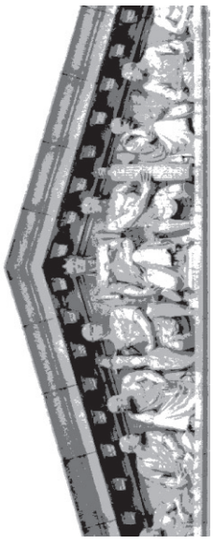

G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. II, No. 9, October 2001

For Hospitals, Laboratories and Physician Practices

CMS Revises Timeline For MSP Data Collection

Hospital Reference Labs To Update Every 60 Days

Hospital reference labs will have to collect or update information to determine whether Medicare has primary or secondary responsibility to pay for covered services only once every 60 days for outreach services, according to a Sept. 25 memo to intermediaries from the Centers for Medicare & Medicaid Services (CMS).

This is a change from previous policy, which required such labs to collect Medicare Secondary Payer (MSP) information each time they ran an outreach test. The change takes effect Jan. 1, 2002. The information is to be collected from a beneficiary or his/her representative. The latter, sources say, may include the physician ordering the test.

For outpatients receiving recurring services, hospitals will have to gather or update MSP information only once every 30 days, according to the memo. A Medicare beneficiary is considered to be receiving such services if he or she receives identical services and treatments on an outpatient basis more than once within the same monthly billing cycle or within the same 30-day period. CMS also dropped the requirement that hospitals collect MSP data if the beneficiary is enrolled in a Medicare managed care plan.

Continued on p. 8

Inside this issue

Treading Safely Across The Labor Minefield

Strategies To Prevent Employment-Based Claims

What are the most important compliance challenges facing healthcare providers? If you answered fraud and abuse, privacy, and self-referral, you're only partly right. In fact, say legal experts, personnel and employment-related claims are on the rise and are potentially more of a threat to an organization's coffers than any other single compliance issue.

While most medium to large laboratories, hospitals, and physician practices have human resource departments responsible for making sure their organization complies with employment statutes, many smaller providers don't do as good a job at keeping up with developments in labor law, believes Jack Lord, senior counsel in the Labor & Employment Law Division of Foley & Lardner (Orlando, FL).

"Physicians are usually more concerned about fraud issues than employment issues. Sometimes it is necessary for doctors to learn the basics of human resources. Cases brought by employees can be very expensive. Even when an employer wins, fees through trial can exceed $100,000. If the employer loses, then there's the award on top of that."

Martin Gringer, a partner with Franklin & Gringer (Garden City, NY), agrees. "Healthcare is a labor-intensive business, so there are going to be a large number of claims.

Continued on p. 10

Provider Groups To Get One More Crack at ABN Instructions

Laboratory, hospital, and physician groups will have one more opportunity to submit comments on draft instructions implementing Medicare's new Advance Beneficiary Notices (ABNs) for Part B items/services before the guidance is finalized, according to an official with the Centers for Medicare & Medicaid Services (CMS).

Raymond Boyd, of the CMS Center for Beneficiary Choices, tells *G-2 Compliance Report* that the agency plans to publish revised draft instructions in the *Federal Register* within the next few weeks and will accept comments for 30 days. CMS hopes to have the implementing instructions finalized by the end of the year, says Boyd. Until that time, providers will not be required to use the new forms, although they do have that option.

The most recent draft of the instructions is similar to the one distributed at the June meeting of the Practicing Physicians Advisory Council, with a few changes. (The latest draft, dated Aug. 31, was to have been discussed at the Sept. 17 council meeting, which was canceled after the Sept. 11 terrorist attacks in New York City and Washington, DC.)

Among the changes, the revised instructions clarify that providers may give beneficiaries a single ABN for an extended course of treatment, which would include lab tests provided on a regularly scheduled basis under a standing order. The new draft also discusses what a provider should do if a beneficiary refuses to sign an ABN but demands the service or item which the provider believes will not be covered (*see related article on frequently asked questions*).

Watch Out For ABN-X

Included in the draft instructions package is a third ABN, called ABN-X, approved for use for excluded services (that is, services that are not Medicare benefits).

But importantly, use of this form is not mandatory, according to CMS officials. The other two ABNS—one for general use, the other for laboratory services—will become mandatory once implementing instructions are finalized.

One example of an "excluded" service would be routine screening in the absence of a sign, symptom, complaint, or disease condition. But this once simple distinction has since been blurred, as Congress has gradually expanded the Part B benefits package to include screening for certain conditions, such as breast, cervical, and colorectal cancer. In January 2002, glaucoma screening will be added to the preventive benefits package.

Billing for Medicare-covered screening is complicated by the fact that the services usually are subject to limits on how frequently they may be performed in a given period for a given beneficiary.

Resource

- Raymond Boyd: 410-786-4544
- Our previous coverage: "Switching To Medicare's New ABN: Challenges Ahead For Compliance Officers," Sept. '01, p. 1

Frequently Asked Questions: Labs & ABNs

The Centers for Medicare & Medicaid Services (CMS) has posted three sets of frequently asked questions on use of the new Advance Beneficiary Notices (ABNs) approved by the Office of Management & Budget. The questions, which may be downloaded from *www.hcfa.gov/medlearn/refabn.htm*, address laboratory use of ABNs, the interaction of ABNs and the Emergency Medical Treatment & Active Labor Act (EMTALA), and beneficiaries' concerns. Below are questions and answers related to laboratory responsibilities.

Q *A physician orders a lab test, and the lab does both the specimen collection and lab test/processing. Is the lab or physician responsible for executing the ABN?*

A Because the laboratory has the risk of financial liability in case of a denial, it is the laboratory's responsibility to execute the ABN. The physician may execute the ABN, but it is not a requirement. If the physician had executed an ABN, the lab need not repeat it.

Q *A physician orders a lab test; the specimen collection is done in the physician office, and is sent to the lab for processing. Is the lab or physician responsible for executing the ABN?*

A Whether the physician or the laboratory collects the specimen, it is still the laboratory's responsibility to execute the ABN because the laboratory has the risk of financial liability in case of a denial. However, we encourage physicians to execute ABNs in these situations, since the physician has the better opportunity to give notice.

Q *If the physician does not execute the ABN, what recourse does the lab have?*

A The lab may contact the beneficiary in order to execute an ABN in person or by telephone (with immediate mail notice follow-up). If the beneficiary: (a) cannot be reached, or (b) refuses to sign an ABN, or (c) initially agrees via telephone and then refuses to sign, the laboratory has two options. It may either perform the test with the likelihood that it may not be able to collect from the beneficiary, or it may choose not to perform the test

(this may be a state law violation in some states).

Q *In the previous scenario, if the beneficiary does not sign an ABN, what is the financial liability of the laboratory when it must perform the test?*

A *Scenario A*—The beneficiary was not reached before the test was performed. The beneficiary cannot be collected from; the laboratory is financially liable.

Scenario B—The beneficiary was given an ABN in person but refuses to sign. The beneficiary will be held financially liable in case of a denial. The lab should keep the following documentation in its files at the time the beneficiary refuses to sign as evidence that the beneficiary was notified of possible denial should he/she later appeal on the basis an ABN was not given:

- A signed document by two laboratory personnel witnessing the provision of the ABN and the beneficiary's refusal to sign.
- Where there is only one person on-site (e.g., in a "draw station"), the second witness may be immediately contacted by telephone to witness the beneficiary's refusal to sign the ABN and may sign the note for the file at a later time.

Scenario C—The beneficiary was contacted by telephone and agreed to sign the ABN but later refuses to sign. The beneficiary is not liable because disputed telephone notice is not acceptable; the laboratory will be financially liable. It is possible that, on appeal, an administrative law judge (ALJ) may determine that the beneficiary is liable if the ALJ finds some evidence that the beneficiary was advised of possible denial to be convincing.

Q *Many times the fee schedule is not available. How can a cost estimate be made and how would this affect the beneficiary in terms of liability if actual costs were substantially higher than what was estimated on the ABN?*

A The physician should estimate cost as she or he would if a private-pay patient asked for cost information. If she or he is unable to give even a reasonable estimate, then the consequences are the same as with any other patient—namely, due to the inability to provide an estimate, the patient might decide to decline the service. For a grossly underestimated cost estimate and the beneficiary refuses to pay the bill, the beneficiary's liability may be up to an ALJ or a court. CMS does not require a physician to provide an estimated cost of the service, but does suggest that he/she provide one so the beneficiary has sufficient information to make an informed decision about whether to receive the service.

Seven Indicted in Money-Laundering Scheme Involving Miami Labs

A federal grand jury has indicted seven people in a multi-million dollar fraud and money-laundering scheme involving several Miami-area laboratories, according to the U.S. Attorney for the Southern District of Florida.

The 35-count indictment charges that between 1995 and 1998, Al Bringas, Luis A. Perez, Loyda L. Lugones, and Pedro L. Lugones were engaged in a conspiracy to defraud Medicare and Medicaid. The four allegedly submitted fraudulent claims worth about $4 million for purported laboratory tests performed by three Miami medical laboratories: AGL Lab Corp., Bio-Logic Laboratories Inc., and Universal Medical Laboratory Inc.

According to the indictment, Perez, Loyda Lugones, and Bringas obtained information about Medicare and Medicaid patients and doctors, and used it to prepare false lab test requisition forms. Perez and Lugones, who are married, used the forms to submit fraudulent claims for reimbursement of tests that were never ordered.

Medicare and Medicaid paid many of the fraudulent claims, sending money to L & L Professional Services Inc., a medical billing company operated by Perez and Lugones. The money was then redirected and transferred to various bank accounts accessed by Bringas, Perez, and the Lugones.

The indictment charges Bringas, Perez, and Loyda Lugones with multiple counts of filing false Medicare claims and mail fraud. The indictment further charges Bringas, Perez, the Lugones, and Perez's brother, Leonardo Perez, in a complex scheme to launder fraud proceeds. Mercedes Vieites is charged, along with Bringas, with two counts of money laundering.

Finally, the indictment charges Bringas and Rosario M. Mantaras, a First Union National Bank customer relations employee, with four counts relating to illegal structuring of bank transactions. According to the indictment, Mantaras, who worked at the bank's Little Havana branch, helped Bringas evade federal rules that prohibit large cash transactions from being "structured," or broken down into smaller accounts. By law, all currency transactions in excess of $10,000 must be reported to the U.S. Treasury Department.

If convicted, Bringas, the Perez brothers, the Lugoneses, and Vieites face a maximum of 20 years' in prison on each money-laundering charge. The other fraud charges against Bringas, Loyda Lugones, and Luis Perez carry a maximum of five years' imprisonment. Mantaras and Bringas face up to 10 years in prison on the structuring violations.

Resource

- U.S. Attorney's Office: 305-961-9001

Waived, PPM Tests Come Under The Microscope
CMS To Increase Education, Oversight

The Centers for Medicare & Medicaid Services (CMS) plans to launch an extensive educational campaign to improve CLIA compliance among laboratories conducting waived and provider-performed microscopy (PPM) procedures in response to recent findings that many labs performing these tests do not follow manufacturers' instructions or are not CLIA-authorized to perform the tests.

"Our intention is to try to get labs to do the right thing," Judy Yost, director of CMS's Division of Laboratories & Acute Care Services, tells *G-2 Compliance Report*. "We're going to use a variety of methods to get the word out on compliance and quality control. We will also conduct on-site visits to verify that the education is actually working."

CMS also plans to work with manufacturers of waived tests to ensure that instructions provided with the tests are clear and easy to follow, says Yost. "We have found a number of examples of instructions that are very difficult to understand. If our surveyors, who are laboratory experts, can't understand the instructions, I can imagine how people working at labs feel."

In addition, notes Yost, the agency is consulting with the Food & Drug Administration on the possibility of post-market review of products that may not work as manufacturers have indicated. "It's not just a one-pronged approach," she says. "We're working on a number of different fronts."

Problems Identified

CMS's new focus on waived and PPM tests comes in response to investigations by both CMS and the HHS Office of Inspector General (OIG) which have identified widespread problems with such testing.

An OIG report released in late August, for example, said that surveyors in Colorado and Ohio found that about half of labs conducting waived and PPM procedures were not following manufacturers' instructions, did not have manufacturers' instructions on-site, or were conducting tests they were not CLIA-authorized to perform.

In addition, Colorado surveyors found that 90% of PPM laboratories lacked written procedures or could not demonstrate the accuracy of the test method or the competency of the testing personnel.

These finding have led CMS to undertake a pilot project in eight other states to survey a sample of waived and PPM labs.

While labs that conduct moderate or high complexity testing are surveyed every two years by state or private sector accreditation agencies, labs conducting only waived tests or PPM procedures are not routinely surveyed. These labs, however, constitute 75% of the laboratories certified under CLIA, says the OIG.

"Because waived and provider-performed microscopy laboratories are not routinely surveyed, surveyors do not have the opportunity to educate staff, or identify and correct problems," the report noted. "Nearly all of our state agency respondents believe that lack of visits to waived and [PPM] labs is a vulnerability."

Even with safeguards, some vulnerabilities also exist for moderate and high complexity labs, says the OIG. Colorado surveyors, for example, found significant problems with waived tests conducted at 40% of moderate and high complexity laboratories. In addition, the OIG believes that current policy allowing labs to voluntarily enroll in the CLIA program is a weakness, noting that it has identified 160 labs which offer lab tests but are not yet certified by CLIA to do so.

Recommendations

Based on its findings, the OIG recommends that CMS take action to reduce vulnerabilities identified in the report. Specifically regarding waived and PPM testing, the OIG suggests that CMS:

- Provide educational outreach to directors of waived and PPM laboratories regarding CLIA requirements.
- Require labs applying for waived and PPM certificates to identify which test systems they will use.
- Establish a mechanism whereby Medicare claim denials can be used to inform state laboratory surveyors about labs which bill for testing outside their certificate.
- Use periodical paper self-assessment tools to help ensure compliance by labs that are not routinely inspected.
- Conduct random on-site inspections of some waived and PPM labs each year if CMS's pilot project finds problems similar to those uncovered in the Ohio and Colorado studies.

Regarding laboratories routinely inspected, the OIG advises CMS to:

- Review during the survey the waived and PPM testing they perform.
- Shorten the time between CLIA application and the initial on-site visit to new labs.
- Formally require accreditation agencies to inform CMS about labs conducting tests in specialties for which they are not accredited.
- Establish a workgroup to develop methods to identify labs not certified under CLIA.

Resources

- Judy Yost, CMS: 410-786-3407
- OIG Report: "Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program" (OEI-05-00-00250), *www.hhs.gov/progorg/oei*

COMPLIANCE PERSPECTIVES

Are Medicare Penalties Unlawfully Excessive?

Patric Hooper, Esq., is a founding partner of Hooper, Lundy & Bookman Inc. in Los Angeles, CA.

In its Aug. 2, 2001 10-Q filing with the Securities & Exchange Commission, Apria Healthcare Group Inc., a publicly owned healthcare company, disclosed that government "representatives" and counsel for the plaintiffs in certain *qui tam* (whistleblower) actions filed against the company have asserted that Apria is liable to the government for submitting false claims to Medicare and other federal healthcare programs in an amount ranging from $4.8 billion to more than $9 billion.

This estimated liability is based on the government's contention that Apria is liable for treble damages of $309 million plus penalties of $5,000 to $10,000 for each of more than 900,000 allegedly false claims. While Apria contends these assertions and amounts are unsupported both legally and factually, the mere fact that it has had to report these figures publicly will no doubt cause harm to the company.

The astronomical money demands made by the government and *qui tam* relators against Apria are only the latest in a series of such demands in the healthcare industry based on the federal False Claims Act (32 U.S.C. §§3729-3733).

Remedy Of Choice

As most healthcare providers are now aware, the False Claims Act is the government's remedy of choice for pursuing healthcare fraud and abuse cases. The Act encourages whistleblowers to initiate actions on behalf of the United States by offering them substantial "bounties" and requires a lower quantum of proof than would be required in a criminal fraud prosecution.

More importantly, however, the False Claims Act provides for potentially extraordinary damages and penalties; *i.e.*, three times the actual damages suffered by the government and statutory penalties ranging from $5,000 to $11,000 per false claim. In healthcare cases where providers often submit hundreds or thousands of claims involving relatively small dollar amounts, the possibility of damages and penalty awards being disproportionate to any loss suffered by the government is very real. Even so, most of the legal literature on healthcare fraud and abuse cases has focused more on liability issues than on the damages/penalties issues.

That focus might well shift in light of the recent decision of the United States Court of Appeals for the Ninth Circuit in *United States of America v. Mackby*, 243 F.3d 1159 (9th Cir. 2001), in which the court concluded that *both* the treble damages and the statutory penalty provisions of the False Claims Act are subject to analysis under the Eighth Amendment to the U.S. Constitution, which prohibits "excessive fines." [1]

In reaching the conclusion that both provisions potentially impose "fines" or "punishment," the Ninth Circuit rejected the government's argument that the treble damages and statutory penalty provisions are exclusively remedial in nature. This holding not only provides relief to defendants in ongoing actions, but also should provide a substantial measure of comfort to those healthcare providers engaged in settlement negotiations with the government and *qui tam* relators during the investigation stage of proceedings.

Government enforcement agencies and private whistleblowers have relied heavily on the damages and penalties available under the False Claims Act to demand (some argue extort) large settlements from targets of healthcare fraud investigations. Faced with the risk of excessive damages being awarded, many providers are reluctantly "forced" to settle rather than challenge the government's positions. While some courts have recognized the potential for abuse caused by this situation, not much has been done to alleviate it.[2]

---

[1] On Aug. 16, 2001, the Ninth Circuit granted the government's petition for rehearing and issued a new opinion. However, the new opinion does not alter the gist of the original opinion.

[2] See, for example, the discussion in *Ohio Hospital Association v. Shalala*, 201 F.3d 418, 419 (6th Cir. 1999), referring to the government's use of "heavy-handed" tactics to threaten Ohio hospitals with "draconian penalties under the False Claims Act," as a means of obtaining double recovery of alleged overpayments.

The government itself is well aware of the potential for damages and penalties to be deemed excessive by a court. Indeed, in settlement agreements with healthcare providers, the government typically insists that the provider agree to waive the Eighth Amendment. Moreover, in those few False Claims Act cases that actually go to trial, the government often decreases significantly its demand for damages and statutory penalties by limiting the number of claims used for purposes of calculating statutory penalties and damages.

The Mackby Decision

In *Mackby*, the Ninth Circuit relied heavily on the U.S. Supreme Court's decision in *United States v. Bajakajian*, 524 U.S. 321 (1998), a case which dealt with the criminal forfeiture of property involved in the unreported transportation out of the country of more than $10,000 in currency. The statute in question in that case required a forfeiture of the entire $357,144 that the defendant, Hosep Bajakajian, had failed to declare. The Supreme Court held, however, that such a result would violate the excessive fines clause of the Eighth Amendment because the full forfeiture would be grossly disproportionate to the gravity of the offense.

The court emphasized that the touchstone of the constitutional inquiry under the excessive fines clause is that the amount of any forfeiture must bear some relationship to the gravity of the offense that it is designed to punish.

Among the factors, therefore, to be considered in a healthcare case, now that the court in *Mackby* has deemed the treble damages and statutory penalties to be subject to an Eighth Amendment inquiry, are:

(1) The nature of the defendant's violation;

(2) Whether the violation was related to any other illegal activity; and

(3) The harm caused to the government, including any loss to the public treasury.

These factors will ultimately have to be considered by the district court on remand in the *Mackby* case to determine whether the $750,000 judgment imposed on Mackby was excessive in light of the fact that the government claims to have overpaid only approximately $58,000.

Case Background

The facts and circumstances in *Mackby* are important. Peter Mackby, a businessman, owned a physical therapy clinic where he employed licensed, independent physical therapists to perform physical therapy services ordered by outside physicians. During the years at issue, 1992-1996, Medicare capped the annual sums payable for physical therapy services for individual beneficiaries when such services were furnished by physical therapists in independent practice. The same limits, however, did not apply to physical therapy services furnished by a physician or incident to a physician's services. For example, for 1995, the annual cap was $900 per beneficiary.

Because the Medicare carrier was purportedly misled by Mackby's clinic's claims (the claims used Mackby's physician father's billing number, thus leading the carrier to believe a physician was involved in providing services), it did not apply the $900 per year limit on Medicare beneficiaries treated at the clinic. Over the period from 1992 through 1996, Medicare thus "overpaid" Mackby's clinic approximately $58,000.

Importantly, in discussing Mackby's liability under the False Claims Act, the Ninth Circuit opined that if the clinic had been held to the physical therapy billing cap and had tried to bill its Medicare patients directly for amounts in excess of the cap, the patients could have, and "it seems reasonable they very well would have," left to seek services from physicians or physician-run clinics where the annual cap did not apply. Thus, the court pointed out that the same patients would have received Medicare benefits covering the full amount of physical therapy services if the claims had not been "false."

This portion of the Ninth Circuit's opinion means Medicare would have paid the same amount for the physical therapy services to some other provider or providers, who would not have been subject to the physical therapy limit. As a result, even if Mackby's clinic had submitted "true claims," the government ultimately would have paid the same sum it actually paid to Mackby's clinic. Therefore, arguably, the government suffered no actual loss.

Although the government will no doubt respond by insisting that it is appropriate for Medicare to require adequate documentation as well as quality healthcare services from providers, it does not necessarily follow that the imposition of a forfeiture equal to 100% of the Medicare payment is reasonable for non-compliance with documentation requirements. Indeed, in many situations, such a forfeiture would appear to be excessive or disproportionate to the conduct of the provider.

On remand, the district court will also have to consider Mackby's conduct to determine whether the forfeiture of the $58,000 of "overpayment" is disproportionate to the gravity of the offense. Mackby's alleged "misconduct" consisted primarily of failing to verify whether he could use his father's billing number to identify his clinic. While the court construed this failure as constituting a reckless disregard of the truth, the behavior was not fraudulent, and the government did not

prove that Mackby had actual knowledge of the falsity of his clinic's claims. Indeed, Mackby's liability resulted primarily from an interpretation of arcane billing rules with which the court required him to be fully familiar.

If the government insists on using the False Claims Act to enforce compliance with hypertechnical and often vague and ambiguous billing rules, the penalties for violating such rules should be deemed excessive if they equal 100 times the amount of the claim, as in *Mackby*, where statutory penalties of $5,000 per claim were imposed on claims averaging only approximately $50 per claim.

The deterrence of future misconduct will also have to be considered. In the healthcare industry, because of the array of actions available to the government to penalize the same act of wrongdoing and because of the severe collateral consequences of such actions, the treble damages and statutory penalty provisions of the False Claims Act are arguably unnecessary as a deterrent.

In other words, because of the availability of other proceedings and their collateral consequences, there is arguably no need to impose substantial punitive damages as a "message" for future offenders. For example, a provider against whom a false claims action is initiated for submitting false Medicare claims faces exclusion from Medicare, Medicaid, and other government healthcare programs, potential revocation of licensure, termination of third-party payer contracts, and many other adverse consequences. Similarly, because of the extreme sensitivity of the healthcare industry to adverse publicity, the investigation and prosecution of false claims actions, themselves, can cause severe consequences to a defendant.

All these factors will have to be examined to determine whether the judgment imposed is excessive under the facts of Mackby's case. Similar factors should be examined carefully by the parties during settlement negotiations of disputed false claims actions.

Factors Affecting Damages

In any event, regardless of whether the Eighth Amendment is available in a particular case, considerable attention should be given to the question of the actual damages suffered by the government, if any. Too often, providers simply assume that 100% of the sum paid by the government should be the starting point for damage discussions, when, in fact, the starting point should be considerably lower.

Questions such as the value of services furnished are of significant importance even in criminal cases. For example, in one of the more notorious healthcare fraud cases, *United States v. Rutgard*, 108 F.3d 1041 (9th Cir. 1997), the Court of Appeals for the Ninth Circuit required the trial court to give Dr. Jeffrey Jay Rutgard, an ophthalmologist found guilty of submitting false Medicare claims, "credit for medical services that he rendered that were justified by medical necessity," (108 F.3d at 1064) in connection with the punishment phase of his case.

More recently, the Ninth Circuit in *United States v. Silver*, 245 F.3d 1075 (9th Cir. 2001), required a trial court, in a product substitution case, to consider the market value of the goods disposed of by the government as an offset against the disposal cost when calculating the actual loss to the government for sentencing purposes. The same should be true in False Claims Act cases. In fact, there are some false claims action decisions where the courts recognize that a multiple damage award would be inappropriate because the government would have ultimately paid out the same amount it paid to the defendant even if a false claim had not been submitted.[3]

Finally, even in those cases in which the provider's conduct does not rise to the level of fraud or abuse, the government routinely asserts that billing errors require disallowance of the entire amount claimed and repayment of 100% of any money paid by the government as a result of the billing error. In other words, where one or more of the many billing requirements of the Medicare program are not met, the government insists that no payment should be made for the services that have been rendered.

Remarkably, the healthcare industry has seemingly acquiesced in this position. Yet, in virtually any other context in which services are actually rendered but a billing error exists, the provider of the services would expect to be paid at least the reasonable value of the services or be reimbursed for the costs incurred in furnishing the services.

There is, in fact, case authority supporting the proposition that when a provider of healthcare services does not dot all the "'i's" and cross all the "'t's," it should nevertheless be compensated for the value of its services to avoid a forfeiture.[4] This equitable concept should not be ignored in connection with Medicare and Medicaid payment disputes simply because the government argues that an error in billing has occurred.

Mr. Hooper may be contacted at Hooper, Lundy & Bookman Inc., 1875 Century Park East, 16th Floor, Los Angeles, CA 90067-2799. Tel: 310-551-8165. E-mail: phooper@healthlaw.com.

[3] See *United States v. Woodbury*, 359 F.2d 370, 379 (9th Cir. 1996) and *United States v. Hibbs*, 568 F.2d 347 (3rd Cir. 1977).

[4] See *Valley View Home of Beaumont, Inc. v. Department of Health Services*, 146 Cal.App.3d 161 (1983).

MSP Data, *from page 1*

"One might say the policy is 'relaxed'," says Larry Small, director of compliance and billing services for PCS Laboratory Services Group in Ann Arbor, MI. "It's like making an impossible situation a little possible."

In the past, hospitals had been unhappy about having to collect MSP data for lab outreach work, especially since hospital personnel typically had no direct contact with the patient. Generally, hospitals get information on these "non-patients" from the physician who orders the testing, notes Small.

While some hospitals may have believed they did not have to gather MSP information if they never actually had an encounter with the patient, CMS's policy is clear that reference labs do have to collect such data, according to an agency spokesperson.

"Hospital reference labs are part of the hospital and are required to complete the MSP questionnaire in order to determine the primary payer of the beneficiary's claims," says the spokesperson, adding that CMS is researching how to give more relief regarding MSP requirements.

"The memo differentiates between a non-patient and an outpatient, which CMS had not done before," explains Small. "It also adds cycles of collection, so a reference lab has to collect the information only once every 60 days. But they still have to collect it, and therein lies the problem. The only thing you can really do is indicate on your requisition and your educational materials for your physicians that it become their responsibility to collect the information and share it with the lab."

CMS says hospitals that do reference lab work should keep an audit trail to show that they gathered current MSP information within the 60-day allowable period and who supplied it. "Acceptable documentation may be the last (dated) update of the MSP information, either electronic or hard copy," says the agency.

If the hospital's use of outdated or inaccurate data results in Medicare making an incorrect primary payment, the hospital will be liable to repay, warns CMS. The agency recommends that providers retain records showing that they gathered MSP information for up to 10 years.

Resources

- Larry Small: 727-866-1311
- CMS Program Memo, Transmittal A-01-116, Sept. 25, 2001
- Our previous coverage: "Defusing a Ticking Time Bomb: Compliance with Medicare Secondary Payer Rules," Apr. '00, p. 5.

OIG Clears Hospital's Policy On Waiving Cancer Screening Coinsurance

A hospital's policy of waiving payment for its early cancer detection program could potentially generate prohibited remuneration under civil money penalty or anti-kickback provisions of Medicare law, according to a recent advisory opinion from the HHS Office of Inspector General (OIG).

Based on the facts of the case, however, the OIG said it would not impose administrative sanctions on the hospital because it concluded that two aspects of the particular waiver policy substantially minimized any risk of fraud or abuse.

The hospital (name redacted from the opinion) operates a cancer hospital at its main campus and a satellite center in the same city. At those locations, the hospital offers an early detection program for breast and gynecological cancers "at no out-of-pocket expense" to patients.

The program, which includes screening and certain follow-up services, is financed by a series of federal and state grants, private philanthropic support, and annual grants from the hospital. It targets a community consisting largely of individuals who are uninsured (67%), Medicaid recipients (12%), and Medicare beneficiaries (5%).

While the OIG says it continues to have serious concerns about the waiver of coinsurance for screening services when the waiver is tied to other services reimbursable by Medicare or Medicaid, it decided not to impose administrative sanctions based on two aspects of the policy:

1 The large majority of patients served are uninsured individuals who might otherwise receive no screening services. As a result, the OIG concludes, it is unlikely that the screening services, in conjunction with the waiver policy, would generate substantial repayments for the hospital's services.

2 Although the screening services would otherwise qualify for the preventive care exceptions that are tied in some cases to non-qualifying services, the non-qualifying services are limited to those necessary to confirm the initial screening results. Follow-up therapeutic services are not covered by the waiver policy, nor are they typically provided for patients by the hospital, the OIG determined.

The advisory opinion applies only to the specific hospital in question. It should not be relied on by any other individual or entity, even if their arrangements appear similar in nature or scope, the OIG makes clear.

Resource

- OIG Advisory Opinion No. 01-14: *www.hhs.gov/oig/advopn/2001/index.htm*

Trash "Auditing" Targets Protected Information
"Hands-On" Approach Designed to Increase Awareness, Compliance

Do you know what's in your organization's trash? Kristy Berrier, a senior compliance auditor with Novant Health in Charlotte, NC, knows what's in hers.

As part of a new program developed by Novant, Berrier sifts through trash receptacles throughout the healthcare system, searching for documents that contain protected health information but have not been disposed of properly.

What To Keep From Prying Eyes

According to the final HIPAA privacy rule, the following identifiers of patients, relatives, employees, or household members are considered *protected information*.

- Names
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, and zip code.
- All elements of dates (except year) directly related to an individual, including birth, admission, discharge, death, and all ages over 89 and all such elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full-face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code

"It's a glamorous job," laughs Berrier, who has been "auditing" trash since early this year.

While Novant had a long-standing policy about proper disposal of confidential materials, corporate managers had no way to measure how the policy was being followed, says Peggy Burke, corporate director of internal audit and compliance.

"We always had a policy," she explains, "but it didn't get a lot of attention before HIPAA."

In fact, release of the federal patient privacy rule in accord with HIPAA (the Health Insurance Portability & Accountability Act) was the impetus for development of Novant's new "trash auditing" program. While the privacy rule, released late last December, is not scheduled to take effect until Apr. 14, 2003, for most health systems and providers, Novant leadership decided to take steps now to monitor that all documents containing confidential information on individuals—both patients and employees—are destroyed in an appropriate manner.

"HIPAA brought the need for this to our attention, but it's also just good business practice," says Burke.

Going Through The Trash

When checking the trash, Berrier relies on the list of protected health information identified in the HIPAA privacy rule. The list includes identifiers ranging from names to e-mail addresses to license plate numbers (*see sidebar*).

"Any documents containing any of these elements would fall into the category of protected health information and would need to be disposed of properly," explains Burke. Facilities have discretion in determining how best to dispose of confidential information. Some choose to shred documents on-site, others contract with outside vendors to collect and shred papers.

Since early this year, Berrier has been traveling to different sites within the Novant system to audit trash. The system includes six hospitals, three nursing homes, two home healthcare agencies, and dozens of physician practices.

Berrier first meets with a facility manager or unit leader to explain why she is there, then begins sorting through papers in waste receptacles, searching for documents that contain protected health information. Before leaving, Berrier gives the manager a copy of the completed audit checklist. Periodically, she aggregates the audit information and sends it to the appropriate leader. A typical aggregate report lists the facilities visited, describes the methods used to dispose of confidential waste at each site, and describes the employees' compliance with the methods.

Employees Receptive

"People are sometimes surprised when I tell them why I'm there," says Berrier, "but they've all been very cooperative. Sometimes they'll call the next day, saying what they've done to correct the problem."

The goal of the trash-auditing program, explains Burke, is to heighten awareness of the importance of proper document disposal. While the program is still too new to measure specific improvements, both Burke and Berrier believe system employees are becoming more sensitive to protection of confidential information.

Resources

- Peggy Burke: 704-384-7638
- Kristy Berrier: 336-277-1130

Employment, *from page 1*

Basically, anyone who is terminated can make a claim for discrimination because everyone belongs to some group. Every time an employee is terminated, or not hired, that's a potential lawsuit."

Trouble Spots

The most common employment claims involve harassment, disability, and family and medical leave issues, say both Lord and Gringer. Retaliation claims—when employees claim they have been fired because they have reported some type of discrimination—are also on the rise, according to Lord.

"It's easier for an employee to make a retaliation claim, most of the time, than it is to make the underlying discrimination claim. It's hard to prove that you are a qualified person with a disability. It's easier to show you've been fired because you filed a discrimination charge with the Equal Employment Opportunity Commission (EEOC)."

Several recent cases demonstrate just how costly these issues can be:

❖ Blood Systems (Scottsdale, AZ) in August agreed to pay an aggregate $650,000 to 23 employees with disabilities who were terminated under its former policy of automatically terminating employees after 90 days of medical leave if they were not released to return to work. Under an agreement with the EEOC, Blood Systems changed the way it handled such leaves to comply with EEOC guidelines and agreed to require managers to undergo training related to the Americans with Disabilities Act (No. 99C 26D).

❖ Beverly Enterprises Inc., one of the largest nursing home operators in the country, agreed in July to pay $1.2 million to settle racial harassment allegations by the EEOC against Bridgeton Nursing Center in St. Louis, MO. The money will be distributed in damages, attorneys' fees, and costs to nine former employees—six African Americans and three whites—all of whom had complained about the discrimination and were then discharged or forced to resign (*EEOC v. Beverly Enterprises-Mo. Inc.*, No. 4:98CV1579).

❖ The U.S. Court of Appeals for the Fifth Circuit in March cleared the way for a black nurse to proceed with her retaliation claim against the city of Houston, based on the suspicious timing of her demotion following her scheduled testimony in another employee's race discrimination case (*Evans v. Houston*, No. 99-20778).

Key Employment Laws To Know

- **Title VII of the Civil Rights Act of 1964:** Prohibits discrimination based on race, color, religion, sex, or national origin. Applies to employers with 15 or more employees.
- **Age Discrimination in Employment Act of 1967:** Prohibits discrimination against individuals age 40 or older. Applies to employers with 20 or more employees.
- **Title I of the Americans with Disabilities Act of 1990:** Prohibits discrimination against qualified individuals with disabilities. Applies to employers with 15 or more workers.
- **Family & Medical Leave Act of 1993:** Entitles eligible employees to take up to 12 weeks of unpaid, job-protected leave in a 12-month period for specified family and medical reasons. Applies to all public agencies and private-sector employers with 50 or more workers.
- **Equal Pay Act of 1963:** Prohibits wage discrimination between men and women in substantially equal jobs within the same establishment. Applies to most employers.
- Sections of the **Immigration Reform & Control Act** that relate to national origin discrimination prohibit the hiring of any person who is not legally authorized to work in the U.S. The citizenship discrimination provisions apply to all employers with at least four workers. The Act also prohibits discrimination in hiring and discharge based on national origin (as does Title VII of the Civil Rights Act) or on citizenship status.

> ***"It's easier for an employee to make a retaliation claim, most of the time, than it is to make the underlying discrimination claim."***
>
> ***— Jack Lord***

Compliance Tips

There are any number of mistakes that can land an organization in hot water, say Lord and Gringer. Here are three common ones and steps you can take to avoid them.

1 Failing to cite and document improper behavior and disciplinary incidents. "In many small businesses, there is a tendency toward paternalism," says Gringer. "Sometime there is a reluctance to discipline employees because they work very closely together. What frequently happens is that employers condone a great deal of bad conduct, then end up terminating someone over something minor—the straw that broke the camel's back, so to speak. It's hard to defend that if there is no record of [prior] problems and discipline."

Solution: Deal with problem behavior as it occurs, and carefully document both the behavior and the response. That documentation will help protect you if an employee later claims he or she has been unlawfully fired. Intervening before a problem gets out of hand can also improve productivity and morale.

2 Failing to treat employees consistently. "The very definition of discrimination is that you are treat-

ing some people differently from others," says Lord. A healthcare practice, for example, that refers one employee who tests positive for drugs to the employee assistance program while another person who tests positive is fired is asking for a lawsuit, Lord points out. "You may end up firing someone because it's more egregious, but you do have to take into consideration the leniency you've shown in the past."

Solution: Establish and follow written policies and procedures on issues such as harassment, discrimination, and disciplinary measures. This will help ensure consistency in how employees are treated. The policies should be developed with the assistance of legal counsel who are familiar with the myriad federal and state employment laws covering healthcare providers and practices. Lord also recommends maintaining consistency among decision-makers so that policies are not constantly being changed.

3 ***Failing to complete appropriate paperwork for employees.*** Some employers, notes Gringer, simply photocopy documents provided by new workers but fail to complete required forms, such as an I-9. "This can be a costly mistake if there's an audit."

Solution: Complete and keep on file on all necessary personnel forms. This may also include written approval of time off under the Family & Medical Leave Act. Employers must advise employees that the time they take off for personal or medical reasons is being counted against their 12-week allotment under the Act if that is the case, says Gringer. Otherwise, employees will be entitled to an additional 12 weeks from the time they get their notification.

Resources

- Jack Lord: 407-244-3246
- Martin Gringer: 516-228-3131

For the Record

Can a laboratory bill for glucose point-of-care (POC) testing for emergency patients, ambulatory surgery patients, or inpatients? The testing is overseen by the lab, and the results are posted to the patient's medical record. All tests require a physician request.

We put this question from a hospital pathology department to coding/billing consultant Joan Logue of Health Systems Concepts Inc. (Longwood, FL). According to Logue, medically necessary Medicare outpatient (Part B) point-of-care lab services, including glucose, may be billed by hospitals. All billing rules and regulations (including local limited coverage policies) which apply to traditional testing also apply to Part B billing for POC tests. However, because of the frequency with which a hospital or nursing home may perform a point-of-care glucose, the Centers for Medicare & Medicaid Services has issued additional guidelines (Program Memorandum AB-00-108). This memo reviews Part B coverage and payment policies for glucose monitoring and specifically addresses POC glucose testing done on instruments cleared by the Food & Drug Administration for home use.

According to the PM, for the point-of-care glucose to be considered reasonable and necessary:

- It must be ordered by a physician;
- The ordering physician must use the result in managing the beneficiary's specific medical problem;
- The lab result must be reported to the physician promptly; and
- The physician must instruct continuation or modification of patient care.

A POC glucose may not be a standing order. There must be documentation of each POC glucose order in the patient's chart and documentation that each result was reported to the ordering physician.

Point-of-care testing for Medicare patients in a Part A stay are included in the DRG and not separately billable to Medicare. However, Medicare beneficiaries in hospital stays who have exhausted their Part A benefits may have medically necessary POC tests covered under Medicare Part B if the testing meets coverage requirements as discussed above for Medicare outpatients.

Point-of-care testing for private (non-Medicare) inpatients may be billable depending on the patient's private insurance plan. However, capturing the charges for high-volume point of care tests on the inpatient nursing unit is often difficult. For this reason, many hospitals include the point-of-care testing performed by the nursing unit staff in the facility routine service charge.

Have a question you'd like answered? E-mail it to Kimberly Scott, managing editor, at *kimscott@yahoo.com*. We'll select one to address in this column.

The Back Page

News-At-A-Glance

Provider Survey: The HHS OIG has issued an abstract of a survey of Medicare and Medicaid providers that have entered into CIAs.

According to the results, of the 115 providers asked if they would continue to operate a compliance program after their CIA expires, 98% percent said they would, and 97% said they would also retain a compliance officer.

Of the 117 providers responding to a question about establishment of a confidential disclosure program, 88% said they have one in place, and 60% said they had received reports as a result of their disclosure program. The survey is available online at *www.oig.hhs.gov.oig.new.html.*

Kickback Probe: Abbott Laboratories is one of several companies under investigation by the government for possible involvement in a kickback scheme, according to a recent *Chicago Tribune* report.

Also listed in the story were Zevex International, Novartis AG, and Kendall Co. The companies are reportedly being investigated for "engaging in a kickback scheme to encourage hospitals, nursing homes, or home care providers to buy pumps and related supplies used to feed seriously ill people by giving the products away or selling them at a discount."

The *Tribune* reports that some providers allegedly billed these products at a higher price to either Medicare or Medicaid. A spokesperson for Abbott's Ross Products division, which produces the equipment, told the *Tribune* they knew of the investigation, but that it is "inclusive of the whole industry," including manufacturers, distributors, and providers.

A spokesperson for the Department of Health and Human Services Office of Inspector General says the office will neither "confirm nor deny" whether Abbott and the three other companies are under investigation.

The spokesperson notes, however, that the OIG is actively monitoring medical device and pharmaceutical companies for potential fraud.

NO CHANGE IN LAB INSTITUTE SCHEDULE

The 19th annual Lab Institute program set for October 24-27 at the Crystal Gateway Marriott Hotel in Arlington, VA will be held as planned.

Even though resuming normal activities as our national leaders have called for, we at Washington G-2 Reports shall never forget the innocent victims and their loved ones whose lives were so tragically altered by the terrible events of September 11.

Travel News: For those using Dulles Airport, ground shuttle transportation is now available between the airport and the Institute meeting site in Crystal City.

New Speakers Added: Rep. Jim McDermott (D-WA) and Tom Scully, Administrator, Centers for Medicare & Medicaid Services (CMS) will co-keynote the Thursday opening session.

Compliance Update: Special HIPAA presentation by Dr. Michael Fitzmaurice, Senior Science Advisor for Information Technology, Agency for Health Care Research & Quality, plus other general & breakout sessions devoted to key compliance topics.

Program Details: See booklet enclosed with this issue. Please call toll-free at 1-800-522-7347 to register or get answers to any questions.

G-2 Compliance Report Subscription Order or Renewal Form

Subscription Service includes 10 issues of the *G-2 Compliance Report*, 4 quarterly Critical Issue Compliance Audiocassettes, the G-2 Compliance Resource Manual, and Compliance FastTrak Fax Alerts, plus exclusive savings on G-2 compliance seminars and publications

❑ ***YES***, enter my one-year subscription to the ***G-2 Compliance Report*** at the regular rate of $399/yr.

---------- *or* ----------

❑ ***YES***, as a current subscriber to the *National Intelligence Report* and/or *Laboratory Industry Report*, enter my subscription to the ***G-2 Compliance Report*** at the special reduced rate of $299/yr, $100 off the regular rate.

Please Choose One:

❑ Check Enclosed (payable to Washington G-2 Reports)

❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____

Cardholder's Signature _____

Name As Appears On Card _____

Ordered by:

Name _____

Title _____

Company/Institution _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

e-mail address: _____

MAIL TO: Washington G-2 Reports, 29 W. 35th St., 5th Floor, New York NY 10001-2299. Or call 212-629-3679 and order via credit card or fax order to 212-564-0465 10/01

G-2 Compliance Report (ISSN 1524-0304). © 2001 Washington G-2 Reports, 1111 14th St, NW, Suite 500, Washington DC 20005-5663.
Tel: (202) 789-1034. Fax: (202) 289-4062. Order Line: (212) 629-3679. Website: www.g2reports.com.

 Publisher: Dennis W. Weissman. *Editor:* D.J. Curren. *Managing Editor:* Kimberly Scott, 301-260-0929.