CCH Health Care Compliance LETTER

Volume 8, Issue 20 health.cch.com October 3, 2005

Submission of Articles. Requests for information about article submission guidelines should be sent directly to Andra Popa at popaa@cch.com.

Comments? Please direct any questions or comments regarding articles appearing in the newsletter to the e-mail address above.

Please see health.cch.com for up-to-date information on steps Congress and CMS are taking following Hurricane Katrina.

OIG and CMS shift thinking on gainsharing

by Paul Danello, J.D., Health Care Practice, Ropes and Gray

Gainsharing has a long history, reaching back to the 1930's in manufacturing industries, as a technique to motivate workers by allowing them to participate in the success of a given enterprise. In health care, gainsharing is an arrangement by which a hospital gives physicians a share of any reduction in the hospital's costs for patient care attributable in part to the physician's efforts. A gainsharing program typically involves a sharing of the cost savings achieved by the hospital through some combination of a percentage payment, an hourly fee, or a fixed fee to the physician.

As far back as 1991, the Health Care Financing Administration (HCFA) [now CMS] launched the Medicare Participating Heart Bypass Center Demonstration Project (to test the feasibility and costs savings potential of paying hospitals and physicians a single fee for all services related to coronary artery bypass graft procedures). In lieu of separate Part A and Part B payments to the hospital and physician, respectively, HCFA paid a global rate that was less than the sum of the applicable Part A and Part B payments. (The hospital and physicians were allowed to split the global payment under any agreed to methodology.) The demonstration project was a success. For a 4-year period, in which four hospitals participated, savings to the Medicare program were estimated at $40 million. Additionally, the mortality rates for these cases decreased at the participating hospitals.

The Office of Inspector General's (OIG's) issuance of a Special Advisory Bulletin ("SAB") in July 1999, however, appeared to preclude gainsharing arrangements. Issuance of OIG Advisory Opinions 00-2 (April 18, 2000) (see ¶500,043) and 01-1 (January 18, 2001) (see ¶500,053) indicated that, at least under certain circumstances, gainsharing arrangements could satisfy the OIG's fraud and abuse concerns. Issuance of OIG Advisory Opinions 05-01 (February 3, 2005) (see ¶500,123), 05-2 to 05-4 (February 17, 2005) (see ¶500,124; ¶500,125; ¶500,126), and 05-5 to 05-6 (February 24, 2005) (see ¶500,127; ¶500,128) will likely lead to renewed interest in gainsharing arrangements.

Nature of gainsharing by hospitals and physicians. Gainsharing programs seek to align incentives of physicians and hospitals by giving physicians a stake in hospital savings achieved by modifying physician behavior to control costs and increase margins on hospital business. Gainsharing programs typically include features to safeguard quality of care and control malpractice liability exposure. Details of ongoing gainsharing and pay-for-performance programs throughout the country are provided by The Leapfrog Group, the National Quality Forum (NQF), the National Committee for Quality Assurance (NCQA), the Agency for Healthcare Research and Quality (AHRQ), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Typical gainsharing programs include a payment to physicians to develop, implement, assess, and refine best practices in the physicians' specialty. Some program designs call for

an incentive payment in the implementation phase only; others include both a fee for oversight and redesign functions as well as an incentive payment tied to achievement of the program's goals. Some typical gainsharing models would include:

- cost management contracts by which a hospital contracts with physician to undertake defined responsibilities that relate to controlling facility costs;
- department management contracts by which a physician group or individual physician is hired either to manage the overall operations of a given department or to provide more limited management services;
- cost per case methodologies by which a hospital defines its baseline costs per individual case and then contracts with specifically identified physicians to reduce costs; and
- joint ventures by which physicians have an equity position in the entity responsible for delivering or managing the delivery of health care services.

OIG Advisory Opinions. In OIG Advisory Opinions No. 05-2, 05-3, 05-4, 05, and 05-6 the OIG once again favorably reviewed proposed gainsharing programs in which a hospital would share with a group of cardiologists and cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures. The only difference between these opinions and Advisory Opinions 05-1 and 01-1 is the cost saving recommendations suggested.

In OIG Advisory Opinion 05-2 and 05-5, the arrangement between the hospital and the cardiology groups sought to implement cost reduction measures in certain cardiac catheterization laboratory procedures. The suggested eighteen recommendations sought either product standardization or to limit the use of certain vascular closure devices to an "as needed" basis.

OIG Opinion 05-3 had recommendations almost identical to those found in Advisory Opinion 05-1 with the twenty-nine recommendations falling into four categories: (1) opening packaged items only as needed, including components of the cell saver unit, (2) performing blood cross-matching only as needed, (3) substitution of less costly items for items currently in use, and (4) product standardization. One important distinction between the recommendations in 05-3 and other opinions is that in 05-3 the recommendations identified substitutions that had no appreciable clinical significance.

OIG Advisory Opinion 05-4 evaluated an arrangement between a hospital and eight cardiology groups, which sought cost savings through product standardization, limiting the use of certain vascular closure devices to an "as needed" basis and substitution of items.

The arrangement in Advisory Opinion 05-6 presented recommendations falling into four categories: (1) opening packaged items only as needed, including components of the cell saver unit, (2) limiting the use of certain surgical supplies to an "as needed" basis, (3) substitution of less costly items for items currently in use, and (4) product standardization.

After reviewing the recommendations, the OIG again found all the recommendations in the arrangements constituted Civil Monetary Penalty ("CMP") violations, with the exception of the unopened surgical tray items recommendations and the substitution recommendations in Advisory Opinion 05-3 and 05-6, which the OIG did not consider CMP violations because the recommendations were of no clinical significance. The OIG used the same analysis as it used previously and decided not to issue sanctions, despite the violations. Additionally, the OIG found the recommendation created the same anti-kickback concerns as in OIG Advisory Opinions 01-1 and 05-1, but again did not issue sanctions.

Current status of gainsharing arrangements. Providers considering whether to enter into any gainsharing program of the type proscribed by the OIG in the SAB should seek experienced legal counsel in structuring the arrangement and evaluate whether to seek Advisory Opinions from OIG under the Anti-Kickback Statute and CMP Law and from CMS under the Stark Law. Providers can use the guidance set forth in OIG Advisory Opinion Nos. 05-01 (February 3, 2005), 05-2 to 05-4 (February 17, 2005), and 05-5 to 05-6 (February 24, 2005) in structuring gainsharing arrangements.

Note that Advisory Opinions 05-1 to 05-6, like Advisory Opinion 01-1, all state that the arrangements involve violations of both the CMP and the Anti-Kickback Statute but that the OIG, in the exercise of its discretion, will not impose administrative sanctions in view of the circumstances and safeguards of the arrangements.

Advisory Opinions 05-1 to 05-6 and Advisory Opinion 01-1 indicate that the OIG considers six principal categories of factors:

CCH Health Care Compliance LETTER

Portfolio Managing Editor
Pamela K. Carron, J.D., LL.M

Coordinating Editors
Susan Smith, J.D., M.A.
Andra Popa, J.D., LL.M

CCH Washington Bureau
Paula Cruickshank
DOJ, FTC–John Scorza
SEC–Peter Feltman
Health Law–Catherine Hubbard
Tax–Jeff Carlson, Steve Cooper

Designer
Kaveh D. Ryndak

Comments from readers are welcome and should be directed to Andra Popa at popaa@cch.com, Tel. 847-267-2476, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

CCH Health Care Compliance Letter is published 24 times a year by CCH INCORPORATED, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.

Fraud & Abuse (cont.)

(a) clinical and financial transparency of quality indicators;
(b) safeguards against adverse impact on patient care;
(c) safeguards against disproportionate federal health care program costs;
(d) safeguards against inappropriate reductions in services;
(e) meaningful patient and physician disclosure and freedom of choice; and
(f) limitations on financial incentives to participating physicians.

Mr. Paul Danello is an attorney in the health care practice of Ropes & Gray. He was recently responsible for guidance to the nation's entire health care industry on the topic of fraud and abuse laws as a member of a team in the OIG. Mr. Danello is a contributing author to the 2006 Health Law and Compliance Update, due to publish in December. Purchaser Information: ©2005, Aspen Publishers, 2006 Health Law and Compliance Update, ISBN 0735553386, $199, Softcover, Annual Editions. To pre-order, please call Aspen Publishers at 1-800-638-8437.

Trends

MedPAC discusses current agenda items
by John Scorza, Contributing Editor

The Medicare Payment Advisory Commission (MedPAC) met on September 8 and 9 in Washington to offer comments and guidance to MedPAC staff on issues including the physician fee schedule, hospital wages and physician efficiencies.

MedPAC staff are reviewing whether the system for setting physician work values in the physician payment system, which assigns relative value units (RVUs) to services, adequately identifies services that are either overvalued or undervalued. The RVUs are reviewed every five years and a review is underway and scheduled to be completed in 2007. Staff noted that accurate values are important because inappropriate values may lead physicians to base care decisions on financial considerations rather than medical necessity.

MedPAC staff are examining how to improve the Medicare system, which adjusts prospective payment rates based on different wage levels in various geographic areas. Staff also are reviewing whether Medicare should continue to measure differences in the cost of labor using hospitals' self-reported wage rates and what percentage of Medicare payments should be adjusted for differences in geographical wage rates, MedPAC Chairman Glenn M. Hackbarth commented.

One long-term effort by MedPAC staff involves identifying efficient physicians, with the goal of developing policies to encourage greater efficiencies in resource use and quality. Staff has chosen six market areas it wants to study and compare: Phoenix; Orange County, California; Boston, Miami, Minneapolis; and Greensboro, South Carolina.

CCH Washington Bureau, September 9, 2005

Medicaid legislation contains NGA reforms
by John Scorza, Contributing Editor

New Medicaid reform legislation is likely to resemble several of the recent recommendations from the National Governors Association (NGA). The Republican chairman of the House Energy and Commerce Committee hopes to mark up the reform legislation within the next few weeks. Democrats at a committee hearing objected that the proposal, in accordance with the budget process, would cut $10 billion from the Medicaid program.

The NGA recommendations contain a number of "common-sense reforms," according to Committee Chairman Joe Barton, (R-TX). As described by Barton during a September 8 hearing, the reforms include "allowing states to charge basic co-pays to higher income beneficiaries, reducing Medicaid overpayments for drugs and making it more difficult for wealthy seniors to shift or hide assets to qualify for nursing home coverage."

Democrats protested that the proposed reforms would harm the most vulnerable U.S. citizens. "Most of the reforms this committee intends to enact are bad for beneficiaries," Rep. Henry Waxman, (D-CA), claimed during the hearing. Waxman and other Democrats said the cuts would be especially ill-advised as thousands of victims of Hurricane Katrina are likely to turn to the federal government for assistance.

Barton responded that services for beneficiaries would not be affected by the legislation, which has not yet been drafted. On the Senate side, Sen. Charles Grassley, (R-Iowa), chairman of the Finance Committee, endorsed the use of some NGA recommendations to achieve the spending reductions called for in this year's budget

continued on page 8

On The Front Lines

Practical considerations for the voluntary disclosure process - Part I

by Ryan D. Meade, J.D.

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).

On The Front Lines (cont.)

[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).

Ryan D. Meade is an attorney with the law firm of Meade & Roach, LLP in Chicago, Illinois. He focuses his practice entirely on health care regulatory issues and has facilitated several voluntary disclosures. Mr. Meade is an adjunct professor of law at Loyola University Chicago School of Law's Institute for Health Law, where he teaches Medicare law. He is also an assistant professor at Rush University's College of Health Sciences. Mr. Meade can be contacted at RMeade@MeadeRoach.com. The law firm of Meade & Roach is a co-sponsor of the Health Care Compliance Association North Central Area Annual Conference, held in Chicago, IL on October 7, 2005.

Trends

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.