes no reference to services or items provided by employees or contractors, one could reasonably understand the payment prohibition to be relatively narrow, just as the regulation describes—to services performed, prescribed or directed by excluded individuals who know or should know of their status.

Reasonable or not, the OIG takes the opposite view and interprets the prohibition expansively. In its view, the regulation applies to "all methods of . . . payment"[3] and includes virtually any item or service performed by an excluded person or entity that contributes in any way to any form of reimbursement. The bulletin advises, for instance, that the preparation of a surgical tray by an excluded person could run afoul of the prohibition, as could inputting information into a computer by an excluded person. Administrative and management services, IT support, and even strategic planning would also be prohibited "unless wholly unrelated to Federal health care programs." Even a volunteer's assistance might trigger the prohibition if he or she was excluded.

OIG takes a similar approach when interpreting 42 CFR §1003.102(a)(2) as authority to issue Civil Money Penalties (CMPs) for violations of the payment prohibition in addition to sanctions for the submission of false or fraudulent claims.[4] In its view, the imposition of penalties are appropriate if an "excluded person participates in any way in thefurnishing of items or services that are payable by a Federal health care program" and if the provider "knew or should have known" of the exclusion. In addition, the

[1] Originally posted on October 3, 2014 on the ***Exclusion Screening***, ***LLC*** website: https://www.exclusionscreening.com/oig-special-advisory-bulletin/

prohibition extends to “all categories of items or services”—whether they involve direct or indirect care, are administrative or management services, or even, as noted previously, if an excluded volunteer at a nursing home provided part of a service that was ultimately reimbursed. As long as the provider’s claim includes “any items or services furnished by an excluded person,” and the provider “knew or should have known” of the exclusion, the OIG is of the view that CMP liability could attach.

II. OIG’s Guidance on Screening: Follow it if you Can; Follow it at your Peril!

According to the advisory, providers can “avoid potential CMP liability” by checking the LEIE (OIG’s **L**ist of **E**xcluded **I**ndividuals and **E**ntities) “to determine the exclusion status of current employees and contractors.” Described as a “tool” that is “searchable” and “downloadable” to enable providers to identify excluded employees and contractors, OIG recommends that providers check it monthly checks to “minimize potential overpayment and CMP liability.”[5] The section on screening suggests that the process is a relatively easy one: providers simply have to “review each job category or contractual relationship to determine whether the item or service being provided is directly or indirectly, in whole or in part, payable by a Federal health care program. If the answer is yes, then . . . screen all persons that perform under that contract or that are in that job category.”[6] Simple as that? Unfortunately, no. There are a number of problems the guidance fails to recognize or understand.

To begin, though the LEIE can be searched, it can only handle five employees at a time; each has to be entered by hand, and potential matches must be verified individually. This might work well enough if a provider only has to screen a handful of employees or contractors, but imagine how long searching 100 employees, five at a time, would take. Or 1,000? Or 10,000? Nor does downloading the database help many providers. Most simply do not have the IT capability to compare their employee database to the LEIE in any reliable or economically viable way.

The OIG’s guidance that providers simply need to use “the same analysis” for contractors and subcontractors “that they would for their own employees” is also problematic.[7] It is difficult enough to identify every employee who contributes in any way to any item or service that contributes to any amount of reimbursement in any form, but how realistic is it to expect a provider to meet that standard for his contractors and subcontractors, and their employees? Wouldn’t almost every person that walked into hospital or nursing home that wasn’t a patient or relative be a candidate? And what about their co-employees working out of their offices?

Still another concern, perhaps the most significant one, is that the guidance can be read to give the impression that providers can satisfy their screening obligations by conducting searches of the LEIE on a regular basis. The OIG might be satisfied with screening the LEIE on a regular basis, but such a screening protocol is unlikely to satisfy the various State Medicaid requirements or State regulations. For instance, approximately 38 states have their own sanction lists and providers are required that to check these state lists. Some States also require providers to certify that none of their employees or contractors have been “suspended, or excluded from Medicare, Medicaid or other Health Care Program **in any state!**”[8] Even the OIG’s advice that checks be done on a “regular” basis would be inadequate in most states, as CMS has directed State Medicaid directors to require monthly screening and most, perhaps all, have followed that directive.

II. Final Thoughts

Exclusion screening has clearly become a "front burner" issue for OIG. Providers should take note of OIG's broad interpretation of their obligations and of its inclusion in the Self-Disclosure Protocol. Providers also need to be aware of the regulations in their States which are typically more onerous that federal ones. Finally, while there are a number of difficult questions that don't have easy answers (such as, Who do I need to screen? Which databases do I screen? How can I accomplish screening? and How do I deal with contractors?), they are easier to deal with sooner rather than later, and they are dangerous to put off.

[1] The 2013 Bulletin "replaces and supersedes the 1999 Bulletin." Dep't of Health and Human Servs. Office of the Inspector Gen., *Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs*, 4 (May 8, 2013).

[2] Update to Self-Disclosure Protocol issued April 17, 2013, Dep't of Health and Human Servs. Office of the Inspector Gen.

[3] "This payment prohibition applies to all methods of Federal health care program payment, whether from itemized claims, cost reports, fee schedules, capitated payments, a prospective payment system or other bundled payment, or other payment system and applies even if the payment is made to a State agency or a person that is not excluded." *Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* at 6.

[4] The regulation authorizes CMPs under circumstances where a person making a claim:

"knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person."

While the regulation's reference to excluded persons seems clearly intended to clarify the circumstances under which CMPs would be applicable to false claims, the OIG's interpretation that it also authorizes sanctions for violations of the payment prohibition is accepted and rarely, if ever, questioned.

[5] *Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* at 15. The OIG recognizes that there is no federal requirement to check the LEIE monthly, recommends it. It also recommends that providers rely on the LEIE over other databases such as GSA-SAM and NPDB.

[6] *Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* at 15. Providers were also advised that they could rely on contractor screening, but that they would remain responsible for overpayment liability and CMPs if it failed to ensure that "appropriate exclusion screening had been performed." *Id.*

[7] *Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs* at 16.

[8] See, for example, Rule § 352.5 of the Texas Administrative Code which states:

Prior to submitting an enrollment application, the applicant or re-enrolling provider must conduct an internal review to confirm that neither the applicant or the re-enrolling provider, nor any of its employees, owners, managing partners, or contractors (as applicable), have been excluded from participation in a program under Title XVIII, XIX, or XXI of the Social Security Act.

An even more exacting obligation is found in Louisiana where provider agreements require applicants to certify that no employee is:

*"**not now or … ever been***: suspended or excluded from Medicare, Medicaid or other Health Care Program ***in any state***" or "**employed** by a corporation, business, or professional association that is ***now or has ever been*** suspended or excluded from Medicare, Medicaid or other Health Care Programs ***in any state***" (emphasis added).