G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

FDA Firm On Hospital Compliance With New Rules For Reprocessed Single-Use Devices

The Food & Drug Administration is reiterating its warning to hospitals that reprocess single-use devices (SUDS) that they are subject to inspection and possible enforcement action if they fail to comply with new government requirements.

The most recent warning came in an Apr. 23 "Dear Hospital Administrator/Risk Manager" letter from David Feigal Jr., director of FDA's Center for Devices & Radiological Health.

"We will now require hospitals that reprocess SUDS [for later use on patients] to meet the same regulatory requirements as the original manufacturer of the product."

The mandate applies to acute care hospitals. It does not apply to hospitals that do not reprocess SUDS, permanently implantable pacemakers, hemodialyzers, or open-but-unused SUDS.

In Feigal's letter, FDA lays out a timetable for enforcement as well as a summary of the seven requirements of the federal Food, Drug & Cosmetic Act with which hospital reprocessors must comply. The regulatory plan staggers the timetable for different classes of devices, beginning with devices judged to pose the greatest potential risk, or class III devices.

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Inside this issue

Ahead Of The Curve On Privacy Compliance

New patient privacy protections under the Health Insurance Portability & Accountability Act (HIPAA) won't take effect till April 2003, but some compliance officers maintain that the time left is shorter than you think—and the effort necessary to comply may be more than you expect.

Avoid being in a reactive mode, says Wes Porter, HIPAA project manager for SSM Healthcare in St. Louis, MO. After the Bush Administration took office in January, many hospitals gambled that the health data privacy rule, promulgated last Dec. 28 by the Clinton Administration, would be substantially delayed, and they tabled their planned privacy programs. SSM, however, decided to proceed with the plan it had launched in the spring of 2000. "Everyone assumed the rule would be postponed and heavily watered down," Porter recalls. "We took the chance it would not be delayed, and in retrospect we're glad we did."

Now that the Bush Administration has given the go-ahead, Porter's HIPAA team is feeling vindicated. SSM, which owns and manages 19 acute care hospitals and three nursing homes in four separate states, offers a useful case study of a strategic approach to the privacy rule.

Getting Underway

SSM's first step was to form a 16-member HIPAA steering committee,

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Privacy Compliance, *from page 1*

with representatives from throughout the healthcare system. Porter, who was compliance officer, moved over to HIPAA full-time and chairs the steering committee, which meets monthly. He reports to the senior vice president of stewardship and the corporate responsibility officer, who answer directly to the CEO of the healthcare system.

Six HIPAA subteams were formed to focus on privacy, technical security, physical security, administrative security, electronic information exchange/national identifiers, and education/training. Porter recommends forming HIPAA task forces at each entity within a system, as SSM has done. "The majority of issues are the same everywhere, but some are unique." In addition, task forces get people more involved and allow them to make their own action plan.

Preliminary status reports show that all of SSM's institutions have strong confidentiality policies in place, with most requiring that employees sign a confidentiality agreement, which Porter calls "a good start." The HIPAA administrative security subteam is now charged with going through all the policies and procedures system-wide to make sure they comply with HIPAA, and to prepare for a standard privacy notice and authorization forms.

There are limits to standardization, Porter warns. For SSM as well as other large health systems, differing state privacy laws that may preempt HIPAA can be a concern. Take the different states where SSM operates, for example. In Missouri and Illinois, privacy is largely a matter of case law, though a pending Missouri bill has provisions very similar to HIPAA's. In Wisconsin, state laws regulate use of outside contractors for retrieving and releasing medical information, and Oklahoma only allows contractors to charge for copying costs, not for retrieval fees.

Being Lean & Effective

One of Porter's chief goals is to assure that the administrative elements of HIPAA compliance are effective, but as lean as possible. "My concern is about drafting policies that no one follows. We don't want to overdo it. There's nothing worse than putting 50 to 100 policies and procedures on the books, and nobody knows they exist."

With the security assessment still in progress, SSM plans to conduct privacy audits in July and August, and Porter predicts the task will be enormous. "We'll be going through and identifying all business associates." With roughly 12,000 written contracts at the corporate office, there may be as many as 2,000 associates, each requiring contractual changes to meet HIPAA standards.

Although SSM's HIPAA program currently has only an operational budget, Porter stresses the importance of risk management analysis to determine where to spend capital dollars. For example, if a physician's voice can potentially be heard next door, "it's probably not good sense to redesign soundproof physician offices, because it's more reasonable to have the door shut and have the physician keep his voice down. On the other hand, some clinics in hospitals are completely open, there's no barrier between desks and you'll often see patients admitted at the same time." The latter would be a better target for capital dollars for renovation, he says.

IT Only Small Part

SSM's technical security subteam is dealing with information technology issues, including encryption, network control management, vulnerability studies, and firewalls.

Contrary to many perceptions, only about 20% of HIPAA's privacy requirements are IT-focused, he stresses. Physical security is a greater issue and potentially a bigger threat. "Charts being left out, doors being left open, non-existent shredding policies, nurses' stations designed so that monitors can be read by anybody"—these are issues the physical security subteam is addressing. "When patients know their rights under the rule, they're not going to know about firewalls. They're going to see charts being left out inappropriately or a surgery schedule with their name on it."

Education and training of personnel should not be an afterthought, Porter emphasizes. "We allocated over a year for education and training. Just walking through the facilities, we're finding a number of things—not capital items, just things like closing patient charts, turning charts upside down so the patient's name is not showing, redesigning the white board so there are no patient names, just initials, and so on. There are a lot of quick fixes that are more culture-based."

Porter, who was attending the first annual meeting of the Privacy Officers Association this month, said that sharing ideas is critical for compliance under HIPAA because the standards are based on customary practices. "If we have diagnoses on the white board and our competitors don't, this is a potential issue because under HIPAA, we're below standards."

Many healthcare systems have a lot of work left to do on HIPAA compliance, he warns. A pattern in the past has been to hire outside consultants to come in at the last minute and give advice—but not in this case. "Now we're developing our own tools, and we're finding the employees are much more receptive."

Resource

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Hospitals See Recordkeeping Woes In HCV "Lookback" Rules

Hospitals are bracing for added recordkeeping requirements when hepatitis C "lookback" rules, proposed jointly by the Food & Drug Administration and the Health Care Financing Administration, become final.

The rules were proposed in the *Federal Register* on Nov. 16, 2000 in a concerted effort to further assure the safety of the Nation's blood supply. FDA officials are still reviewing comments on the proposal. But few in the hospital and bloodbanking industry expect substantive changes in the final version.

The rules specify the quarantine and notification procedures that must be followed by facilities involved in collecting, processing, and administering blood when it is determined that blood and blood components are at increased risk of infection with the hepatitis C virus (HCV).

About four million Americans are thought to be infected, but many may be unaware of it because the disease usually manifests no symptoms for about 20 years. HCV can cause serious liver damage and is thought to be the leading cause of late-stage liver failure and cirrhosis in the U.S., says HCFA.

FDA procedures regarding HCV already in place are thought to have cut the transmission risk significantly, but HCFA says it is possible that HCV-tainted blood could enter the blood supply, noting that about 7% of the 4 million infected got the virus from a blood transfusion before these procedures were implemented.

How Heavy A Burden?

The notification procedures proposed are not that different from current procedures, says Kay Gregory, director of regulatory affairs for the American Association of Blood Banks. "They pretty much codify existing practices. Most blood centers and hospitals are already doing this because of FDA guidance on HCV lookback, which has been out for several years."

But some blood experts say the rules will have a broad financial and administrative impact on hospitals.

Under the proposal, HCFA would require hospitals to adopt procedures set forth by FDA for the lookback. This requirement would be part of HCFA's Conditions of Participation for laboratory services under Medicare/Medicaid.

FDA would require blood establishments (including plasma facilities) to prepare and follow written procedures for handling blood at increased risk of HCV infection and

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Medicare's Physician Fee Schedule

New Physician Supervision Rules For Diagnostic Tests

To avoid any danger of submitting a false claim to Medicare, physician practices and hospitals should note revised physician supervision requirements that take effect July 1, 2001.

The requirements are a condition of Medicare coverage and apply to a range of diagnostic tests payable under the Medicare physician fee schedule, including diagnostic imaging and ultrasound.

In a program memorandum to carriers (B-01-28), the Health Care Financing Administration defines the level of physician supervision required and assigns the level required—general, direct, and personal—to a CPT code for each affected procedure: for example, diagnostic radiology in the 70010-76400 series and diagnostic ultrasound in the 76506-76986 range.

General supervision requires the physician's overall direction and control, but not his or her presence while the procedure is being performed. Training of non-physician personnel who perform the procedure, as well as maintenance of the necessary equipment and supplies, is the continuing responsibility of the physician.

Direct supervision in an office setting requires the physician to be in the suite and immediately available to furnish assistance and direction while the procedure is being performed.

Personal supervision requires the physician to be in the room during the performance of the procedure.

Certain sleep testing codes in the range of CPT 95860 through 95937 will have new supervision levels as of July 1. "This will make it possible for physical therapists to acquire the certification required to perform these services without supervision," the memo notes.

The program memo can be found at *www.hcfa.gov/pubforms/transmit/memos/comm_date_dsc.htm*. Note that the CPT codes in the transmittal are for the year 2000; they do not reflect the CPT 2001 update.

Not affected by the revised requirements: diagnostic procedures for hospital inpatients, clinical diagnostic laboratory tests, or diagnostic mammograms regulated by FDA.

Also unaffected: supervision requirements under CLIA and the Stark physician self-referral law.

HCV Lookback Rules

Notification Is Most Controversial Component

Under the proposed regulations, hospitals that have administered or released blood potentially at risk of HCV infection must:

- Make at least three attempts to notify the patient (or the attending or ordering physician to ask them to notify the patient) that potentially infectious blood was transfused. If the physician is not available, the hospital must make at least three attempts to notify the patient or the patient's legal representative.
- Immediately notify the patient or the patient's legal representative of the need for HCV testing and counseling.
- Document in the patient's medical record the notification or attempt at notification.

The hospital would have 12 weeks from the date it was notified by the blood bank to notify the patient or document extenuating circumstances that caused notification to exceed 12 weeks.

The hospital also would be required to retain records on blood product source and disposition for at least 10 years (vs. the five currently required), ensure that the records can be promptly retrieved, and fully fund a plan to transfer the records to another entity if the hospital ceases operations.

HCV "Lookback", *from page 3*

meet time limits for:

- Quarantining prior collections from a donor found to be at increased risk of transmitting HCV (and further testing of the donor).
- Notifying transfusion recipients of the need for HCV testing and counseling.
- Keeping records related to HCV-infected blood.

Celso Bianco, MD, president of America's Blood Centers, thinks it will be a recordkeeping nightmare. Hospitals don't have procedures that are so well documented, he says. "Usually, if the search for a physician or patient doesn't go anywhere, they'll just drop the case. Now they'll be forced to document that they did everything."

Prior lookback studies, he points out, show that about half of recipients of HCV-infected blood die within the first year because of their primary disease. Now, hospitals will be required to have some documentation that the patient really died. "If it happened in a hospital, that's easy, but if they died at home or in a nursing home, it's more complex."

S. Gerald Sandler, MD, director of the Blood Bank and Blood Donor Service at Georgetown University Medical Center in Washington, DC, says that between 1-2% of people living in the U.S. are infected with HCV, but the lookback program is an ineffective way of informing them that they have the disease. "We have conducted about 250 HCV lookbacks since they began. And we have not identified a single person who found out for the first time by a call from me or their doctor that they are infected with hepatitis C."

Apart from the patients who were deceased, Sandler adds, many were not traceable "after an incredible effort." In many cases, they involved emergency room visits with minimal records.

Requiring three attempts to contact the patient is unnecessary, the American Hospital Association believes. In comments to FDA, AHA executive vice president Rick Pollack requested that hospitals be permitted to satisfy the notification provision by making one attempt using a traceable method, such as certified mail, return receipt requested.

"A signed returned receipt means the patient was successfully notified. A returned letter should be proof that notification was attempted and was unsuccessful, meaning further attempts will be similarly unsuccessful."

With the record retention requirement increased to 10 years under the proposed rules, AHA maintains that using information in the patient record—for example, the last known address or telephone number—should be acknowledged as a good-faith effort by a hospital to contact the patient.

Resource

- Sharon A. Carayiannss, FDA Center for Biologics Evaluation & Research: 301-827-6210.

OSHA To Begin Enforcement Of Safety Needles Mandate

On July 17, the Occupational Safety & Health Administration will begin enforcing requirements that employers must involve end-users (phlebotomists or other front-line workers) in selecting safe needles and sharps and must maintain a sharps injury log.

The requirements were mandated by Congress and took effect Apr. 18, but OSHA has been conducting a 90-day outreach and education initiative before starting to enforce the revisions to the bloodborne pathogens standard.

States and territories that run OSHA-approved state programs have until Oct. 18 to adopt the revisions or amend their existing standards with more stringent requirements.

Information on the new requirements is available on OSHA's Website at www.osha.gov *and in our previous coverage in the following issues: Apr. '01, p. 1 and Mar. '01, pp. 5-8.*

COMPLIANCE PERSPECTIVES

Challenging & Winning Medicare Overpayment Determinations

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Every clinical laboratory, like other types of providers in the Medicare program, faces the likelihood of receiving a written overpayment determination from the carrier. The most common grounds: billing the wrong procedure code and lack of medical necessity.

The carrier may have conducted a 100% case review or performed what it believes to be a statistically valid random sampling (SVRS) and extrapolation. This is a review of a certain number of randomly chosen records, with results then extrapolated over the universe of claims submitted during the audit period.

Sometimes, the carrier doesn't use either approach, but reviews a non-SVRS of claims, approximates the results if extrapolated, and asks the provider to accept that calculation or to submit additional information and agree to be bound by the revised findings. The provider is warned that otherwise, an SVRS and extrapolation will be undertaken, which could result in a higher overpayment determination.

Sometimes, the carrier reviews a certain number of records, judges that the provider is billing wrongly in all cases for a particular procedure code, and simply applies that determination over 100% of the claims submitted for that code during the audit period.

Regardless of the reason for the overpayment finding, the method of calculation, or the manner in which the audit was conducted, laboratories have the right to contest the determination. But the typical reaction is to concede and pay the money back, or try to work out a repayment schedule.

Even when the lab believes it did not bill incorrectly, it is often afraid to fight Medicare for several reasons. The first is the perception that you can't beat Medicare. The second is the assumption that it is too costly to fight. The third is fear that if you challenge Medicare, the government will retaliate, subjecting you to continuing audits and investigations.

Despite those fears, labs should be of the mindset to fight all overpayment determinations with which they disagree.

Avenues Of Appeal

To better understand why you can prevail, it is necessary to understand the five-step appeals process. The first step is to request an informal review by carrier staff who did not participate in the initial decision. The lab may submit additional documentary evidence, but at this stage of the process is not likely to be successful.

The second step is to request a carrier fair hearing before a hearing officer employed by or under contract with the Medicare carrier. This officer is generally familiar with lab testing and Medicare billing rules, but cannot have been involved in the prior determinations.

Carrier fair hearings may be in-person, via telephone, and on-the-record. The latter is based on facts in the file, including any additional information furnished to the hearing officer by the provider; if the decision is unfavorable, the provider may still request an in-person or telephone hearing, both of which are informal and "non-adversarial."

At in-person hearings, the provider appears, with counsel if desired, and presents oral and written testimony, evidence, and arguments challenging the carrier's determination.

The rules of evidence are relaxed, meaning affidavits, letters, documents, and other forms of "hearsay" can be included in the record.

The lab may review the carrier's file in the possession of the hearing officer prior to the start of the hearing.

The telephone hearing is handled in the same manner, but over the phone. Additional evidence usually may also be submitted after the hearing.

One reason why labs can win at this level is that the carrier is not represented at the hearing. The lab is there with its witnesses and counsel. There is no hostile cross-examination, although the hearing officer will ask whatever questions are nec-

essary to understand the case fully. Hearing officers, however, are bound by local carrier medical review policies and often appear reluctant to overturn carrier determinations.

Telephone hearings are generally no more or less successful than in-person hearings. Deciding which to request can depend on the lab's feeling whether its presentation is more effective when done in person or not. Key witnesses, such as the lab director, may be particularly impressive or credible in person. A telephone hearing has the advantage of saving travel time and expense. Either way, many preliminary matters may be addressed by telephone in advance of the hearing. It is always useful, whether the hearing be in person or by telephone, to give the hearing officer in advance any new written materials on which you will rely.

Medicare's 5-Step Appeals Process

- Informal review by carrier staff
- Carrier fair hearing (in-person, via telephone, or on-the-record)
- Hearing before an Administrative Law Judge
- Hearing before Appeals Council
- Bring action in federal court

If the results are still unsatisfactory, the next step is an appeal to an Administrative Law Judge (ALJ) of the Social Security Administration (SSA). These hearings are always in-person, conducted at the local SSA office. They are slightly more formal than carrier fair hearings. The ALJ is employed by SSA, not the Medicare carrier. The hearing is also non-adversarial, in the sense that neither the carrier nor HCFA appears. The ALJ asks whatever questions he or she feels necessary, and the lab can present its own case in the same manner as at the carrier fair hearing.

This forum is even more favorable to the lab for a number of reasons. The ALJ is not affiliated with Medicare and tends to be much more favorably inclined to the provider. Further, the ALJ is not bound by local carrier rules or policies. In medical necessity cases, ALJs often resent carrier second-guessing of physicians. The carrier's file often fails to explain why medical necessity was found to be absent. Thus, the ALJ may accept a credible explanation of medical necessity from the lab at the hearing.

By this time, the laboratory will have won most appeals. Nevertheless, if the ALJ decision is unsatisfactory, the provider may turn to the SSA Appeals Council. This appeal is done on the papers submitted; a hearing is not usually granted. The Council may decline review, in which case the ALJ decision becomes final. The Council may also remand the matter to the ALJ for further consideration or action. It is rare, however, for the ALJ decision to be overturned.

The final stage is to bring an action in federal court. This involves a lawsuit against Medicare and is recommended only in rare cases involving substantial overpayment issues.

The reason why a lab should fight, therefore, is that it can win, either at the carrier fair hearing or before the ALJ.

A major reason why is that carriers make critical mistakes. The mistakes may be in the coding that the carrier contends should apply, but sometimes the error is more fundamental. In one case, after review of the carrier's file, it was discovered that the carrier had simply identified the wrong provider. In other cases, even when the carrier may be correct about a wrong procedure code being billed, the method of calculating the overpayment is so flawed that the determination cannot stand.

For example, the erroneous calculation may be the result of the carrier's not using proper methodologies. The Medicare Carrier's Manual (HCFA Pub. 14-3) contains detailed guidelines for proper sampling and extrapolation techniques. It emphasizes, however, that the most accurate and desirable method is a review of all individual claims. Thus, sampling is appropriate when an objective sample can be drawn that is fair to the government and the lab, and when too many claims are involved for there to be a case-by-case review of individual claims.

Common Carrier Errors

Carriers often fail to follow proper sampling and extrapolation techniques. Usually, the investigators are not trained statisticians. The lab can consult its own statistician to review the carrier's method. Frequently, that is not necessary because the flaws are obvious.

A common error carriers make is to extrapolate the findings over a universe of claims larger than that audited. For example, the audit may cover claims for a one-year period, but the carrier applies the findings to all claims over a four-year period. In most cases, it is simply unacceptable for a disallowance to be determined over a claims period larger than the audit period.

Another common error occurs when the carrier reviews a small number of claims, which is not in-

Prevailing In Overpayment Challenges: Case Examples

Contesting A Carrier's Rulings On Proper Coding

A lab had received a carrier Notice of Overpayment of almost $400,000, covering claims processed during a five-year period, encompassing seven separate coding issues.

The lab's request for a fair hearing prompted the unusual occurrence of the carrier itself initiating a review of its overpayment determination, possibly the result of a suggestion by the fair hearing officer. Non-SVRSs were selected, then estimates were given of what the overpayment would be if extrapolated, a clearly improper technique. The review by the carrier reduced the overpayment to about one-half and left just two coding issues to be resolved.

The first issue involved the proper code for certain urine cultures.

The carrier's investigator had reviewed just 30 claims for a one-year period and found that in each case one particular method of performing the test was used and the wrong code billed. The carrier determined that the wrong code was billed 100% of the time. Rather than applying that finding to the claims reviewed, or to one year of claims, the carrier extended the 100% disallowance to the universe of claims under that code for a four-year period.

At the hearing, the lab was able to show that it did not use the particular methodology consistently over the four-year period, but rather changed the methodology early in the disallowance period when a new technique was developed. Thus, the 100% extrapolation was improper. The carrier had never notified the lab that it would extrapolate the small claim sample over a multi-year universe, thereby depriving the lab of the opportunity to show during the audit that it was using a different method and properly billing for it. The hearing officer thus determined that the carrier did not use due diligence in its review or when it extrapolated its review findings.

Further, the lab prevailed on the issue of which code was proper. The lab sought clarification from AMA's CPT Information Services, whose response was favorable to the lab. The carrier was criticized for not seeking the same clarification after the lab had shared the AMA response with it during the audit.

On the second coding issue, the carrier had concluded that the lab never used the particular tissue culture method for which it billed.

The carrier based its determination on just five service dates in April 1997, but calculated the overpayment over a universe of four years for over 5,000 services. This was erroneous because extrapolation of results over a larger universe of claims requires that an SVRS be done, which was not done here. Further, during part of the disallowed time period, the particular code relied on by the carrier was not even in use.

Since the carrier did not exercise due diligence in its review or in extrapolating its findings from one month over a four-year period, virtually the entire $400,000 overpayment determination was reversed.

Billing & Medical Necessity

In this separate case, the only issue was billing for blood osmolality.

Here, a different carrier reviewed claims over just seven months. The carrier's medical consultant found no medical necessity, resulting in a determination that the lab was overpaid in all instances. The carrier then determined that because of this, payments were disallowed for all osmolalities for a three-year period. The reasoning: first, the tests had not been specifically ordered by the requesting physicians and were add-ons; second, because of that, the osmolality testing was not medically necessary.

The hearing officer, in advance of the hearing, accepted the argument from the lab that it was improper to extend the overpayment calculation over a larger date range than that which was sampled, since the service in question was not one which was never covered by the carrier. This immediately reduced the overpayment from over $120,000 to just over $5,000.

The medical necessity denial also could not stand at the hearing.

The carrier just reviewed the lab requisitions, from which it was impossible to make an across-the-board decision regarding medical necessity. The carrier had never requested the physicians' medical records. The lab presented testimony that osmolality testing was indicated for the nursing home population being served for several possible diagnoses. Further, the lab was able to show that physicians did make individual decisions to order osmolality testing, so it was not simply an add-on.

The finding of 100% disallowance was improper because the carrier did not have sufficient information to determine medical necessity: it did not review the medical records, the lab did not have access to these records, the testing was consistent with diagnoses prevalent among the nursing home population, and the physicians did make individual decisions when ordering the testing. Thus, the entire overpayment was reversed.

tended to represent an SVRS. Yet, the carrier goes ahead to assert 100% error in the lab's billing of a particular code. The carrier then disallows 100% of the billings for that code over either the same audit period or over a larger claims period, such as four years. In either case, the extrapolation is improper because Medicare cannot extrapolate from a non-SVRS. This form of extrapolation can be defeated by showing that the carrier's assumption of a 100% error rate is erroneous. It may simply be that what the carrier thought was standard practice was, in fact, not so.

The actual cases discussed on p. 7 are examples of how labs can prevail. The cases were telephone hearings, requiring minimal time. (Even in-person hearings are abbreviated, generally not requiring more than one hour.) Cost, even of attorneys, therefore, should not be an obstacle to pursuing a carrier fair hearing.

Waiver Of Liability

Even when overpayments result because tests were not medically necessary, a laboratory can still prevail under the concept of "waiver of liability."

The Social Security Act states that even if services are found not to be medically necessary, a lab is still entitled to payment if it did not know, or could not reasonably have been expected to know, that the services were not medically necessary.

Labs do not make medical determinations. They receive test orders and generally do not question the physician's judgment. ALJs are reluctant to second-guess the physician and also are more understanding of the lab's limited role.

Thus, unless the lab has been put on prior notice that a particular test is not medically necessary for a particular diagnosis, such as through carrier advisories or prior adverse determinations, the lab can and should make strong use of the waiver-of-liability defense.

In response to a "no medical necessity" determination, the lab should argue first that the test was medically necessary. Its medical director or consultant can testify; it can also provide testimony from the ordering physician, either in person or in writing.

Second, even if the test were not medically necessary, the lab did not know or was not in the position to know this. You can establish this by showing that the test ordered was consistent with the diagnosis provided.

In one case, almost $100,000 was at issue over the carrier's payment denial for certain tumor marker tests as "experimental in nature."

Based on FDA approval and testimony from an outside expert presented by the lab, the ALJ determined that the test was covered. Further, due to inconsistent payment by the same carrier, as well as coverage by other carriers, the ALJ remarked that the lab could not reasonably have been expected to know that payment would not be made.

Exercise Your Rights

The discussion above shows that laboratories can and most often do win overpayment determinations. The process need not be expensive. The issues are generally not complicated and involve a relatively minor amount of work in putting together the lab's case and evidence.

When you think you're right and the carrier isn't, dispel common fears that you can't beat Medicare, that it costs too much to fight, and that your challenge to Medicare may invite retaliation from the government. There are three words of advice applicable to most cases where an overpayment determination is reached that you don't agree with: "Fight, fight, fight"

Fear of retribution by the carrier is misplaced. Carriers make overpayment determinations all the time, and these are subjected to appeals all the time.

There is simply no evidence that providers pursing their legal appeal rights have been subjected to further adverse actions by Medicare. More likely, the carrier has gone on to someone else's business, regardless of the outcome of your appeal.

Do not hesitate to pursue your appeal rights.

Laboratory personnel, not carrier investigators, are experts in lab testing. Labs should rely on their expertise and good faith in challenging erroneous overpayment determinations.

Resource

For guidelines on proper sampling and extrapolation techniques, see the Medicare Carrier's Manual (HCFA Pub. 14-3). It can be purchased in hard copy or on CD-ROM from:

National Technical Information Service
5285 Port Royal Road
Springfield VA 22161
Tel: 703-605-6060
Fax: 703-487-4793

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How Compliance Helped One Lab Cut Medicare Denials By 95%

Ellen Heim thought she was attending a routine meeting soon after her hospital's compliance program was launched nearly three years ago. So, she was surprised when the laboratory, where she was director of outreach, was put under an unwelcome spotlight.

The head of patient accounts at Heim's hospital, Holy Family Memorial Center, announced that Medicare denials were a problem—and the lab was the biggest culprit.

Heim had directed outreach for two years, but still was startled. "We said we had never heard about any denials … No one ever asked us to do anything about it."

Once she started poring over data from the billing department, the problem was clear: the lab was losing over $15,000 per month, or $180,000 per year, because of denied claims.

Her lab's response shows how a targeted compliance effort can improve not only Medicare compliance, but also the bottom-line.

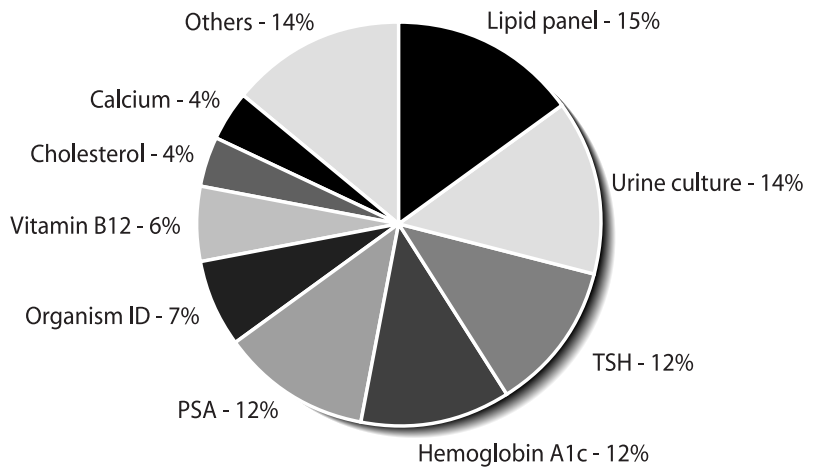
Tracking Down The Problem

Holy Family Memorial is located in Manitowoc, WI (population 30,000), a small town with no unusual demographics. It has 320 beds and 12 clinics in its network as well as two pharmacies, several nursing homes, plus home health agencies, hospice programs, and cancer care. Ten clinics outside the network send in lab test orders and are also outreach competitors.

Heim's first step was to form a rapid-response team. Members came from various hospital departments: the lab, patient accounts, health information systems, billing, and coding. The team was charged with scrutinizing the 300,000 billable test orders, sorting out their origins and determining which tests were being denied and whose orders were involved. When it came to Medicare denials, the team wanted to know which tests were the "frequent flyers."

Lipid panels and urine cultures, as it turned out, were frequently denied by Medicare as screening tests. So too were prostate-specific antigen tests. But Medicare covers the PSA test for diagnoses of chronic prostatitis—which many of the patients had—so Heim and her team felt that if the lab got more specific and complete diagnosis data from physicians, the denial rate would drop dramatically.

Most Frequently Denied Lab Tests*



*Identified by Heim's rapid-response team at Holy Family Memorial

Narrowing The Focus

Few of the denials were for inpatient work, the team found. Nursing homes accounted for 40%, while 58% were for hospital outpatient work or orders from clinics both within and outside the Holy Family Memorial Network. Investigators began breaking down the denials by clinic. They determined that the leading source (Clinic A) was responsible for 17% of the total.

In a way, this was good news, Heim recalls, because Clinic A was considered the friendliest in the network. "This was the clinic that had always strived to be a team player. When you'd say this isn't going right, their response was 'What can we do to fix it?'"

The team decided to meet with Clinic A physicians, nurses, and administrative staff to discuss corporate compliance and Medicare denials. "We hashed it around and said we're not trying to point a finger at anybody, but where are we dropping the ball?" Often, what occurred was that a patient might come in for, say, fatigue, but since the patient was also a diabetic and it was time for a hemoglobin A1c, the test was ordered, but the diabetes diagnosis was left off.

Once the team showed how denials from Clinic A were amounting to losses of over $30,000 per year, the staff was willing to adopt a billing compliance plan. Heim focused on three tools to help them:

- Local medical review policies: Heim distributed the relevant policies and the "frequent flyer" list of denied lab tests. She compared the two and pointed out that Medicare would deny payment for any test without the appropriate diagnosis code. Ordering screening tests is not bad medicine, she pointed out. It's

just that Medicare won't pay for them. But often the patient's chart will support a diagnostic test, as in the case of chronic prostatitis.

- Streamlining paperwork: The lab reworked its requisition form to make it easier for doctors to include the correct diagnosis codes and written narratives of medical necessity. "We're not asking you to lie," Heim emphasized to the physicians, "because then we'll all end up in orange jumpsuits. We're just asking you to be more conscientious about compliance."
- Advance beneficiary notice: At the compliance team's urging, the lab began using ABNs for all screening tests ordered. This policy was relatively easy with Clinic A because it was within the hospital's network and staffed by employees within the lab's immediate control. The medical assistants would greet the patients and enter their demographics and test orders. If the orders came without correct codes (or without any code), the assistants would call the doctors to check the diagnosis. If there wasn't one, the patient was asked to sign an ABN.

Compliance Report Cards

Feedback was a key part of Heim's plan. Each month, each physician and nurse in the clinics received compliance report cards with an explicit accounting of denials. For instance, in any given month, Physician X might have had 23 tests denied (10 lipid panels, five calciums, three PSAs, etc.) for a total of $3,000. By comparison, Physician Y might have had 14 denials (five lipid panels, three HbA1c, etc.) for a total of $1,500.

"This really caught their attention," Heim recalls. So did repeated telephone calls to obtain more specific diagnostic information. "Once we got them in the groove of writing down better information, their compliance really improved."

In fact, the medical assistants became so adept at spotting inadequately supported test orders, and the doctors so proficient at providing the correct diagnoses, that denials at Clinic A dropped sharply.

Nursing Homes Were Next

The next to receive visits from Heim and her compliance team were the other network clinics and nursing homes. At the latter, they met with the administrator, medical director, finance director, nurses, and unit clerks. The team's approach: present the numbers of tests ordered and claims denied, along with compliance educational materials.

"We came up with a plan for each [skilled nursing facility]," Heim says. "They soon learned we'd stop bugging them with phone calls if they gave us better information." They also got monthly report cards from the lab.

One of the main difficulties was correcting denials from clinics that ordered tests but were outside the Holy Family Memorial Network. "When you say I'm having trouble with Medicare denials, and they're competitors, they don't really care," Heim recalls, adding that, luckily, she was able to find one or two people whom the lab could call. She recommended that labs "establish a relationship any way you can. Dig out the person with compassion."

Denials Plummet

Within five months of launching its initiative to reduce the number of claim denials, Holy Family Memorial saw its Medicare lab test denials plummet by 69%. To keep the momentum, the lab began sending updated comparative data to everyone in the system. "It got competitive and got the clinics more excited about doing a better job," Heim says.

The initiative didn't bat 1,000. "Some doctors were better than others. Some went back to their charts. And some didn't give a darn."

Holy Family Memorial's Report Card

Month	# Medicare Denials	Loss
Sep 98	274	$15,373
Oct 98	235	$12,718
Nov 98	180	$8,848
Dec 98	144	$7,235
Jan 99	83	$4,762
Feb 00	28	$1,764
Nov 00	5	$800

There were also phases with less progress. About six months into the initiative, Heim and her team hit their first plateau, with denials leveling off to around $4,000 a month for several months. But technology intervened to help continue the downward trend.

"We had educated the lab people to just look for frequent flyers manually for a couple of years, but finally in January 2000, we got software that would tell us, when ordering the test, whether Medicare would pay for it."

If there was any doubt, the people in the lab would contact the doctor or the nurse's station and ensure there was a correct diagnosis listed or a signed ABN if the test was for screening. Partly as a result of the new medical necessity software, the numbers started to drop again.

Tracking Results

Constant tracking of results paid off. For example, along the way the lab found that PSAs and HbA1cs were no longer a problem, but TSHs and urine cultures still were, largely due to new emergency room physicians. "They just weren't familiar with making sure we had the right diagnostic information," Heim says, so a program was devised to raise awareness. "We had all these new variables and attacked each one to reduce our denial rate."

By February 2000, Medicare denials had dropped to $1,764; by No-

vember 2000 they fell to an astonishing $800, with only five claims denied. Overall, through its targeted compliance program, the lab was able to cut the number of Medicare-denied claims by nearly 98% and the revenue loss by nearly 95% in slightly more than two years.

Could other labs get the same results? Heim says some of the task was easier because many of the denials occurred within the Holy Family Memorial Network, making it easier to educate the doctors and nurses. "But I think our levels of denials were about the same as others were getting. We're all in the same boat."

In any case, at the corporate level, the program has won fervent support. Although Heim has moved on to a job in marketing of home medical services, the hospital's management is preparing to start another internal group to work on denials in other areas, and they've asked Heim to bring her successful experience in the laboratory to bear by joining the effort.

Resource

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FDA Firm, *from page 1*

FDA is taking action, Feigal said, "because of public health concerns about the cleaning, disinfecting, and sterilizing of previously used SUDS, and the effect reprocessing may have on the functional integrity of the reused device."

Safety concerns have long been raised by Congress and device manufacturers, and FDA announced last year that it would change its regulatory approach to reprocessing SUDS. Last August, a General Accounting Office report said hospitals lack familiarity with rules governing medical device makers, so FDA began issuing letters and other guidance to help hospitals get ready.

The New Rules

Hospitals reprocessing SUDS must meet seven requirements applicable to original device manufacturers: registration and listing; medical device reporting; medical device tracking; medical device corrections/removals; quality system regulation; labeling; and premarket submissions (premarket notification or 510(k) and premarket approval application or PMA).

Failure to comply exposures the hospital to a number of enforcement actions:

❖ Public health alerts and notifications: A hospital could be required to directly notify healthcare providers, consumers, and other involved parties of devices that pose actual or potential risk to public health.

❖ Warning letter: FDA may issue such a letter to a hospital to inform it that the agency has found serious regulatory violations and may begin action without notice if the violations are not promptly corrected.

❖ Mandatory recall: FDA officials may require a hospital to recall a reprocessed SUD if there are concerns about it causing serious, adverse health consequences or death.

❖ Seizure: A medical device may be seized if it is considered to be out of compliance with quality system requirements (adulterated) or if labeled with an incorrect device description (misbranded).

❖ Injunction: FDA can seek an injunction against a hospital to prevent its manufacture or distribution of a device that violates a requirement of the federal Food, Drug & Cosmetic Act.

❖ Civil money penalties: Up to $1 million per proceeding may be imposed against violators.

❖ Prosecution: Violators may be criminally prosecuted.

Guidance Help

Feigal's letter advised hospitals to be alert to agency pronouncements about reprocessed SUDs. In fact, one day after the letter, FDA released a guidance document on adverse event reporting. Its main point is that the hospital must meet reporting requirements for both a user facility and a manufacturer, meaning additional work for hospitals.

FDA recommends the following resources for more on the new policy:

❖ SUD reuse issue: *www.fda.gov/cdrh/reuse*

❖ Enforcement priorities: *www.fda.gov/cdrh/comp/guidance/1168.pdf*

❖ Adverse event reporting: *www.fda.gov/cdrh/osb/guidance/1334.pdf*

❖ Division of Small Manufacturers Assistance: 1-800-638-2041. E-mail: DSMA@CDRH.fda.gov

FDA Enforcement Timetable

The first deadline has passed. As of last Feb. 14, hospitals that reprocess SUDS posing the greatest potential risk (class III) had to submit PMAs or 510(k)s. If by this Aug. 14, however, a hospital reprocessor has not obtained an FDA marketing approval order or clearance, the agency will take enforcement action if the reprocessing practice continues.

Aug. 14 is also the submission deadline for:

❖ Hospital reprocessors to comply with non-premarket requirements for class I, II, and III devices.

❖ 510(k)s for any class II SUD, unless the classification regulation specifically exempts the device.

Effective Feb. 14, 2002, the hospital must have FDA marketing approval or clearance for class II SUDs or the agency will take enforcement action if reprocessing continues. That date also is the submission deadline for 510(k)s for any class I SUD, unless it is specifically exempt by regulation.

Effective Aug. 14, 2002, the hospital must have FDA approval or clearance for class I SUDS or enforcement action will be taken if reprocessing continues.

The Back Page

News-At-A-Glance

Physician recruitment incentive passes anti-kickback muster. In a May 3 advisory opinion (01-4), the HHS Office of Inspector General gave the green light to a tax-exempt rural hospital's bid to recruit a new physician by providing a loan subject to favorable terms, together with conditional loan forgiveness. Though the proposed arrangement did not fit within the safe harbor for payments or benefits offered by hospitals to attract doctors to shortage areas, the OIG concluded it contained sufficient safeguards against fraud and abuse in patient referrals and would benefit the public by increasing access to medical services in medically underserved areas.

Three doctors and two medical managers have been charged in a kickback scheme that bilked more than $1 million from Medicare, Medicaid, and private payers. The charges, announced by the U.S. attorney's office in Chicago on May 17, included alleged kickbacks for patient referrals and medically unnecessary hospital admissions as well as lab and other diagnostic tests between October 1996 through 1998. The alleged fraudulent conduct involved doctors, a medical administrator, and a medical management company, each affiliated in some capacity with Edgewater Hospital on the city's north side. Counts of racketeering and conspiracy have also been filed against several of the defendants.

Overbilling Medicare for magnetic resonance imaging will cost a Massachusetts provider $600,000. The U.S. attorney's office in Boston announced that Shields Health Care Group (Quincy, MA) has agreed to pay this amount to settle civil allegations of misconduct from the early 1990s until May 1995. During this period, the government alleges, Shields billed for MRI services, when the service actually performed was magnetic resonance angiography (MRA), which was not covered under Medicare.

Starting in 1991, the government says, when Shields performed a neck MRA, it would submit a claim for the neck MRA and a separate claim for an MRI study of the neck. While the neck MRA claim was denied because the service was considered investigational, Shields was reimbursed for the neck MRI studies, when the service actually furnished was a neck MRA that necessarily included some preliminary MRI images.

To settle a whistleblower lawsuit brought by a patient, Tenet Health Corp. has agreed to pay $175,000 to resolve charges that one of its Florida hospitals overcharged Medicare and patients for surgical outpatient pathology services. The False Claims Act case was filed in 1996, and the government joined it last year. In the lawsuit, the patient Abe Hertz (now deceased) alleged that Tenet-owned Delray Community Hospital (Delray Beach, FL) billed Medicare three times the legitimate charge for pathology tests of tissue samples taken during two colonoscopies, as well as additional exams and tests performed on Hertz's wife and a neighbor.

The dollar amount of the settlement was relatively small, attorneys representing Hertz's widow noted, because Medicare paid the actual cost of the services stated by the hospital in its annual cost reports; however, beneficiaries paid a 20% co-pay based on a greater charge. Attorneys added that thousands of inflated copayments were received from patients during the six or more years that the hospital is believed to have engaged in this practice.

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