G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. IV, No. 1, January 2002

For Hospitals, Laboratories and Physician Practices

Medicare Adopts Uniform Lab Coverage Policies

Key Benefits: Payment Predictability, Consistency

The Centers for Medicare & Medicaid Services has finalized a rule establishing new national Medicare Part B coverage and payment policies for 23 frequently performed clinical diagnostic laboratory tests, effective Nov. 25, 2002.

The rule affects such basic tests as blood counts, lipid tests, thyroid and iron studies, as well as HIV diagnosis and monitoring. In general, tests are not covered if done for screening purposes in the absence of symptoms and similar conditions, if unnecessary for diagnosis or treatment or if their medical necessity is not documented.

End To Carrier Variations

The new policies will replace varying local medical review policies (LMRPs) developed by Medicare carriers and will apply to clinical laboratories regardless of setting, whether in physician offices, hospitals or independent facilities.

The national policies were developed via a negotiated rulemaking process that involved Medicare officials and representatives of clinical lab, physician, hospital, medical management, coding and consumer groups. The rulemaking was required by the Balanced Budget Act of 1997 in response to provider complaints that the LMRPs were inconsistent and incomplete in the covered diagnoses supporting the medical necessity of certain lab tests.

Lab industry groups say the rule will give them predictability for coverage and payment and also end competition based solely on one carrier having more generous coverage than another.

Staggered Timetable

Several "provider friendly" administrative changes in the final rule

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Inside this issue

Former Damon VP Convicted In Bundling Scheme

Defendant To Seek Court Acquittal

The former senior vice president of Damon Clinical Laboratories (Needham, MA) was convicted in federal court on Dec. 17 on a charge of conspiracy to defraud Medicare by "tricking" physicians into ordering unnecessary blood tests.

After a three-week trial, William Thurston was convicted on the charge of "bundling" an infrequently ordered test, ferritin, into a commonly ordered blood test panel. Because the test was "hidden" in the panel, physicians in effect were "tricked" into ordering the medically unnecessary test, according to Michael Sullivan, the U.S attorney for the District of Massachusetts. The goal of the bundling scheme, he said, was to offset Medicare rate reductions for laboratory services.

By bundling the tests, Damon received a flat fee for the panel plus

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Stark II: CMS Delays 'Set in Advance' Requirement
Other Physician Self-Referral Curbs Take Effect Jan. 4, 2002

The Centers for Medicare & Medicaid Services has postponed for one year the "set in advance" compensation requirement under the physician self-referral rule. The new effective date is Jan. 6, 2003.

Attorney Linda Baumann with Reed Smith LLP (Washington, DC) says this will, at least temporarily, suspend CMS's narrow interpretation of the requirement in the Stark II Phase I final rule (published Jan. 4, 2001), and will allow arrangements involving all types of percentage compensation to qualify for protection under the Stark exceptions, assuming other requirements of the exceptions are satisfied.

The rule had allowed certain, very limited types of percentage compensation arrangements to qualify for protection as long as the compensation was set in advance. But it specifically stated that "percentage compensation arrangements do not constitute compensation that is 'set in advance' in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same services from the same purchaser."

Many of the comments CMS received on the issue pointed out that physicians are commonly paid for their professional services using a formula that takes into account a percentage of a fluctuating or indeterminate measure (for example, revenue billed or collected for physician services).

According to a Dec. 3, 2001 *Federal Register* notice, the delay in the "set in advance" requirement is intended to prevent hospitals, academic medical centers and other entities from having to renegotiate thousands of physician contracts, and will also give CMS officials the opportunity to reconsider the matter.

Attorney Robert Mazer with Ober/Kaler (Baltimore, MD) says the reprieve is significant. "Though the agency discusses the issue in the context of arrangements for physician services, the delay goes beyond those types of arrangements, for example, to arrangements for the lease of equipment where the entity owning the equipment is physician-owned," he notes.

Are You Ready For Stark II? Key Points To Keep In Mind

- To determine whether a particular service is a designated health service (DHS), refer to the list of applicable CPT and HCPCS codes (*Federal Register*, Jan. 4, 2001, Attachment, pp. 963ff).
- A physician does not make a referral if he or she personally performs the clinical laboratory test or other DHS. If the service is furnished in a hospital, any technical component is deemed to have resulted from the referral, but the personally performed professional component (physician's interpretation) would not.
- Exempt are requests by a pathologist for clinical lab services or pathology exams if the services are furnished by, or under the supervision of, the pathologist pursuant to a consultation requested by another physician. The same is true for requests by radiologists for diagnostic radiology services and by radiation oncologists for radiation therapy. The consultation must be documented in the patient's medical record and result in a written report to the physician requesting the consultation.

  Only the referral to the DHS provider is protected. If that provider knows or has reason to suspect that the referral originated from the referring physician, and has a direct or indirect financial relationship with that physician, the DHS provider cannot submit a claim to Medicare for the DHS unless the financial relationship fits within a Stark exception. Moreover, the referring physician may not refer to the consultant if he or she knows or has reason to suspect that the consultant will order the DHS from an entity with which the referring physician has a direct or indirect financial relationship not protected by an exception.
- DHS providers may give a physician one or more non-cash gifts per year with an aggregate value of up to $300, so long as the gifts are not based on referrals or other business generated by the physician. The exception does not protect gifts to a medical group (a 10-person medical group cannot be given a $3,000 instrument, for example).
- Excluded from the definition of "remuneration" is a laboratory's provision of items, devices or supplies used solely to collect, transport, process or store specimens for the lab. This does not permit a lab to furnish physicians, without charge, with sterile gloves or biopsy needles and like devices, such as reusable aspiration and injection needles. A lab may, however, provide physicians with single-use needles, vials and specimen cups, but may lose the benefit of this exception by providing more supplies than the number of specimens sent by the physician.
- The penalty for submitting a claim that a person knows or should know results from a prohibited self-referral can be up to $15,000 for each service, plus two times the reimbursement claimed. The provider may also be excluded from Medicare and Medicaid. Those who enter into circumvention schemes can be fined up to $100,000.

Mazer adds that it is impossible to predict what final decision CMS will reach on this issue: "It cannot be safely assumed that percentage arrangements will be permissible forever, particularly when certain safe harbors to the Medicare/Medicaid anti-kickback prohibition exclude such arrangements."

CMS will accept comments on the delay through Feb. 1, 2002.

Other provisions in Phase I of the final Stark II rule go into effect as scheduled on Jan. 4, 2002. They primarily address general self-referral prohibitions, exceptions for physicians' services, in-office ancillary services and prepaid plans and certain related definitions. Officials plan to address other issues in a Phase II rulemaking.

The Stark law generally prohibits a physician from referring Medicare and Medicaid patients to entities with which the physician (or an immediate family member) has a financial relationship, whether by ownership/investment interest or a compensation arrangement (unless the relationship is covered by a statutory or regulatory exception). The law also bans submission of a claim to any payer for designated health services (DHS) furnished pursuant to a prohibited referral. DHS include:

- Clinical laboratory services
- Physical and occupational therapy
- Radiology and certain other imaging services (MRIs, CT scans, ultrasound)
- Radiation therapy
- Durable medical equipment and supplies
- Parenteral/enteral nutrients, equipment and supplies
- Prosthetic, orthotic devices and supplies
- Home health services
- Hospital inpatient, outpatient services
- Outpatient prescription drugs

Resources

- *Federal Register*, Dec. 3, '01, p. 60154
- Linda Baumann: 202-414-9488
- Robert Mazer: 410-347-7359
- Our previous coverage: "Stark II Final Rule = Some Compliance Guidance," Feb. '01, pp. 5-8.

Justice Department Recovers Record High In Fraud Payments

The Department of Justice (DOJ) collected more than $1.2 billion in healthcare fraud recoveries in fiscal 2001, setting a new record, according to Robert McCallum, assistant attorney general.

The recoveries included DOJ settlements and judgments related to cases filed under the whistleblower provisions of the False Claims Act. Whistleblowers were awarded more than $210 million for cases resolved during the fiscal period, Oct. 1, 2000 -Sept. 30, 2001.

"This new record demonstrates the Department's continued commitment to pursue those who defraud the United States, whether by providing defective products, billing for phantom services or otherwise misusing public funds for private gain," McCallum said.

Healthcare fraud payments include the $745 million settlement with HCA-The Healthcare Company for a number of fraudulent billing schemes by the largest U.S. chain of for-profit hospitals. DOJ also recovered $104 million from Quorum Health Group for submitting alleged false cost reports to Medicare for hospital expenses and $103 million from Vencor, a major nursing home chain, for alleged false claims to Medicare, Medicaid and TRICARE, the military's healthcare program.

Resource

- Department of Justice: 202-514-2007

Lab Billing Investigation Concludes In Ohio

Ohio officials announced in December that 75 Ohio hospitals will pay $22 million to resolve allegations of fraud involving automated panel tests billed individually rather than bundled.

The settlements are the final ones for the "Ohio Hospital Project," a state investigation that began in 1996 and later expanded to a national probe dubbed "Operation Bad Bundle," according to the Ohio Hospital Association (OHA). The investigation is continuing in other parts of the country, notes OHA.

Across the nation, about 350 hospitals have paid more than $85 million as a result of Operation Bad Bundle. In Ohio alone, officials have recovered $46.8 million from 185 hospitals, according to state auditor Jim Petro and the U.S. attorney for the Southern District of Ohio, Greg Lockhart.

The government alleged that hospitals overbilled Medicare and Medicaid by billing separately for lab tests that should have been grouped. Since the investigation began in 1996, the billing rules for automated lab tests have changed, notes OHA.

Last August, OHA settled a federal lawsuit challenging the lab investigation. As a result of the settlement, Ohio hospitals are no longer required to file detailed compliance reports with the HHS Office of Inspector General *(GCR, Aug. '01, p. 4)*. The compliance reports had been part of the agreements that hospitals had been required to sign with the Federal Government.

Uniform Lab Coverage, *from page 1* will be effective Feb. 21, 2002, and will be implemented primarily via CMS program instructions to contractors. The changes include clarifications that the physician's signature is not required on the lab test order and that contractors may not use frequency screens to deny claims without previously published guidance on the reasonable utilization of a test or service.

The uniform lab policies and other provisions that require changes in claims processing systems (such as date of service) will be effective on Nov. 25, 2002, though labs or contractors may ask CMS to grant a grace period of up to 12 more months.

In the final rule, CMS made important clarifications to provisions in the original uniform lab proposal published in March 2000. Among them:

- The date of service is defined as the specimen collection date. For tests requiring a specimen from stored collections, it should be the date the specimen was obtained from the archives.
- Contractors may not deny a claim before contacting physicians directly in an attempt to obtain missing medical necessity documentation. If a physician doesn't comply, the contractor will notify the lab that billed for the test and deny the claim.
- More covered diagnosis codes are added to various policies, including blood glucose, digoxin, fecal occult blood, GGT, lipids, thyroid testing, prothrombin time, partial thromboplastin time and HIV diagnosis.
- Men as well as women are eligible for coverage of collagen cross-links testing.

Resource

- *Federal Register*, Nov. 23, '01. Online at *www.access.gpo.gov/su_docs*

Lab Tests Under Uniform National Policies

The national coverage policies follow a uniform format that includes a narrative description of the test(s), clinical indications for their use, coverage limitations and related ICD-9-CM diagnosis codes. (Blood counts are the exception; for these, only non-covered ICD-9 codes are specified, since listing covered codes would be lengthy. This will require special attention in setting up computerized systems to handle CBCs, notes Kathy Ayres of the Clinical Laboratory Management Association.)

Culture, bacterial, urine	87086, 87087, 87088, 87184, 87186	Collagen cross links	82523
		Blood glucose testing	82947, 82948, 82962
HIV prognosis, including monitoring	87536, 87539	Glycated hemoglobin/glycated protein	82985, 83036
HIV testing, diagnosis	86689, 86701, 86702, 86703, 87390, 87391, 87534, 87535, 87537, 87538	Thyroid testing	84436, 84439, 84443, 84479
		Lipids testing	80061, 82465, 83715, 83716, 83718, 83721, 84478
Blood counts	85007, 85008, 85013, 85014, 85018, 85021, 85022, 85023, 85024, 85025, 85027, 85031, 85048, 85590, 85595	Digoxin	80162
		Alpha-fetoprotein; serum	82105
		CEA	82378
		hCG	84702
		CA 125	86304
		CA 15-3 (27.29)	86300
		CA 19-9	86301
Partial thromboplastin time	85730	PSA, total	84153
Prothrombin time	85610	GGT	82977
Serum iron studies	82728, 83540, 83550, 84466	Acute hepatitis panel	80074
		Fecal occult blood	82270

Source: *Federal Register*, Nov. 23, 2001. CPT Codes ©American Medical Association

COMPLIANCE PERSPECTIVES

Compliance Officer Roundtable: *Present & Future Challenges*

G-2 Compliance Report (GCR) recently held a roundtable conference call with five industry leaders responsible for compliance activities within their organizations: ***Hyde Frederickson****, compliance officer for IHC Laboratory Services (Salt Lake City, UT);* ***John Steiner****, corporate compliance officer for the Cleveland Clinic Foundation (Cleveland, OH);* ***Peggy Burke****, corporate director of internal audit and compliance for Novant Health (Charlotte, NC);* ***Robert Footlik****, lab compliance officer for Cedars-Sinai Medical Center (Los Angeles); and* ***John Moody****, manager for charge capture and charge description for the University of Alabama Hospital (Birmingham).*

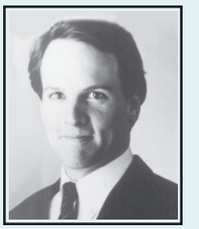
We asked about compliance challenges they face, what they consider the most important regulation(s) in recent years and their plans for 2002. Featured here are excerpts from our conversation (edited for space). More from our roundtable discussion will be presented in the next issue.


Peggy Burke, Novant Health


Robert Footlik, Cedars-Sinai Medical Center


Hyde Frederickson, IHC Laboratory Services


John Moody, University of Alabama Hospital


John Steiner, Cleveland Clinic Foundation

Surprises & Challenges

GCR: What has surprised you most in your day-to-day compliance responsibilities?

Burke: The sheer variety of questions or concerns that come to us. It seems like we serve as sort of a first responder to a lot of questions that people have.

Moody: I was surprised at the time I spend doing research and reading to stay on top of the issues. There is also the issue of frequencies of updates. I am involved with the charge capture and charge description maintenance in our organization, and am responsible for all the APC coding changes under Medicare outpatient prospective payment (OPPS). It seems that those come along about every month or two, and in between, there are two or three revisions or correction notices.

GCR: Have you run into anything unexpected in your role as compliance officer?

Frederickson: I was surprised at how much work it turned out to be. Four years ago when we formalized our program, we really did not know what to expect, but it has turned out to be a full-time job for all those years.

The other unexpected thing is the degree of respect that our compliance program has earned within the organization and the way we are looked to within Intermountain Healthcare as a compliance leader. That has been gratifying.

Moody: One thing that surprised me in my previous life, when I was the laboratory billing coordinator and compliance officer, was when we started with the medical review policies and the ABNs (Advance Beneficiary Notices) and educating our physicians on medical necessity documentation and related issues. We also became more involved in having to deal with the Medicare Secondary Payer questionnaire. All

of a sudden, we had more issues regarding registration and documentation of insurance coverage.

Burke: I think what was a little unexpected was that when people call us with an inquiry, they believe we will have a readily available answer right there on the phone. Very often, even a very simple question can involve very complex research to give what ultimately may be a fairly simple answer. Or, if the question is ambiguous, we try to explain, "This is our interpretation of what we need to do." So, there may not be any such thing as a simple compliance question.

GCR: What do you see as your biggest compliance challenge?

Steiner: Deciding what priorities to set and how much time and effort to dedicate. The process we use to set priorities involves a series of internal worksheets that I divide into active and passive.

A passive worksheet keeps track of regular pronouncements, for example, the HHS Office of Inspector General's work plan. We review it and delegate a lot of the follow-up to others, but from a compliance standpoint, it is logged in as an important publication.

On the active side, we work up an issue across the system. Perhaps it is a red flag coming from the Centers for Medicare & Medicaid Services (formerly HCFA) or some other specific issue we need to address. We keep a log of issues and make certain that each region looks at it. This is a simple explanation of how we set priorities. Sometimes we react, sometimes we plan.

Burke: I continually struggle with evaluating the risk exposure of all the things facing us and deciding which presents the greatest risk and how are we going to address it. There are many worthy projects, but you can't do everything at the same time.

We use a risk assessment process to look at the different challenges we face. Each situation presents a slightly different type of risk exposure. The other challenge for us is to ensure that operations are put into place. We have a lot of different service sites; so, it is a challenge, for instance, to make sure the ABNs are executed, that the goal is accomplished in an appropriate way. There are lots of different operational subtleties to consider.

Frederickson: We have what we call "process mutation." We might implement a process, then audit it six months later only to find that it is turning into something different from what it was designed to be. Then we rein everybody in and straighten out the process and review it again in another six months.

GCR: So, the process mutates rather than evolves?

Frederickson: Yes, because it is not generally going in a positive direction. "Mutation" seems to fit better.

Burke: I concur. Processes are environmentally adaptive. Sometimes, how a process ends up—once you've turned your back on it and walked away—is not something you expected.

Moody: I agree. As compliance officers, we [tend to] see things in black-and-white. We have to do this, that, and the other. When we go down to the front-line people, we find there is some give-and-take, and we really have to be creative to get guidelines implemented and still work within the process established by the people providing clinical services. That is a challenge, but it actually makes things more interesting. If it were cut-and-dry, we would just send a memo and do an audit.

Instead, we get down to the working folks who are making things happen, and we see their issues, work with them and say, "Okay, you have to do this, but can you add this step to help us make sure we do everything right?" It is often a win-win situation.

Footlik: My biggest compliance challenge of late is ABN compliance and all the form changes. Now we are faced with an additional optional form, the Medicare ABN-X [for statutorily excluded services].

Compliance Buy-In

GCR: Do you feel compliance has become an integral part of your corporate culture?

Footlik: Yes, without a doubt. It has been an evolution. Since we implemented our corporate compliance plan and established a corporate compliance committee with representatives from the different areas of our health system, it has definitely had an impact on the corporate climate.

GCR: Is there buy-in by employees?

Footlik: There will always be skeptics, but for the most part, the answer is yes.

Steiner: I agree. I think there are two simple dynamics. First, in many cases, board members from the business world have worked or are working in a regulated environment. It could be banking. It could be securities. It could be a large manufacturer with government contracts. So, they have a good understanding of the importance of compliance.

Second, the actors—particularly the principal investigators and/or the clinicians who have responsibility for day-to-day patient care—fully understand where the majority of the payments come from, and that's from government payers. So, they also understand why compliance is critical.

Burke: We have always had the commitment to try to do the right thing. We have very good support from the Board of Trustees through

senior management all the way down. The compliance program gives the company a kind of evidentiary statement that they are trying to do the right thing. I think it has been well accepted, and I feel a lot of support.

Moody: I believe it has become an integral part of the culture at the University of Alabama Hospital. There has been quite a change in the understanding that the practitioners, the clinicians all have now vs. when we first began focusing on compliance issues. They may not always be able to cite a particular regulation, but they ask themselves, "Does the situation pass the smell test?" If it doesn't smell right, they'll send up a red flag. Compliance is definitely all the way down to our front-line people; it is integrated into our system. The increased awareness actually makes the role of the compliance officer easier.

Projects & Innovations

GCR: As you face each new year, or this year in particular, what are some of the main projects you plan to undertake?

Footlik: We usually start well before January with the OIG work plan because that generally sets the tone for the year. Our corporate compliance committee reviews the entire plan. As an adjunct to that, there is a laboratory compliance subcommittee, which I chair, and the laboratory piece from the work plan is further evaluated by that subcommittee. Then, of course, each new year we face the matter of updating the chargemaster, including implementing new CPT codes.

Moody: We get the OIG work plan as soon as it comes out and start going through the issues, identifying what many have called the "hot buttons," and we incorporate those into our training. As the chargemaster manager, I kick off our CPT code updates. I purchase the CPT and HCPCS codebooks for the various revenue departments. We have to deal with new codes, with deleted codes, as well as terminology and grammatical revisions. We make those changes Jan. 1.

Burke: One thing we are working on this year is online compliance education. We are rolling out the "compliance edge" product, a Web-based training program. We've had challenges trying to get adequate education resources. We have 13,000 employees, and trying to get around and educate all of them in an appropriate and timely manner is a problem. To cut back on our costs, we are looking at an online pilot program this year for selected departments.

GCR: So, each year you work on updating your training and education programs?

Moody: That's right. We typically do PowerPoint presentations. When I find a new transmittal or program memorandum that will have an impact, I give a heads-up to the audience for that particular presentation; it's easier to keep things up-to-date that way.

Frederickson: One thing we plan for each year is training. We run two training sessions a year for all our staff. For the last year, we have been operating online training that we developed ourselves, and it has become more sophisticated as the technology and our ability to use it have improved. We have a quiz online that is taken by staff members right after they finish the review of the training. The results are sent directly to the human resource database that keeps track of all the training that all individuals need to take.

Thus, we have an automated process for both administering the training and recording its completion. That makes it much simpler to keep track of who has done what and who needs to do what. One area where we will specifically focus this year is how to work through the Medicare Secondary Payer process for non-patients in a hospital laboratory. We see that as a huge concern that could actually define whether we stay in that non-patient testing business or whether we decide to do something different in the way we do testing for our clinicians.

GCR: Is anyone else involved in online training?

Footlik: We utilize the online training program from Healthcare Compliance Strategies Inc., an excellent program. It is tailored pretty much to our institution, and there are different modules—basic and more advanced. It is on a CD, but we have networked, and it is Web-based. It keeps track of the progress each person has made in completing the training. So, you do not have to do it all at once. You can leave off at any point, do something else and come back the next day or the next week. It knows exactly where you left off. It will pick up from that point.

When you have completed the training, it automatically notifies our Corporate Compliance Department that you have completed it successfully, and that gets recorded in our HR database. One of my goals is eventually to get a specific laboratory piece developed, because this is a general corporate program.

GCR: Any other innovative programs that you have implemented in the last year?

Steiner: We built internally and have offered for about 18 months now an entire clinical research orientation program. It covers about 14 topics and is targeted mainly to the support personnel. Some principal investigators do attend, but it was designed to reach the broad base of employees who work in clinical tri-

als. It is a live presentation. Last year, we did it four times; this year, we will do it three times. Basically it boils down to four half-day sessions.

Key Regulations

GCR: What do you think is the most significant regulation in the last few years affecting compliance?

Frederickson: I am not sure there is a specific one, but I think the whole area of medical necessity and how to implement what the government has interpreted has been the biggest issue we continue to face.

Steiner: The Balanced Budget Act of 1997 authorized increased funding for enforcement. It also created a stream of funding for the Medicare Integrity Program. So, with major funding flowing downward, we are seeing increasing communications from contractors on all different issues. The contractors have been told: "Be more active."

GCR: So, it is not specifically one rule that concerns you. It's just that there is greater funding of enforcement initiatives.

Steiner: That's right. In terms of enforcement, there are two main things the government looks at: First, is it covered? Second, if it is covered, was it medically necessary?

Burke: I certainly agree. However, going back to your question about the most significant regulation in the last few years, I think it has to be the APCs under Medicare's OPPS. For a hospital-based laboratory or for outpatient hospital services, this has made a very substantial difference in the way we do business.

GCR: How so?

Burke: It has required extensive remodeling of the chargemaster. The level visits for clinic, for outpatient visits have been challenging and I think not well defined. I think the regulations were rolled out without a lot of clear instructions to providers. It has been a real challenge, because something is rolled out, then 30 days later it changes, then 30 days later it changes again. Especially with the pass-through items, it has been hard to stay on top of it, hard to train people, hard to make changes in our chargemaster that fast, much less make changes in our practices that fast.

Footlik: I agree with everything that has been said, but add that the standards under HIPAA (Health Insurance Portability & Accountability Act) have been very significant. As far as I am concerned, HIPAA is a monster, but we are also facing implementation of Phase I of the Stark II physician self-referral regulations this year, which impacts how clinical laboratories deal with providers who order their services and what they can and cannot provide to those providers in terms of supplies.

But, down the line, perhaps the most significant regulation in the past few years may turn out to be the negotiated rulemaking which was just finalized [including uniform coverage policies for 23 common diagnostic tests].

Rather than be subject to all those different LMRPs [local medical review policies that limit test coverage to specific diagnoses], a year from now or so we will have national coverage policies, and that might greatly affect the use of ABNs.

Moody: I'd like to expand on the APC issue. Of course, getting the chargemaster up-to-date has become a lot more important, but there's still a lot of confusion on use of certain modifiers.

Interestingly enough, in the laboratory the big issue has been the -59 and the -91 modifier. The CPT codebook actually lists those modifiers right in the microbiology section. We talked with our local contractor and said, "In the case of blood cultures, where you are doing multi-samples on different sites on the same day, the CPT codebook suggests that we use the -59 modifier." The contractor, though, said we should use the -91 modifier. Our contractors are even having difficulty interpreting some of the guidelines.

[Editor's note: Both modifiers -59 and -91 have a place in coding repeat clinical diagnostic tests. The final rule for uniform Medicare lab policies (*related story, p. 1*) states that -91 should be used when billing for the same test performed on the same day to obtain subsequent test results, such as blood tests. Modifier -59 addresses billing concerns brought to the attention of the committee negotiating the uniform lab policy rule by the microbiology community, and would be used, for example, to bill for multiple blood cultures collected on the same day from different sites to document etiology of sepsis.]

I was involved in the technical implementation of APCs for our hospital, and it was six months after the start date before [the government] spelled out how we should address certain issues.

It was quite challenging, and I'm concerned that we are looking at the same thing with HIPAA. We are probably looking at the same thing with the national lab coverage policies too, where we again will be aiming to hit a moving target.

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ABNs: What Is A Lab's Liability When A Patient Won't Sign?
No Easy Answer On Responsibility To Perform Testing

Can a lab be held liable if it declines to perform an ordered test because a Medicare beneficiary refuses to sign an Advance Beneficiary Notice (ABN)?

In some cases, the answer could be yes, say Thomas Bartrum, an attorney with Baker, Donelson, Bearman & Caldwell, PC (Nashville, TN), and Jeffrey Sherrin, an attorney with O'Connell & Aronowitz (Albany, NY).

An ABN is required when the provider knows that the test or service is not covered or has genuine doubt that it will be covered, and the beneficiary will be financially responsible. While Medicare rules do not require providers to furnish tests or services when a beneficiary refuses to sign an ABN, labs potentially could be liable under state laws governing medical treatment, agree Bartrum and Sherrin.

"There is a liability issue above and beyond Medicare," says Bartrum. "If a physician orders a test and a lab fails to provide it, that could be a basis for a liability suit. It's generally in the lab's best interest to provide the test [even if it might not get paid]."

Potential liability would come down to two questions, explains Sherrin: Did the patient have a right to expect the testing to be performed by the lab, and was the patient harmed by the delay resulting from the lab's refusal to perform the testing?

"Let's say you don't run the test and the patient is harmed as a result," Sherrin comments. "In 99 of 100 cases, that's not going to be the case, but it could happen. In that instance, there could be some liability."

Medicare's Advice

Under draft ABN guidelines issued by the Centers for Medicare & Medicaid Services last October, beneficiaries must select one of two options on an ABN. Option 1 indicates that the beneficiary wants the ordered item or service and is willing to be personally responsible for payment. Option 2 indicates that the beneficiary declines to receive the item or service.

"There is no third option," state the draft instructions. "The beneficiary cannot properly refuse to sign the ABN at all and still demand the item or service. *If a beneficiary refuses to sign a properly executed ABN, the physician or supplier should consider not furnishing the item or service, unless the consequences (health and safety of the patient, or civil liability in case of harm) are such that this is not an option (emphasis added)*. If the beneficiary refuses to sign the ABN, the physician or supplier should annotate its copy of the ABN, indicating the circumstances and persons involved."

If the beneficiary demands the service but refuses to pay, the lab should keep on file a document signed by two laboratory personnel witnessing the provision of the ABN and the beneficiary's refusal to sign. The beneficiary will be held financially liable in case of denial, according to the draft instructions.

What To Do

When a beneficiary refuses to choose either Option 1 or 2 on the ABN and refuses to sign the form, the lab will have to determine how important the testing is, advises Sherrin. If it could be critical, the lab should probably go ahead and provide it.

"If there's some uncertainty, I would say call the [ordering] doctor and explain that you don't think Medicare will pay for the test and the patient won't sign the ABN. Ask the doctor, 'How important is it?' But ultimately, if it's a close call or if you can't reach the physician, do the test and worry about the payment later, because the risk of being wrong could be much greater than the cost of the test."

Resources

- Thomas Bartrum: 615-726-5720
- Jeffrey Sherrin: 518-462-5601
- Our previous coverage: Nov.-Dec. '01, p. 3; Oct. '01, p. 2; Sept. '01, p. 1

The Centers for Medicare & Medicaid Services plans to publish final instruction for carriers on ABN use within the few next months, though use of the new general ABN and the lab ABN forms probably won't become mandatory until summer 2002, a CMS official said during the December 2001 meeting of the Practicing Physicians Advisory Council (PPAC).

CMS also has drafted a decision tree and physician reference guide to help providers understand when and how to use an ABN. The material should be finalized and distributed to provider groups during the first half of 2002.

The approved general-use and lab ABNs, along with the draft ABN-X for voluntary use with statutorily excluded services, may be downloaded from the CMS Website at www.hcfa.gov/medlearn/refabn.htm.

Quest Settles "Carrier-Shopping" False Claim Charges

Quest Diagnostics (Teterboro, NJ) has agreed to pay nearly $353,000 to settle a federal lawsuit alleging that the company submitted false claims to Medicare for clinical lab services.

Under the agreement, Quest will pay $352,926 to the Federal Government, and the Department of Justice will drop allegations filed against Quest in a whistleblower suit (*United States v. Quest Diagnostics Inc.*, D. Colo., No. 98-B-2224).

Justice filed papers on Nov. 19 notifying the U.S. District Court for the District of Colorado of the settlement, according to John W. Suthers, U.S. attorney in the district.

Donna Scott, a former controller at Quest's clinical lab in Billings, MT, filed suit alleging that the company engaged in a scheme to defraud Medicare by submitting false claims for processing and payment in Colorado, rather than submitting the claims to carriers in other jurisdictions.

Scott alleged the Quest labs in Salt Lake City and Albuquerque submitted claims for tests performed in Utah and New Mexico to the Colorado Medicare carrier in order to receive higher payment than they would have received otherwise. Scott will get $71,100 as her share of the settlement proceeds.

Problem Identified

Quest spokesman Gary Samuels denies that the company submitted claims in Colorado to receive higher payment. The claims were incorrectly submitted, he says, because of a technical problem in Quest's claims submission process that the company itself identified in 1998 and self-reported to the government.

When the problem was first detected, Quest repaid $122,144 to Medicare. At the time, Samuels explains, that represented the company's estimates of overpayments received as a result of the differences between Utah's and Colorado's Medicare lab fee schedules for certain diagnostic lab services.

"We identified the problem and made a good-faith effort to rectify it," he says. "We have made the necessary changes to ensure that claims are not mistakenly submitted to the wrong carriers."

Resources

- U.S Attorney, District of Colorado: 303-454-0100
- Gary Samuels: 201-393-5597

KPMG Held Liable For Preparing False Cost Reports

Accounting firm giant KPMG, with U.S. headquarters in New York, has agreed to pay $9 million to resolve allegations that it helped six hospitals defraud Medicare by preparing false cost reports between 1990 and 1993.

The case is significant because it is the first time that a major auditing firm has been held liable for perpetuating cost-report fraud.

The government alleged that KPMG prepared and submitted fraudulent cost reports and home office cost statements for a hospital group from 1991 through 1992. The hospital group was later purchased by HCA Inc.

"KPMG's participation in the fraud proved costly," says Stephen Meagher, an attorney in the San Francisco, CA, office of Phillips & Cohen, the law firm representing whistleblower John Schilling. "KPMG received less than $200,000 for its work, but it has been held accountable for more than the full loss to the government from the cost reports it prepared for HCA."

KPMG did not admit guilt in the settlement, and no criminal charges were filed against the company. A company spokesman says KPMG agreed to settle to avoid the cost of litigation and to put the decade-old matter to rest.

In consideration of KPMG's obligations under the settlement, the Centers for Medicare & Medicaid Services agreed that it would not recommend debarment or suspension of KPMG from federal healthcare contract work based on the alleged conduct.

2002 Outpatient Pay Rates On Hold

The 2002 hospital outpatient prospective payment (OPPS) rates set to go into effect Jan. 1 will be postponed while calculation errors are corrected, the Centers for Medicare & Medicaid Services announced Dec. 18.

Since issuing the final OPPS regulation on Nov. 30, CMS discovered a number of technical miscalculations in the assignment of the cost of certain new technology devices to related procedure codes. Once the corrections are made, the revised rates and codes will be published in the *Federal Register*, CMS officials said. There are more than 300 ambulatory payment classification (APC) codes for outpatient procedures and 53 APCs that involve new technology devices.

Hospitals will be paid for outpatient services they provide to Medicare beneficiaries at 2001 rates until the new rates are published. CMS does not expect the review to go beyond Mar. 31, 2002.

Hospital groups had been pushing for at least a six-month delay. During that interim, they argued, hospitals should be paid at 2001 outpatient rates and Medicare should make no pro-rata cuts (an estimated $1 billion) in special pass-through payments for new technologies.

Bundling Scheme, *from page 1*

a payment for the ferritin test as if doctors had ordered the latter separately, the government charged. Prior to 1998, physicians ordered ferritin less than 10% of the time, but that figure jumped sharply after Damon began bundling the tests.

Thurston, who was one of four Damon executives charged in the scheme, faces a potential maximum sentence of five years in prison, three years of supervised release, and a $250,000 fine. Thurston retired recently from ARUP Labs (Salt Lake City, UT), where he was a senior VP.

Defendant To Contest Verdict

Thurston's attorney, Joseph Russoniello, a partner with Cooley Godward (San Francisco, CA), calls the verdict a travesty and says he plans to ask U.S. District Court Judge Edward Harrington to set it aside and acquit Thurston. Russoniello also represented former Damon VP Gerald Cullen, who was acquitted by Harrington last Oct. 31, on the basis of insufficient evidence.

"The verdict came as a complete and total shock to everyone in the courtroom," says Russoniello. "It took three weeks to try the case, and the jury gave it only two and a half hours. We're going to do everything we can to set the verdict aside, and I'm confident that if the court gives the testimony a hard look, it will conclude that the verdict shouldn't stand."

Russoniello maintains that the evidence against Thurston "was very thin" and notes that Harrington early in the trial ruled that there was not enough evidence to convict Thurston on a separate part of the charge, which alleged that he had conspired to bundle apolipoprotein tests and to unbundle kidney dialysis tests in order to obtain additional Medicare payment.

In July 2000, former Damon president Joseph Isola pleaded no contest to one conspiracy count for his role in the bundling practice and was sentenced to three years' probation (*GCR, Aug. '00, p. 12*). Beno Kon, the former Damon chief financial officer, died Nov. 7, 2000, before his case went to trial.

As a corporation, Damon (now defunct) pled guilty in 1996 to conspiracy to defraud Medicare and paid $119 million to the Federal Government, including a $35.3 million criminal fine and $83.7 million to resolve related civil liabilities. At the time, it was the largest amount ever recovered in a federal healthcare fraud prosecution.

Resource

- U.S. attorney for the District of Massachusetts: 617-748-3139
- Joseph Russoniello: 415-693-2014

HIPAA Code Set Deadline Extended

Healthcare entities subject to data exchange requirements under the Health Insurance Portability & Accountability Act (HIPAA) will get an extra year to comply with standards for electronic transactions and code sets under legislation enacted by Congress. At press time, the bill was awaiting the President's signature.

HR 3323 extends to Oct. 16, 2003, the deadline for compliance with the standards. To qualify for the extension, however, providers, payers and clearinghouses must present to HHS a comprehensive plan detailing their budget, schedule, work plan, implementation strategy and other information by Oct. 16, 2002.

The legislation also requires that all Medicare claims for services and supplies furnished under Parts A and B be submitted electronically by Oct. 16, 2003, with some exceptions. Electronic claims would not be required in cases where there is no method available to submit them. Nor would electronic submission be required of institutional providers with fewer than 25 full-time employees or physicians, practitioners, facilities or suppliers with fewer than 10 FTEs.

A reader asks whether the Occupational Safety & Health Administration has banned use of glass blood drawing tubes.

Amber Hogan, a compliance specialist with OSHA, says no, but does recommend that labs and other healthcare providers use plastic tubes whenever possible.

"In our minds, glass should never be used because of the safety concerns, but we understand there are times when glass is necessary because of test requirements. We believe that if you don't have to use glass, you should be using plastic."

OSHA does, however, prohibit the use of glass capillary tubes, according to an OSHA spokesperson. In a November 1999 compliance directive on enforcement procedures for occupational exposure to bloodborne pathogens (CPL 2-2.44D), OSHA says that employers must use engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent.

"It is OSHA's view that preventing exposures requires a comprehensive program, including engineering controls (*e.g.*, needleless devices, shielded needle devices and plastic capillary tubes) and proper work practices (*e.g.*, no-hands procedures in handling contaminated sharps, eliminating hand-to-hand instrument passing in the operating room)."

The directive is available on the OSHA Website at *www.osha-slc.gov/OshDoc/Directive_pdf/CPL%202-2.pdf*.

Have a compliance 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

OSHA Standard Updated: The Occupational Safety & Health Administration has issued a new compliance directive for enforcing the bloodborne pathogens standard, revised last January and effective last Apr. 18. The directive implements changes that require employers to select safer needle devices as they become available and to involve employees in identifying and choosing those devices. The standard also requires most employers to maintain a log of injuries from contaminated sharps. The directive includes engineering control evaluation forms, a Website resource list and a model exposure control plan. To access the directive, go to *www.oshasic.gov/OshDoc/Directive_data/CPL_2-2_69.html.*

OIG Savings Break Record: The HHS Office of Inspector General saved federal health programs a record-breaking $18 billion in fiscal 2001, the OIG asserted in its *Semiannual Report to Congress: April-September 2001*, issued Dec. 7. Of that amount, $16.1 billion came from recommendations it made to various programs; $1.5 billion was collected as the result of investigations. In addition, the OIG excluded 3,756 individuals and entities from participation in federal healthcare programs, a greater number than in any prior fiscal year. The largest recoveries involved HCA–The Healthcare Company Inc. (more than $800 million to resolve fraud charges) and Quorum Health Group ($77.5 million to settle charges of improper Medicare cost reporting practices). The OIG report is available online at *http://oig.hhs.gov/semann/01fsemi.pdf.*

Blood Glucose Meter Settlement: Johnson & Johnson Inc. has agreed to pay $45 million to settle a lawsuit alleging that a subsidiary made defective blood glucose meters which gave false readings. The settlement was announced Nov. 26 as a jury trial was set to begin in the U.S. District Court for the Northern District of California in San Jose. Plaintiffs alleged that LifeScan, a California-based subsidiary of J&J, knowingly marketed the "SureStep" blood glucose monitoring system with defects. The settlement "in no way implies or acknowledges any wrongdoing by LifeScan," said J&J in a statement.

Compliance Study Results Due Soon: The findings of a comprehensive study to determine whether healthcare compliance programs are effective are likely to be published by February 2002, according to project leader Lori S. R. Pelliccioni. The study, funded by PricewaterhouseCoopers, where Pelliccioni is a partner, is comprised of data analysis of seven traditional compliance program elements. It is expected to show which elements are effective in reducing or preventing wrongdoing .

Safe Harbors: The HHS Office of Inspector General is soliciting proposals and recommendations on development of new anti-kickback safe harbors and modifications to existing ones, as well as comments on development of new OIG special fraud alerts, according to a notice in the Dec. 16 *Federal Register*. Safe harbors offer protection from prosecution for arrangements that otherwise might run afoul of the Medicare anti-kickback statute. Comments are due by Feb. 19, 2002. For more information, contact Joel Schaer, 202-619-0089.

G-2 Compliance Report (ISSN 1524-0304). © 2002 Washington G-2 Reports, 1111 14th St, NW, Suite 500, Washington DC 20005-5663.

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