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In search of: The excluded

By Martha Ann Knutson, JD, CHC

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So far in 2011, the Department of Health and Human Services Office of the Inspector General (OIG) has announced settlements with five different health care organizations for employing individuals who have been excluded from participation in the federal health care programs. The continuing occurrence of such settlements, after more than a decade of experience with the related requirements, suggests either confusion in the provider community about responsibilities related to exclusion or that the processes related to identifying the excluded in a timely way are so challenging that occasional non-compliance is inevitable.

What's the duty?

In 1981, OIG took over administration of the process for excluding and reinstating individuals, entities, or companies from participation in the federal health care programs (e.g., Medicare, Medicaid, Tricare, veterans programs, etc.). The penalty of either time-limited or permanent exclusion may be levied in addition to civil monetary penalties or as a stand–alone administrative sanction for certain missteps. Exclusion is mandatory in certain cases, permissive in many others, but generally the conduct that triggers it contains an element of fraud or misconduct relating to a federal program, controlled substances, or patient neglect/abuse.

Exclusion is not limited to direct care providers. Currently there are lawyers, accountants, billing companies, and the comptroller of a tribal organization on the exclusion list. Additionally, excluded individuals may still be licensed as health care providers, because the actions leading to exclusion may or may not constitute a basis for revocation under the law of the state that licensed them. However those who have been excluded may not, during their exclusion, submit claims to the federal health care programs.

Since passage of the 1997 Balanced Budget Act (BBA), it has also become important for those not excluded to know if they employ, credential, or contract with the excluded, because no federal health care program payment can be made "for any item or service 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."[1]

Put simply, if a non-excluded health care provider bills the federal government for items and services that meet these definitions, it can find itself subject to all the various potential penalties for false claims—including exclusion—if it "knew or had reason to know of the exclusion."

Defining the boundaries

It's pretty clear when a billable service is delivered to a patient by or under the "medical direction" of an excluded provider. But in most settings, defining who, besides direct care providers, "furnished" a particular service can be more challenging, and the regulations do not include a definition.

In 1999, OIG issued a Special Advisory Bulletin to provide "guidance" to both the excluded and those who might employ or contract with an excluded individual or entity.[2] The BBA prohibited contracts or employment of excluded individuals or entities "for the provision of items or services for which payment may be made under" a federal health care program.[3] In the Special Advisory Bulletin, OIG made it clear that it would take a broad view of who "provides" items and services. According to OIG, those

billing the federal health care programs may not employ excluded individuals to provide "administrative and management services that are not directly related to patient care" but are a "necessary component" of providing such care. Trying to give guidelines for the many possible relationships between individuals and health care entities, OIG provided a series of examples of prohibited non-direct care services:

- Preparation of surgical trays
- Review of care plans
- Inputting prescription information for pharmacy billing
- Selling, delivering, or refilling orders for durable medical equipment
- Processing claims for payment
- Accounting
- Utilization review

The common denominator in the examples is that the wages, benefits, or contract price of the individual or entity providing the service was paid, at least in part, by revenues from a federal health care program. Thus, excluded individuals can be employed—but only if (1) they are exclusively paid by non-federal sources of funds and (2) the services they provide relate solely to non-federal program patients. The Special Advisory Bulletin also suggests the Advisory Opinion process as a route for testing if a particular relationship would run afoul of this prohibition—an offer that two organizations and one individual have accepted in the past twelve years.[4]

Finally, OIG stated that the "knows or should know" language in the BBA created an affirmative duty on the part of health care providers to check the program exclusion status of those they employ and contract with, before initiating the relationship, "or run the risk of civil monetary penalties (CMP) liability if they fail to do so." The agency urged program participants to check its online List of Excluded Individuals and Entities (LEIE) before hiring or contracting and "periodically" thereafter.

The LEIE is not the limit of the background checking duties of most providers. Exclusion lists are maintained by other federal and state agencies, which may impose duties to check them. For example, it is frequently suggested that a search of the federal Excluded Parties List System (maintained at www.epls.gov by the General Services Administration) should be part of a prudent background investigation. Additionally, many state Medicaid programs maintain their own exclusion lists in various formats.

Working this out in practice

Those who have been in the Compliance field for more than a day or two realize that the biggest challenge with requirements like this isn't understanding the expectations—it is making them part of day-to-day operational reality. In other words, who is going to check, how often, and how can the organization be sure this has been done?

Organizational challenges

At least three, and possibly many more, organizational "players" are involved in an effective exclusion-checking process. The Human Resource department (HR) traditionally oversees the background checks completed before employment. That same function may or may not be responsible for the engagement of contracted staff who work through an agency arrangement. And HR usually has little interest in being responsible for subsequent checking. The office responsible for credentialing medical staff, employed or voluntary, also has a role. Those involved in contracting and the department that has control over the vendor list of those to whom payments are made, have seats at the table.

One or more folks from the IT area will need to participate at least in the initial process design. The Compliance department, of course, has an interest in the overall process being workable and appropriately documented so that from time to time, it can be

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tested. Legal resources may also be needed to draft contract expectations and remedies if the decision is made to rely, in whole or in part, on checks done by others.

Outsourcing the checking

Hiring someone else to check is one possible solution. Some vendors have packaged checking the OIG database with other pre-employment background checks of criminal and licensing records. That works for the initial check, but leaves the organization without expertise for the periodic follow-up checks. Outsourced checks are also often limited to those directly employed by the organization. What about the contractors and medical staff, volunteer board members, and agency staff? Someone (or maybe more than one individual) in the organization will still have to be responsible for periodically transferring the necessary data to the vendor and receiving the results of the check. It's very important to spell out responsibilities with the vendor in advance on what follow-up actions they—or you—will be responsible for taking when Dr. Smith or Nurse Jones looks like a "hit."

LEIE challenges

The database has more than 50,000 entries at present, with more than 1,700 of those added so far in 2011. The oldest entry dates back to 1978 (a physician from Lansdale, Pennsylvania—at least in 1978) and more than 2,700 of the entries relate solely to excluded businesses. Physicians are identified with the now defunct Unique Physician Identifier Number (UPIN) identifiers—and not the National Provider Identifier (NPI) numbers built into systems to be compliant with the electronic transactions standards over the past few years.

A backup verification system is on the website for double checking a possible name match with a Social Security number (SSN) or employer identification number (EIN), but first you have to find a "hit" based on the name.

So, say you want to enter into a contract with Metropolitan Ambulance and you search for that name on the list. You reassuringly won't find it—but, if previously the company was trading under Metro Ambulance, you might be contracting with an excluded provider. You cannot search the database by EIN or SSN, although doing so would greatly improve efficiency and the reliability of any match or pass finding. OIG can provide letters to non-excluded companies and individuals who have names similar to those appearing on the list. The non-excluded parties are happy to send you a copy of their OIG letter, but you have to first identify the issue and then find the person at the firm who knows about the letter.

Services provided on prescription
So, say a patient walks into your outpatient lab with a small white piece of paper torn from a physician prescription pad containing a handwritten (and signed) order for a complete blood count (CBC). The paper even contains a legible reason for the test. If you take the patient's blood, report the result to the physician, and bill the test to a federal health care program, did you violate your affirmative duty if it turns out that the ordering physician was excluded?

Reasonable compliance professionals can—and have—come to opposite conclusions on this one. Some argue that this is a service furnished "on the prescription" of an excluded provider and that, at a minimum, the program shouldn't pay. Others contend that unless the lab has either contracted with or employed the referring physician, there is no duty under the BBA to check for exclusion before submitting the claim. There is no written guidance at present from OIG on this point, although one presenter in the 2011 HEAT Provider Compliance Training sessions[5] suggested that such claims would not be reimbursable. (Another HEAT speaker confirmed that matters related to the exclusion responsibilities are the most frequent topic raised through the OIG self-disclosure process.)

At least one program safety contractor has taken the position that organizations do have a duty to screen for exclusion in such cases and not submit a claim for the service. (Following up to divert the next patient coming in with an order from the excluded doctor is yet another practical wrinkle.)

How often is "periodically"?
In the Supplemental Compliance Guidance for Hospitals,[6] OIG said that checking "routinely (e.g. at least annually)" was a mark of an effective compliance program. The same frequency has been used in more than one Corporate Integrity Agreement. Then in 2008, a letter issued to State Medicaid Directors set out an expectation that the Medicaid agencies would check the LEIE upon enrollment of providers and monthly thereafter. That monthly expectation is making its way outward in letters from those state agencies to providers as an expectation—greatly magnifying the "periodic" burden. More frequent checks, on the other hand, may mean less liability exposure for that person or contractor who somehow slips by in the initial check.

Stay tuned

In November 2010, OIG requested comments on the original Special Advisory Bulletin guidance, and received a few comments by January 2011.[7] For the most part, those comments focused on some of the practical issues discussed here. The comments also highlighted the need for a distinction in OIG's response to those providers who had a system to meet their affirmative duty and self-disclosed a failure of their system, and those who either didn't have an effective system or didn't self-disclose when they discovered an oversight. OIG is under no statutory obligation to issue additional guidance. So until it does, despite the ambiguities and challenges outlined here, the obligation still remains for each provider and supplier to have effective procedures to ensure that it doesn't and couldn't have known of an excluded provider in its midst. ■

1. 42 CFR § 1001.1901 (b)(1)
2. 64 FR § 52791ff (1999)
3. 42 USC § 1320a-7
4. See AO 07- 17, AO 03-01 and AO 01-06
5. HEAT Provider Compliance Training webcast, May 18, 2011, Washington DC. Available at http://oig.hhs.gov/newsroom/video.
6. OIG: Supplemental Compliance Guidance for Hospitals. January 2005. Available at http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf
7. All six are available at www.regulations.gov Docket ID HHSIG-2010-0003