Practical considerations for the voluntary disclosure process - Part 2

by Ryan Meade, J.D.

While it is well settled that a health care provider must return any overpayments it receives from federal health care programs, providers often experience considerable tension between what they know they must do (self-disclose the overpayment and return the money) and the fear of not knowing where the voluntary disclosure will lead. Every voluntary disclosure is different and it is true that the government could expand its investigation beyond the issues self-disclosed, but the process of disclosing and resolving issues tends to follow some general paths. There are also actions that providers can take before they ever need to undertake a voluntary disclosure that can ease anxiety at the time of the disclosure and put the provider in a better position when it makes a voluntary disclosure. A provider should anticipate that one day it will likely need to make a voluntary disclosure and begin preparing now by instituting an active auditing and monitoring plan as a pivotal component of its compliance program.

This article discusses the actual process of voluntarily disclosing and what providers can do to prepare for the seemingly inevitable day when the provider must voluntarily disclose an overpayment. Specifically, this article covers: 1) the process of making a voluntary disclosure to the various government agencies and Medicare contractors; 2) possible outcomes to the voluntary disclosure; and 3) lessons learned as to what a provider can do before a problem occurs in order to be in the best position if an issue needs to be self-disclosed. Part 1 of this article (see the October 3, 2005, issue, pg. 4), discussed the decision making process in preparation for a voluntary disclosure.

1. The process of making a voluntary disclosure

Voluntary disclosures are typically made to one of three entities: A) the Office of Inspector General (OIG) for the Department of Health and Human Services; B) the local United States Attorney's Office (the USAO); or C) the local Medicare contractor through its voluntary refund process. The voluntary disclosure process will be different for each possible recipient of the disclosure.

A. Disclosures to the OIG

The OIG published the Provider Self-Disclosure Protocol (OIG Protocol) in 1998, which provides detailed instructions on information that the provider should assemble and report when disclosing an overpayment and compliance issue to the OIG.[1] The OIG encourages the use of the OIG Protocol and has stated that this method will expedite the review process.

The OIG Protocol requires the provider to describe the compliance issue, the cause of the issue, estimate the amount of the refund as well as to provide additional information such as how the issue was identified, the corrective action to stop the problem from recurring and "the impact on, and risks to, health, safety, or quality of care posed by the matter disclosed."[2] The OIG Protocol encourages the provider to submit a written narrative to describe the issue and the surrounding facts. Any time a provider utilizes the OIG Protocol, the provider must carefully craft its response because the information the provider supplies will be used to determine whether a violation of law occurred and whether fines and penalties should be assessed. Providers should consider having legal counsel assist the provider in preparing the self-disclosure information under the OIG Protocol.

Significantly, the OIG Protocol insists that the provider need only use the process if there is a potential violation of law.[3] If the compliance issue resulted in a straightforward overpayment in which the provider believes that no laws have been violated, the overpayment should simply be sent back to the local Medicare contractor that paid the erroneous claims.

The determination of whether there has been a violation of law is easier said than done. Factors that may not look to the provider like reckless disregard for the truth of a claim [4] may appear so to a government regulator or to the Medicare contractors. Medicare contractors may refer to the OIG or the USAO voluntary refunds.

Consequently, when in doubt whether a law has been violated, it is often wise for a provider to err on the side of caution and disclose the matter to the OIG or USAO and advance an argument as to why the provider believes that no law has been violated. If

the facts are ambiguous or they could be easily misconstrued, then the provider should disclose to the OIG or USAO rather than to the Medicare contractor because the voluntary refund might be referred back to these enforcement agencies. However, the provider should consult its own legal counsel before making such decisions and determinations of potential liability.

Upon submission of the information under the OIG Protocol, the OIG typically assigns an OIG official to review the case and work with the provider to gather more facts. The additional information that government will ask for depends on the circumstances of the disclosure and how complete the information is that was submitted to the OIG. Common questions include clarifications of unclear facts in the narrative, the level of expertise of the people who managed the processes that produced the error, timelines related to the error and discovery of the errors, and samples of erroneously filled-out forms that could have led to the error.

The OIG may agree to hold a meeting or discuss the matter by phone and help the provider and the provider's counsel fine tune the documentation and information required by the OIG. If the provider already has a relationship with the OIG, the provider may find calling the OIG more efficient than simply following the OIG Protocol and submitting the documentation without notice.

B. Disclosures to the USAO

Providers also can choose to disclose to the local USAO. The attorneys in the USAO act as the lawyers for the United States and the various federal agencies that administer federal health care programs. The USAO is part of the federal Department of Justice and has independent authority to investigate health care fraud matters.

If a disclosure is made to the USAO, the process may proceed similarly to a disclosure to the OIG in that the prosecutor assigned to review the matter will ask for specific information and will likely have the provider or the provider's counsel put the facts surrounding the matter in writing. Both the OIG and USAO may conduct interviews of the provider's employees.

Most importantly, it is essential to cooperate with government requests. Of course, there may be times when the government officials go too far or request documents that are not relevant or germane to the issue. In such instances, legal counsel must have the appropriate discussions with the government to try to convince them to narrow the request. Requests from the government during a voluntary disclosure are reasonable, however, because the government generally realizes that the provider takes compliance seriously.

C. Disclosures to Medicare Contractors

The third option for disclosure is through the voluntary refund process that the local Medicare contractors (fiscal intermediaries or carriers) offer. This process usually requires the provider to complete forms that describe the reason for the overpayment and various other information. The voluntary refund forms typically require far less information than required through the OIG Protocol. The provider also may send a letter explaining the circumstances of the issue and how the overpayment was calculated.

Once the provider has sent the voluntary refund forms (as well as a check), it is difficult to predict the next steps that a Medicare contractor will take. The contractor will likely cash the check but the facts and the approach of the contractor determine to what extent the contractor will investigate or ask follow-up questions. Sometimes the contractor may disagree with the method used to calculate the overpayment and the provider will need to defend its approach. If an exact overpayment cannot be calculated and the provider must develop an estimate of the overpayment, it is important that the provider has thought through the estimate methodology before submitting anything to the contractor to be sure that the methodology is a defensible, reasonable approach that can be explained to the contractor should the contractor question the refund amount.

If the facts are such that the contractor believes that fines and penalties are required, the contractor could refer the matter to the OIG or USAO or to the local program safeguard contractor (PSC) for further investigation. A representative from the Medicare contractor may contact the provider directly to ask questions. There is also the possibility that the voluntary refund will ramble around the bureaucracy of the Medicare contractor for quite some time without the contractor even cashing the check until the matter is resolved.

In sum, the specific steps in the process can be unpredictable. In self-disclosing, the provider should be willing to cooperate fully with the government, be patient as to the time that it takes to investigate and resolve the issue, and prepare itself for the unexpected by aggressively auditing other areas.

2. Possible outcomes to the voluntary disclosure

There is always the risk in a voluntary disclosure that the government's investigation may move into areas not antici-

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pated by the provider or expand beyond the issue self-disclosed. The facts of the matter and the approach of the official will influence how this develops. There is very little way to control this risk other than the provider being sure that it has an active auditing and monitoring program so that if the investigation is expanded, it does not stray into areas the provider has not analyzed for risk.

A. A range of outcomes

The best outcome for a provider is if a refund is approved and the straight overpayment is returned without fines, penalties or interest. This outcome happens more frequently than providers realize. Penalties associated with the voluntary disclosure can range in severity. The lightest form of a penalty is the assessment of interest.

Certainly the most severe penalty that the government can impose (other than criminal sanctions and imprisonment) is exclusion from the Medicare Program. Voluntary disclosures often do not end in exclusion from Medicare if the provider cooperates and is sincere about correcting its errors. However, the OIG has the authority for permissive exclusion if it judges the circumstances to be very serious.

B. Corporate Integrity Agreement

If the government assesses penalties under the False Claims Act or the Civil Monetary Penalties Act, the most common resolution is for the provider to enter into a settlement agreement with the local USAO or Department of Justice and the OIG. In conjunction with a settlement agreement, the OIG usually requests that the provider enter into a CIA or a CCA.

When the OIG first began requiring CIAs as a condition of settlement it was in the context of using its leverage to exclude providers from the Medicare Program. As a condition for not excluding the provider from Medicare, the OIG offered a CIA as part of a settlement. CIAs have now become fairly common practice as parts of settlements and resolutions of suspected violations of the FCA. The OIG publishes the CIAs with the providers' names on its websites.

A CIA typically lasts from three to five years and involves strict timelines for bringing the provider's compliance program to a level the OIG believes is sufficient to control risk of false claims. A CIA usually will have a timeline for training employees, adopting new policies and performing audits and also usually requires independent review organizations to audit the provider at least annually and provide the report to the OIG. A CIA has severe penalties for any violations during the course of the term of the agreement. CIAs can cover the whole institution and all billing to Medicare or the CIA may be focused on the specific problem or department that gave rise to the issue.

C. Certificate of Compliance Agreement

Recently, the OIG has offered providers an alternative to a CIA. The CCA is considerably less onerous than a CIA and does not require an independent review organization to audit the institution. At its core, a CCA requires the provider to certify that the essential elements of its compliance program are maintained and that the specific problems that gave rise to the compliance issue are addressed. A CCA usually requires the compliance officer to certify the compliance program elements annually, as well as to submit an annual report that chronicles the overpayments received by the organization during the course of the year. There may also be certain material events that need to be reported to the OIG during the course of the year prior to the annual report. A CCA may also contain a declaration (by a senior administrator of the provider, such as the CEO) that the elements of the compliance program are in place at the time of the signing of the document and a commitment to maintain the current level of resources for the compliance program. Like a CIA, a CCA contains severe penalties for violating the terms. The OIG places some of its CCAs on its website. Providers with effective compliance programs should consider making the case that a CIA is not warranted and that a CCA is more suited to the situation.

3. Lessons learned: How to be prepared

When a provider needs to make a voluntary disclosure, it usually does not have time to pause and place everything in order within the organization, to do comprehensive audits and "look under every rock," so to speak. When the provider knows it has received an overpayment it must act to return the overpayment in a timely fashion. The provider usually cannot wait to be comfortable that there are no other issues that the government can find.

Consequently, it is absolutely critical that a provider have a good auditing and monitoring system in place. Instituting a comprehensive and active auditing and monitoring system not only helps to demonstrate that the provider has an effective compliance program, but provides the provider with information as to its risk exposure. Acting swiftly with a voluntary disclosure is less worrisome when the organization has been auditing and monitoring its risk and maintaining its compliance controls.

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1 63 Fed Reg. 58399, October 30, 1999, (see ¶156,019).
2 Id. at 58401-58402.
3 Id. at 58400.
4 Reckless disregard for the truth of the claim is one of the standards available to the government to argue in support of fines and penalties for violations of the federal False Claims Act, 31 USC §3729, (see ¶10,120).