On The Front Lines

# Practical considerations for the voluntary disclosure process - Part I

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*The easiest part of a voluntary disclosure of a Medicare compliance issue is, in theory, deciding whether to do one. Federal law is clear that if a provider receives funds not owed to it, then the money must be returned.[1] Period. End of story. But theory gets a little tarnished when mixed up with anxiety of the unknown, the provider's internal politics, the fear that a voluntary disclosure may expose the provider to an investigation broader than the issue disclosed, and nervousness over public embarrassment in disclosing an error. Before the voluntary disclosure is actually done, organizations go through the same mix of emotions that any human being goes through when that person needs to admit a mistake.*

Providers can survive voluntary disclosures. If the facts of a compliance issue are bad, then sometimes a voluntary disclosure may actually be the only thing that saves a provider. The government has also expanded the options for resolving self-disclosed compliance problems that include less onerous outcomes than a Corporate Integrity Agreement.[2]

This article focuses on voluntary disclosures of federal health care program overpayments because they are quite distinct from voluntary disclosures of other substantive compliance errors. For instance, there is arguably no obligation to disclose mitigated compliance problems involving the Anti-kickback Statute or the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA)

For convenience, this article refers generally to Medicare overpayments, though any federal health care program[3] can be substituted for "Medicare" as the government payor.

Part 1 of this article will discuss 1) the "big picture" of voluntary disclosures; 2) figuring out what to disclose; 3) the need to identify whether a billing error is random or systemic before making a voluntary disclosure; 4) what to do leading up to a disclosure; and 5) deciding what government agency or Medicare contractor is the appropriate recipient of the voluntary disclosure. Part 2 of this article will appear in the next issue and will cover: 6) the process of making a voluntary disclosure to the various government agencies and Medicare contractors; 7) possible outcomes to the voluntary disclosure; 8) lessons learned on 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.

Since there is very little information published and available to compare outcomes and approaches to voluntary disclosures, much of this article draws on the author's own experience in helping a number of providers work through voluntary disclosures. Providers should consult their own attorneys when assessing liability and embarking on the path of a voluntary disclosure.

## 1. The "Big Picture" on voluntary disclosures

It may be helpful to start at the end, making the voluntary disclosure. There are essentially three ways to do a voluntary disclosure: 1) utilize the Provider Self-Disclosure Protocol published by the Office of Inspector General ("OIG") for the Department of Health & Human Services;[4] 2) disclosure to the provider's local United States Attorney's Office ("USAO"); or 3) submission of a voluntary refund to the provider's local Medicare contractor (fiscal intermediary or carrier).[5]

Disclosure to the OIG and the local USAO not only facilitates the provider's obligation to return overpayments but also will enable a resolution on the government's position on liability for fines and penalties.[6] Disclosure through voluntary refund to a Medicare contractor will likewise fulfill the provider's obligation to return overpayments but it will not resolve potential fines and penalties. The Medicare contractor may refer the voluntary refund to the OIG or the local USAO for an assessment of liability for fines and penalties and the provider could still end up dealing with the OIG or USAO.[7] This is a risk in making a voluntary refund through a Medicare contractor, yet at the same time, it seems unnecessary to use the OIG or USAO route if the overpayments disclosed to the Medicare contractor are small and random.

Each voluntary disclosure needs to be judged on its own facts and involves a case-by-case determination as to the best approach. Though the OIG recommends that providers only need to self-disclose overpayments to the OIG that are the result of likely

violations of law,[8] a provider may want to undertake a voluntary disclosure to the OIG or USAO if the matter is a "borderline" case and the provider has a good argument as to why the provider should not be subject to fines and penalties. If the provider is fairly confident that due to the facts, size and circumstances, submitting a voluntary refund to a Medicare contractor would be referred to the OIG or USAO anyway, then disclosing directly to the OIG or local USAO may save time in resolving the provider's lingering anxiety over potential fines and penalties and may put the provider in the best light with the OIG or USAO.

## 2. Figuring out what to disclose

As mentioned above, if a provider receives an overpayment related to reimbursement from the Medicare Program, the provider must return the money. This obligation exists whether the overpayment was the result of a mistake by the provider or a mistake by the Medicare contractor.

When undertaking a voluntary disclosure, the two principal things that need to be determined are the scope of the problem and the cause of the problem. The scope of the problem revolves around whether the errors are random or systemic, and if systemic, then why the errors occurred. The cause of the problem should be identified as human negligence, purposeful error, a process error, software error, or other explanations. The interplay of the scope and the cause may affect to whom the provider discloses and the eventual resolution.

The steps of the internal investigation should be carefully documented because it will be important in the voluntary disclosure and any subsequent government inquiry for the provider to establish that it undertook a quick response to suspected compliance issues.

## 3. Identifying random billing errors versus systemic billing errors to determine the scope of the problem

Before a voluntary disclosure is undertaken the scope of the billing problem needs to be determined because this will influence which government agency or Medicare contractor to disclose to and impact the liability analysis.

Generally, billing errors can be considered random errors or systemic errors. The concept of "random errors" versus "systemic errors" is not necessarily used by all government personnel charged with enforcing Medicare compliance, nor are these terms written into the law. These terms represent concepts that the author has used to think through the scope of a billing error and attempt to identify what errors the provider has "knowledge" of. Other attorneys, consultants and compliance personnel may utilize different concepts that may be helpful to a provider's particular circumstances.

A random error occurs for no known reason. In other words, its root cause cannot be identified. The error could have occurred due to as simple of a mistake as transposing numbers or a physician mixing up pre-labeled encounter forms and thereby assigning the wrong codes of services on an isolated day. Any number of things can cause random errors. Yet, errors are still errors and any resulting overpayment must be returned to the Medicare Program, but if an error is truly random, then it is difficult for the provider to determine if or when the error occurred in other instances. When random errors are small and the provider has exhausted its ability to figure out why the errors occurred, the provider might decide, with the assistance of counsel, that its repayment obligation extends only to the actual errors identified in the sample because it has no ability to determine when or if the error repeated itself outside the sample.

Systemic errors are entirely different from random errors. As the term implies, a systemic error is when an erroneous claim was systematically generated whenever certain circumstances occurred. Whenever X occurred, then Y always happened.

As an example of a typical systemic error, if a hospital's chargemaster was coded so that the charge capture service was mapped to the wrong revenue code, then every time the service was performed and "charged" on the front-end, an erroneous claim would have been generated. When a chargemaster is coded incorrectly, it is by necessity a systemic error because the chargemaster process is mechanical and systematic.

Likewise, if a physician misunderstands a billing rule and each time applies the rule incorrectly, that is a systemic error. If a physician believes that office E & M codes are chosen solely on the basis of time, then in every instance of the physician choosing a code, the wrong criteria will be used, even if occasionally the physician accidentally codes the service correctly.

There are as many ways to have a systemic error as there are processes used by a provider.

The key fact about systemic errors is that the provider knows that they happened whenever certain circumstances occurred, even if the provider does not have actual knowledge of every instance of an overpayment. In cases of systemic error, the provider is said to have "constructive knowledge" of the errors and overpayments, so even if the provider does not specifically know that what is being done is generating an incorrect bill, the government will treat the provider as if it did. From the government's perspective of enforcing the law and assessing fines and

penalties, constructive knowledge is no different from actual knowledge.

When a provider identifies a systemic error, the obligation to repay and self-disclose runs as far back as the error began or the length of the statute of limitations, whichever is earlier. Under the federal False Claims Act, the statute of limitations is six years and in certain circumstances, the government can exercise the ability to extend the statute of limitations to ten years.[9]

While there can be much debate over whether a provider has received an overpayment (arguing over interpretation of a legion of ambiguous billing rules or trying to determine whether the identified errors are random or systemic), once a provider determines - and *knows* - that it has received an overpayment, the obligation to return the overpayment is triggered.[10]

## 4. What to do leading up to a voluntary disclosure

The provider has a small window of time between determining that an overpayment exists and needing to make its voluntary disclosure. Perhaps the most important thing that a provider should do once it knows it has a systemic error is place a bill hold on the claims that are subject to the systemic error. Once a bill hold is in place, then a deeper investigation of the cause of the problem should be undertaken.

### A. Bill holds

Ideally, a systemic error would be fixed immediately and not interrupt the claims process, but this rarely occurs. Fixing systemic errors can sometimes be as easy as changing a code in a computer program, but more often than not systemic errors require modification of behavior, operational changes, training, auditing, and perhaps even re-training before the systemic error can be fixed.

The reason it is important to quickly place a bill hold on claims involved in an erroneous process is because once a provider knows that erroneous claims have been submitted pursuant to a systemic error, then the provider also knows that when the same circumstances occur again, then the same error will occur. If the provider has knowledge of a systemically erroneous process and the provider allows erroneous claims to be submitted knowingly, the provider may cross into a dangerous liability zone and could be accused of acting with specific intent to defraud the Medicare Program.

Placing bill holds on erroneous claim processes once the systemic error is known is perhaps the single most important action a provider can take to protect itself from the most serious fines and penalties. Putting on a bill hold shows a quick response to an identified problem, one of the hallmarks of an effective compliance program.

It is important to note that placing a bill hold on certain claims does not mean that the services should cease being provided nor does it mean that the services will not eventually be billed. Rather, it provides temporary breathing room to make sure the organization is not intentionally sending out inaccurate claims while it fixes the problem that is causing errors.[11]

It is critical for managing legal risk and showing a commitment to compliance that a bill hold be implemented as quickly as possible after learning of a systematic problem. As Part 2 will discuss in resolving the underlying issue of a voluntary disclosure, a bill hold can be one of the determining factors in whether the government is convinced that the provider has an effective compliance program and is serious about "doing the right thing."

While systemic errors necessitate bill holds if the systemic problem cannot be immediately corrected, sometimes situations of random errors should receive bill holds as well. This would occur in instances in which the provider conducted a statistically significant sample of claims and the findings identified random errors. Statistically significant samples can be viewed as providing constructive knowledge of billing errors in the universe of claims from which the sample is derived.

Though a billing review could yield a random error rate of five percent for example, if the sample is statistically significant, then the review arguably provides knowledge of five percent errors across the universe of claims even if the provider cannot identify why the errors occurred.

If there is no systemic problem that can be addressed to minimize the risk of erroneous claims, but the provider has a statistically significant sample showing random errors, then the provider should place the subject area on bill hold and conduct training of the personnel or practitioners responsible for submitting claims. The personnel should be audited until a successful pass rate is achieved and then the bill hold can be lifted.

### B. Investigating the cause

After a bill hold has been placed on the subject claims, the provider should try to understand as many facts related to the problem as the provider can. This usually necessitates conducting interviews with people.

For example, if the chargemaster problem is quickly identified as a software problem that needs technical code changes, the Compliance Officer should gather facts on who is responsible for maintaining the software, when the software was last updated, how long the problem has been going on, whether any documents exist discussing changing (or not changing) the codes in the chargemaster, and what institutional or departmental policies exist governing the maintenance of the chargemaster.

As another example, if the underlying problem involves an erroneously drafted encounter form (perhaps it is missing codes and leads the physician to upcode routinely), then the Compliance Officer should identify who developed the form, how long the form had been used, what the form looked like before the current one was drafted, who approved the

erroneous form, and any other facts surrounding the development, use and oversight of the encounter forms for the physician's practice.

Facts surrounding the compliance issue are important because the potential liability turns on the facts. The False Claims Act does not impose penalties for mere technical billing errors or even negligent billing errors. Billing errors are subject to False Claims Act liability only when an erroneous claim is submitted with the provider having one of the following levels of "knowledge": 1) actual knowledge of the erroneous information in the claim; 2) acts in deliberate ignorance of the truth or falsity of the information in the claim; or 3) acts in reckless disregard of the truth or falsity of the information in the claim.[12]

The facts surrounding the issue to be voluntarily disclosed are critical because if the facts fit into the second or third level of knowledge, then the provider could be subject to civil fines and penalties. If the facts support the first level of knowledge, then technically the provider could be subject to civil fines and penalties under the False Claims Act but it may be more likely that the government would consider potential criminal sanctions due to the purposefulness of the error.

Conversely, if there are no facts to support specific intent to submit an erroneous claim, then that should be emphasized during the voluntary disclosure in order to avoid a potential criminal investigation. If the facts support an argument that the issue did not arise because of deliberate intent to defraud, reckless disregard or acting in ignorance of the truth, then there may be an argument that can be presented during the voluntary disclosure that the provider is not subject to False Claims Act liability at all.

The facts can instruct the provider as to the appropriate recipient of the voluntary disclosure. When there is clearly no violation of law, the facts may suggest that the appropriate entity to disclose to is the Medicare contractor through a voluntary refund.

## 5. Making the voluntary disclosure

The first days or couple of weeks of a compliance investigation can be very intense. The Compliance Officer needs to understand the scope of the problem and the cause of the problem quickly because if a voluntary disclosure needs to be made, the provider should make the voluntary disclosure as soon as possible after gathering the critical amount of facts.

Usually the total overpayment need not be quantified at the time of the voluntary disclosure if the self-disclosure is made to the USAO or OIG. In fact, it is rare to be able to quickly identify the full amount of the refund needed. What is most important is that the provider has determined what the problem is, placed a bill hold on any similar claims being submitted to the Medicare Program, and has a sense of whether there is a potential violation of law. If the provider can easily determine that there is no violation of law and that the errors are simply technical errors, then the provider should as quickly as possible quantify the overpayment and utilize the voluntary refund process for the applicable Medicare contractor.

Deciding whether to disclose to the local USAO or the OIG is a trickier matter. If there are any potential criminal implications, then a provider's attorney may advise that the self-disclosure be made to the local USAO, since the USAO and the Federal Bureau of Investigation (FBI) will likely take the lead in investigating any criminal matters associated with the issue. If the local USAO is already working with the provider on other compliance matters or unrelated issues and has developed an understanding and knowledge of the provider, then voluntary disclosure to the local USAO may be the best course for a provider to take, even if the facts do not suggest criminal exposure. If there is no current interaction with the local USAO and the facts do not suggest criminal liability, then a provider's attorney may advise disclosure directly to the OIG. The OIG's Provider Self-Disclosure Protocol promises a speedy review and resolution to the issue.[13]

To whom the provider makes the voluntary disclosure will be a case-by-case decision, which the provider should carefully review with its legal counsel. The totality of the facts should be considered and whether (and what type of) legal liability may be at risk for the provider.

The timing of the voluntary disclosure is important and can also be a critical factor in the government's decision on how to resolve the issue. The False Claims Act strongly encourages self-disclosure within 30 days of identifying the compliance issue.[14] As we shall see in Part 2 of this article, a timeline that shows a quick response and action can weigh heavily in the government's decision-making.

When the provider makes a voluntary disclosure, the ideal set of facts the provider should have on hand is:

- When the issue was first identified
- When a bill hold was placed on the subject claims
- The scope of the overpayment (random versus systemic, when did it begin, etc.)
- The cause of the overpayment
- A corrective action plan that proposes how the provider will continue to maintain compliance and quantify the overpayment

Of course, there may be circumstances that necessitate a voluntary disclosure before all of the above are neatly assembled and ready for presentation to the government. If there is a threat of a whistleblower or the matter is extremely serious, then the provider and its counsel should consider making the voluntary disclosure with all due haste and present a plan to the government for quickly assembling the full facts of the problem.

Part 2 of this article will appear in the October 17, 2005, issue and will discuss the process for making a voluntary disclosure to the various entities as well as possible resolutions.

1 A variety of federal laws can be invoked identifying an obligation to return government money not owed to a person or entity. The most common citation for this obligation with respect to federal health care programs is 42 USC §1320a-7b(a)(3).

2 Part 2 of this article, appearing on October 17, 2005, will discuss the OIG's Certification Compliance Agreements.

3 42 USC §1320a-7b(f) (see ¶16,445).

4 63 Fed. Reg. 58399, October 30, 1998 (see ¶156,019).

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[5] This article considers a voluntary refund to a Medicare contractor to be a type of voluntary disclosure. As will be discussed in more detail in Part 2 of this article, most Medicare contractors' voluntary refund forms require the provider to state a reason the provider received the overpayments.

[6] When referencing fines and penalties associated with overpayments or submitting billing errors, this article will focus on liability under the federal False Claims Act, 31 USC §3729, et seq (see ¶100,006).

[7] CMS Medlearn Matters #MM3274, July 30, 2004: "Providers need to be aware that the acceptance of a voluntary refund as repayment for the claims specified in no way affects or limits the rights of the federal government, or any of its agencies or agents, to pursue any appropriate criminal, civil, or administrative remedies arising from or relating to these or any other claims."

[8] The OIG has stated: "Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity (e.g., a contractor such as a carrier or an intermediary) that processes claims and issues payment on behalf of the Government agency responsible for the particular Federal health care program (e.g., HCFA [(CMS)] for matters involving Medicare)," 63 Fed. Reg. 58400, October 30, 1998.

[9] 31 USC §3731(b).

[10] It is important to note that not all billing errors produce overpayments. This article discusses situations in which an overpayment occurs. It is beyond the scope of this article to discuss the legal status of billing errors that do not produce overpayments.

[11] The way a bill hold is placed on claims and the specific claims that should be held is beyond the scope of this article.

[12] 31 USC §3729(b).

[13] 64 Fed. Reg. 58400, October 30, 1998.

[14] 31 USC §3729(a)(7)(A).

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resolution. But he would let states affected by the hurricane opt out of reforms enacted by Congress.

A number of witnesses at the House hearing were apprehensive about aspects of pending recommendations. One witness for the American Association of Retired Persons (AARP) was especially critical. Byron Thames, a member of the AARP's board of directors, testified that the AARP has serious concerns about making poor people pay higher co-pays. He warned that "even small increases in cost sharing requirements can very quickly add up to create significant barriers to necessary care."

On improper asset transfers, Thames acknowledged there are legitimate concerns about the practice. State loopholes should be closed, he said. But Thames added that some proposed changes now under consideration -including extending the "look-back" period from three to five years - could hurt innocent people who are not trying to "game the system."

Thames cautioned against proposals that would require older homeowners to use their home equity to fund long term care. He objected to certain "program flexibility" proposals, including ones that would place caps on federal funding to states through block grants and per capita caps.

*CCH Washington Bureau, September 8, 2005*

## Correction:

In Vol. 8, Issue 19 of the Health Care Compliance Letter (see page 3) "Concealment and false statements net two convictions" should have read "Indictments for concealment and false statements stand." At the time of this publication, the defendants in *United States v. Dose* have not been tried for the indictments discussed in the article.