Medicare compliance: We found a witch!

By Mark A. Bonanno

Editor's note: This article was written prior to April 15, 2008, when the U.S. Department of Health and Human Services Inspector General issued an Open Letter to Providers. Please note that the April 15 Open Letter to Providers explains that the OIG has streamlined its internal process for resolving these cases. In turn, the OIG will expect providers to complete their disclosure and damages assessment within three months from the time of acceptance into the Self Disclosure Protocol and expect full cooperation from disclosing providers during the verification of the matter disclosed.

According to the Open Letter, providers who disclose in good faith, fully cooperate with OIG, and provide requested information in a timely manner will generally not be required to enter into Corporate Integrity or Certification of Compliance Agreements with OIG.

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In a comedic scene in the 1975 movie *Monty Python and the Holy Grail*, a group of villagers accused a woman of being an evil witch and wanted to burn her at the stake. Acting out of fear, the villagers dressed up the woman like a witch by putting witch-like clothes on her, a witch-like hat, and a witch-like nose, just before bringing her to the knight who oversaw the village. During an on-the-spot trial, the knight ordered her to be placed on a large set of suspect weighing scales located in the village center. She weighed the same as a duck, and was therefore, judged to be a witch. As the legal logic went, a duck floats and so does wood. Witches, apparently, are made of wood, so if the woman weighed the same as a duck, she must be made of wood, and therefore, (you guessed it) she must be a witch. The woman never had a chance at a fair trial – at least one that she could have afforded.

What does this movie scene have to do with Medicare compliance? Very little, but it is a humorous story to lead off about a not-so-funny scenario in health care today. Like the poor woman in the *Holy Grail*, individuals may be accused and judged guilty of Medicare fraud by colleagues who may be acting out of fear and misinformation regarding fraud and false claims. If the individual eventually is brought before a government official, the private accusation that preceded any official public evaluation, creates a difficult—if not impossible—task of resolving the actual legal issues correctly.

The purpose of this article is to explain a procedure known as the Provider Self-Disclosure Protocol; highlight the difference between fraud, false claims, and overpayments; and discuss a hypothetical scenario that is similar to the scene from the *Holy Grail*. Afterward, some practical guidance is offered for organizations and individuals caught up in the confusing world of health care billing investigations.

So how would a health care provider, such as a physician, become threatened with the proverbial burning at the stake, like the woman in the movie from 1975? To start to answer that question, we have to go back in time again, but only to 1998.

The protocol

Shortly after the federal government's expansion of health care anti-fraud initiatives arising out of a program known as Operation Restore Trust[1] and the beefed-up anti-fraud provisions in the Health Insurance Portability and Accountability Act of 1996[2] (HIPAA), the Department of Health and Human Services Office of Inspector General (OIG) issued guidance on a new Provider Self-Disclosure Protocol in 1998 (Protocol).[3] The published intent of the Protocol was to facilitate the resolution of matters that potentially violate federal law and not to address matters involving overpayments or errors that should be brought to the attention of the Carrier or Fiscal Intermediary (that is, the insurance company hired to process claims for the federal government).[4] The Protocol set forth procedures for providers to follow in submitting their written disclosures of the matters, including a statement about why the provider believes federal law may have been violated.[5]

On its surface, the Protocol sounded nice and protective. And, in certain situations, it probably would be nice and protective. Nevertheless, what was missing from the Protocol was a roadmap of how voluntary disclosures would be evaluated by the OIG. In fact, the OIG specifically stated that it would not be bound by any findings made by the provider, and it was not obligated to resolve the matter in any particular manner.[6]

Another significant problem was that the discretion to file under the Protocol was left to the provider, whether it was a larger health care entity or an individual. Such an approach set up the potential consequence that health care organizations like hospitals would act akin to federal prosecutors and judges in both pointing a finger at an alleged perpetrator and assessing whether fraud may have occurred in their institutions. In that scenario, where a larger corporate entity attempted to scapegoat an individual, the use of the Protocol might

end up being abusive and devastating for both parties, especially in situations where the alleged fraud or false claims could be explained rationally as billing mistakes or even a negligent understanding of the billing rules.

If the Protocol is rushed to as a defensive tool for a larger entity, it could end up being a trap for the unwary. In fact, one piece of information that should be discussed more openly at seminars is the potential result that once providers file under the Protocol, they tend to box themselves into monetary settlements that start at roughly two times the amount of the alleged damages. Why? The answer is almost a "just because" answer, and it is tied back to the underlying legal basis for the Protocol.

When a provider files its disclosure, the OIG General Counsel's Office assumes that the provider, not necessarily someone who works for the provider, is admitting it may have violated federal law, namely the False Claims Act and other federal statutes, such as the Civil Monetary Penalties Law where the penalty for violations can be double or triple the amount of the actual damages.[7] Further, what the effect of any admission made under the Protocol does is subject the provider to the whim of the OIG in assessing its full range of penalties, which could include exclusion from participation in the federal health care programs.[8] And, exclusion—the true hammer of the OIG—is potentially a business or career-ending threat.

Fraud, False Claims, and Overpayments

Given that backdrop, we need to review some federal laws and the legal meaning of the words "fraud," "false claims," and "overpayments."

Fraud. Probably due to highly publicized, multi-million dollar settlements and government press releases about health care fraud perpetrators going to jail, there may be a perception that any improper payment in health care is a crime. That is a false perception. In fact, the government acknowledges:

> [T]here appear to be significant misunderstandings within the physician community regarding the critical differences between what the Government views as innocent "erroneous" claims on the one hand and "fraudulent" (intentionally or recklessly false) health care claims on the other. Some physicians feel that Federal law enforcement agencies have maligned medical professionals, in part, by a perceived focus on innocent billing errors. These physicians are under the impression that innocent billing errors can subject them to civil penalties, or even jail. These impressions are mistaken.[9]

Such an acknowledgement might provide some comfort to the vast majority of providers who just do their work, submit bills for services through a complex insurance-based payment system, and hope they got the rules right, but the impression that tripping up—just once—can lead to serious problems is not unfounded.

Many federal statutes criminalize bad conduct in the health care industry.[10] For most of the statutes, however, the state of mind a person or corporate entity must possess is that they knew what they were doing was wrong and they purposefully went ahead and did it anyway. In other words, someone actually is plotting and scheming about a way to steal money from the government. Does that really happen? Yes, fraud happens. But, do most health care providers intentionally set out to bilk the federal government? Doubtful.

Government prosecutors will state publicly that ignorance of billing rules is no defense or that the rules are clear simply because they are published on the Internet, but that is one view of the world. If a billing rule takes not only legal counsel but highly trained billing experts to figure it out, something is not quite right with the rule. Are billing rules complicated? Sometimes they are, and sometimes they are a moving target.

The federal Anti-kickback Statute is an example.[11] That law generally makes it a crime to bribe providers for their referrals. The actual language of the statute encompasses not only offers or payments for referrals but also solicitation or receipt of any remuneration for those referrals. Remuneration is a broad concept and includes anything of value, not just cash.[12] Potential application of the law is extremely broad. As the joke goes at seminars, "Are free pizzas to physicians at a hospital function illegal?" And, the lawyerly response is: "Potentially, if they are intended as an inducement for those physicians to refer their Medicare or Medicaid patients." While that is meant as a light-hearted anecdote, the law does affect many financial arrangements in health care.

Given the potential for endless application, the OIG promulgated a series of regulatory exceptions known as "safe harbors."[13] If a transaction follows an applicable safe harbor, it should be protected from prosecution. If a transaction comes close to a safe harbor, however, but is slightly off one or more elements, it is not necessarily illegal, but it will not get safe harbor protection. In addition to safe harbors, the OIG issues periodic "advisory opinions" to requestors, asking if their particular arrangement will be prosecuted as a kickback.[14] The answer only applies to the requestor, but the OIG makes the opinions available for public review. As such, advisory opinions further refine the OIG's stance on particular arrangements. Therefore, knowing precisely which transactions work, and which do not, is by no means

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crystal clear. There are lawyers that devote much of their entire practice to understanding and advising clients about the kickback and other health care fraud and abuse laws.

The point here is that compliance with Medicare rules can be a highly complex process. For that very reason alone, most billing problems of the average health care provider are not fraud, but something far less criminal.

False claims. The main statute federal prosecutors use to enforce health care billing issues is the civil version of the federal False Claims Act.[15] The nice thing about the statute from the government's perspective is that it not only provides for increased monetary damages (up to triple the amount of the overpayments), but a separate monetary penalty of up to $10,000 for each claim that is declared to be improperly filed.[16] In short, seemingly minor billing problems quickly can be turned into big dollar cases under this statute.

For example, a former in-house lawyer for a health care company was sued under the statute in 2007.[17] The lawyer apparently had signed two pieces of paper (known as certifications) that were required to be filed with the OIG and stated that to the best of her knowledge, her company was in compliance with federal law.[18] The government later found out that the company had potential Stark Law violations that, if proved, would have amounted to about $18 million in overpayments. Federal prosecutors filed a False Claims Act suit against the lawyer as an individual, arguing that her signing those two pieces of paper caused 70,000 false claims to be presented to the Medicare program. As a result, the total monetary penalty she faced was $754 million (or $18 million times 3 = $54 million … plus 70,000 claims times $10,000 per claim = $700 million). This an unusual case and novel legal theory for the government, but the point is that the False Claims Act is a powerful and fear-instilling tool in the anti-fraud arena.

The other danger for health care providers is that the statute permits folks with knowledge about potential false claims to bring whistleblower or *qui tam* lawsuits against the provider as though they were federal prosecutors.[19] For their role in the case, the whistleblower (known legally as a relator) could receive around 25% from any monetary judgment or settlement.[20] Typical whistleblowers might include a billing clerk or compliance officer who knows that many claims are not being filed properly or not being refunded if overpayments are detected.

This introduction to the False Claims Act probably sounds dreadful. In light of that dread, a question that gets asked frequently by health care providers is whether all claims submitted to Medicare that result in overpayments are false claims. The answer is an emphatic "no." A true false claim is one that you sort of had to know was false. In legal jargon, to be found guilty of filing false claims, the person either "actually knew" about, "deliberately ignored," or "recklessly disregarded" the falsity of the claim.[21]

What is "knew" or "knowingly"? The accused person must have actual knowledge that the information being presented to the government is false. Generally, this standard means that the person must be more than negligent in their understanding.[22]

What is deliberate ignorance? Well, think about a person who digs a hole in the sand, puts their head in it, and covers up their head, but somehow manages to go about their merry business of filing complex health care claims.[23]

What is reckless disregard? Here, think about a medical office manager who was told by a Medicare Carrier staff person to obtain proper billing numbers for the office providers, even though that meant more paperwork, but that manager went ahead and billed without proper numbers because the paperwork was too burdensome to do right away.[24]

In short, the main thing to take away from these legal terms is that the False Claims Act requires something more than mere negligence on the provider's part in the submission of Medicare claims.

Another more legally complex issue under the False Claims Act is the concept of causation or who actually caused false claims to be submitted for payment.[25] If you are treating a Medicare patient, deciding what codes to put on the claim form, filing out the claim form, and putting the paperwork in the mail (or rather, hitting the send button on the computer), in all likelihood and legally, you caused that claim to be submitted to the federal government. You are potentially on the hook for false claim liability if you knew the billing code you put on the claim form was a level or two higher than the level of service you knew you provided to the patient.

If, however, you work as an employee in a clinic and you treated a patient, filled out paperwork on the services provided, gave that paperwork to a billing staff person who is employed at the clinic, and waited for your salary-based paycheck to be direct-deposited into your bank account, there is a open-ended legal question about whether you caused that claim to be submitted to the government. Notably, that claim was not prepared by you, you may not have seen the actual coding put on the claim, the coding could have been changed by someone other than you, the claim was submitted by the clinic, and the list goes on. In short, causation can be a legal gray area.[26]

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Those are some nuances about the False Claims Act. The take home message: Overpayments are not always false claims.

Overpayments. If you have billing problems, you hope they are overpayments. In a legal sense, overpayments are payments that result from mistakes in claim processing. Notably, overpayments could even be the result of negligence in how your claims are processed. For further explanation, let us turn to the actual words of the OIG.

Periodically, the OIG issues compliance guidance for various organizations involved in health care claims submission, such as hospitals, third-party billing companies, and physicians. In 2000, the OIG issued guidance for individual and small group physician practices.[27] Specifically, the OIG stated this about erroneous claims that could lead to overpayments:

> [U]nder the law, physicians are not subject to criminal, civil or administrative penalties for innocent errors, or even negligence. The Government's primary enforcement tool, the civil False Claims Act, covers only offenses that are committed with actual knowledge of the falsity of the claim, reckless disregard, or deliberate ignorance of the falsity of the claim. The False Claims Act does not encompass mistakes, errors, or negligence. The OIG is very mindful of the difference between innocent errors ("erroneous claims") on one hand, and reckless or intentional conduct ("fraudulent claims") on the other. For criminal penalties, the standard is even higher—criminal intent to defraud must be proved beyond a reasonable doubt.
>
> [E]ven ethical physicians (and their staffs) make billing mistakes and errors through inadvertence or negligence. When physicians discover that their billing errors, honest mistakes, or negligence result in erroneous claims, the physician practice should return the funds erroneously claimed, but without penalties. In other words, absent a violation of a civil, criminal or administrative law, erroneous claims result only in the return of funds claimed in error.[28]

Not much more really needs to be said. Overpayments happen. Someone even may have been negligent in allowing overpayments to happen. None of that should amount to fraud or false claims liability.

To review, the problem with using words like "fraud" or "false claims" in health care is that those words mean something, and therefore, the words should not be used in a careless manner. Too often, billing staff, administrators, consultants, and even legal counsel engage in the "oh, my goodness" panic response when bad billing issues are first discovered. That initial response sets the wrong tone in an organization and makes it very difficult to resolve matters correctly and sanely.

The private sector must stop thinking "crime" and "fraud" when billing issues are first detected. That accusation is for the government to make. Instead, the private sector must focus on correctly identifying the issue (which is the most difficult part of any internal investigation) and appropriately developing a corrective action plan.

With the legal jargon explained a bit more, we still need a better understanding of how the Protocol works.

The Village and Dr. Goodwitch

Perhaps an example will help, so we will look at Village Surgical Group, PC (the Village), a professional corporation that operates as a unified group practice made up of a large number of physicians, let's say 25 surgeons.

Dr. Ima Goodwitch is one of the surgeons. She is a Type A personality, in the hospital at 6:00 a.m., booked for procedures and patient visits all day, and leaves the hospital in the early evening. Like a lawyer, Dr. Goodwitch believes if she works all day, she should be billing all day. She is good at recording her work day, but she has a loose understanding of coding from what was learned long ago in her early training. Nevertheless, she is prompt with her paperwork and turns it all over to the in-house administrative staff back at the Village so she can put it out of her mind. The Village gathers the paperwork and turns it over to a third-party billing company that prepares and processes the claims. All billings go out under the Village's tax identification and group number, but Dr. Goodwitch is paid basically on an "eat what you kill" basis, with a percentage retained for the billing company and the Village administration. This is a fairly common scenario so far.

One day, however, the Village administrator creates a new policy that all Village surgeons will be subject to retrospective claim reviews as part of a brand new compliance plan (the Plan). A retrospective review means that claims already have been processed and payment has been received by the group. In contrast, a prospective review would look at claims that have been coded by the provider but are awaiting submission for payment. If problems are detected in a prospective review, the claims could be corrected prior to submission to avoid potential overpayment situations. According to published OIG recommendations, a sample of five claims will be reviewed and critiqued annually.[29] On paper, this policy does not sound too burdensome and should be fairly benign. The surgeons think nothing of it, approve the Plan, and let the administrator get to work.

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The administrator engages the biggest law firm in town, Billem & Milkem, hires a compliance officer, Jill Papermaker, and starts to build a very thick Plan manual.

In the first year of the Plan, Jill conducts all of the claim reviews herself. She notes the billing mistakes and other issues, such as poor handwriting seen in charts. She sends out a round of rather threatening letters to all of the surgeons, explaining their mistakes and that they need to do a much better job before the next claim review. Along with Jill's review letters, she included a copy of the Plan policy manual that contained over 100 new policies for the Village. Each surgeon had to sign and return an acknowledgement form stating that they read and understood the manual. Paychecks would be held back by the Village until the signed notices were sent back.

With respect to Dr. Goodwitch's review letter, Jill explained that one of the five claims reviewed needed better documentation to support the use of an evaluation and management services (E/M) code known as "modifier -24." There was no further explanation, other than a reference to the new policy manual and a citation that read "Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.6."[30] Upon receipt, Dr. Goodwitch skimmed the review letter, stared at the policy manual on its edge to assess the thickness of it, and tossed both in her to-be-filed-away pile (one of about 20 such piles her in cramped office). Not wanting to delay her paycheck, she immediately signed the acknowledgement form and dropped it in Jill's office mailbox.

Dr. Goodwitch just assumed she had to make better chart notes to support modifier -24. She had been told by an attending, during her residency training, that you have to get into the practice of documenting and billing for your entire day because medicine, like it or not, was a business. In other words, when you see a patient, you find a way to bill for the service. She thought this was just a matter of fairness and sticking to a routine coding process day after day, year after year, to maximize her reimbursement for her work. She had heard about issues such as billing for services not performed, upcoding (intentionally billing for a more expensive service or higher E/M code than the one actually rendered[31]) and clustering (coding/charging one or two mid-levels of codes exclusively, under the philosophy that the undercharges and overcharges will average out over an extended period[32]), but those practices were bad billing in her book. (Had she taken the time to read the citation in the 2007 Medicare Claims Processing Manual that Jill referenced, Dr. Goodwitch would have seen that E/M services provided by the same physician to surgical patients during the relevant postoperative period, if covered under a global surgical package, are not separately billable unless they are unrelated to the surgery.[30])

In the second year of the Plan, a newly hired coding expert, Jack Stickler, did the next round of claim reviews. Like Jill, he also noticed on one of Dr. Goodwitch's claims that modifier -24 may not have been used correctly to bill for an E/M visit in the hospital a few days after a patient's surgery. Jack decided to investigate the matter and called Dr. Goodwitch.

"Eight months ago, you billed for an E/M visit with Mrs. Lancelot, one of your Medicare patients. Why did you do that?" asked Jack.

"I do not really remember," Dr. Goodwitch responded truthfully. She added: "I am guessing that I billed it that way because my routine practice, I learned a while back, was to use the -24 code so I could bill for the E/M visit when patients came back complaining of pain after surgery."

Jack panicked in response to what Dr. Goodwitch relayed to him. He told Dr. Goodwitch: "You cannot bill for E/M visits after surgery. That is fraud!"

Dr. Goodwitch just thought Jack was too green at his job and did not think much of his comment. She responded: "What are you talking about?"

Jack was flustered. He said: "I will have to get back to you."

Jack took his claim review information to the Village administrator and said they should call their law firm right away. The Village administrator agreed. After a telephone conference, the corporate lawyer said he would think about the situation and get back to them. A few hours later a lengthy legal memo was faxed to the administrator with instructions to do a much larger audit on Dr. Goodwitch's claims. Jack jumped right on the new project because he knew exactly what days Dr. Goodwitch generally saw patients after surgeries and was able to amass a fair number of claims that used modifier -24.

Jack's findings soon made their way around the Village. After multiple closed door meetings in the administrator's office with the corporate lawyer as well as the employment lawyer, the judgment was that Dr. Goodwitch was fraudulently billing for her services. Use of the "f word" (fraud) immediately spread around the Village and chaos erupted.

The other Village surgeons started calling the administrator and were angry about Dr. Goodwitch and wanted her fired immediately. The administrator said they could not do that right away and had to be careful because they did not want a lawsuit for wrongful termination. She added that they needed to build an airtight case against Dr. Goodwitch.

To build such a case, the Village called a board meeting and asked Dr. Goodwitch to attend and explain herself. At the meeting, Dr. Goodwitch admitted she may not fully understand modifier -24. She added that if she made mistakes, she was sorry, and she would help correct problem claims. The administrator asked Dr. Goodwitch to leave the meeting so the rest of the Village could discuss the matter in private. Somewhat bewildered, Dr. Goodwitch got up and left.

As soon as the conference room door closed behind her, one surgeon angrily spouted: "See, we got her. She admitted she misused modifier -24. I would never use that modifier incorrectly."

Jack added: "Yeah, I bet it goes back a long way."

There was an uncomfortable silence. The corporate lawyer impulsively chimed in: "Well, we need to contain the problem, and we will do that. I have some ideas which I will let you know about shortly."

The next day another very long legal memo slid out of the Village fax machine. Rather than take any chances, the lawyerly decision was made to do another really big audit and look for any claims over the past six years where Dr. Goodwitch used modifier -24. To figure out how much money was at stake, an assumption was made that all of the claims should be labeled "bad" claims rather than do any analysis to see whether properly billed claims existed. Another lawyerly decision was made to report Dr. Goodwitch under the OIG's Protocol without telling her, because the lawyer stated it would be the only way to protect the Village and prevent Dr. Goodwitch or others from becoming whistleblowers under the False Claims Act.

The Village members were mentally rowdy and jubilant when they finally reported the matter to OIG, because they felt they had found a way to protect and distance themselves from Dr. Goodwitch and her alleged evil ways. Or, at least they thought they did.

While this all sounds like a campy 1970s movie, the unfortunate and likely outcome of the above tale is that the OIG would extract monetary settlements from and impose integrity agreements upon both the Village and Dr. Goodwitch. Why? Well, that is another "just because" matter.

Even though The Village and Dr. Goodwitch may not have committed fraud, the goal for the OIG under the Protocol, at least to the outside observer, is to settle cases and get noncompliant providers locked into federal agreements that make it easier for the OIG to keep an eye on the compliance and noncompliance of the provider. This outcome may be true, even if an independent analysis of Dr. Goodwitch's post-surgical services revealed that the bulk of the services were properly billed. Again, if the goal is settlement and a provider like the Village voluntarily comes forward with money in hand, there may be little incentive to undertake a detailed and balanced review of a matter.

Disclosures of potential overpayments under the Protocol are pretty much "found" money, so there is no need for the OIG to spend a large amount of resources picking apart the logic and numbers behind a disclosure. Further, under a settlement, no party admits any wrongdoing. And, in today's world, where defense costs could be well into the six figures to fully adjudicate a matter, sometimes a guaranteed settlement is the low cost and saner option, especially if the amount in controversy under the federal programs is not even six figures itself.

A Discussion

So, is there anything that can be done to avoid this type of tale?

For the Village. If you are in a position similar to the Village, find counsel who understands the nature of the Protocol and how to properly analyze the Village's, not necessarily Dr. Goodwitch's, legal obligations.

One key mistake, seen above, is to assume the billing problems of Dr. Goodwitch stand on their own and that having the Village file under the Protocol means only Dr. Goodwitch will be investigated and penalized. This assumption is not true if the Village is the actual billing entity that causes the third-party billing company to file claims. Like it or not, the billing problems belong to both Dr. Goodwitch and the Village. And, if the Village files under the Protocol, it would be admitting that it (the Village) may have violated federal law, not Dr. Goodwitch.

In a large group like the Village, a solid analysis of the problem from the group's perspective is essential. This is difficult when the staff and surgeons of the Village get fearful and angry about Dr. Goodwitch. An independent and objective analysis is highly recommended because a review by insiders, including longtime corporate counsel, may be tainted by individuals seeking to cover their own mistakes, misunderstandings, or even negligence.

For example, if Dr. Goodwitch is the only group member with billing problems compared to the other 24 surgeons and each surgeon bills about the same number of claims, that means, at most, 4% of the claims being billed by the group have potential problems. And, if a focused retrospective review of the problem is done correctly with as much credit given to the surgeon as possible, that error rate

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may be far less than 4% for the group. From a health care fraud and abuse perspective, an error rate of less than 4% hardly seems like a fraud issue for the group and likely is not a false claims issue either, especially if the group caught the problem and Dr. Goodwitch agreed to cooperate with a corrective action plan.

Notably, the group might have been negligent in allowing the problem to have gone on for so long, but even the OIG has acknowledged that mere negligence is not a false claim and certainly is not fraud.[33] Use of the Protocol, therefore, must be carefully considered, because the Village should not be admitting to something it does not have to admit, simply out of fear and anger.

From a practical perspective, keeping the matter on the administrative and Carrier side of the Medicare world likely will save the group tens of thousands, if not hundreds of thousands, of dollars in defense costs associated with the Protocol. In the above example, the Village might have inquired about their Medicare Part B Carrier's voluntary refund process (usually found outlined on the Carrier's Web site). Typically, if the Village can demonstrate that it correctly identified and rationally responded to the problem, a voluntary refund might be part of a reasonable alternative to the Protocol. Should the Village make such a decision without the benefit of seasoned counsel or at least a consulting phone call to such counsel? Probably not.

The other more serious aspect to Protocol filings is the likely result that OIG will impose on the Village, and potentially the Villager, either a Corporate Integrity Agreement (CIA) or a lighter version of a CIA known as a Certification of Compliance Agreement (CCA). Neither a CIA nor CCA, however, are gold stars by any means, because they are documents (actually contracts with the federal government) that tell you how to run your business, give the government reports on your business, and open the door to periodic government site visits.

Traditionally, site visits were planned events and touted as meetings to assist with compliance, rather than formal investigations. But, the low-key nature of site visits may have changed. In 2007, OIG indicated that it will conduct unannounced site visits for some CIA and CCA parties.[34] This not-well-published news was an unfortunate change in OIG's practice, because surprise site visits likely mean that OIG will be using the visit as an ongoing investigative tool, rather than an educational tool.

Regardless of a planned or unannounced site visit, government personnel are just people too. Does the Village really want an OIG attorney randomly selecting a Village staff member to grill them about compliance? While the average attorney or physician might be used to intense face-to-face questioning, the average staff person likely is not, and could be emotionally affected by the event.

Notably, on April 15, 2008, OIG posted another in a series of open letters to health care providers about the Protocol.[35] In the letter, OIG indicated that if a provider has adopted effective compliance measures, it generally would not require a disclosing provider to enter into a CIA or CCA as part of a settlement with OIG. Because there is so little public information available about the Protocol, it is difficult to know if the latest open letter signals a major change in how OIG will resolve voluntarily disclosed matters. Until more public information is available about the outcome of settlements under the Protocol, providers still should carefully consider whether the Protocol is the proper response to take as part of their corrective action plan to correct identified compliance issues.

In short, the Village needs to obtain calming, level-headed counsel who understands the trappings of the Protocol as well as cost-effective, compliant, and perhaps more reasonable alternatives to the Protocol.

For the Villager. If you are being labeled a witch like Dr. Goodwitch, find counsel who not only understands the Protocol, but knows how to go about contacting the right individual within the government to get a proper dialogue going as early as possible. By the time the Village has filed under the Protocol, however, it may be too late. Most documents filed with OIG would be shielded from disclosure. Even attempts to obtain copies of documents under the Freedom of Information Act[36] may take too much time and money to pursue and might set the wrong tone with OIG.

As the Villager, again, the cost of defense easily could get into the hundreds of thousands of dollars. Some professional liability policies may have endorsements that cover the cost of defense in a governmental investigation regarding billing matters. But, those endorsements tend to limit the cost of defense to an unrealistic figure such as $15,000 or $25,000. Check to see if the Village has some type of errors-and-omissions policy that provided coverage for the Village as well as the Villager.

Unlike the Village, even if Dr. Goodwitch merely was negligent in her billing, she could face the real threat of not only losing her billing rights with Medicare, if excluded, but her license to practice medicine with the state medical board. In short, she could lose her livelihood. This is another reason why use of the Protocol is potentially abusive and devastating when used as a sword against an individual and as a shield for a larger corporate entity.

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The potential problem with state medical boards is that billing issues tend to be reviewed and judged by other physicians who are not necessarily billing experts. Furthermore, Dr. Goodwitch's hands may be tied by state public record laws that prevent her from getting enough information prior to formally contesting any alleged statutory violations.[37] Without such information, she will be unable to engage in a meaningful dialogue with the board.

Another potential issue Dr. Goodwitch may face regarding state medical practice acts would be instances where regulatory definitions are broader than statutory terms. For example, state medical practices acts generally call for disciplining physicians who engage in "unprofessional conduct" versus outright "fraud." Logically, one would assume that the burden of proving fraud, normally considered a crime, is higher than the burden of proof for unprofessional conduct, which generally is treated like negligence or repeated negligence. Nevertheless, some medical boards have amended their administrative regulations that further define the statutory term "unprofessional conduct" to include the term "fraud." In other words, if a physician enters into a settlement agreement with a medical board and admits to general unprofessional conduct to resolve a case that is about negligent billing, he or she inadvertently could be admitting to fraud if the underlying regulation is broader than the statute. (Whether such a practice by a medical board is legitimate or even constitutional is beyond the scope of this article.)

By the time Dr. Goodwitch gets invited to any investigative meeting of the board, the board members already may be visualizing a fraudulent witch. Depending upon how badly the Village may have dressed up Dr. Goodwitch, she may find herself working her way up from a very dark hole. The challenge for Dr. Goodwitch when she goes before a state medical board is to be as cooperative as possible without rolling over.

During the course of her employment, if Dr. Goodwitch started hearing words like "fraud" and "Protocol" and "OIG" when members of the Village addressed her, she should start documenting her work day and the steps she took personally toward compliance. She should seek legal counsel familiar with the issues, and understand that if the Village does act out of fear and anger, more than one attorney or law firm may be necessary. The potential legal fronts that a target like Dr. Goodwitch may face likely are alien and mind-boggling to the layperson. Dr. Goodwitch may need an attorney who is familiar with health care laws, an employment lawyer, insurance defense counsel, and litigation counsel.

In addition to legal counsel, the most important asset on Dr. Goodwitch's team will be a billing consultant who understands the unique aspects of the specialty area billed by Dr. Goodwitch. These folks are hard to find, because competence in the billing trade requires knowledge of the particular codes for that particular medical specialty. Many billing issues are not well understood by administrators, attorneys, and government officials, because the issues are so detailed and complex. A competent billing consultant will be valuable in explaining the facts regarding potential problems.

In short, Dr. Goodwitch needs an advocate and possibly an entire legal team, depending upon how much fear and anger exist in the Village.

Conclusion

In sum, both the Village and the Villager need to think carefully about responding to allegations regarding Medicare fraud and potential use of the Protocol. The Village needs to be careful to avoid turning an overpayment case into a false claims case when it does not have to do so. The Villager needs to get an advocate in her corner to try and help her remove the witch nose, hat, and clothes put on her by other Villagers. Remember, the Protocol was designed to deal with real witches, not dressed up ones. ■

1 Statement on Initiatives to Combat Medicare and Medicaid Fraud Pub. 1 Pub. Papers 632 (May 3, 1995).
2 Health Insurance Portability and Accountability Act, Pub. L. 104-191, §§201-250 (1996).
3 See Publication of the OIG's Provider Self-Disclosure Protocol, 63 F.R. 58399 (Oct. 30, 1998) (hereinafter "Protocol").
4 Protocol, 63 F.R. 58400.
5 Protocol, 63 F.R. 58401.
6 Id.
7 See 31 U.S.C. 3729 (setting forth the potential penalties under the False Claims Act which call for double rather than triple damages where a person cooperates with a government investigation); and 42 U.S.C. 1320a-7a (describing the potential penalties under the CMPL which call for up to triple damages); see also 42 C.F.R. 1003.106 (discussing mitigation of damages under the CMPL and setting a floor of double damages for certain false claims violations).
8 42 U.S.C. 1320a-7.
9 See OIG Compliance Guidance for Individual and Small Group Physician Practices, 65 F.R. 59434, 59436 (Oct. 5, 2000).
10 See, e.g., 18 U.S.C. §287 (false, fictitious or fraudulent claims); 18 U.S.C. §669 (theft or embezzlement in connection with health care); 18 U.S.C. §1035 (false statements related to health care matters); 18 U.S.C. §1341 (frauds and swindles); 18 U.S.C. §1343 (fraud by wire, radio, or television); 18 U.S.C. §1347 (health care fraud); 18 U.S.C. §1518 (obstruction of criminal investigations of health care offenses); and 42 U.S.C. §1320a-7b (criminal penalties for acts involving federal health care programs).
11 42 U.S.C. §1320a-7b(b).
12 42 U.S.C. §1320a-7b(b).
13 See 42 C.F.R. §1001.952.
14 See 42 U.S.C. § 1320a-7d(b) (setting forth the statutory authority granted under HIPAA to the Secretary of the Department of Health and Human Services for issuing written advisory opinions).
15 31 U.S.C. § 3729.
16 31 U.S.C. §3729(a).
17 United States v. Sulzbach, No. 07-61329 (S.D. Fla. filed Sep. 18, 2007).
18 Complaint at 2, United States v. Sulzbach, No. 07-61329 (S.D. Fla. filed Sep. 18, 2007).
19 31 U.S.C. § 3730(b).
20 31 U.S.C. § 3730(d).
21 31 U.S.C. § 3729(b).
22 See, e.g., Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1053 (8th Cir. 2002) (stating that the standard for liability under the False Claims Act is knowing—not negligent—presentation of a claim); and U.S. v. Prabhu, 442 F. Supp. 2d 1008, 1028-29 (D. Nev. 2006) (stating that the False Claims Act knowledge standard does not extend to honest mistakes but only to lies); see also David E. Matyas & Carrie Valiant, Legal Issues in Healthcare Fraud and Abuse: Navigating the Uncertainties § 4-2(a)(2) (American Health Lawyers Ass'n 3d ed. 2006).
23 See, e.g., United States v. Lorenzo, 768 F. Supp. 1127, 1132 (E.D. Pa. 1991) (finding that dentist deliberately knew that information on claim forms was misleading); see also Matyas & Valiant, supra note _, at § 4-2(a)(2)(i).
24 See, e.g., United States v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001) (finding that managing director of clinic acted in reckless disregard of Medicare requirements by failing to ensure proper billing numbers were used by the clinic); see also Matyas & Valiant, supra note _, at § 4-2(a)(2)(ii).
25 See 31 U.S.C. § 3729(a)(1) and (2).
26 Compare United States v. Krizek, 111 F.3d 934, 942 (D.C. Cir. 1997) (stating that where a physician had delegated to his wife the authority to submit claims on his behalf, he was no less liable than his wife for false submissions), with United States ex rel Kinney v. Hennepin County Medical Center, 2001 WL 964011 (D. Minn. 2001) (stating that admitting physicians who medically certified the necessity of ambulance runs did not cause false claims to be presented by the hospital because the physicians did not delegate to the hospital the authority to submit claims, they did not have control over the content of the claims submitted, and they did not have a right to review the claim forms being submitted).
27 OIG Compliance Program for Individual and Small Group Physician Practices, 65 F.R. 59434 (Oct. 5, 2000) (hereinafter "Guidance").
28 Guidance, 65 F.R. 59436.
29 Guidance, 65 F.R. 59437.
30 See generally Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.6, §40.1.A, §40.2.A.7.
31 OIG Guidance, 65 F.R. 59439.
32 In reality, this overcharges some patients while undercharging others. OIG Guidance, 65 F.R. 59439.
33 Guidance, 65 F.R. 59436.
34 OIG Will Engage in Unannounced Site Visits to Ensure Compliance with CIAs, Health Provider Alert, Crowell & Moring (April 27, 2007).
35 Daniel R. Levinson, An Open Letter to Health Care Providers, Dept of Health and Human Services, Office of Inspector General (April 15, 2008).
36 5 U.S.C. §552.
37 See, e.g., ORS 677.190(1) (unprofessional conduct); and O.R.S. §677.190(21) (making a fraudulent claim). See, e.g., O.A.R. §847-010-0073(1)(b)(D).