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For Hospitals, Laboratories and Physician Practices

New JCAHO Lab Accreditation Process Emphasizes Ongoing Improvement

Under a new lab accreditation process launched this year by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the accreditor is placing much greater emphasis on ongoing operational improvement and how lab standards affect patient care than ever before.

JCAHO implemented the new accreditation process, dubbed "Share Visions—New Pathways," in January. The goal of the new approach is to take away emphasis on pre-survey preparation, with labs gearing up for inspection every two years, and increase emphasis on continuous compliance accreditation, according to Joanne Born, M.T. (ASCP), executive director of Laboratory Accreditation Services for the commission.

"We have restructured the processes to be more customized for laboratories," explains Born. "There is now more focus on actual performance and how the standards come together to treat and care for individual patients receiving lab services. We still need to take a look at CLIA [Clinical Laboratory Improvement Amendment] requirements and some written documentation in terms of quality control, equipment maintenance, ➥ *p. 10*

Lab Group Calls For Screening Test Billing Changes

In an effort to reduce claim denials for screening tests covered by Medicare, the American Clinical Laboratory Association (ACLA) is calling on the Centers for Medicare & Medicaid Services to allow laboratories to submit a single CPT code for a service, whether for screening or diagnosis.

As Congress continues to increase the number and kinds of screening services that are covered under the Medicare program, clinical laboratories face mounting difficulties trying to bill correctly for such services, explains ACLA in a recent issue brief. There are separate procedure codes for screening and diagnostic versions of the same test, with separate ICD-9 diagnosis requirements for each set of codes.

"Claims are routinely denied because of the way that lab requisitions are completed by the physician, in combination with Medicare's complex, counter-intuitive coding rules, which require the laboratory to determine whether to bill a CPT code or a HCPCS code, even though the laboratory test being performed is exactly the same," says ACLA. "As a result, patients are sometimes asked to pay out-of-pocket costs for services that are actually covered by Medicare." ➥ *p. 2*

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According to the association, labs should be able to submit a single CPT code for a service, with the appropriate diagnosis code from the physician indicating whether the service was for screening or diagnostic purposes. Medicare's payment logic should then be modified to consider whether or not the patient is entitled to the screening benefit based on past payment history, not based on whether the lab submits a HCPCS or CPT code.

The Problem

While most screening tests are statutorily excluded from coverage, Medicare does cover a few tests for both screening and diagnostic purposes: PSA, Pap smears, and occult blood. Beginning in January 2005, lipid and cholesterol tests will also be covered.

The same issue arises with each of these covered screening services, notes ACLA. When a lab receives an order for a test that can be used for screening or diagnosis, it must determine whether to bill the screening code or the diagnostic code. There are only two ways for the lab to obtain the information necessary to make this determination: 1) separately list the tests on the requisition form (*e.g.*, Screening PSA, Diagnostic PSA, described as the "dual test offering") or 2) list the test on the requisition form (*e.g.*, PSA, described as the "single test offering") and try to determine itself whether to submit the HCPCS code or CPT code based on the ICD-9 code(s) provided by the ordering physician.

Either course of action potentially creates problems, notes ACLA, which cites three examples:

1 In the case of a dual test offering, the physician orders a screening PSA, but provides a diagnostic ICD-9 code. Result: The laboratory bills the PSA HCPCS code because the physician selected the screening test on the order, but the claim may be denied because the diagnosis does not support the procedure code.

2 In the case of a dual test offering, the physician orders a diagnostic PSA, but provides a screening ICD-9 code (*e.g.*, routine exam). Result: The laboratory bills the PSA CPT code because the physician selected the diagnostic test on the order, but the claim will be denied as routine screening, and the patient will be responsible for payment, even though the test is statutorily covered under Medicare.

3 In the case of a single test offering, the physician simply orders a PSA test and provides a screening ICD-9 code (*e.g.*, routine exam) but not the covered screening code. Result: If the lab decides to bill the PSA CPT code, the claim will be denied as routine/screening even though a screening PSA is covered under Medicare. If, however, the lab bills the PSA HCPCS code, the claim will be denied because the screening code is not the one specified by Medicare to support the procedure code. In either event, the lab will likely receive a "screening" denial and the patient will be responsible for payment, even though the test is a statutorily covered benefit under Medicare.

Put Onus On Carrier

The solution to the problem is simple, argues ACLA. These services should be billed using the standard CPT codes, and the HCPCS codes for screening laboratory tests should be discontinued. The Medicare carrier claims adjudication logic should be able to make an appropriate coverage determination without the use of a HCPCS code, the group maintains.

For example, Congress permits coverage of a screening PSA for male beneficiaries once per year, ACLA notes. "It would be more efficient for the laboratory to accept the order for the PSA, along with whatever ICD-9 codes the physician deems appropriate, and bill the CPT code 84153 and the physician-supplied ICD-9 codes to Medicare," the group explains. "The same is true for all of the other screening testing services."

The carrier should evaluate whether the beneficiary has had a PSA test within the previous year, and if her has not, the test should be covered, says ACLA. If the beneficiary has had a PSA test within the previous year, Medicare's logic should evaluate whether or not the submitted ICD-9 codes support medical necessity. If the codes do not support medical necessity, then the test is not covered, and the patient would be responsible for payment.

Resource

ACLA: 202-637-9466

Sentencing Commission Proposal Could Have Chilling Effect On Attorney-Client Privilege

The U.S. Sentencing Commission is getting ready to send Congress proposed changes to sentencing guidelines that could have a chilling effect on the ability of attorneys to provide compliance advice to health care providers.

The commission April 8 approved recommended changes to organizational sentencing guidelines, which apply to corporations, partnerships, labor unions, pension funds, trusts, nonprofit entities, and governmental units. The proposed amendments, which will be sent to Congress May 1, include a new section that identifies the purposes of an effective compliance and ethics program, sets forth seven minimum requirements for such a program, and provides guidance on implementation. The seven requirements, previously included in the commentary to the organizational guidelines, would be elevated to guideline status.

The proposed changes automatically become effective Nov. 1, 2004, if Congress takes no action on them

The amendments would require an organization not only to exercise due diligence to detect and prevent violations of law, but also to promote an organizational culture that encourages compliance. They would also require that businesses periodically assess the risk that criminal conduct will occur as an essential component of an effective compliance and ethics program.

Waiver Of Privilege

The amendments also would include language that may force corporations to waive the attorney-client and work product privileges in order to receive mitigation for cooperating with the government. To qualify for the reduction in sentence, the cooperation must be timely and thorough and should include "the disclosure of all pertinent information known by the organization."

The proposed change specifies: "Waiver of attorney-privilege and of work product protections is not a prerequisite to a reduction in culpability score…unless such waiver is necessary in order to provide timely and thorough disclosure of all pertinent information known to the organization."

Corporate counsel objected to the change at a March 17 hearing on the recommendations, arguing that it would create a difficult choice for corporations: Either fully comply and receive the appropriate mitigation, or else retain attorney-client and work product information and shield itself from potential third-party litigation, but lose the sentence reduction for cooperation.

"As a practical matter, this would diminish the ability of attorneys to give effective compliance advice to corporations and corporate officers if it's understood at the inception of representation that there can be no truly confidential and deliberative discussion," says Kathleen McDermott, an attorney with Blank, Rome, Comisky & McCauley LLP (Washington, D.C.).

Under current policy, federal prosecutors rarely request waivers of privilege. However, if the proposed change were to take effect, such waivers could potentially become routine investigative tools that ultimately play into the punishment that corporations receive.

"That is not wise public policy. It will really chill how attorneys give advice," maintains McDermott, who served as a federal prosecutor for eight years. "During that time, I never had to ask anyone to waive attorney-client privilege to conduct an effective law enforcement investigation. It's not necessary for good investigation."

Resources

- Kathleen McDermott: 202-772-5813
- U.S. Sentencing Commission: *www.ussc.gov*

Tenet Pays $22.5 Million To Settle Stark Charges

In the largest False Claims Act settlement for alleged violations of the Stark physician self-referral law, Tenet Healthcare Corp. (Santa Barbara, CA) has agreed to pay the United States $22.5 million to resolve charges that a hospital it owns in Florida improperly billed Medicare.

Tenet Sells Troubled Hospital

Tenet Healthcare Corp. (Santa Barbara, CA) said April 16 that it will sell its troubled Redding Medical Center to Hospital Partners of America Inc. (HPA) to satisfy part of a 2003 settlement with federal officials involving allegedly unnecessary surgeries performed at the hospital.

HPA (Charlotte, NC) will pay about $60 million for the 246-bed facility in Redding, California, in partnership with a group of local physicians. RMC Inc., the Tenet subsidiary that owns the hospital, will retain its presale liabilities including dozens of civil lawsuits filed by patients who underwent surgeries at the hospital.

Tenet said it expects the sale to be completed by June 30. RMC will keep the sale proceeds.

Tenet reached a $54 million settlement with federal prosecutors and the Department of Health and Human Services Office of Inspector General in August 2003, stemming from an investigation into the performance of thousands of allegedly unnecessary cardiac surgeries at the Redding hospital, and billing for those procedures to federal health care programs. As part of that agreement, Tenet agreed to sell the hospital (*GCR*, January 2004). The sale will allow the hospital to continue to participate in Medicare and other federal health programs, Tenet said.

The government alleged that North Ridge Medical Center in Ft. Lauderdale and its parent companies entered into a number of prohibited financial relationships with North Ridge physicians in 1993 and 1994 and billed Medicare for referrals from these doctors through the late 1990s. The government also alleged that these Stark statute violations gave rise to the defendants' violations of the False Claims Act, according to the Department of Justice. The Stark statute prohibits hospitals from billing Medicare for services rendered to patients by doctors with whom the hospital has a financial relationship, unless the relationship falls under specified exceptions.

The case was originally filed by Sal Barbera, a former Tenet executive, under the whistleblower provisions of the False Claims Act. Barbera will receive $5.18 million as his share of the settlement.

In a separate settlement, Tenet has agreed to pay $8.25 million to settle a federal transfer-discharge inquiry involving "substantially all" of its hospitals. The Department of Justice had been investigating certain hospital billings to Medicare for inpatient stays reimbursed under the diagnosis-related group system from Jan. 1, 1992, to Dec. 31, 2000.

CMS Revises Policy On Power Wheelchairs

The Centers for Medicare & Medicaid Services (CMS), which recently retracted a power wheelchair policy statement deemed by many to be overly restrictive, says it will implement a new three-pronged approach designed to clarify CMS policy, limit fraud, and improve quality.

CMS officials pulled a December 2003 bulletin to durable medical equipment regional carriers (DMERCs) after the home health industry complained that DMERCs had virtually stopped paying claims for power wheelchairs.

The first prong of the new plan is to develop guidance on coverage of power wheelchairs. CMS intends to solicit input from clinicians on appropriate coverage criteria. The agency will also address requirements for ordering mobility equipment through a proposed regulation.

The second prong will focus on billing and payment. Currently, most power wheelchair are billed under a single code (K0011), for which Medicare has set a single ceiling amount of $5,296.50, even though different models have substantially different market prices. CMS is working with a national coding panel to develop a new set of codes that better describe the wheelchairs currently on the market. Further, CMS plans to implement competitive bidding for a number of durable medical equipment items, including power mobility devices.

The third prong of the new plan, say officials, is to ensure that there are strong quality controls for suppliers to ensure that beneficiaries receive high-quality power mobility services.

COMPLIANCE PERSPECTIVES

Stark II – Phase II Rulemaking: Are We There Yet?

New Regulations Complete Two-Phased Rulemaking

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On March 26, 2004, the Centers for Medicare and Medicaid Services (CMS) published the second phase of the rulemaking addressing the federal self-referral prohibition, "Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships" (*69 Fed. Reg. 16054*). The self-referral ban—referred to frequently as "Stark II," reflecting its close association with Congressman Fortney ("Pete") Stark—prohibits a physician from referring clinical laboratory tests and other so-called "designated health services" (DHS) covered by Medicare to an entity with which the physician has a financial relationship.

Providers of clinical laboratory services and other DHS have been clamoring for detailed guidance regarding this law for almost a decade. The Phase II rulemaking, which will become effective on July 26, 2004, completes, for now, the regulatory framework for a law in effect since Jan. 1, 1995. (According to CMS, the statute's application to Medicaid services has been reserved for a future rulemaking. In addition, the Phase II rulemaking is an interim final rule with comment period, requiring CMS to publish the final regulation after review of comments.)

Phase I of the rulemaking, addressing several aspects of the statute, was published on Jan. 4, 2001, and generally became effective on Jan. 4, 2002. CMS states that Phase I and Phase II should be read "as a unified whole." Except where the agency clearly indicated a policy change, Phase I remains in effect. Different language in the Phase II rulemaking reflects the agency's attempt to "explain or clarify" the Phase I rulemaking only, not change it. By contrast, the 1995 final rule addressing an earlier version of the statute limited to clinical laboratory services (Stark I) has now been superseded and will not be in effect.

CMS stated that in preparing the Phase II rulemaking it attempted to provide flexibility to minimize the law's effect on many common business arrangements, while maintaining the "core statutory prohibition." As discussed below, the agency was successful in many respects—common business and commercial practices can be maintained. This article addresses provisions in the Phase II rulemaking that are most likely to be significant to clinical laboratory services providers.

Lease Arrangements

Clinical laboratories frequently lease space from physicians, for example, for draw stations. Several provisions in the Phase II rulemaking affect those arrangements. The Stark statute requires that rental charges reflect fair market value, not taking into account volume or value of referrals or other business generated between the parties. Fair market value must reflect use of the space for general commercial purposes, without regard to its proximity or convenience to potential referral services. In the Phase II rulemaking, CMS cautions against use of "comparables" in determining fair market value where the parties to the "comparable" arrangement were in a position to refer to one another.

Additionally, according to the agency, good faith reliance on a proper valuation does not establish its accuracy. Accordingly, if CMS (or, as discussed below, a *qui tam* relator) disagrees with a valuation relied on by a clinical laboratory, it could assert that the statute has been violated. Obviously, a valuation report that is well-researched and includes a thorough analysis—reflecting fair market value concepts incorporated in the statute and regu-

The Phase II rulemaking provides additional comfort to laboratories that lease space primarily or exclusively to draw blood or test specimens from the practice from which the space is rented

lations—will be more difficult to challenge than less complete documentation used to support particular rental amounts.

Regulations resulting from the Phase II rulemaking permit a party to an arrangement for rental of office space to terminate the lease—with or without cause—so long as the parties do not enter into a new contract during the first year of the agreement's original term. Any new lease must comply independently with the rental of office space exception. Holdover month-to-month rental arrangements will also be permitted for up to six months based on the terms previously in effect. However, the arrangement must follow an agreement that was in effect for one year or more, and which satisfied the statute's office lease exception.

The Phase II rulemaking provides additional comfort to laboratories that lease space primarily or exclusively to draw blood or test specimens from the practice from which the space is rented. Laboratories were concerned that these arrangements might not be found "commercially reasonable even if no referrals were made between the parties" as the statute requires. However, CMS states in the Phase II rulemaking that "referrals" means referrals of DHS covered under Medicare only. Therefore, if the arrangement would make commercial sense to reasonable parties based on the physician's or group practice's non-Medicare referrals, plus testing for patients of other physicians (including Medicare patients), the "commercially reasonable" requirement should be satisfied.

Additionally, as a result of the Phase II rulemaking, parties to a lease arrangement may rely on the exception for rental of office space, even if the tenant subleases all or part of the space. However, the landlord cannot use space that it has "leased" to another person or entity—whether or not the space has been subleased. Therefore, a clinical laboratory that rents space from a medical group cannot allow the group practice (or any related person or entity) to use the space to take vital signs—exclusively or concurrently with the laboratory—while the space is being leased. (Likewise, the group practice's use of a laboratory employee to take vital signs could result in a financial relationship between the laboratory and group practice physicians.) According to CMS, a laboratory cannot avoid the stringent requirements of the exception for rental of office space by relying, instead, on the fair market value exception. While that exception may protect equipment leases, it does not apply to lease of space.

Exceptions For Payment For Services

The Phase II rulemaking addresses compensation-related restrictions included in various exceptions covering a DHS provider's payments to physicians, including group practices that furnish DHS in their offices. The employment exception prohibits compensation from taking "referrals" into account. However, "referrals" are defined generally to include only requests for DHS covered by Medicare. In addition, personally performed services are not considered "referrals." Thus, so long as compensation paid to a physician-employee is fair market value, it can reflect services ordered by the physician that are not considered "referrals," including clinical laboratory services that are not covered by Medicare and services that are not considered DHS.

By contrast, the exceptions for personal service arrangements (for independent contractors), fair market value, and academic medical centers also prohibit consideration "of other business generated between the parties." This includes non-federal health care business generated by the referring physician (except for personally performed services).

As a result, the amount paid to the physician cannot take into account any services the physician ordered (except those he or she performed personally). Group practice physicians—whether owners, employees, or independent contractors—can receive compensation that reflects indirectly their referrals of clinical laboratory services and other DHS for Medicare patients through profit-sharing arrangements, so long as the group practice compensation arrangement satisfies specified requirements.

Percentage arrangements are also treated favorably in the Phase II rulemaking. After delaying implementation of a Phase I provision preventing many percentage arrangements from satisfying the "set in advance" requirement, CMS eliminated this provision. As a result of this change and regulations specifying that personally performed services are not

Laboratory Services From Consultations

Under the Stark statute, a pathologist who requests clinical laboratory or anatomic pathology services as part of a consultation is not considered to have made a referral, so long as the pathologist furnished (or supervised) the requested services. The Phase II rulemaking permits another pathologist in the same group practice to furnish or supervise the services.

This change will make it unnecessary for pathology group practices to change procedures solely to comply with the federal self-referral law.

referrals (or other business generated), physicians furnishing services under the exceptions for *bona fide* employment, personal services (independent contractors), fair market value, and academic medical centers, as well as group practice physicians, can receive a percentage of revenues or collections from their personally performed services. Group practice physicians can also receive percentage compensation for services furnished "incident to" their personally performed services.

While the prohibition against paying physicians based on the volume or value of referrals—incorporated in virtually all exceptions—generally prohibits paying physicians for referrals, the Phase II rulemaking states that it also prevents paying physicians to limit utilization of clinical laboratory services and other DHS. These types of incentives are permitted only in furnishing services to enrollees of certain health plans, *i.e.*, qualified physician incentive plans under the personal service arrangement exception, or as part of an arrangement covered by the prepaid plan or risk-sharing exception.

CMS also provided a "safe harbor" under which an hourly fair market value for physician services can be determined based on amounts paid to area emergency room physicians or based on specified recognized surveys. Use of a safe harbor is strongly encouraged. According to CMS, entities using other methods to determine fair market value "will continue to bear the risk that their rates may not be considered fair market value." The safe harbor could be of significant assistance to hospitals negotiating service contracts with physicians. The safe harbor could provide a measure of clarity, and, where appropriate, support for their contention that amounts requested by a physician are potentially problematic.

The personal services arrangement exception (for independent contractor arrangements) requires that the contract cover all services to be provided by the physician. The Phase II rulemaking permits incorporating other agreements into each personal services contract or cross-referencing to one or more master lists of contracts that are maintained and updated centrally. Financial statements that include relevant information and are cross-referenced in the agreement may serve as a master list. The master list must be available for inspection and must preserve the historical record. As in connection with the lease exception, the Phase II rulemaking permits a personal service arrangement to be terminated, with or without cause, if the parties do not enter into another contract for the same or substantially the same services during the first year of the original contract term.

Contractually Required Referrals

With increasing frequency, health systems and other organizations require physicians under contract to refer clinical laboratory and other ancillary services to a particular service provider, often part of the same organization. The Phase II rulemaking clarifies that *in limited circumstances* this requirement will not prevent a financial arrangement from complying with an exception to the self-referral ban. According to CMS, referral requirements may be permissible as part of employment, managed care, and other contract arrangements if they relate to the physician services covered under the contract and are "reasonably necessary to effectuate the legitimate business purpose of the compensation arrangement."

A hospital, for example, that contracts for part-time physician services might require the physician to refer patients to the hospital's laboratory while working for the hospital. The hospital could not, however, require that physician to use the hospital laboratory when the physician is not working for the hospital. Similarly, it is unlikely that requiring a physician tenant in a medical office building to refer tests to his hospital landlord would be acceptable.

Temporary NonCompliance

The Phase II rulemaking created a new exception for arrangements "involving temporary noncompliance." This exception may be used when an arrangement has "unavoidably and temporarily fallen out of compliance"

with an exception to the self-referral ban. This exception might apply, for example, when fully signed copies of renewal agreements have been delayed (such as an agreement for physician services) or a geographic area has been redesignated from rural to urban, preventing continued reliance on the rural provider exception. The exception is subject to multiple conditions. The arrangement must have satisfied another exception (other than the exception for non-monetary compensation up to $300 or medical staff incidental benefits) for at least 180 consecutive days and must comply with the federal anti-kickback statute and applicable billing rules. The arrangement must have fallen out of compliance for reasons beyond the entity's control. Also, the entity must attempt to rectify the problem promptly. Finally, the exception can be relied on for 90 days only and can be used for the same physician once every three years only.

Payments By Physicians

The statute protects payments made by a physician to a laboratory for clinical laboratory services. It also excludes a physician's payments to an entity for "other items or services" furnished at fair market value. Under the Phase II rulemaking, "legitimate discounts" for those other items or services are permissible, *i.e.*, the discounted charge will fall within the range of values that is considered fair market value. CMS makes clear, however, that the exception for payments by a physician may not be used for items and services covered by another exception, such as for leases or personal services. The more stringent requirements included in those exceptions must be satisfied.

Gloves; Professional Courtesy

CMS clarifies that a laboratory may not provide referring physicians with gloves—whether or not they are "sterile gloves"—under the statutory provision permitting a laboratory to furnish items used to collect, transport, process, or store specimens.

The Phase II rulemaking permits "professional courtesy" under limited circumstances. Among other things, it must be offered to all physicians on the entity's medical staff or in its local community or service area. The professional courtesy cannot be offered to federal health care program beneficiaries. Any waiver or reduction of coinsurance must also be disclosed to the insurer.

Remuneration Unrelated to DHS

The exception for remuneration paid by a hospital to a physician that does not relate to DHS was defined narrowly. Benefits offered to physicians selectively cannot be protected. Additionally, if the related cost can be included on the Medicare or Medicaid cost report, the exception will not apply. For example, payments to physicians for general administrative or utilization review services would be considered related to DHS and would have to comply with another exception.

Publicly Traded Entities

The Phase II rulemaking may facilitate companies "going public" and making use of the statutory exception for ownership in certain publicly traded securities and mutual funds. A physician or family member can purchase stock prior to a public offering, so long as the stock is generally available to the public at the time of the physician's referral. Existing publicly traded entities also received regulatory relief. They will not have to report information about shareholders whose ownership interest is protected by the exceptions for publicly traded securities or mutual funds.

Conclusion – A New Day In Stark II Enforcement?

Providers of clinical laboratory services must continue to comply with any applicable state self-referral statute. It may prohibit arrangements that are permissible under the federal law. However, as a result of the Phase II rulemaking, effective July 26, 2004, some arrangements between laboratories and physicians that were not permissible under federal law will become legally acceptable. In fewer situations, arrangements will become noncompliant.

Potentially more significant for many laboratories, as of July 26, 2004, the stakes of noncompliance may increase dramatically. Regulations implementing the self-referral ban will then be essentially complete. It may then become increasingly difficult to defend questionable practices based on lack of regulatory guidance. This development may not be lost on government agencies, or potential *qui tam* plaintiffs, seeking to pursue noncompliant arrangements under the False Claims Act. Laboratories should use the intervening time wisely to ensure that their arrangements with referring physicians can withstand careful scrutiny.

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OIG Warns Physicians About Added Charges

Physicians who participate in Medicare face potential liabilities if they bill Medicare patients for services already covered by the program, the acting head of the Department of Health and Human Services Office of Inspector General warned March 31.

While participating providers can charge Medicare beneficiaries extra for items and services not covered by Medicare, and can collect deductibles and coinsurance, they run the risk of substantial penalties and exclusion from Medicare and other federal health programs if they request any other payment from patients, says acting principal deputy IG Dara Corrigan in a new alert.

"We are hearing reports about physicians asking patients to pay additional fees, and we believe that this is an ideal time to remind physicians and Medicare patients about this potential liability," explains Corrigan. "Charging extra fees for already covered services abuses the trust of Medicare patients by making them pay again for services already paid for by Medicare."

In a recent case, the OIG alleged that a physician violated his assignment agreement when he presented to his patients—including Medicare beneficiaries—a "Personal Health Care Contract" asking patients to pay an annual fee of $600.

While the physician characterized the services to be provided under the contract as "not covered" by Medicare, the OIG alleged that at least some of these contracted services were already covered and reimbursable by Medicare. Among other services offered under the contract were the "coordination of care with other providers," "a comprehensive assessment and plan for optimum health," and "extra time" spent on patient care.

To resolve these allegations, the physician in this case agreed to stop offering these contracts to his patients and to pay a settlement to the OIG.

Pathologists Call For Full Disclosure Of Costs

Should ordering physicians be required to disclose their costs when billing patients or insurers for outsourced anatomic pathology or cytology services? The College of American Pathologists (CAP) believes the answer is yes.

"Full and open disclosure of anatomic pathology or cytology services serves the interests of concerned parties, including patients, enforcement entities, and third-party payers and deters fraud and other unlawful conduct that escalates patient health-care costs," the CAP and Tennessee Society of Pathologists (TSP) wrote in a March 29 memorandum in support of legislation pending before the state legislature.

Tennessee Senate Bill 2846 and House Bill 3131 would amend state law by requiring a physician to disclose on a bill or statement the name and address of a laboratory used for anatomic pathology or cytology services and the net amount paid to the laboratory.

In the memo, CAP and TSP note that the legislation is consistent with disclosure standards in the American Medical Association's ethics policy. What's more, said the groups, 10 other states already have mandatory disclosure for pathology costs: Arizona, Connecticut, Delaware, Louisiana, Maine, Maryland, New Jersey, Pennsylvania, Texas, and Vermont.

Requiring disclosure of costs by ordering physicians who bill patients will discourage mark-ups for anatomic pathology and cytology services and "instill confidence" in the ethics of Tennessee's health care system, argue the CAP and TSP. "It should be apparent that added charges to the cost of anatomic pathology and cytology services needlessly inflate health care costs and should be deterred by disclosure or preferably avoided, as would be the case under direct billing for these services," the groups wrote.

New JCAHO Lab Process, *from page 1*

etcetera, but we will not be spending as much time reviewing policies and procedures and individual documents without making their connection to the patient and the specimen that's being processed and analyzed in the laboratory."

Under the new process, labs will no longer receive a score, which JCAHO determined was counterproductive. Instead of focusing on achieving a particular score, the commission wants labs to focus on achieving continuous compliance with the standards. While standards will still be scored, the organization will no longer receive an overall evaluation score.

Data Driven Process

The new lab accreditation survey also includes a greater emphasis on data, notes Born. Data comes primarily from two areas:

1 The electronic application for survey, which helps determine the clinical service groups within the organization where laboratory services are provided, such as individual departments (hematology or chemistry) or point-of-care testing areas such as the emergency room or intensive-care unit.

2 Pre-survey documentation derived from previous survey experience and proficiency testing data. The Priority Focus Tool will pull data from the Centers for Medicare & Medicaid Services (CMS) database, which helps identify priority focus areas in need of review. The Priority Focus Process uses automated sets of rules to sort the data and turn it into information that focuses the survey on critical areas, explains Born. It also virtually eliminates any unconscious surveyor bias or habit because organizations with the same profile will have a consistent and predictable set of priority focus areas. Sentinel events or complaints about lab services also help target specific focus areas.

Labs that are found to be out of compliance with one or more standards during a survey have 90 days to submit an acceptable Evidence of Standards Compliance (ESC) report. That report, says Born, should detail the action that the organization has taken to bring itself into compliance with a standard or clarify why the organization believes it was in compliance with the standard at the time of survey for which it received a recommendation. Organizations that successfully address their recommendations will be accredited, and their "Quality Check" summary will be updated accordingly on JCAHO's Website.

For standards that have a specific Measure of Success (MOS) attached, labs found to be out of compliance will have to monitor and measure their performance for four months and report back to JCAHO on their sustained MOS. The new follow-up process, however, will involve less paperwork than in the past, Born explains. ESCs and MOS reports are submitted online via a secure extranet.

Tracer Methodology

Part of the new survey process is the inclusion of tracer methodology to track patients and their specimens through the continuum of lab services, according to Born. For example, a patient comes to an emergency room where stat electrolytes are drawn. The blood specimen then is sent to the main laboratory in the hospital, where it is divided among the appropriate service areas for analysis.

2004 Laboratory National Patient Safety Goals

JCAHO has established seven patient safety goals for all of the programs it accredits and has tailored three of these to labs. These goals, advises Born, should be implemented as part of a lab's ongoing operational improvement. New goals will be established in 2005.

1. Improve the accuracy of patient identification.

a. Use at least two patient identifiers (neither to be the patient's room number) whenever collecting laboratory samples or administering medications or blood products.

b. Immediately at the start of any invasive procedure, conduct a final verification process to confirm the correct patient, procedure, site, and availability of appropriate documents. The verification process uses active—not passive—communication techniques. The patient's identity is re-established if the practitioner leaves the patient's bedside prior to initiating the procedure.

2. Improve the effectiveness of communication among caregivers.

a. Implement a process for taking verbal or telephone orders or critical test results that require a verification "read back" of the complete order or test results by the person receiving the order or test results.

b. Standardize the abbreviation, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols not to use.

3. Reduce the risk of health care-acquired infections.

a. Comply with current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines.

b. Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-acquired infection.

Joanne Born

"The tracer technique would involve us tracing that patient's specimen from the time it's collected at the bedside of the patient in the emergency room, through the collection process, through the specimen and aliquotting process, to the point where it's distributed to the instrumentation for analysis and all the way through the end when the result is given back to the physician," says Born. Supporting documents would be reviewed and might include medical records, lab result reports, competency records, etc.

As surveyors trace specimens through the process, they will also interview staff members. Staff won't have to know Joint Commission standards; they will only have to know how to do their job, Born emphasizes, noting that this is a significant change from the previous survey process, in which surveyors would spend a great deal of time reviewing documentation but have limited interaction with staff.

Response from labs that have been surveyed under the new process thus far has been positive, says Born, who notes that lab personnel especially seem to like the tracer methodology. "This allows a lot more interaction and lets us see how the lab processes really work," she explains. "Surveyors will do a lot more interviewing and a lot less paper-trailing." They will focus on "connecting the dots" to understand how the lab delivers services to patients. The tracer methodology also increases the opportunity to educate staff and share best practices.

Future Plans

Ultimately, JCAHO plans to develop a Periodic Performance Review (PPR) process that laboratories will use to monitor their own compliance in between regularly scheduled surveys. Born says she hopes to have the self-monitoring process in place by 2006. The Joint Commission will not penalize laboratories that identify standards deficiencies in their PPR. In the meantime, labs should continue checking the commission Web site at www.jcaho.org to keep up with changes to standards and survey processes. The commission also plans to review its quality control requirements in conjunction with the final quality-system rule issued in early 2003, notes Born. Currently, JCAHO is surveying for compliance with the quality control (QC) standards as written in the *2004 Comprehensive Accreditation Manual for Laboratories*. A new Laboratory Professional and Technical Advisory Committee established early this year is in the process of reviewing the new CLIA QC requirements and will make recommendations on how they must be integrated into the JCAHO survey process, she explains.

Resources

- Joanne Born: 630-792-5197
- JCAHO lab accreditation Web site: *www.jcaho.org/accredited+organizations/laboratory+services/laboratory+accreditation.htm*

***Q:** What is considered the "testing facility" when you are printing the name and address on a laboratory report?*

A: According to Megan Sawchuk, M.T. (ASCP), associate director for JCAHO's Standards Interpretation Group, the testing facility is the laboratory where the test was performed and the final result generated. The name and address of the testing facility must appear on any laboratory report, including interpretive pathology and cytology reports. CLIA certificates are issued by a laboratory's physical address, so this requirement is usually very straightforward, she notes. However, when a pathologist travels to multiple locations, labs sometimes are unsure which address to use.

For example, ABC Laboratory contracts with a pathologist from XYZ laboratory to perform frozen sections. The physical location of the testing is at the contracting facility, ABC Laboratory, so its name and address must be on the report, explains Sawchuk. It doesn't matter that the pathologist works elsewhere.

Questions also arise about "traveling" pathologists who perform cytology tests and have offices at more than one laboratory. Again, the rule is that the name and address of the laboratory where the final interpretation is made must appear on the report, even if the slides are taken from one office to another.

❖ Covered entities under the federal privacy rule "are achieving significant compliance" one year after the regulation's compliance date, according to a survey by the American Health Information Management Association. However, only 23% of respondents said their organizations were "fully compliant" with the privacy rule, issued under the Health Insurance Portability & Accountability Act of 1996. Another 68% of respondents said they were "currently between 85% and 99% compliant while only 8% report being 50% or less compliant at this time." The survey is available at *www.ahima.org/hipaa/survey.cfm*.

❖ A federal appeals court April 13 rejected an action by 79 hospitals and two health care corporations challenging Medicare outlier reimbursement rates for patients with abnormally high costs (*Universal Health Services Inc. v. Thompson*). Affirming a lower court's decision, the U.S. Court of Appeals for the Ninth Circuit held that the hospitals waived their arguments by failing to raise them in the notice and comment rulemaking before the Department of Health and Human Services. The appeals court disregarded the hospitals' contention that HHS erred in its methodology in determining their entitlement to additional reimbursement. "Because the hospitals failed to raise the arguments advanced in these cases in the annual notice and comment rulemakings determining the outlier thresholds that directly affected their Medicare reimbursements, we conclude that those arguments are waived," wrote Judge William Schwarzer.

❖ A Pennsylvania-based insurance company and Medicare contractor has agreed to pay $1.5 million to resolve allegations that it violated the False Claims Act by changing Medicare information to improve its evaluations, the Department of Justice April 21. Highmark Inc. (Pittsburgh), agreed to settle the allegations that employees of its Veritus division, a Medicare contractor, tampered with and altered Medicare files and claims information in an effort to improve scores on Medicare evaluations of the division's performance from 1992 through 1994.

❖ The Blue Cross and Blue Shield Association has announced a new anti-fraud strike force that will collaborate with the FBI and other national, state, and local law enforcement agencies to fight major insurance fraud schemes. As part of its ongoing effort to protect consumers from scams and fight fraud, the association also announced a new consumer outreach program to encourage individuals, physicians, and other health care professionals to report suspicious activities. For more information, go to *http://bcbs.com/antifraud*.

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