Fraud and abuse compliance is an increasingly important issue for medical group practice administrators and physician executives. Due to the complexity and dynamic nature of the health care regulatory environment, compliance violations are nearly inevitable. Recognizing this, well-managed practice groups will have procedures in place to ferret out violations. When a practice discovers an incident of noncompliance, it has an opportunity to act before the government or a whistleblower takes the problem out of its hands.

This article examines a potent tool for managing the risk associated with such incidents: the Department of Health and Human Services Office of Inspector General (OIG) Self-Disclosure Protocol. In appropriate cases, notifying the government of your organization’s error can mitigate the potentially catastrophic consequences of a fraud and abuse violation.
Pros, cons to disclosing your group’s mistake

The OIG protocol is intended for matters that may involve potential fraud against federal health care programs. It’s not meant to cover mere inadvertent billing errors or Medicare overpayments, which can be handled through other avenues, such as reporting to the Medicare contractor. Nor is it intended for Stark Act violations, unless the same conduct implicates the Anti-Kickback Act, as well. Most self-disclosures involve fraudulent overpayments, billing/coding violations, transgressions of the antikickback act or Stark law, or the hiring of excluded individuals. Even when the protocol applies, the decision to use it requires careful investigation, evaluation, judgment and the assistance of legal counsel.

Self-disclosure has both benefits and risks.

Benefits of self-disclosure

On the benefit side, the OIG encourages self-disclosure, and it may be more lenient toward providers who follow the protocol. For instance, if the OIG settles the matter, it may base its settlement offer on a financial impact assessment at the lower end of the available range by looking at antikickback damages (based on the value of the improper payments or remuneration) rather than Stark damages (based on the value of improper claims). It may also reduce the multiplier it applies to the financial impact assessment.

Also, following the protocol may avoid the presumptive imposition of a corporate integrity agreement or corporate compliance agreement that could otherwise burden your practice with costly oversight obligations for years to come.

Self-disclosure gives your organization a chance to gain control over the situation and cast the disclosed incident in a manner that avoids misunderstandings by the government.

Risks of self-disclosure

On the other hand, self-disclosure entails substantial risks. The protocol provides no guarantees of leniency, immunity or benefits. In fact, the OIG may deny all benefits if it perceives that your practice has not followed the protocol in good faith or in a timely manner. Further, resolving issues through self-disclosure can be expensive and disrupt daily operations and employee morale. Making a self-disclosure can trigger investigation by the OIG, other agencies or potential civil litigants. Moreover, providing information to the government may create waiver issues related to the attorney-client privilege and work-product protections.

In appropriate cases, notifying the government of your organization’s error can mitigate the potentially catastrophic consequences of a fraud and abuse violation.

Other disclosure considerations

Other issues may be relevant to the disclosure decision, including:

- The strength of the evidence of intent to defraud. Is there evidence of recklessness or deliberate indifference?
- The likelihood of a whistleblower coming forward;
- The strength of the compliance program;
- The likelihood of criminal exposure; and
- Whether disclosure should be made to the OIG or another agency/entity.

Make your self-disclosure decision in a timely manner to avoid losing the benefits. For example, the False Claims Act states that providers who effectively self-disclose within 30 days of obtaining information about a violation may limit their damages to double rather than triple.
**What to do – Five steps**

You need an action plan for your practice to support the decision-making and self-reporting process. With the assistance of legal counsel, design the plan around five steps:

- Define the scope of the transgression;
- Preserve relevant documents;
- Investigate;
- Remedy; and
- Audit.

*Define the scope* – To determine the scope of the issue, your group’s legal counsel or counsel’s delegate should interview the source of the internal report and other central witnesses. Often, this initial effort uncovers additional allegations. This is helpful to avoid the discovery of other issues after the initial disclosure, necessitating supplemental disclosures. A close examination of documents may also be necessary to better understand the scope of the allegations.

*Preserve relevant documents* – You must secure relevant documents as soon as your organization receives notice that a federal investigation may take place — or risk criminal prosecution. Cast a wide net: Preserve both hard-copy and electronic files. Ensure that e-mail and other electronic data are not inadvertently destroyed through regular purging cycles. In appropriate cases, qualified forensic experts may make copies of your hard drives to preserve electronic evidence. Depending on the size of your practice, you may have to distribute a memo to employees instructing them not to destroy relevant documents and data.

*Investigate* – The OIG protocol requires a complete investigation of a fraud-and-abuse disclosure. A thorough investigation can be costly, but it’s far better for your practice to undertake than to wait for the government to conduct its own investigation. The investigation will usually pick up where the initial “define the scope” inquiry left off and then focus on the details of the incident. Anyone allegedly involved should not have a role in the investigation, which should be directed by legal counsel.

*Remediate* – Remediation is critical to successful self-disclosure. The facts of each case will drive the remediation plan, but most remedial efforts aim to:

- End the noncompliant conduct (including taking appropriate disciplinary action);

A convincing audit is important to demonstrate that your group has remediated the problem and eliminated the need for the OIG to continue external oversight through a corporate integrity agreement or corporate compliance agreement.
• Improve procedures, policies, controls and systems; and

• Train members of the practice in appropriate conduct.

Remediation may also include refunding payments to the fiscal intermediary or others. The protocol, however, states that the OIG should approve any such refunds.9

Audit – Taking remedial action alone is not enough; your group also must demonstrate that the action was effective. An audit will document the impact of the remediation. Depending on the circumstances, you may want to consider hiring a consultant to conduct the audit to provide the OIG with an independent assessment. A convincing audit is important to demonstrate that your group has remediated the problem and eliminated the need for the OIG to continue external oversight through a corporate integrity agreement or corporate compliance agreement.

Resolution

The self-disclosure process is not a speedy one. Anecdotal evidence suggests that, in the past, only about half the disclosures were resolved within a year from filing. The OIG announced its intention to resolve disclosures more promptly in its April 15, 2008, Open Letter to Providers. As part of that initiative, the OIG established new deadlines requiring more timely action by those making disclosures.

Self-disclosure normally ends through settlement. The size of the settlement depends on numerous factors, including whether the financial impact on Medicare is measured by the low or high end of the range, the size of the multiplier applied to the financial impact number and whether a corporate integrity agreement is involved. Also, depending on the allegations and the scope of the release desired, agencies other than the OIG may get involved in the settlement, which can affect the terms.

An effective tool against fraud and abuse

As of mid-2008, the OIG protocol had accepted 379 disclosures of Medicare fraud and abuse. Of those, 165 were resolved, returning more than $118 million to the Medicare Trust Fund. Since then, the rate of recovery has accelerated, with total recoveries most likely reaching or exceeding the $200 million mark. With the additional guidance provided in the OIG Open Letters of April 24, 2006, and April 15, 2008, the provider community appears increasingly interested in using the protocol. Applied appropriately, self-disclosure offers an effective tool to mitigate compliance risk for medical groups confronting potential fraud and abuse violations.

join the discussion: Has your organization voluntarily disclosed a fraud-and-abuse incident to the OIG? Tell us at mgma.com/connexioncommunity or connexion@mgma.com

notes

5. This article is limited to the OIG protocol and does not discuss self-reports to others such as fiscal intermediaries, the United States Attorney General’s office or state Medicaid Fraud Control Units.
9. See Protocol at 58,403.