G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

E & Y Charged With Giving Bad Lab Advice
Government Seeks Recovery Of $900,000

The federal government is seeking to recover more than $900,000 from the national accounting firm of Ernst & Young (New York) over allegations of improper lab-billing advice.

A complaint filed by the U.S. Attorney for the Eastern District of Pennsylvania seeks damages and penalties under the False Claims Act for payments Medicare made to nine hospitals that were advised by the accounting firm. According to the complaint, filed January 5, the hospitals retained Ernst & Young from 1991 through 1995 and paid for billing advice that allegedly caused the submission of false claims for laboratory services.

According to the complaint, the advice was based upon the result of analyses performed by Ernst & Young for two types of reviews: 1) a charge description master review, which was performed at four of the client hospitals, and 2) an outpatient laboratory review specifically related to an investigation in the case filed against Harry Metzinger, who operates Metzinger Associates, a consulting company based in New Jersey.

As a result of the Metzinger investigation, five of the client hospitals were notified that they were potentially in violation of governing reimbursement law and regulations. Each of these hospitals hired ➟ *p. 2*

Inside this issue

CMS Issues Guidelines For CLIA QC

Laboratories facing a survey under the Clinical Laboratory Improvement Amendments (CLIA) now have a new tool to help them prepare: interpretive guidelines issued by the Centers for Medicare & Medicaid Services (CMS) on January 12.

The guidelines, which should be viewed as a companion to the CLIA quality control regulation that became effective April 24, 2003, will be used by surveyors during the inspection process to determine a laboratory's compliance with a particular standard. They also can—and should—be used by laboratories to help them better understand the CLIA requirements, notes James Westgard, Ph.D., a professor in the Department of Pathology and Lab Medicine at the University of Wisconsin and president of Westgard QC, an educational consulting firm based in Madison, Wisconsin.

Equivalent QC Procedures

In some cases, the guidelines actually include very different information from what is contained in the final CLIA QC rule, says Westgard. For example, the interpretative guidelines for "equivalent" QC ➟ *p. 9*

Robert Mazer

Government Seeks Recovery, *from p. 1*

Ernst & Young to perform an independent review, as requested by the U.S. Attorney's Office. According to the government, certain reports submitted by Ernst & Young were misleading as to the extent of improper billing and submission of claims to the Medicare program and failed to disclose the extent of improper billing by the hospital—or Ernst & Young's role in causing improper billing.

The government charges that Ernst & Young advised the hospitals to submit claims to Medicare that reflect the billing of additional hematology indices that were not medically necessary. Specifically, the firm recommended billing separately for additional indices 1) when the tests were performed automatically on the hematology equipment, 2) routinely when another complete blood count was ordered, and 3) without the requisite physician's order. "At no time during these reviews did Ernst & Young advise the hospitals to stop billing the tests separately when they were not medically necessary," says the complaint.

Ernst & Young has denied any wrongdoing, saying its work was fully consistent with professional standards and coding guidelines at the time and that it has no incentive for providing improper advice. "We received a flat fee for the consulting work and in no way shared in or benefit from reimbursements received by the hospitals," said the company in a statement. "We intend to defend the matter vigorously and believe that the facts will show that our services were entirely proper."

Liability Of Providers

This case should serve as a warning to both consultants and healthcare providers, notes Robert Mazer, a shareholder with Ober/Kaler (Baltimore, MD). Both parties have a duty in entering into a consulting agreement, and both potentially could face some liability when advice is wrong even though a provider might be able to make a case that it should not be held liable for bad advice.

"A laboratory provider that has relied on the reasonable advice of a reputable consultant should have a strong argument that it should not be penalized for following that advice," says Mazer. "This is unlikely to avoid repayment of reimbursement improperly paid and related interest."

Documentation is key, Mazer adds. Providers should be able to show the actual advice they were given and establish that the consultant providing the advice was made aware of all the relevant facts. The provider must also have followed the advice. "If the provider acted other than as advised—or the facts changed from those addressed by the consultant in rendering that advice—protection may be lost, or worse, the advice could help establish that the provider knew what the law required, but elected to act otherwise," he explains.

To ensure they select the appropriate consultant for an engagement, healthcare providers should require references from entities to which the consultant has furnished similar services and consider making inquiries with the intermediary or carrier regarding the consultant's general reputation, advises Mazer. Providers should also:

- Describe precisely the scope of the engagement and the "deliverables" required, and specify that all recommendations be consistent with applicable laws, regulations, and third-party requirements.
- Ensure that the method of compensating the consultant reflects the purpose of the engagement. In other words, avoid compensating the consultant based on a percentage of increased revenues.
- Require maintenance of professional liability insurance by the consultant (but don't necessarily assume that limits won't have been exceeded).
- Require indemnification from the consultant for liability resulting from the consultant's negligence or other harmful actions.
- Carefully review all of the consultant's recommendations, document such review, and if appropriate, obtain government or legal confirmation that the recommendations are consistent with applicable requirements.
- Make use of the attorney-client privilege where it is appropriate to do so.

Resources

- Robert Mazer: 410-347-7359
- Government complaint against Ernst & Young, *www.usdoj.gov/usao/pae/News/Pr/2004/jan/youngcomplaintfinal.pdf*

Providers Get Some Leeway In Medicare Appeals

New Law Allows Repayment Flexibility

Healthcare providers who have difficulty repaying money to the federal government may be allowed to establish an extended payment schedule under changes made by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (DIMA).

The legislation, enacted into law in December, gives the Department of Health and Human Services (HHS) more flexibility in recovering overpayments from a provider or supplier. HHS can enter into a six-month to three-year repayment schedule in cases of "hardship." Five-year repayment schedules are allowed in cases of "extreme hardship."

HHS, however, is granted discretion to decline to enter into a repayment schedule if there is reason to believe the provider or supplier may file for bankruptcy, discontinue operation, or has engaged in fraud or abuse.

The law also prohibits HHS from recouping overpayments from providers and suppliers appealing under certain circumstances prior to the issuance of an adverse reconsideration decision from a qualified contractor and limits the circumstances under which recoupment can be made based on a statistical sample.

"This should be helpful for providers who find it difficult to repay money to the government," says Michael Cook, an attorney with Baker & McKenzie (Washington, D.C.). "I also think the limit on statistical sampling is very significant. Overall, the administrative reforms in the law are a good thing for healthcare providers."

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—Michael Cook, Esq.

Appeals & Recovery

DIMA also makes a number of changes to the Medicare appeals and recovery process, including transferring responsibility for appeal from the Social Security Administration to HHS and expediting access to judicial review. HHS is required to submit a plan to Congress by April 1, 2004, detailing the transfer. The plan must also assess the feasibility of treatment the Departmental Appeals Board (DAB) decisions as having precedential authority.

HHS also is required to establish a process under which providers, suppliers, and beneficiaries can seek judicial review without exhausting all administrative remedies. The issue must involve a question of law that the DAB does not have authority to resolve, and there must be no material issues of fact in dispute. Requests for expedited reviews must be handled within 60 days. The law also increases from 30 to 60 days the time frame in which a provider, supplier, or beneficiary can file certain administrative appeals.

HHS must also establish a process for the enrollment of providers and suppliers, including deadlines for acting on enrollment applications and renewals, and hearing rights in the case of a denial or nonrenewal.

What's more, the Secretary of HHS is to establish a process for providers and suppliers to correct minor errors in claims that were submitted for payment. The provision requires the Secretary to permit hospitals to correct wage data that affect geographic reclassification even after cost reports have been settled and, for 2004, the resubmittal of an application for geographic reclassification.

Contracting Reform

DIMA establishes Medicare Administrative Contractors (MACs), which will replace the

fiscal intermediaries that administer Part A claims and the carriers that administer Part B claims. Any agency, organization or "other person" with the capacity to perform MAC functions (*i.e.*, not just a health insurer) will be eligible to be a MAC through a competitive bidding process. The MAC contracts have a five-year term. Carriers and intermediaries have enjoyed immunity from lawsuits under the False Claims Act, but MACs will have no such immunity.

Although HHS has the authority to enter into agreements earlier, the effective date for MAC provisions is Oct. 1, 2005. The competitive bidding process for all MAC contracts will be fully implemented by Oct. 1, 2011.

CLIA Waiver Authority Moves Back To FDA

The authority to establish criteria for waived tests under the Clinical Laboratory Improvement Amendments (CLIA) is moving back to the Food and Drug Administration despite apparent objections from officials with the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control (CDC).

The issue of which agency has final say over waived tests has long been a contentious one, with authority moving among the three different agencies over the past decade. In 2001, FDA issued draft guidance of alternative criteria for obtaining waived-complexity status but withdrew the proposal after being told that CMS has final authority over waiver criteria. FDA and CDC have remained involved, however, in establishing new criteria for waived-complexity status.

In the latest move, the Department of Health and Human Services (HHS) said last November 13 that it is giving back to the FDA the authority to implement CLIA's complexity categorization provisions. CDC reportedly will oversee the Clinical Laboratory Improvement Amendments Committee (CLIAC) efforts to develop a consensus on the appropriate waiver criteria. CLIAC will address the issue when it meets Feb. 10-11 in Atlanta.

Prior Determination Process

DIMA establishes a process that allows a MAC to provide early determination of whether a proposed physician service is covered. A MAC would issue the coverage determination to participating physicians or individuals who have received an advance beneficiary notice (ABN) from their physician that a service is probably not covered.

If the MAC lacks sufficient information to render an opinion, it must provide a description of the additional information it would need to make a determination. If the MAC makes the determination that the physician's service is covered, the MAC is bound by that determination absent evidence of fraud or misrepresentation. If declining coverage, the MAC must indicate the basis for its decision. The physician may then still provide the service and seek administrative or judicial review.

Issuance Of Regulations

Under the new law, HHS in consultation with the Office of Management and Budget, is required to set timelines for the issuance of final regulations after the publication of a proposed regulation or an interim final regulation. The timeline may not be longer than three years unless "exceptional circumstances" are cited.

When the Secretary issues an interim final regulation, if a final rule is not issued within the timeline established, the interim rule will not continue in effect unless the Secretary publishes a notice of one-year extension with explanation. In keeping with judicial precedent, the final regulation must be a "logical outgrowth" of the proposed regulation or interim final rule.

"Congress was trying to put some predictability into the regulatory system and force some discipline," notes Cook. "This establishes consequences if HHS fails to issue a final rule when it say it will – at least in the case of an interim final rule."

Resources

- Michael Cook: 202-452-7013
- Medicare Prescription Drug, Improvement & Modernization Act of 2003, P.L. 108-173, available online at *www.gpoaccess.gov/index.html*.

COMPLIANCE PERSPECTIVES

Compliance Risks For Pathologists in Business Relationships with Hospitals

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It is important for pathologists to be wary of compliance risks in their contractual relationships with hospitals. For the most part, these compliance risks fall within the category of fraud and abuse and involve situations where the hospitals could be viewed as receiving kickbacks from the pathologists in exchange for referrals from the hospitals to the pathologists. This article discusses the primary fraud and abuse compliance risks that pathologists may encounter in their relationships with hospitals.

Part A Compensation

❖ ***Types of Part A Services***. Medicare Part A services are those that pathologists provide to hospitals and for the benefit of the hospitals' Medicare patients. Some private payers and other government payers designate similar Part A-equivalent services. Pathologists generally cannot bill patients or payers for these services, and the pathologists' only source of compensation for these services is the hospital. The most significant Part A services provided by a pathologist to a hospital are professional component of clinical pathology services. Medical director services, teaching services, and research also are Part A services.

❖ ***Legal Issues***. Remuneration between a hospital and pathologists may implicate the Medicare and Medicaid anti-kickback law, particularly if the pathologists are required to pay direct or indirect remuneration to the hospital as a condition of providing services to the hospital's inpatients and outpatients. This issue arises most often in the negotiation of appropriate Part A payments to the pathologists. If the Part A payment is below fair market value, the government could allege that the pathologists have paid a kickback to the hospital in exchange for the opportunity to provide services at the hospital.

The Medicare program provides for reimbursement of the professional component of clinical pathology services to Medicare beneficiaries through Medicare Part A DRG payments to hospitals, rather than through Medicare Part B payments to pathologists. When Congress decided to shift the reimbursement for professional component services from Medicare Part B to Medicare Part A, the Centers for Medicare and Medicaid Services (CMS) allocated payment for professional component services into its DRG calculations. The intention of Congress and CMS is that hospitals will pay a portion of the DRG amount to pathologists as compensation for their professional component services to Medicare beneficiaries.

The Department of Health and Human Services Office of the Inspector General (OIG) has explained that a hospital's demand for compensation from its hospital-based physicians is suspect under the anti-kickback law. (HHS OIG *Management Advisory Report: Financial Arrangements Between Hospitals and Hospital-Based Physicians*, pp. 3-4, January 31, 1991.)

In discussing its anti-kickback concerns, this OIG report specifically highlights situations in which no, or token, reimbursement is paid to pathologists for Part A services in return for the opportunity to perform and bill for Part B services at that hospital. The OIG's Compliance Program Guidance for Hospitals also cautions against arrangements with hospital-based physicians that compensate the physicians less than fair market value for their services, including no, or token, Part A compensation for pathologists. (See, OIG's *Compliance Guidance for Hospitals*, footnote 25, February 1998.)

By refusing to pay adequate compensation to

pathologists for their professional component of clinical pathology services, hospitals and their individual administrators and trustees may violate the anti-kickback law, thereby subjecting themselves to criminal and civil penalties. Moreover, it is important to note that some courts have determined that a violation under the anti-kickback law by a hospital can be used as the basis for an action under the federal False Claims Act. This means that individuals who have knowledge of an anti-kickback violation have a tremendous financial incentive to bring a *qui tam* action against a hospital that is in violation of the law, as a successful plaintiff shares in the federal government's financial recovery.

The contract between a hospital and a pathology practice should explain whether the Part A payment from the hospital is intended to cover professional component of clinical pathology services only for Medicare and Medicaid hospital patients, or whether the compensation also covers some or all Part A-equivalent services provided to patients covered by private payers.

A. Contract Considerations

The contract between a hospital and a pathology practice should explain whether the Part A payment from the hospital is intended to cover professional component of clinical pathology services only for Medicare and Medicaid hospital patients, or whether the compensation also covers some or all Part A-equivalent services provided to patients covered by private payers. This is especially important if the pathology group bills or wishes to commence billing for professional component of clinical pathology services to private patients.

It is advisable to include language that requires the hospital to compensate the pathologists for professional component of clinical pathology services for patients covered by private payers if the payers include the reimbursement for such services in the hospital's reimbursement. The contract also should require the hospital's cooperation in the development of appropriate notification language for hospital admission as well as registration forms.

B. Determination of Fair Market Value

Approximately one-half of the total work hours of the typical pathologist are spent providing Part A and Part A-equivalent services, although this percentage can vary significantly in individual situations. The federal government has not mandated that a specific formula be utilized to determine the fair market value of Part A services provided by pathologists. Nevertheless, many hospitals and pathologists consider the Medicare reasonable compensation equivalent (RCE) in determining the amount of Part A compensation to be paid. As explained below, however, the Medicare RCE amounts should not be relied upon as sole indicators of the fair market value of the services provided by pathologists.

The Medicare RCE formula is intended to be used only for the payment of salaries to pathologists who are employed by hospitals and explicitly does not cover professional component of clinical pathology services or teaching services. "The reasonable compensation equivalent (RCE) limits set forth in this notice do not apply to costs of physician compensation that are attributable to furnishing inpatient hospital services paid for under the hospital inpatient prospective payment system or that are attributable to GME costs." (62 *Federal Register* at page 24483, May 5, 1997).

In addition, the RCE formula does not cover the additional costs that the hospital would incur as the employer of the pathologists, such as the costs of fringe benefits, employment taxes, malpractice insurance, practice overhead, etc. Therefore, the RCE amounts established by the Medicare program do not reflect the full value of the compensation and expenses paid by a hospital for the services provided by its employed pathologists.

To accurately reflect the full fair market value of these services, the RCE amounts must be

increased to include professional component of clinical pathology services that are compensated under the prospective payment system and teaching services of the pathologists, as well as expenditures for fringe benefits, employment taxes, malpractice insurance, practice overhead, etc. The value of medical director services also can be separately included under cost-based records of the hospital.

Many hospitals use Part A reimbursement data from "selected" hospitals to justify compensation amounts that the pathology practices consider inadequate. Oftentimes, the data is skewed, and the services provided by the pathology practices in the survey are not representative of the types and volume of services that another pathology practice provides.

For example, if a pathology practice provides services on a full-time basis, arrangements where pathologists cover a rural hospital on a part-time basis should be excluded from fair market value comparisons. These part-time arrangements often involve a fraction of the volume of services that pathologists would provide under full-time arrangements with larger hospitals, and generally do not include any services with respect to outreach work.

Furthermore, comparison data should not include any other hospitals that may be in violation of the Medicare and Medicaid anti-kickback law. A comparison of Part A compensation amounts paid by other hospitals is only legitimate from a legal compliance perspective if the other hospitals are in full compliance with the government's guidelines and if the services provided by all of the pathology practices are substantially comparable in terms of volume and scope, including, without limitation, the complexity of care, the volume of clinical laboratory testing, blood bank services, outreach services, reference work, the extent of charity care, and the like.

Many hospitals utilize bed size in their analysis, which is problematic for several reasons. Bed size does not take into account the complexity of care, the volume of outreach and reference work, whether blood bank services are included, whether substantial charity care is provided, the quality of the care provided, and the credentials and specialization of the pathologists. As a general matter, bed size should not be determinative of the amount of Part A compensation paid to pathologists, although it can be one among many other factors.

Some hospitals argue that the only accurate method of determining fair market value of pathologists' services is to solicit one or more proposals from other pathology practices or firms offering nationwide pathology contracting services. One of the reasons that the OIG issued its 1991 report and its guidance in the model compliance plan for hospitals is that the OIG was concerned about declining levels of Part A reimbursement to pathologists, especially in situations where the pathologists are threatened with either the loss of the contract or a "bidding" process for the contract. A hospital that threatens to put a pathology contract "up for bid" raises serious legal compliance concerns with the OIG.

Technical Component of Anatomical Pathology Services

As with professional component of clinical pathology services, the compensation arrangements between hospitals and pathologists for technical component of anatomic pathology services can raise concerns under the Medicare and Medicaid anti-kickback law. If a hospital purchases technical component services from a pathology laboratory and fails to compensate the pathology laboratory adequately for these services, the government could allege that the hospital has received a kickback, in the form of below market pricing, from the laboratory in exchange for the hospital's continued referrals. Therefore, it is critical that pathology laboratories charge, and hospitals pay, reasonable amounts for the technical services.

The determination of fair market pricing may be more difficult in practice, however, than in theory. Pathology laboratories are not required to charge Medicare rates to the hospital, but laboratories should not set their hospital fee schedules at "below cost" prices. Pathology laboratories should avoid fee schedules that provide greater discounts than the cost savings realized by the laboratories from account billing arrangements with hospitals.

Similarly, if a pathology practice purchases technical component of anatomic pathology services from a hospital, it is imperative that the hospital not overcharge the pathologists for such services. Excessive prices paid by a pathology practice for purchased technical component services from a hospital are suspect as a kickback to the hospital in exchange for the hospital's referral of inpatient and outpatient pathology services to the pathology group.

Fee Restrictions

Fraud and abuse issues also arise with respect to managed care contracts. Many hospital agreements require pathologists to participate in all managed care plans as directed by the hospital, regardless of the terms of the managed care contracts. If a pathologist is forced to accept unreasonably low reimbursement from a managed care plan to avoid termination of the hospital agreement, then the government could allege that the pathologist has paid a kickback to the hospital. This alleged kickback is the low managed care reimbursement accepted by the pathologists that permits the hospital to secure a more favorable managed care contract for itself.

Excessive prices paid by a pathology practice for purchased technical component services from a hospital are suspect as a kickback to the hospital in exchange for the hospital's referral of inpatient and outpatient pathology services to the pathology group.

Along these same lines, pathologists must also take care to control their own fees. Pathologists should insure that hospitals do not control their fees for private medical services to patients. This is especially problematic if the hospital does not exert this type of control over referring physicians on its medical staff. Furthermore, such actions implicate federal and state antitrust laws because independent providers of healthcare services could be accused of price-fixing and collusion on pricing.

Improper Charge-Backs

Fraud and abuse issues are raised if a hospital wishes to charge its pathologists for the use of hospital space, equipment, and personnel. If the hospital proposes to charge only pathologists or other hospital-based physicians (the recipients of the hospital's referrals) for such technical component items, and not its referring physicians, then the hospital is demanding a kickback from the pathologists or other hospital-based physicians in exchange for the referral of hospital patients, in violation of the anti-kickback law.

For example, when a surgeon utilizes a hospital's operating room, the surgeon has the use of the hospital's space, equipment, personnel, billing information, and processes, which enable the surgeon to conduct his or her practice of medicine and generate a professional fee. However, hospitals generally do not charge surgeons for the use of the operating room, equipment, operating room personnel, billing information, and processes.

Furthermore, charging pathologists for such technical component items also may constitute billing fraud on the part of the hospital, thereby triggering the federal False Claims Act as well as other federal and state laws. This is because Medicare's payments to hospitals, as well as virtually all private payer reimbursement to hospitals, specifically cover the technical component of laboratory and pathology services provided by the hospitals. If a hospital also receives payment from pathologists for these technical component items, then the hospital is "double dipping."

In addition, if the hospital claims any of these items on its Medicare cost report and also receives payment from pathologists for the items, then a false claim has been filed. Similarly, with respect to private health plans, the hospital could be viewed as filing a false claim under applicable federal and state laws if the hospital charges the health plans for technical component services for which it also receives payment from pathologists.

In the final analysis, pathologists must take great care to ensure that the arrangements they have in place with hospitals do not violate anti-kickback laws. This means making sure they are fairly reimbursed for the services they provide and are not charged for the use of hospital space, equipment, or personnel.

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CLIA QC Rule, *from p. 1*

procedures deviate greatly from the requirements for appropriate QC procedures stated in the final rule. According to the final rule, labs must analyze two control materials of different concentrations at least every day or 24-hour period unless CMS approves a procedure that provides equivalent quality testing. Under the "equivalent QC" in the interpretive guidelines, however, labs may reduce the QC from the minimum requirement of testing two controls per day to testing only two controls per week or two controls per month, says Westgard.

Performing QC tests less often could increase a lab's liability if a test system does not work properly, acknowledges CMS in the guidelines: "Since the purpose of control testing is to detect immediate errors and monitor performance over time, increasing the interval between control testing (*i.e.*, weekly or monthly) will require a more extensive evaluation of patient test results when control failure occurs. The director must consider the laboratory's clinical and legal responsibility for providing accurate and reliable patient test results versus the cost implications of reducing the quality control testing frequency."

Performing QC tests less than once per day is a bad idea, both from a quality and a legal perspective, argues Westgard, who believes that labs should do more than the minimum required. "I suspect that 'equivalent QC' was probably a poor choice of words," he says. "There isn't any way that a QC procedure performed only weekly or monthly can provide the error detection capability that is equivalent to one performed daily. 'Alternative QC' would have been a better term if the intention was for the government to demonstrate some flexibility to accommodate current and future changes in measurement technology."

DO's & DON'Ts

- **DO** obtain a copy of Appendix C for your laboratory. You can decide whether to store that copy on your computer or to print a copy. One advantage of a printed copy is that its sheer size makes it evident there is a lot of direction being given to inspectors, and it should also be obvious that the laboratory needs to pay attention to these materials. At a minimum, print the two sections on the Quality System for Nonwaived Testing since these materials contain new information not available elsewhere.
- **DO** read the appropriate interpretive guidelines and probes for clarification and guidance in addressing specific rules that you find critical or troublesome for your laboratory. The specific interpretive guidelines and probes given in the SOM should be helpful for formulating strategies, implementing plans, and preparing for inspection.
- **DON'T** be constrained or limited by the SOM. Recognize that the CLIA rules are minimum requirements for quality management. To assure quality test results for your patients, it may require doing more than the minimums specified by CLIA.
- **DO** what is right to manage quality—let that be the guiding principle, not the CLIA rules and the SOM interpretative guidelines.

Source: Westgard QC, www.westgard.com/cliafinalrule8.htm

Format & Content

Officially, the guidelines are issued as Appendix C of the State Operations Manual (SOM). Unlike the previous Appendix C that was organized in table format, the new version follows the format: Deficiency "D-tag" Number, CLIA Standard, Interpretive Guidelines, and Probes. All CLIA standards have a "D-tag" assigned. When a laboratory is found in noncompliance with a particular standard, the surveyor cites the associated "D" number rather that the specific standard.

The "Interpretive Guidelines" section is designed to provide more information to both the laboratory and surveyor on how to meet the particular requirement. The "Probes" section, which is in the form of questions, is included to assist the surveyor in determining whether the laboratory is in compliance with the standard. It is useful for the laboratory to be familiar with the probes since the surveyor should be following these directions during the inspection, says Westgard.

If your laboratory is inspected for CLIA compliance, you should be very familiar with the guidelines and use them as a companion document to the final rule, he advises. The Interpretive Guidelines section will further clarify the intent of the standard and, perhaps, provide assistance on what documentation or what strategies should be included to meet the standard. The Probes section provides some clues as to what the surveyor will want to find. Simply having a response to each probe can eliminate many potential inspection problems, says Westgard.

Resources

- James Westgard: jowestgardmed.wisc.edu
  CLIA interpretive guidelines: *www.cms.gov/clia/appendc.asp*

Revised Fee Schedule Freezes Most Lab Payments

Select Procedures To See Increase Under Revised Mapping

Advance orders are now being accepted for our 2004 edition of the Medicare Reimbursement Manual, which puts the revised 2004 lab fee schedule right at your fingertips. For more information, contact us at 800-522-7347 or visit our Web site at www.g2reports.com.

Laboratories will see an increase in Medicare payment for selected chemistry and microbiology codes under a revised Part B fee schedule for laboratory services. The modified fee schedule, which updates one released in November, reflects changes mandated by the Medicare Prescription Drug, Improvement & Modernization Act of 2003 (DIMA).

While the revised schedule freezes most lab fees at their 2003 price levels, some procedures—mainly in chemistry and microbiology—will see a significant increase this year, doubling or tripling in price, based on CMS's revised mapping of these codes.

CMS also froze one component of the formula used to calculate the Medicare travel allowance to perform a specimen collection for either a nursing home or a homebound patient. The personnel cost is held to the 2003 level of $0.45, while the standard mileage rate rises from $0.36 in 2003 to $0.375 in 2004. As a result, the full payment rate on a per-mile basis (code P9603) is $0.825 and on a flat-rate basis (P9604) is $8.25, effective January 1.

Below are the major revisions CMS made to 2004 lab test fees in accordance with DIMA. This updates the coverage in the January issue of *G-2 Compliance Report*. (CPT codes © American Medical Association).

NEW LAB CODES

CPT/ HCPCS Code	Descriptor	Natl. Fee Cap, 2004
84156	Protein; urine	$5.12
84157	Protein; other source	5.12
85055	Reticulated platelet assay	37.41
87269	Infectious agent antigen detection, immunofluorescence; giardia	16.76
87329	Infectious agent antigen detection, enzyme immunoassay; giardia	16.76
87660	Trichomonas vaginalis, direct probe	28.02

REASSIGNED LAB CODES

Descriptor	New CPT/HCPCS Code	Natl. Fee Cap, 2004
Starch granules, feces	89225	$4.67
Water load test	89235	7.69

REVISED PRICING FOR SELECTED CODES

CPT/HCPCS Code	Descriptor	Natl. Fee Cap, 2003	Natl. Fee Cap, 2004	% Chg
80157	Carbamazepine, free	$13.89	$18.52	+33
83663	Fetal lung maturity assessment; fluorescence polarization	13.22	26.43	+100
83664	Fetal lung maturity assessment; lamellar body density	6.61	26.43	+300
87046	Culture, bacterial; stool, aerobic, addtl. pathogens, isolation/presumptive ID of isolates	3.30	13.18	+300
87071	Culture, bacterial; aerobic, isolation/presumptive ID of isolates, any source except urine, blood, stool	6.59	13.18	+100
87073	Culture, bacterial; quant., anaerobic, isolation/presumptive ID of isolates, any source except urine, blood, stool	6.59	13.18	+100
87254	Viral isolation; centrifuge enhanced (shell vial) technique, includes ID with IF stain	6.83	27.32	+300
87300	Infectious agent antigen detection, IF technique, polyvalent for multiple organisms	8.38	16.76	+100
88400	Bilirubin, total, transcutaneous	3.51	7.02	+100

FECAL OCCULT BLOOD: NEW SCREENING CODES

HCPCS Codes	Descriptor	Natl. Fee Cap, 2004
G0328, G0328QW	Fecal blood screen, immunoassay	$18.09

PAP SMEARS

The national minimum Medicare payment for the following Pap smear codes remains at $14.76: 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148 and P3000.

NEW HCPCS CODES FOR CBCs

Code	*Descriptor*	*Natl. Fee Cap, 2004*
G0306	Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count) and automated differential WBC count	$10.86
G0307	Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count)	9.04

Stark's Percentage Compensation Provision Delayed — Again

The Centers for Medicare & Medicaid Services (CMS) has once again delayed the percentage compensation provision in Phase I of the Stark law banning most physician self-referrals.

The delay—the fourth by the agency since the law took effect in January 2003—will give CMS more time to reconsider the definition of compensation that "set in advance" as it relates to percentage compensation methodologies, according to a December 24 *Federal Register* notice.

The extension now is in effect until July 7, 2004, says CMS, which expects to address the definition of "set in advance" in Phase II of regulations implementing the Stark law. The agency says it expects to publish the final rule before July 7.

Percentage compensation arrangements, used primarily by academic medical centers and medical foundations, base physician compensation on such factors as percentage of revenue. Under Phase I of the Stark regulations, many of the exceptions hat apply to compensation relationships require that the compensation be "set in advance."

According to the rule, however, percentage compensation arrangements do not qualify under the "set in advance" criteria. The delay will allow the organizations to continue using the percentage compensation arrangements until CMS settles the matter once and for all.

CMS Releases Final Provider Identifier Rule

Healthcare providers will be required to use a unique national provider identifier (NPI) for filing and processing of all healthcare claims by May 23, 2007, according to a final rule published in the January 23 *Federal Register.*

Providers will be assigned one NPI for all healthcare transactions, whether federal, such as Medicare; state-administered, such as Medicaid; or private.

The NPI will replace all "legacy" identifiers currently being used. Congress mandated the modifier in the administrative simplification provisions of the Health Insurance Portability & Accountability Act (HIPAA).

"The use of the NPI will improve the Medicare and Medicaid programs, and other federal health programs and private health programs, and the effectiveness and efficiency of the healthcare industry in general, by simplifying the administration of the healthcare system and enabling the efficient electronic transmission of certain healthcare information," said the Centers for Medicare & Medicaid Services in issuing the rule.

CMS is expected to follow release of the NPI rule with the publication of both a standard for unique identifiers for health plans and for claims attachment transactions, although the department has not said when the remaining rules will be released.

Record Fraud In- vestigations: State insurance fraud bureaus are conducting a record number of investigations that are leading to the highest level of convictions and civil actions ever documented, reports the Coalition Against Insurance Fraud in a new study. The coalition, an insurance watchdog group based in Washington, D.C., found a 31% increase in criminal prosecutions in 2002, a 14% rise in cases presented for prosecution, initiation of 18% more investigations, and referral of 4.5% more suspected fraudulent actions. California, Florida, New Jersey, and New York accounted for nearly half of all antifraud results in several categories.

Whistleblower Windfall: Father John Corapi and Joseph Zerga will receive $8.1 million in payment under the federal False Claims Act based on their whistleblower complaint alleging that unnecessary cardiac surgeries were being performed at Redding Medical Center in Redding, California. The award will be paid to Corapi and Zerga out of a record $54 million recovery by the United States in the civil case, according to U.S. Attorney McGregor Scott. The negotiated amount constitutes 15% of the total recovery and represents the statutory minimum for which whistleblowers are generally eligible under the FCA.

Sports Clinic Settlement: Kerlan-Jobe Orthopaedic Clinic, which treats players for the Los Angeles Lakers, Los Angeles Dodgers, and the Los Angeles Kings, has paid the government $2.65 million to resolve allegations in a whistleblower lawsuit that it defrauded Medicare and other federal health programs for eight years, U.S. Attorney for the Central District of California Debra W. Yang announced January 20. The clinic made the payment, without admitting to any wrongdoing, on behalf of itself and 17 of its physicians, said Yang.

Clinic Challenges Fine: The owner of a California physical therapy clinic has asked the U.S. Supreme Court to review a decision that a fine of $729,455 assessed against him for False Claims Act violations was not excessive. Attorneys for Peter Mackby asked the high court to review an August 2003 ruling by the U.S. Court of Appeals for the Ninth Circuit that the fine Mackby was ordered to pay did not violate the excessive fines clause of the Eighth Amendment. The appeals court affirmed the district court's decision that, considering the harm caused by Mackby, owner of Asher Clinic in Larkspur, California, when he used the false personal identification number of his father, a physician, for Medicare reimbursement for which he was not eligible, the penalty and damages were reasonable.

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