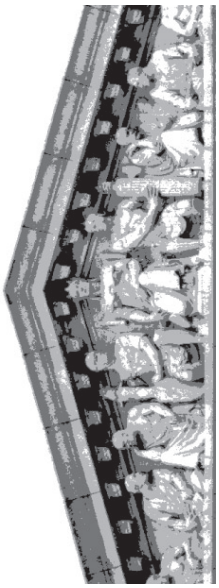

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

Medicare Seeks Payback Rule Changes
Providers Would Get 60 Days To Self-Report

The Centers for Medicare & Medicaid Services wants to revise the definition of "overpayment" and stipulate that any overpayment must be reported to the government within 60 days of discovery.

According to the CMS proposal in the *Federal Register* (Jan. 25, 2002), the revised definition of overpayment "would cover not only excess Medicare funds received by a provider, supplier or individual, but also funds received by other entities" that provide reimbursable services to beneficiaries, such as managed care organizations.

It is unclear, cautions attorney Lena Robins, whether providers would have to report an overpayment within 60 days of learning about it or within 60 days of confirming that an overpayment was received.

CMS may clarify this issue when it formally responds to comments received on the proposal, adds Robins, who is with Foley & Lardner in Washington, DC. Comments are due by Mar. 26.

While the proposed rule does not specify the consequences of failure to meet the 60-day deadline, CMS warns in the preamble that failure to report an overpayment "within a reasonable period of time may, in certain circumstances, establish criminal liability" and prompt a referral to the HHS Office of Inspector General.

Affirmative Duty To Report

The proposed rule, combined with a recent civil settlement by Allina Health Systems, appears to reaffirm the government's view that

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When Are Lab Discounts "Bad Business"?
"It Depends," Say Govt. & Compliance Experts

The question is an "oldie but goodie": Can laboratories offer discounts on tests to non-federal payers that aren't also offered to Medicare or other federal healthcare programs?

The last real guidance from federal officials came almost two years ago—"It depends."

"Intent is important," explains Robert Mazer, an attorney with Ober/Kaler in Baltimore, MD. "It is appropriate to offer discounts, but you have to make sure they are not tied to other referrals."

"Substantially In Excess"

The question of discounted fee schedules isn't new. The Social Security Act prohibits healthcare providers, including labs, from charging Medicare or Medicaid "substantially in excess of … usual charges." But the terms "substantially in excess" and "usual charges" have been subject to some interpretation over the years, notes attorney Peter

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Inside this issue

Lab Discounts, *from page 1*

Kazon with Mintz Levin Cohn Ferris Glovsky & Popeo, PC in Washington, DC.

Prior to 1997, both the Health Care Financing Administration (now CMS) and the HHS Office of Inspector General took the position that usual or customary charges were based on what laboratories charged third-party payers (such as Medicare or insurers) and did not include charges to physicians, other providers or certain managed care plans. Thus, under the "substantially in excess" provisions, it was permissible for labs to offer discounts to physicians or hospitals on non-Medicare testing.

In 1997, the OIG proposed changing its interpretation to bar providers from billing Medicare or Medicaid for charges "substantially in excess of … usual charges or costs for such items or services to any of their customers, clients or patients." Had this wording been adopted, Kazon says, it might have been interpreted as requiring that labs had to charge Medicare the same price they charged other customers. After numerous provider groups strenuously objected, the OIG withdrew the proposed change.

New Interpretation

In an April 2000 letter clarifying an advisory opinion on kickbacks (issued in 1999 and discussed below), the OIG put forth a new interpretation, noting that a provider "need not worry" about the "substantially in excess" provisions "unless it is discounting close to half of its non-Medicare/Medicaid business."

"The government has never really been able to come up with a regulatory interpretation of what 'substantially in excess' means," Kazon points out. "The OIG did come up with the 50% rule in the [April] letter, but I don't think that really answered the questions. And whenever the OIG has had an opportunity to define the term in regulations—which is the appropriate way to do it—the OIG has declined to [do so]."

Anti-Kickback Hazards

Separate issues regarding lab discounts arise under Medicare anti-kickback law. Several OIG guidance documents and advisory opinions warn that a discount could be an unlawful kickback if it is an inducement for referrals. The OIG addressed this in a Special Fraud Alert on laboratory practices issued in 1994 and again in the Compliance Program Guidance for Clinical Laboratories issued in 1998.

> ***"Any discount you provide to non-federal payers should stand alone and separate from any other arrangements."***
> ***-Robert Mazer***

The latter specifically states: "[P]olicies should ensure that laboratories are not providing any inducements to gain a physician's business, including charging physicians a price below fair market value for their non-federal healthcare program tests. Laboratories that charge physicians a price below fair market value to induce them to refer their federal healthcare program business may be risking anti-kickback enforcement and false claims actions."

The OIG weighed in again in a December 1999 advisory opinion (No. 99-13). At issue was whether a company providing pathology services could offer discounts to physicians in order to match the prices of its competitors, with some of the discounted charges below the actual cost of providing the services. While the discount was not conditioned on physicians sending their Medicare work to the pathology company, the company assumed that the physicians receiving the discounts would refer virtually all of their work to it.

Peter Kazon, Esq.
Mintz Levin

Robert Mazer, Esq.
Ober/Kaler

The OIG said it could not exclude the possibility that the pathology company might be offering improper discounts with the intent to induce referrals or more lucrative federal healthcare program business. Nor could it exclude the possibility that the physicians might be soliciting improper discounts in exchange for referrals. Thus, the OIG concluded, the proposed arrangement might constitute prohibited remuneration under the anti-kickback statute.

"Intent" Is Critical Factor

The OIG most recently addressed the issue of discounts in its April 2000 letter to a provider seeking clarification of advisory opinion 99-13. The provider asked whether the opinion required labs to raise their charges to meet or exceed Medicare's fee schedule.

The OIG noted that practices identified as "suspect"—such as offering discounts—were not violations *per se* of the anti-kickback statute. "The statute is a criminal statute and requires proof beyond a reasonable doubt that the parties had unlawful intent," wrote the OIG. "It is not only what the parties did, but why they did it that is crucial to a prosecution."

A kickback violation is not determined by the size of the discount, but by whether the discount is implicitly or explicitly tied to referrals

Continued on p. 3

Instructions Issued On Uniform Lab Coverage Rule
CMS Explains Changes That Took Effect Feb. 23

The Centers for Medicare & Medicaid Services this month issued the first set of instructions implementing administrative changes mandated by the Nov. 23, 2001 final rule establishing uniform Medicare lab coverage and payment policies (*GCR, Feb. '02, p. 1*).

The changes, detailed in a March 5 program memorandum to carriers and intermediaries, have an effective date of Feb. 23, 2002 and a contractor implementation date of Apr. 18. They apply to every diagnostic clinical laboratory service payable under Medicare Part B, regardless of where the service is performed. Among the changes:

❖ Physicians and labs may use the narrative field on the claim form to report additional diagnoses if the Medicare contractor's system will not accept all of the codes in the "diagnoses" field.

❖ In cases where a contractor chooses to perform manual prepay review of a service and the laboratory has submitted multiple diagnosis codes, the contractor must examine all submitted diagnosis codes when making a coverage or coding determination.

❖ Labs should use the GY modifier to indicate that a service is statutorily excluded or the GZ modifier to indicate that a service is expected to be denied as not reasonable and necessary. A less preferable method is for a lab to submit a separate claim for the procedure that is not covered.

❖ Ordering practitioners may include non-physicians, such as clinical nurse specialists, clinical psychologists, nurse practitioners and physician assistants.

❖ CPT modifiers "91" and "59"—both of which identify multiple services for the same beneficiary on the same day—are not interchangeable. Modifier "59" indicates distinct procedural services and should be used to report multiple service submissions by a lab for the same beneficiary on the same day (typically, this involves microbiology). Modifier "91" indicates repeat clinical diagnostic lab services performed on the same beneficiary on the same day, such as arterial blood testing at different intervals during the day.

The memo also addresses a lab's use of ICD-9-CM diagnosis codes in place of narrative descriptions as well as documentation requirements for physicians and labs. In addition, it clarifies that Medicare does not require the signature of the ordering physician on a laboratory requisition and that contractors may not use frequency screens that could result in a frequency-based denial unless the information has been published by CMS or the contractor.

The instructions (Transmittal AB-02-030) will be available on the CMS Website at *www.hcfa.gov/pubforms/transmit/memos/comm_date_dsc.htm*.

Lab Discounts, *from page 2*

of federal business, the OIG added. In order to establish a violation, there must be evidence to support a linkage between the discounts and the referral of non-discounted federal healthcare program business.

"Where there is evidence of a connection between the two, the size of a discount may provide further indicia of intent," the OIG wrote, adding that it did recognize that there may reasons why a company might agree to sell services below its average fully loaded costs.

"Notwithstanding, we think that pricing arrangements that couple the referral of Medicare business reimbursed above the provider's average fully loaded costs with charges for private business that are below the provider's average fully loaded costs merit close scrutiny."

Err On The Side Of Caution

Given the OIG's views, labs that wish to offer discounts to physicians or other providers should be careful not to tie the discounts to any referrals of Medicare or Medicaid business or other federally funded healthcare programs, advise both Mazer and Kazon.

"Any discount you provide to non-federal payers should stand alone and separate from any other arrangements," Mazer says.

According to Kazon, it is significant that the OIG has recognized that a price below fully loaded costs may still be reasonable; however, the OIG is unlikely to accept as "reasonable" a discount that is too low, such as one that only covers "marginal cost" (for example, the incremental cost of doing additional tests).

Kazon also recommends that labs not charge Medicare more than they charge other similarly situated third-party payers.

"A lab should typically charge Medicare and other similarly situated third-party payers the same amount for a given test, even though the amount charged does not usually affect what Medicare pays."

Resources

❖ Peter Kazon: 202-661-8739

❖ Robert Mazer: 410-347-7359

❖ OIG documents at *oig.hhs.gov*: Special Fraud Alert (Oct. '94), */fraudalerts.html#1*; Compliance Program Guidance for Clinical Laboratories (Aug. '98), */authorities/frnotices.html*; Advisory Opinion 99-13 (Dec. '99), */fraud/docs/advisoryopinions*; April '00 letter, */fraud/docs/safeharborregulations/lab.html*

ABN Instructions Revised, ABN-X Form Withdrawn

As expected, the Centers for Medicare & Medicaid Services has made several revisions to instructions that will implement the new standard-format Advance Beneficiary Notices (ABNs) for Medicare Part B covered services.

The ABN alerts the beneficiary that there is genuine doubt on the part of the provider that Medicare will pay for the service and in this instance, the beneficiary agrees, in advance of the service being furnished, to be responsible for payment.

In one major revision, CMS has withdrawn the optional form ABN-X (CMS-R-131-X) for services excluded by statute from Medicare coverage, such as wellness exams and related lab tests.

Agency officials decided the ABN-X was an unnecessary complication to the ABN process. Medicare does not require a physician or supplier to get a signature from patients in order to bill them for a service that is statutorily excluded from coverage, although the practice is not prohibited. In place of the ABN-X, CMS plans to incorporate information about non-covered items into an educational brochure that providers and suppliers can give to beneficiaries.

No Change To Lab ABN

The ABN for laboratory services (CMS-R-131-L) and the ABN for general use, including lab testing (CMS-R-131-G), have not changed. They may be used by providers even before final instructions on ABN use go out to carriers and intermediaries from CMS. Both ABN forms are available on the CMS Website at *www.hcfa.gov/medicare/bni/*.

Use by all providers of the new approved standardized forms will be required later this year, probably by early fall.

Revisions to the pending ABN instructions would:

- Clarify that use of the GZ modifier is optional, not mandatory. The modifier typically would be used when a lab gets a specimen from a physician but cannot get an ABN signed because of time and other constraints.
- Prohibit the practice of having blank ABNs signed by beneficiaries (that is, before the ABN is completed).
- Make minor editorial changes to the list of statutorily excluded services. Examples include routine physicals, most tests for screening and most vaccinations.
- Clarify use of the Medicare Health Insurance Claim (HIC) number on the ABN in an emergency case. Carriers are instructed not to invalidate an ABN solely for lack of an HIC, except in the rare situation where the beneficiary recipient of an ABN alleges the form was signed by someone else with the same name and the matter cannot be resolved with certainty by the contractor.
- Clarify that electronically scanned and fax copies of ABNs for use by beneficiaries are acceptable.
- Clarify the procedures for use of a witness when a beneficiary refuses to sign the ABN by noting that a witness may sign on the unused patient signature line or in the margins.

Resource

- *Federal Register*, Feb. 19, '02. Pending ABN instructions are posted on CMS's Paperwork Reduction Website, *www.hcfa.gov/regs/prdact95.htm*.

Payback Rule, *from page 1*

healthcare providers have an affirmative duty to report Medicare overpayments, says Robins.

Allina, a health system based in Minnesota, agreed Dec. 31, 2001, to pay $16 million to settle allegations of Medicare billing fraud and to enter into a five-year corporate integrity agreement with the OIG. According to the U.S. Department of Justice, which investigated two False Claims Act suits brought against Allina, the health system did repay specific overpayments identified through internal audits, but "did nothing to ensure that other false claims were repaid, nor did [it] take sufficient steps to ensure the accuracy of its billings going forward."

The Allina settlement, says Robins, indicates that the government believes providers should not only report known overpayments but also should investigate potential overpayments and ensure that safeguards are in place to prevent future improper billings.

Compliance guidance from the OIG makes clear that failure to disclose a known overpayment from a federally funded healthcare program could subject a provider to criminal and civil liability. The guidance also provides a 60-day window for self-reporting (entities under a corporate integrity agreement generally have 30 days to report and repay).

"Obviously, all providers should take their compliance obligations very seriously, and if they identify an overpayment, they should report and refund it," advises Robins. "Otherwise, they are at risk of criminal sanctions or administrative recoupment. In the government's view, you may be at risk for more far-reaching liability than just the overpayment amount."

Resources

- Lena Robins: 202-672-5300
- *Federal Register*, Jan. 25, '01. Online at *www.access.gpo.gov/su_docs*.

COMPLIANCE PERSPECTIVES

Compliance Responsibilities In Transfusion Medicine—2002

William B. Lockwood, PhD, MD, is director of transfusion services at the University of Louisville Hospital and Norton-Kosair Children's Hospitals in Louisville, Kentucky, and president of Lockwood & Associates Inc., Blood Banking and Clinical Laboratory Consultants in Corydon, Indiana

Conforming to regulations (compliance) is not an option—it's a necessity. This is true for all areas of the clinical laboratory, but even more so for the facilities that collect and manufacture blood components (blood centers), that receive blood components and further manufacture them into additional components (blood banks), and that receive, store and dispense blood components (transfusion services).

All these transfusion medicine entities face the scrutiny of many regulatory and accrediting agencies that have oversight in determining that current laws, standards and guidelines are being met by the organization. The organization may also have its own set of rules (mission statements, company goals) that encourage adherence to outside agency requirements for good laboratory practices in order to provide increased quality of patient care.

Changes to the standards of practice in transfusion medicine occurred in 2001, and several new requirements must be implemented in 2002.

Various agencies have oversight for compliance with rules and regulations in transfusion medicine, the most heavily regulated of clinical laboratory departments. The applicable compliance issues, agencies having authority over those issues and facilities impacted are listed in the table below.

Compliance Oversight In Transfusion Medicine[1]

Compliance Issues	*Agency*	*Facility*
Regulations	• Food & Drug Administration (FDA) • Occupational Safety & Health Administration (OSHA) • Nuclear Regulatory Commission-NRC (or agreement state) • Health & Human Services -CLIA, compliance in billing • State (laboratory laws)	• Blood centers • Blood banks • Transfusion services
Accreditation	• American Association of Blood Banks (AABB)	• Blood centers • Blood banks • Transfusion services
Accreditation	• College of American Pathologists (CAP) • Joint Commission on Accreditation of Healthcare Organizations (JCAHO)	• Blood banks • Transfusion services

[1]Depending on the uniqueness of the operations, some of these facilities may be exempt from inspection by the agencies above.

Regulatory Changes In 2001-02

FDA

Reporting Deviations

On Nov. 7, 2000, FDA published a final rule[1] to amend requirements for reporting errors and accidents (now termed deviations) by facilities engaged in manufacturing blood components. The implementation date was May 7, 2001.

Previously, only "licensed" establishments had to report to FDA any errors that occurred during the manufacturing process. The new rule mandated reporting by *all* facilities (registered or licensed) that had *control* of the component of any deviations that may affect the safety, quality, purity or potency of a manufactured blood component. For the first time, registered hospital transfusion services were required to begin reporting deviations.

Establishments must develop their own policies and processes to meet FDA guidance regarding:

- *Manufacturing:* testing, processing, packaging, labeling, storing and distributing.

[1]21 CFR 600.14, 21 CFR 606.171.

❖ *Blood component integrity:* safety, purity or potency.
❖ *Occurrence type:* unexpected and unforeseeable.
❖ *Location:* the establishment or contract facility.
❖ *Control:* maintenance of continued component integrity.
❖ *Disposition:* release of a blood component from the manufacturer's control.

If the establishment determines that all of the above have been involved in the suspect blood component release, then the deviation is reportable to FDA.

Blood centers have been reporting deviations to FDA for several years and have become attuned to the interpretation of the above tenets. However, many registered blood establishments, as they begin to submit reports, are finding variability in the interpretation of the rule by different facilities.

The Biological Product Deviation Reporting (BPDR) form[2] requires the categorization of the reported deviation by blood and non-blood deviation codes.

Most of the currently available codes were developed from deviations submitted prior to the publication of the final rule and, therefore, represent blood center activities more than those activities found in the hospital transfusion service. The facility should submit a code that "best" describes the activity that was out-of-compliance without miscoding the event.[3]

[2]Form FDA 3486.

[3]Example: Use code LA-81-06 (extended expiration date) in transfusion service for labeling error if a pooled platelet expiration date was calculated incorrectly and entered on the bag label.

FDA has been responding via electronic mail with suggested code changes when a report has been filed using the Center for Biologics Evaluation & Research (CBER) Website[4].

FDA has not released any information on the number of reports or type of deviations submitted since May 7, 2001. As both the agency and the registered establishments gain experience with the reporting of these deviations, refinement in the process is expected.

Software Validation

FDA has recently released a computer software validation document, *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (Center For Devices & Radiological Health/CBER, Jan. 11, 2002).

FDA has not released any information on the number of reports or type of deviations submitted since May 7, 2001. As both the agency and the registered establishments gain experience with the reporting of these deviations, refinement in the process is expected.

This guidance document applies to software as medical devices used by blood establishments and outlines requirements for both the manufacturer and the end-user.

More and more blood establishments are using computers to manage their operations. Hospital transfusion services that convert from manual to electronic processes will require knowledge of software validation principles. These regulations apply to in-house developed software, off-the-shelf software, contract software and shareware.

These establishments must have persons knowledgeable about the importance of careful test planning, defining expected outcomes, and proper documentation of test results. Objective validation should include:
❖ Defined user requirements.
❖ Validation protocol used.
❖ Acceptance criteria.
❖ Test cases and results.

[4]*www.fda.gov/cber/biodev/biodev.htm*

❖ A validation summary.

The facility should describe in its Quality Plan the intended use of the software, hardware/software requirements, version control, needed safety-related features (including security processes) and disaster recovery. Validation documentation should be easily retrievable for any inspection agency.

OSHA

Bloodborne Pathogen Standard

This now familiar standard was revised on Jan. 18, 2001, under a final rule implementing provisions of the Needlestick Safety & Prevention Act[5].

The major elements of the rule are concerned with the annual re-evaluation by employers of their engineering controls for selection of safer needle devices (including needleless devices) set forth in the Exposure Control Plan, and input from non-managerial employees in selecting the devices. These elements of the final rule should have been implemented by Apr. 18, 2001.

The recordkeeping requirements of the final rule did not become effective until Jan. 1, 2002.

This part of the rule requires employers to maintain a log (paper or electronic) for all needlestick and sharps injuries and, at a minimum, it must contain the following documentation:
❖ Type and brand of device involved in the needlestick/sharps incident.
❖ Department or work area where the needlestick/sharps exposure occurred.
❖ Explanation of how the injury occurred.

A list of sharps currently in use by the facility, indicating the type and brand of the device, must also be maintained. In addition, the recordkeeping must keep the sharps-related injuries documented separately from other work-related

[5]29 CFR Part 1910.

employee injuries.

Citations may be issued for noncompliance as evidenced by no revision to the Exposure Control Plan or no documentation of safety devices or blood exposures.

Accreditation Changes In 2002

AABB

The major accrediting agency for the blood industry, AABB, has introduced a revision of the *Standards for Blood Banks and Transfusion Services* in the 21st edition published in January 2002.

The changes incorporated in this edition will become effective May 1, 2002, and facilities seeking AABB accreditation status will be assessed using the requirements of the 21st edition after that date.

The goal of the revision, as stated by AABB, is "to maintain and enhance the quality and safety of transfusion and transplantation of blood components, and to be consistent with available scientific information, while focusing on donor and patient advocacy."[6]

As in the past, many changes to the *Standards* are revisions for clarity, grammatical enhancements, addition of statistical quality control parameters or to reflect policy/practice changes in the industry. Highlights of some of the new additions in the corresponding Quality System Essentials are outlined below.

Organization

❖ A new standard to require the facility to have an emergency operating plan in case of disasters has been added. Policies, processes and procedures must be described in the Quality Plan and/or facility standard operating procedures (SOP) in the event that natural or other disasters cause interruption of routine operations (supply, storage, distribution, tracking, documentation, computer functions).

❖ A new standard requires the medical director to approve all medical and technical policies, processes and procedures. In addition, any exceptions to existing policies, processes, or procedures due to unique clinical situations require documented justification and pre-approval by the facility medical director. This may require the firm to develop an "emergency change" form to document such occurrences.

Process Control

❖ The facility must have policies, in addition to processes and procedures, which define the recipient informed consent criteria. The medical director shall participate in the development of these policies.

❖ The medical director is no longer required to review/approve blood collection from a donor-patient (autologous collection). An order from the patient's physician is still required.

❖ Blood collection facilities must not use an earlobe puncture to obtain a blood specimen to determine donor hemoglobin eligibility. The earlobe sample overestimates the hemoglobin level vs. the fingerstick method and may allow acceptance of donors with lower hemoglobin content.

❖ A new standard quantifies the amount of whole blood allowed to be removed from a donor in a seven-day period of collections (≤ 2400 mL for donors weighing more than 175 pounds and ≤ 2000 mL for donors weighing less than 175 pounds).

❖ Blood collected as a therapeutic phlebotomy from an individual with hemochromatosis may be used for allogeneic transfusion, providing the donor meets the current donation criteria, there is no charge to the donor, and the collection program has been approved by FDA.

❖ Red blood cells collected in an additive solution (AS-1/AS-3) may be frozen any time up to the expiration date. This will allow autologous units to be frozen should the original surgery date be postponed.

❖ A new requirement to compare the prior patient records of the previous 12 months for blood type (ABO/Rh) before issuing the component has been added.

❖ A process shall be in place to ensure that an adequate dosage of Rh Immune Globulin is administered and given as soon as possible after dose calculation is completed.

Documents and Records

❖ Several new standards have been included that require processes and procedures, including management oversight, of computer systems. Computer backup of all critical data shall be stored in an off-site location.

Deviations, Nonconformances & Complications

❖ A new standard has been included that requires evaluation of the effect of nonconformance on component quality, documentation of any corrective actions and notification of the customer if nonconformance affects component quality.

Process Improvement Through Corrective & Preventive Action

❖ Facilities are now required to have a process for corrective action related to investigation of customer complaints.

AABB has also released for implementation on Jan. 1, 2002, the first edition of the *Perioperative Autologous Blood Collection and Administration*.

These standards incorporate the 10 Quality System Essentials for donor center/transfusion service establishments and require compliance with other autologous blood collection services (*i.e.*, cell salvage).

Establishments wishing to be AABB-accredited for these services must submit a separate request for this accreditation, and additional fees are required.

Facilities that use a contract service must ensure that the contract

[6] *AABB News*, November/December 2001.

agency complies with these standards, and the hospital medical director must document active involvement in oversight of the program.

CAP

Another accreditation agency, CAP, has recently revised several section checklists used in the performance of clinical laboratory inspections. The transfusion medicine checklist has several revisions or modifications requiring conformance by facilities beginning in the 2002 cycle of inspections. Highlights of these changes are outlined below. Phase II deficiencies will require immediate corrective action in order to maintain accreditation status.

❖ Performance of a direct antiglobulin test (DAT) will require use of both IgG *and* complement antiglobulin reagents. The addition of the complement requirement will allow for the detection of more patients harboring a hemolytic state.

❖ Perioperative blood recovery and reinfusion programs (hospital-based or contracted) must demonstrate that the hospital medical director actively participates in their development of any policies and procedures.

❖ Thawed fresh frozen plasma stored at refrigerated temperatures for up to five days after thawing shall be relabeled as "thawed plasma" (AABB has also added this requirement).

❖ A granulocyte or platelet must be crossmatch-compatible with the recipient's plasma if the component contains more than 2 mL of red blood cells (Phase II).

❖ The medical director must approve any new policy or change in existing policy before the policy is implemented (Phase II).

❖ The laboratory information system must be validated if used for blood banking/transfusion medicine activities.

❖ The facility must have a policy in place for notification of FDA when a transfusion-related fatality occurs. FDA currently requires a telephone notification within 24 hours and a written report within 7 days.[7] (Phase II).

[7]21 CFR 606.170

Keep Eye Out For More

There are other new regulations not discussed here that will have a global impact on all areas of healthcare, including blood industry establishments. For example, HIPAA standards, fraud in billing rules, the Stark physician self-referral ban and ambulatory payment classifications under the Medicare outpatient prospective payment system.

In addition, blood industry-specific rules may be forthcoming in 2002 relating to donor screening health history questions, donor testing, tissue banks and deviation reporting.

The blood industry must stay aware of any changes in regulatory or accreditation requirements in order to plan for any impact on budgets, staff, space, equipment and operations. Compliance is indeed a necessity in order for the blood industry to continue to provide the safest blood possible to the nation.

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Arizona Court Overturns Denials Of Indirect Pathology Service Claims

The Arizona Health Care Cost Containment System (AHCCCS) improperly applied Medicare guidelines in denying payments for indirect pathology service claims, the Arizona Court of Appeals ruled in January (*Arizona Society of Pathologists v. AHCCCS,* 1-22-02).

AHCCCS, the state program that pays for healthcare for Arizona's indigent population, began denying payment for pathologists' indirect services, saying it was following Medicare guidelines, which allow pathologists to bill for direct but not indirect services.

Under indirect services billing, a pathologist bills a nominal fixed fee for each lab test, regardless of the time the pathologist devotes to a particular test.

The practice, accepted by some private insurers as an administrative convenience, spreads costs across all patients and allows pathologists to charge a portion of their overhead to all patients.

Pathologists Challenge Policy

The Arizona Society of Pathologists and the Mallon-Alvarez Pathology Group challenged the state's policy before the Governor's Regulatory Review Council, which sided with the pathologists, saying AHCCCS had failed to issue the policy through appropriate rulemaking. When the state agency continued to deny claims, the pathologists filed suit in state court.

The trial court, concluded that the billing of indirect pathology services was for items or services not provided as claimed. The pathologists appealed.

The appeals court reversed and remanded the lower court ruling. It concluded that AHCCCS did not have a lawful basis for changing its policy to deny coverage of indirect pathology services claims.

The text of the opinion is available online at *www.cofad1.state.az.us/opinionfiles/cv/cv010029.pdf.*

CMS Chief Pledges Fair Treatment For Providers
"It's Time To Restore Balance," Says Scully

The head of the Centers for Medicare & Medicaid Services, Thomas Scully, pledged last month that healthcare providers will be treated fairly even as the agency pursues the "bad" ones.

"It's time to restore balance," he stated, noting that many providers participating in Medicare and Medicaid believe CMS focuses too much on punishing those who commit "innocent" mistakes or voluntarily disclose problems. Scully spoke Feb. 7 at the National Congress on Health Care Compliance in Washington, DC.

Before the early 1990s, taking advantage of lucrative loopholes in Medicare and Medicaid regulations was common and widely accepted throughout the healthcare industry, Scully said. And when federal investigators began cracking down on providers in the 1990s, good providers began feeling "terrorized," he acknowledged.

"The perception is that we're randomly picking on providers. That's not true, but we can do a better job of proving it."

Positive Reinforcement

One way he suggested would be to establish an ombudsman within the U.S. Department of Health & Human Services to furnish guidance on self-disclosure and other compliance issues, essentially serving as a go-between between providers and federal regulators.

HHS and CMS also could do a better job of creating sound policies, Scully said. "Fraud costs money, but so do bad policies. If you create really bad policies, people will follow them, and there are people out there with big incentives to do so."

On the issue of Stark II, Scully promised that Phase II of the final physician self-referral rule would be published soon. Most of the Stark II provisions in Phase I became effective in January 2002, but CMS has been promising further revisions and clarifications. The Stark statute prohibits physicians from referring laboratory and other designated health services to entities with which they have a financial relationship and from billing any payer or the patient for the referred service. A host of exceptions apply to ownership investments and compensation arrangements that might otherwise trigger the Stark ban.

"I think you're going to see a whole new fine-tuning of Stark within about two months," said Scully.

FBI Won't Ease Up On Healthcare Fraud Probes

The Federal Bureau of Investigation has no intention of easing up on healthcare fraud probes simply because of the new focus on countering terrorism in the U.S. and abroad, the chief of the FBI's health care unit has cautioned.

Though agency officials did consider diverting money from various enforcement programs following the attacks of Sept. 11, the health care unit ultimately was left intact, said Timothy Delaney on Feb. 7 at the National Congress on Health Care Compliance in Washington, DC.

"Healthcare fraud came up" when FBI director Robert Mueller III began looking for ways to shift resources to homeland security, Delaney acknowledged. While the healthcare enforcement program "was on the chopping block," officials decided to leave it largely untouched, in part because it gets funding to fight fraud through the Health Insurance Portability & Accountability Act (HIPAA).

Because of the HIPAA funding, the FBI has been able to increase the number of agents assigned to healthcare fraud to 435 who currently are working on 3,000 open cases, he said. In 1992, only 112 agents were detailed to anti-fraud efforts in healthcare.

More Agents To Be Hired

Though the FBI is diverting some funds from other enforcement programs, the agency does plan to hire about 2,000 more agents during the next two years, many with healthcare backgrounds, according to Delaney. Already, the FBI has hired some former healthcare compliance officers and others from the industry, he said.

The FBI's health care unit, established in 1992 as a separate unit within the financial crimes section of the criminal investigative division, works closely with the HHS Office of Inspector General and the Centers for Medicare & Medicaid Services to investigate alleged fraud against federal healthcare programs.

The FBI recently was actively involved in investigating Fresenius Medical Care North America, the world's largest provider of kidney dialysis products and services. Fresenius agreed to pay $486 million to resolve allegations of fraud at National Medical Care, Fresenius's kidney dialysis subsidiary.

In another case investigated by the FBI's health care unit, Beverly Enterprises of California, a subsidiary of Beverly Enterprises Inc., agreed to pay $170 million to settle civil charges of alleged fraud, as well as a $5 million criminal fine.

Are You Sure Your Business Associates Comply With Privacy Standards?
To Be Sure, Get Modified Contracts, Relationships in Place Now

With implementation of new standards for the protection of information about an individual's health status only about a year away, you should be working now to establish new or modified contracts with business associates to ensure that they comply with the privacy standards, advises Keith Korenchuk, a partner with the law firm of Davis Wright Tremaine LLP (Washington, DC).

The new standards, mandated by the Health Insurance Portability & Accountability Act (HIPAA), become effective Apr. 14, 2003, for most health plans, providers and clearinghouses.

Under the final rule implementing the standards, published Dec. 28, 2000, "business associates" of HIPAA-covered entities must provide satisfactory assurance that they will appropriately safeguard patients' health information. Covered entities include health plans, providers that transmit health information in an electronic form and healthcare clearinghouses.

Who are business associates? Generally, they are people or organizations that either (1) receive individually identifiable health information on behalf of a covered entity and assist with an activity involving that information or (2) provide certain identified services to a covered entity, explains Korenchuk, who spoke at the Second Annual Privacy and Data Security Summit, held in Washington, DC on Jan. 30-Feb. 1.

Business associates include billing firms, lawyers, consultants, accounting firms, clearinghouses and vendors. There is no business associate relationship between covered entities and employees, between providers and a health plan or between a hospital and medical staff members, notes Korenchuk.

Contract Requirements

The privacy rule mandates that contracts with business associates include specific requirements, he continued. For example, contracts must state that the associate may use and disclose information only as authorized in the contract, and uses and disclosures may not exceed what the covered entity may do under HIPAA (though there is an exception for uses involving aggregation of data).

Contracts must also state that associates:

- Implement appropriate privacy and security safeguards.
- Report unauthorized disclosures to the covered entity.
- Make available protected health information (PHI) under access, amendment and accounting of disclosure rights.
- Incorporate any amendments to PHI.
- Make its records available to the U.S. Department of Health & Human Services for determination of the covered entity's compliance.
- Return or destroy PHI upon termination of the business associate arrangement, if feasible.
- Ensure that agents and subcontractors comply with HIPAA.
- Authorize termination by covered entities.
- Give covered entities the right to review contracts between business associates and their subcontractors.
- Provide details on their insurance and discuss indemnification or liability.
- May use PHI for management and administration.
- Establish effective date and "placeholder" provisions.

What's Your Liability?

In developing contracts with business associates, it's important to consider your liability if an associate misuses or fails to protect a patient's health information, says Korenchuk.

Under the privacy rule, if a covered entity knows of a pattern or activity constituting a breach by a business associate, the entity must take reasonable steps to cure the breach or end the violation.

"This may mean more risk management or revising policies and procedures. Whatever it is, it needs to be spelled out in the contract."

Specifically, the privacy rule requires "a covered entity to mitigate, to the extent practicable, any harmful effect that is known to the covered entity arising from disclosures of PHI in violation of the covered entity's policies and procedures or HIPAA by the covered entity or its business associate."

If the violation cannot be fixed, the entity should terminate the arrangement with the associate if feasible and report the breach to HHS.

"What does it mean if termination is not feasible?" asks Korenchuk. "I don't think anybody has a good idea of what that is, and I suspect that as we go forward, we'll see some litigation on this."

Penalties for failing to adequately protect PHI include $100 per violation, not to exceed $25,000 per year. Entities that knowingly disclose or obtain PHI without authorization can also be hit with criminal penalties of up to $250,000 and 10 years in jail.

What Should You Do Now?

If you have not already identified your business associates, Korenchuk advises that you start listing everyone who receives individually identifiable health information (name, street address, city, state, social security number; (*for a complete listing of PHI, see GCR, Oct. '01, p. 9*). Determine who is likely to be a business associate and educate them about the new privacy requirements.

"Once you've cast that net over what you're doing, you have to make several strategic decisions," he says. "The first is to decide whether you will be proactive or wait. Do you want your business associate relationships to have a uniform look, which means being more out in front, or do you want to respond to the countless business associate agreements that might be proposed by the covered entities that you do business with or by the business associates themselves?"

Next, decide whether the new contract language will be an addendum to an existing contract, be integrated into the contract or stand alone. In many cases, once you begin modifying contracts, you'll find other revisions that also need to be made.

"If you have 1,000 business associates and you want to make substantive changes in only 5% of the contracts, it can become a fairly lengthy process," Korenchuk says. "I suspect that for most of us, it won't be as easy as sending out a two-page agreement."

As you take an inventory of existing contracts to determine what modifications are needed, you will also have to make decisions about how to handle "second tier" business associate relationships. How much of the business associate obligations should be passed through to their agents and subcontractors?

"That will be a function, in part, of what the final security regulations might say and of what state tort law and privacy law say," Korenchuk explains. While there is language in the privacy rule that requires business associates to get some assurances when they redisclose PHI, it is unclear how much more needs to be done and what the liability is if, for example, a second-tier entity posts medical records on the World Wide Web.

"It's not particularly clear right now, and that's a function of how this has been phased-in. It doesn't give a lot of us a great deal of clarity, and that's an unfortunate part of what may have been a broader positive goal."

Resource

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Miami Man Sentenced In Bogus Test Scheme

A Miami man was sentenced Feb. 6 to 18½ months in jail and ordered to pay nearly $1.5 million in restitution for his role in a fraud scheme involving bogus lab tests, according to the U.S. attorney for the Eastern District of California.

Roberto Llanes of Miami was found guilty of paying kickbacks, directly and indirectly, to doctors and clinics in exchange for ordering trace mineral tests from Monterey Medical Labs. The tests ostensibly measured heavy metals in blood and urine.

Llanes paid kickbacks of approximately $150 per patient directly to certain doctors, prosecutors charged, and also provided funds to recruiters to use to pay kickbacks to doctors and clinics for ordering tests. Medicare was billed $800-$1,000 for each panel of tests. Between Sept. 1997 and June 1999, Monterey Medical Labs billed Medicare for more than $1.5 million in tests, said the U.S. attorney's office.

Llanes is the fourth defendant involved in the scheme to plead guilty and the first to be sentenced. Also charged are Michael Conte, Armando Aguilar, Roberto March Sr. and Roberto March Jr. Conte, 53, of Monterey, CA, owned Monterey Medical Labs, where the tests were conducted.

Under HIPAA rules to protect patient privacy, must a healthcare provider or other covered entity obtain permission from a patient prior to notifying public health authorities of the occurrence of a reportable disease?

No, according to guidance from the Centers for Medicare & Medicaid Services:

"All states have laws that require providers to report cases of specific diseases to public health officials. The privacy rule allows disclosures that are required by law. Furthermore, disclosures to public health authorities authorized by law to collect or receive information for public health purposes are also permissible under the privacy rule. In order to do their job of protecting the health of the public, it is frequently necessary for public health officials to obtain information about the persons affected by a disease. In some cases, they may need to contact those affected in order to determine the cause of the disease to allow for actions to prevent further illness.

"The privacy rule continues to allow for the existing practice of sharing PHI [protected health information] with public health authorities authorized by law to collect or receive such information to aid them in their mission of protecting the health of the public. Examples of such activities include those directed at the reporting of disease or injury, reporting deaths and births, investigating the occurrence and cause of injury and disease, and monitoring adverse outcomes related to food, drugs, biological products and dietary supplements."

The guidance is found in Q&As online at *www.hhs.gov/ocr/hipaa/govtaccess.html*.

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.

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News-At-A-Glance

TX Hospital Settles Overpayment Case: St. Joseph's Hospital in Houston, TX, has agreed to pay nearly $1.6 million to put to rest allegations that it knowingly failed to disclose an overpayment by Medicare. The settlement resolves the hospital's liability for failing to disclose a known overpayment of $798,000, said the U.S. attorney for the Central District of California. The allegation was made by whistleblower Mark Razin of Long Beach, CA, a former employee of Healthcare Financial Advisors (Newport Beach), now owned by Certus Corp. HFA was a financial consultant to hospitals across the country. St. Joseph's, one of the Christus chain of hospitals, denies any wrongdoing.

GA Unit Faulted On Overpayments: The Georgia Department of Community Health made more than $1.75 million in improper lab service payments between Oct. 1, 1996 -June 30, 1999, according to a report by the HHS Office of Inspector General. Inadequate claims processing edits and audits were to blame, the OIG said. It recommended that the state adjust the HCFA-64 form for the federal portion, initiate recovery from providers for the full amounts and correct claims processing deficiencies. The report is online at *oig/hhs.gov/oas/reports/region4/40105002.pdf*.

Payment Error Rate Down: The Centers for Medicare & Medicaid Services improperly paid about 6.3% of all Medicare fee-for-service claims in fiscal 2001, or $12.1 billion out of a total $191.8 billion in claims paid, the HHS Office of Inspector General concluded in a report report. In 1996, when the OIG began this type of review, the error rate was 13.8%. It has dropped every year since. CMS officials have pledged to trim the error rate further, to 5%. The report is online at *oig.hhs.gov/oas/reports/cms/a0102002.htm*.

Privacy Rule Change Sought: Healthcare groups are urging HHS to revise the HIPAA privacy rule to make the prior consent requirement discretionary. The rule, issued last December, requires providers to get a patient's prior written consent to use or disclose individually identifiable health information for treatment, payment or healthcare operations.

A coalition of about 80 groups argued in a recent letter to HHS Secretary Tommy Thompson that the requirement would confuse patients, increase patients' waiting time and inconvenience providers. In a separate letter the coalition asked HHS to modify its standard for de-identifying medical information.

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