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For Hospitals, Laboratories and Physician Practices

Get Ready For Uniform Lab Test Coverage Policies
Some Changes Take Effect This Month

Experts are advising clinical laboratory executives, managers and compliance officers to start preparing now for the introduction this year of new, uniform national Medicare Part B coverage and payment policies for 23 frequently performed diagnostic tests. The policies are set forth in a final rule in the Nov. 23, 2001 *Federal Register*.

The effective date for the policies is Nov. 25, 2002, but there are several administrative changes and clarifications that take effect on Feb. 21, 2002 (these are to be implemented primarily through program instructions to carriers, says the Centers for Medicare & Medicaid Services). Among the points clarified: a physician's signature is not required on the lab test requisition, and contractors may not use frequency screens to deny claims without having previously published guidance on the reasonable utilization of a test or service.

Because your laboratory may need to modify computer systems and perhaps even various forms and processes, you should begin now to evaluate your lab's readiness for the upcoming changes, advise attorney Jeffrey Boothe, a partner with Holland & Knight (Washington, DC), and C. Anne Pontius, president of Laboratory Compliance Consultants (Raleigh, NC).

Suggested Prep Steps

❖ ***Review the tests and codes (both CPT procedural codes and ICD-9-***

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Are You Prepared For The Worst?

Since the Sept. 11 terrorist attacks and the anthrax exposures, many healthcare organizations are taking a hard look at their ability to respond to a disaster. While most agencies that accredit hospitals and laboratories require facilities to have a disaster plan in place, specific elements of those plans are typically left to the individual providers.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), for example, requires hospitals and ambulatory care, behavioral health, home care and long-term care organizations to develop, implement and test emergency management plans. The plans must be executed twice a year, either in response to an actual emergency or in planned drills.

Laboratories are not required to have an external disaster plan under JCAHO standards but must have a plan to handle internal emergencies, according to Joanne Born, executive director of JCAHO's laboratory program. The internal plan should address four phases of emergency management, she says: mitigation, preparedness, response and recovery.

In addition, modified JCAHO emergency management requirements for 2001 mandate that organizations, including labs, conduct a hazard vulnerability analysis. The

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Emergency Plan, *from page 1*

purpose is to identify the disasters most likely to strike your organization and its community and the probable impact if they were to occur.

Leave Nothing To Chance

"Given recent events, every healthcare organization should be re-evaluating and perhaps redefining the realm of possible disasters that may affect its operations," writes JCAHO in a special December 2001 issue of *Joint Commission Perspectives*. "The foundation already exists in emergency management plans, but you may have to build on it."

The College of American Pathologists, which also accredits labs, requires that laboratories have a section on internal and external disaster preparedness in their safety manuals, according to Ron Lepoff, lab director at the University of Colorado Hospital and upcoming chair of CAP's Commission on Laboratory Accreditation.

The plans should include a series of policies and procedures to be followed in the event of an internal disaster, such as fire, flood, electrical outage or spill of hazardous materials, and in the event of an external disaster, such as a tornado, earthquake or other mass casualty situation, notes Lepoff.

The Occupational Safety & Health Administration requires *written* emergency action plans for facilities with 10 or more employees, says Sheila Dunn, DA, head of Quality America Inc. (Asheville, NC). The written plan must be kept at the workplace and be available for employee review. For employers with 10 or fewer employees, the plan need not be written.

Here's a summary of OSHA requirements prepared by Quality America:

Facilities with 10 or more employees must have in place:

1. Emergency escape procedures and escape route assignments.
2. Procedures to be followed by employees who remain to run critical facility operations before they evacuate.
3. Procedures to account for all employees after emergency evacuation has been completed.
4. Rescue and medical duties for employees who are to perform them.
5. The preferred means of reporting fires and other emergencies.
6. Names or regular job titles of persons or the department to be contacted for further information or explanation of duties under the plan.
7. A description of your employee alarm system.
8. Types of evacuation to be used in emergency circumstances.
9. A sufficient number of persons properly trained and designated to assist in the safe, orderly emergency evacuation of employees.
10. Designated times when the plan is reviewed with each covered employee. Plans must be reviewed initially when the plan is developed, whenever employees' responsibilities under the plan change, upon initial assignment for new employees and whenever the plan is changed.

Customize Your Plan

Plans will vary by provider depending on location and likely hazard. While JCAHO offers guidance for healthcare organizations in developing an emergency preparedness plan, there is no single model for organizations to follow.

"There's really not a whole lot out there in terms of models," Dunn observes. "It's mostly a matter of starting from scratch."

JCAHO has, however, developed an emergency management checklist to help you determine that appropriate elements are in place, should an emergency occur (*see page 3*). JCAHO cautions that the checklist items are just a starting point and should be revised to fit your organization's specific circumstances.

Quality America has a new publication, "The HELP Book: Healthcare Emergency and Lifesaving Plan." It contains sample emergency procedures for ambulatory medical facilities that can be adapted to individual facilities.

Providers that have given little thought to emergency plans should begin by sitting down with staff and brainstorming about possible emergencies, then develop procedures in response to those threats, advise both Dunn and Born. Once a rough plan is in place, providers should test and revise it as needed.

"You need to really give thought to 'What if'," says Born. "What if the power went out? What if we had a bomb threat? What if there were a chemical spill nearby? How would that affect us? You need to determine risk and how you would and should respond. After that, education really becomes key."

In conducting a hazard vulnerability analysis, JCAHO advises providers to identify possible hazards, then rate the probability of their occurrence (high, moderate, low) and how well prepared you are to deal with each situation (good, fair, poor). Organize your analysis in any way that meshes with your overall emergency plan, the agency advises.

JCAHO also notes that the American Society for Healthcare Engineering offers a hazard vulnerability assessment tool on its Website (*www.ashe.org*). The tool uses three factors—probability of occurrence, risk and preparedness status—to give various disasters a quantitative score. You can then rank disasters to ascertain where your organization should focus its preparedness efforts.

Resources

- Joanne Born: 630-792-5197
- Sheila Dunn: 828-645-3661
- Ron Lepoff: 303-372-0336
- *Joint Commission Perspectives*, December 2001, *www.jcaho.com*
- *How To Meet the Most Frequently Cited Laboratory Standards*. Available for purchase from JCAHO, 630-792-5800
- *The HELP Book: Healthcare Emergency & Lifesaving Plan*. Available for purchase from Quality America, 800-946-9956

Emergency Management Checklist

	Issue assessed	*Action plan developed*	*Staff contact assigned*
Identification of authorized personnel			
● Individual designated as incident commander on all shifts	_____	_____	_____
● Lines of authority and role responsibility identified, communicated to all staff	_____	_____	_____
● Identification of and access for authorized personnel	_____	_____	_____
Activation of the plan			
● Who can activate it, under what circumstances and how will it be communicated?	_____	_____	_____
● Activation stages established and roles outlined with each stage:	_____	_____	_____
— Alert—Disaster possible; increased preparedness	_____	_____	_____
— Stand by—Disaster probable; ready for deployment	_____	_____	_____
— Call out—Disaster exists, deployment	_____	_____	_____
— Stand down—Disaster contained; resume normal operations	_____	_____	_____
Notification process			
● System in place to notify staff of potential or actual disaster	_____	_____	_____
Response plan by department			
● Standard dept. operating procedures established to detail how depts. will continue to provide service during a disaster	_____	_____	_____
● Plan developed for how organization will provide supplies and staff in response to external emergencies	_____	_____	_____
Command structure and center			
● Creation of a command structure and center away from the emergency department	_____	_____	_____
● Standard operating procedures, chain of command for command center established	_____	_____	_____
● Equipment and space designated for extra service providers, such as volunteers	_____	_____	_____
● Coordination with external agencies established	_____	_____	_____
Security plan to control access & egress			
● Procedures to lock down or minimize access and egress established and tested	_____	_____	_____
● Plan established to control vehicular and pedestrian traffic	_____	_____	_____
● Process established to verify credentials of healthcare and emergency workers from outside the organization who arrive to assist	_____	_____	_____
Alternative communication systems			
● Alternative communication arrangement made for system failure or overload	_____	_____	_____
● Organized runner or messenger service in place	_____	_____	_____
● Communication networks established with local emergency agencies	_____	_____	_____
Reception of casualties			
● Plan of action in place whereby casualties can be received, identified, triaged, registered, admitted, transferred or transported and treated	_____	_____	_____
Facility evacuation			
● Discharge routine in place to handle large number of patients	_____	_____	_____
● Staff member identified to be responsible for removal and control of patient records, documents	_____	_____	_____
Relocation of patients and staff			
● "Safe" area within the facility identified, should other areas become uninhabitable	_____	_____	_____
● Agreements made with other healthcare facilities to receive overflow of patients	_____	_____	_____
● Satellite location of care identified	_____	_____	_____
● Transportation requirements for movement of staff and patients predetermined and confirmed	_____	_____	_____
● Sequence of transfer established	_____	_____	_____
Facility isolation or quarantine			
● Staff members designated for auxiliary power; rationing of food and water; waste and garbage disposal; rest and rotation of staff; rationing of medication and supplies; laundry and staff and patient morale	_____	_____	_____
Environment of care and lab assessment			
● Contingency identified for ventilators, IV pumps and poles, suction machines, beds, stretchers and wheelchairs	_____	_____	_____
● Medical supplies, linens maintained and readily available	_____	_____	_____
● Local suppliers of medical equipment and supplies identified and 24-hour contact information available	_____	_____	_____
Pharmaceuticals			
● Current level of medications identified	_____	_____	_____
● Pharmaceutical allocation plan makes provision for prophylaxis of caregiving staff and their immediate family	_____	_____	_____
● Other healthcare facilities that can provide needed pharmaceuticals identified	_____	_____	_____

Uniform Lab Test, *from page 1*

CM diagnosis codes) for which Medicare has established national coverage/payment policies. The tests and related CPT codes are listed in our January 2002 issue, p. 4; the extensive list of ICD-9-CM codes for each test can be found in the Nov. 23, 2001 *Federal Register*.

While the national coverage policies offer predictability and consistency, their introduction will be significant, Pontius notes, for those labs in Medicare contractor areas with relatively few local limited-coverage policies (or LMRPs-local medical review policies). She advises aligning the new national policies with existing LMRPs to see whether the new policies are more or less restrictive. "You should really compare them to see just how big of a change this will be for you."

❖ ***Watch for guidance from carriers and fiscal intermediaries.*** Since these Medicare contractors must announce policy changes through bulletins to providers, be on the lookout for official word about the changes effective Feb. 21, says Boothe, who also is an advisor to the Clinical Laboratory Management Association. "Look for the bulletins, but also exercise diligence and vigilance to make sure the contractor follows through on them."

If you can't meet the Nov. 25 compliance date, you need to develop a work plan outlining when you think when you will be ready.
—Jeffrey Boothe

❖ ***Evaluate your computer systems and software.*** The final coverage rule defines the date of service as the specimen collection date. For tests requiring a specimen from stored collections, the date of service is defined as the date the specimen was obtained from the archives. If your lab's computer systems are programmed to report—in the date-of-service field on the claim form—the date when the test was performed or the date of accession, this will have to be changed.

System changes may also be needed to handle blood count codes, Pontius points out. For virtually all of the lab tests subject to the new policies, specific covered ICD-9-CM codes are identified. Blood counts are the exception. For these procedures, only excluded (non-covered) ICD-9-CM codes are specified, because the list of covered codes is quite long.

❖ ***Can you meet the Nov. 25 compliance date?*** "If you can't, you need to develop a work plan outlining when you think you will be ready," says Boothe. Labs may apply for an extension of up to an additional year, but must request this in writing to the Centers for Medicare & Medicaid Services 90 days before the effective date (by Aug. 27) and must indicate the date when they will achieve full compliance. Medicare contractors may also seek an extension, so you'll want to check if your contractor intends to do so.

Jeffrey Boothe, Esq.

C. Anne Pontius

Medicare's Uniform Lab Test Policies
Changes, Clarifications Effective Feb. 21

- The signature of the test-ordering physician is not required for Medicare purposes on a laboratory requisition.
- Appropriate diagnosis codes may be assigned to a narrative diagnosis, even if the narrative's wording does not exactly match the descriptor of the ICD-9-CM code.
- The narrative field on the claim form may be used to report additional diagnoses if the Medicare contractor's system will not accept all of the codes in the "diagnoses" field.
- Medicare contractors may not use a frequency screen that could result in a frequency-based denial unless the contractor has published information about the appropriate frequency for the service.
- The term "screening" or "screen" in a CPT code descriptor does not necessarily mean that the test is for preventive screening in the absence of signs or symptoms of illness or disease.
- Contractors must review all claims data and relevant documentation before denying coverage for a test. For example, a claim for services that exceed utilization parameters cannot be denied without a review of all relevant documentation submitted with the claim.
- Medicare also will issue instructions clarifying how to use modifier codes to indicate multiple services that are medically necessary to diagnose or treat a beneficiary's condition.

Resources

- Jeffrey Boothe: 202-828-1896
- C. Anne Pontius: 919-859-3793
- Our previous coverage: Jan. '02, pp. 1, 4
- *Federal Register*, Nov. 23, '01. Online at *www.access.gpo.gov/su_docs*

COMPLIANCE PERSPECTIVES

The Devil's In the Details: Top 10 Pathology Billing & Coding Issues

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Pathologists, independent clinical laboratories and hospital outpatient departments often find that getting paid for their work is the most difficult part of the job. Regulatory and procedural hurdles amount to a virtual gauntlet for pathology service providers, with little relief in sight.

From effective charge capture to proper coding, the devil is in the details. Discussed here are the top 10 billing and coding issues affecting pathologists, plus tips for ensuring compliance.

1. Fine Needle Aspiration

Effective Jan. 1, 2002, new codes for fine needle aspiration billing were implemented. CPT procedure codes 88170 and 88171 have been deleted. These procedures have been reclassified as surgical codes. The replacement procedure codes are:

—10021, Fine needle aspiration without imaging guidance.

—10022, Fine needle aspiration with imaging guidance.

In addition to the code for the actual fine needle aspiration, the following procedure codes should be billed if performed:

—88172, Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy of specimen(s).

—88173, Cytopathology, evaluation of fine needle aspirate; interpretation and report.

When procedure code 10022 is billed, the following codes should be billed for the radiological supervision and interpretation:

—76003, Fluoroscopy, guidance for needle placement (eg, biopsy, aspiration, injection, localization device).

—76360, Computerized axial tomographic guidance for needle biopsy, radiological supervision and interpretation.

—76942, Ultrasound guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation.

Only one of the supervision and interpretation codes should be billed and only if guidance is utilized.

If procedure code 10021 (without guidance) is performed, a radiologic supervision and interpretation code should not be billed.

Managed care contracts should be reviewed, and any code combination limitations or specialty code limitations should be revised to allow full payment under the new codes. Medicare does not classify these procedures as multiple surgical procedures and, as such, multiple specimen modifiers are not needed.

2. Bone Marrow Charges

Effective Jan. 1, 2002, procedure codes 85095 (Bone marrow; aspiration only) and 85102 (Bone marrow biopsy, needle or trocar) have been deleted, and the descriptor for procedure code 85097 has been revised to read "Bone marrow, smear interpretation."

The new codes are:

—38220, Bone marrow aspiration.

—38221, Bone marrow biopsy, needle or trocar.

Procedure code 88305 remains the code for cell block interpretation.

The new codes should help providers get paid for these services. In the past, Medicare carriers would attempt to bundle payment for bone marrow services into other pathology services. Now that these services are classified as surgical procedures, the services should be unbundled from the other pathology charges. Two concerns arise, however. One, in start-up, some carriers may bundle the services into the surgical procedure to be performed only by a surgeon. Two, Medicare has classified these as surgical procedures and may reduce payment by 50%. Other payers may follow suit and reduce the allowance.

In the past, Medicare did not pay for procedure codes 85095 and 85097 on the same day for the same beneficiary unless the procedures were performed at separately identifiable sites and documented appropriately. Expect the same rule to apply to procedure codes 38220 and 38221.

In addition to the bone marrow biopsy, additional 88305's may be billed for an aspirate clot interpretation and cell block interpretation. Procedure code 88311 may be charged when a decalcification procedure is performed. The decalcification procedure must be documented in the report. All special

stains should be charged separately, in most cases using procedure code 88313. A peripheral blood smear read as part of the bone marrow procedure should be charged as procedure code 85060.

Use modifier -59 with procedure code 38220 if 38220 and 38221 are performed on the same day at separately identifiable sites. A common rejection of bone marrow procedures occurs when multiple procedure code 88305's are performed. If possible, the procedures should be grouped and billed as units. If this is not possible, modifier -76 should be used on the second and subsequent procedures.

3. Peripheral Blood Smears

Medicare allows procedure code 85060 (Blood smear peripheral, interpretation by physician with written report) only in an inpatient setting. Providers should check their managed care contracts to see if the contract pays according to Medicare guidelines or if peripheral blood smear interpretations are payable in an outpatient and/or a non-patient setting. Remember, a pathologist must sign the peripheral blood smear report.

4. Flow Cytometry

Flow cytometry procedures are payable under procedure codes 88180 (Flow cytometry; each cell surface, cytoplasmic or nuclear marker) and 88182 (Flow cytometry; cell cycle or DNA analysis). When billing 88180, each cell surface, cytoplasmic or nuclear marker is billed separately. As with all procedures, there must be documentation in the pathologist's report that the pathologist interpreted each marker billed.

Since flow cytometry procedures are often ordered after other procedures have been performed, the charges may not be captured. The billing staff needs a mechanism to ensure that all flow cytometry charges are captured and billed.

5. Special Stain Documentation

Depending on which classification, special stains should be billed as procedure codes:

—88312, Special stains (list separately in addition to code for surgical pathology examination); Group I for microorganisms (eg, Gridley, acid fast, methenamine silver, each).

—88313, Special stains (list separately in addition to code for surgical pathology examination); Group II, all other, (eg, iron, trichrome), except immunocytochemistry and immunoperoxidase stains, each.

—88314, Special stains (list separately in addition to code for surgical pathology examination); histochemical staining with frozen section(s).

—88319, Determinative histochemistry or cytochemistry to identify enzyme constituents, each.

—88342, Immunocytochemistry (including tissue immunoperoxidase), each antibody.

Procedure code 88314 is most commonly used when tissue must be frozen to remove fat prior to making the special stain.

The above stains are billed as each stain or antibody. It is important that pathologists, freestanding independent laboratories and hospital laboratories be cognizant of which special stains are in each category and that the appropriate special stain ordered is performed. Many times, special stains are performed but not clearly documented in the chart. Failure to properly document stains may lead to charges of fraud.

6. Pap Smears

Pathologists, freestanding clinic laboratories and hospital laboratories should be aware of Pap smear reporting requirements. Several procedure codes are available for technicians performing the screening based on the methodology:

—88150, Cytopathology, slides, cervical or vaginal; manual screening under physician supervision.

—88152, Cytopathology, slides, cervical or vaginal; with manual screening and computer-assisted rescreening under physician supervision.

—88153, Cytopathology, slides, cervical or vaginal; with manual screening and rescreening under physician supervision.

—88154, Cytopathology, slides, cervical or vaginal; with manual screening and computer-assisted rescreening using cell selection and review under physician supervision.

If the Pap smear is screened using the Bethesda System, use procedure codes 88164 through 88167. If the Pap smear is prepared using the "thin prep" method, use 88142-88145 to report the work. When the Pap smear is screened by an automated system under physician supervision, use 88147-88148.

When a physician is required to read the Pap smear, procedure code 88141—Cytopathology, cervical or vaginal (any reporting system); requiring interpretation by physician (list separately in addition to code for technical service)—should be billed in addition to the smear. The type of screening used, whether the Bethesda System or thin prep, should be identified and the appropriate code billed. 88141 is billable in any setting. Some managed care plans have improperly denied 88141 as a duplicate of the screening procedure. These denials should be appealed.

Procedure code P3000 should be billed if a screening Pap smear is performed. Report P3001 in addition to P3000 if a physician interpretation is required. Providers must follow the diagnosis reporting requirements for screening vs. diagnostic Pap smears and ensure that screening smears are not billed more frequently than once every two years per Medicare guidelines.

7. The Technical Component

Outside independent laboratories may continue to bill Medicare for the technical component (TC) of inpatient and outpatient anatomic pathology services through Dec. 31, 2002, if the lab had such an agreement with the hospital in place on or before July 22, 1999. Medicare had proposed eliminating separate TC payment to such labs, contending that the TC is included in the hospital's prospective payment and the labs should turn to the hospital for reimbursement. Congress then intervened, enacting a "grandfather" provision barring Medicare from going ahead with the new policy through 2002.

In the past, Medicare had considered the cost of outside labs providing the services to patients and determined that the minimal additional expense did not affect the program in a negative manner and provided better patient access to care.

A report is due to Congress in April 2002 on the potential financial impact of the change. Some observers expect an extension of the "grandfather" provision. A hospital may change independent laboratories during calendar 2002, but if a change is made, the hospital must file an attestation statement with the Medicare intermediary and provide a copy to the independent lab.

8. Reporting Multiple Units

Each separately identifiable specimen should be uniquely identified in the report and billed by the appropriate CPT code when multiple units are performed. A specimen received without multiple separately identifiable specimens—although there are multiple pieces of tissue—should be billed as one unit. If multiple units are in the same container and are separately identified by a suture or some other method and interpreted as such, they may be billed as independent units.

9. Diagnosis Reporting

On Sept. 26, 2001, the Centers for Medicare & Medicaid Services released Program Memorandum AB-01-144 that changed diagnosis reporting requirements, effective Jan. 1, 2002. Providers may now report a diagnosis based on study findings (previously, they had to bill based on the reason for the study being ordered, as specified in the 1997 Balanced Budget Act). While providers can utilize the findings of a test as criteria for diagnosis, the ordering provider is still expected to furnish a diagnosis and list the procedure to be performed.

Among the instructions in the memo is a note reminding physicians that they are "responsible for the accuracy of the information submitted on the bill." Other instructions from the memo:

> A. Determining the Appropriate Primary ICD-9-CM Diagnosis Code For Diagnostic Tests Ordered Due to Signs and/or Symptoms
>
> 1. If the physician has confirmed a diagnosis based on the results of the diagnostic test, the physician interpreting the test should code that diagnosis. The signs and/or symptoms that prompted ordering the test may be reported as additional diagnoses if they are not fully explained or related to the confirmed diagnosis.
>
> 2. If the diagnostic test did not provide a diagnosis or was normal, the interpreting physician should code the sign(s) or symptom(s) that prompted the treating physician to order the study.
>
> 3. If the results of the diagnostic test are normal or non-diagnostic, and the referring physician records a diagnosis proceeded by the words that indicate uncertainty, then the interpreting physician should not code the referring diagnosis. Rather, the interpreting physician should report the sign(s) or symptom(s) that prompted the study. Diagnoses labeled as uncertain are considered by ICD-9-CM coding guidelines as unconfirmed and should not be reported. This is consistent with the requirement to code the diagnosis to the highest degree of certainty.

The CMS memo also addressed concerns raised in the Balanced Budget Act that required physicians to list the services they order. The memo cites 42 CFR 410.32, which requires that diagnostic tests "must be ordered by the physician who is treating the beneficiary." An order is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may be:

—A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility.

—A telephone call by the treating physician/practitioner or his/her office to the testing facility.

—An electronic mail by the treating physician/practitioner or his/her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner (or his/her office) and the testing facility must document the call in their respective copy of the beneficiary's medical records.

10. Clinical Pathology Billing

Some managed care plans reimburse the professional component (PC) of clinical pathology services, others don't. Providers must stand firm in asserting their right to bill for the PC.

Managed care plans that do not pay for it should not be allowed to bundle the PC charge into the technical component, but should classify the services as non-covered, which allows the provider to bill the patient.

Hospital-based pathologists should include payment of the PC when negotiating any contract.

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Compliance Study Identifies Effectiveness Indicators
Providers Can Now Obtain Objective Program Measurements

Want to find out how your organization's compliance program stacks up against compliance programs in other organizations and against industry benchmarks?

Now you can, thanks to a new compliance study that researchers say provides the first objective measurements of compliance program effectiveness.

Capturing The Intangible

"There's really never been an objective way to measure compliance effectiveness," says Lori Richardson Pelliccioni, the lead researcher for the study and a partner in the Los Angeles office of PricewaterhouseCoopers (PwC). While the HHS Office of Inspector General has issued general guidance on the seven recommended elements of a compliance program and encouraged providers to voluntarily police themselves, the absence of specifically defined standards has made it difficult for providers to know if their compliance program is, in fact, "effective," Pelliccioni observes.

"Now, for the first time, we've defined effectiveness and created a way to measure it. This study has allowed us to develop objective ways of determining just how effective a program is and to report those findings using percentiles, which allows providers to compare how they are doing vs. others in the industry."

Examining Relationships

Pelliccioni and a research team embarked on the study in June 1999, in collaboration with faculty from the Department of Health Services in the School of Public Health at the University of California, Los Angeles. Their aim was to examine what, if any, relationship existed between the seven-element corporate compliance program, as defined by HHS, and effective compliance.

They began with a literature review of more than 18,000 compliance-related articles covering all industries subject to compliance programs, including healthcare, banking, defense and environmental industries. They culled out 593 best practices, which two expert panels later winnowed down to 137, including the practice of making managers accountable for compliance activities within their department.

The researchers then developed four data-collection instruments and randomly selected 30 acute-care hospitals to participate in the study. An indicator questionnaire, administered in face-to-face interviews with up to seven hospital organization leaders, was used to assess the existence of compliance program components. Self-administered employee and physician awareness questionnaires assessed their respective level of knowledge about their organization's compliance program as well as the level of their knowledge about compliance in general.

Lead researcher Lori Richardson Pelliccioni will discuss the Compliance Effectiveness Study at a special session during Washington G-2 Reports' Compliance Forum 2002, to be held Apr. 4-5 at the Orlando Airport Marriott in Orlando, FL

Finally, using a coding accuracy database, coders conducted a retrospective billing review of 3,000 inpatient and 3,000 outpatient claims for select Medicare and Medicaid services rendered between March 1999 and February 2000. Researchers then examined the statistical relationship between the seven recommended elements of a compliance program and the effectiveness standards defined by the study.

Not All Elements Equal

"What we discovered was that not all of the seven elements contribute equally to effective compliance," says Pelliccioni. In fact, researchers identified four of the seven elements as having a statistical relationship to one of the outcome measures: training and education; lines

Compliance Program Effectiveness: *Sample Scoring Report*

	Compliance Component Score (%)*	*Industry Mean* (%)*	*Percentile**
Standards & Procedures	72%	70%	41% - 60%
Oversight Responsibility	81%	77%	41% - 60%
Education & Training	86%	65%	81% - 100%
Lines of Communication	77%	70%	61% - 80%
Auditing & Monitoring	88%	62%	81% - 100%
Enforcement & Discipline	80%	70%	61% - 80%
Response & Prevention	89%	82%	61% - 80%
Cumulative Score	82%	70%	81% - 100%

* Scores presented are for presentation purposes only and do not reflect actual results.

of communication; response and prevention; and auditing and monitoring.

As a result of these findings, researchers determined that three primary factors are good measures of how effective a compliance program is—employee awareness, inpatient coding /billing accuracy and outpatient coding/billing accuracy. "The more aware your employees are of your organization's compliance activities, the more effective your program is likely to be," Pelliccioni notes.

Drawing from the 137 baseline practices identified earlier in the study, Pelliccioni and her team then identified specific practices related to each of the three indicators—what the researchers referred to as "effectiveness attributes." For example, having reporting mechanisms in place, including a hotline, is directly related to employee awareness, while having formal policies delineating circumstances that will trigger an investigation is directly related to inpatient coding/billing accuracy, she explains.

Assessment Program

Using the findings from the study, expected to be published by April, Pelliccioni and her team developed a system for measuring providers' compliance. The "Compliance Effectiveness Performance Assessment" program, available through PwC, allows providers to obtain an independent assessment of just how effective their compliance programs are. Providers can contract with PwC to conduct an assessment onsite or can sign up for an online assessment program, which is a little less expensive.

While the study focused on acute-care hospitals, Pelliccioni says the resulting program can be used for different kinds of healthcare providers, including labs and outpatient facilities.

As part of the assessment, PwC will evaluate your organization's compliance program components to determine whether they contain the critical attributes identified by the study; evaluate your employees' assessment of your compliance program through employee questionnaires; and evaluate your coding and billing accuracy.

At the end of the review, which Pelliccioni says should take less than six weeks, the company will provide you with a performance assessment score and how it compares to the industry mean, as well as a summary of your organization's performance on each of the seven elements, performance against the baseline effectiveness attributes and a summary of recommendations for improvement.

For example, if an organization scored low on standards and procedures, PwC might recommend that it increase the frequency with which it updates those policies.

"This is an opportunity for providers to get specific recommendations for improvement," says Pelliccioni. "By being able to measure the effectiveness of their program for the first time, they can see how they score compared with other providers, and then we can help them improve. It's really a unique program."

Resource

❖ Lori Pelliccioni: 213-452-7986

Qualification Alternatives Proposed For High-Complexity Lab Directors

The Centers for Medicare & Medicaid Services is proposing to expand the qualification requirements under which an individual with a doctoral degree may act as director of a laboratory performing testing categorized as high-complexity under CLIA (Clinical Laboratory Improvement Amendments).

The proposed change results from comments the agency received about the requirement that lab directors be board-certified (a requirement that had been waived until Dec. 31, 2002, to allow current lab directors to complete certification requirements). In lieu of board certification, CMS proposes alternatives based on training and experience.

"Upon consideration, we realize that individuals currently serving as laboratory directors are qualified based on training and experience, and have demonstrated the level of competency necessary to direct laboratories performing high-complexity testing," says CMS in a Dec. 28, 2001 *Federal Register* notice.

Three Alternatives Proposed

1 Hold an earned doctoral degree and be certified by an HHS-approved board, or

2 Be or have been director of a lab performing high-complexity testing before Jan. 1, 2003, and hold a doctoral degree in a chemical, physical, biological or clinical lab science from an accredited institution, have two years of lab training or experience or both, and two years' experience directing or supervising high-complexity testing, or

3 Hold an earned doctoral degree, and although never having been the director of a laboratory, high complexity have at least six years of lab training or experience or both, including two years' experience directing or supervising high-complexity testing.

For more information, contact Cecilia Hinkel, 410-786-3531.

HIPAA Compliance Turns Into Major Headache For Providers
Piecemeal Implementation Triggers Lots Of Frustration

While most healthcare compliance officers are well along in preparing for implementation of HIPAA privacy standards, scheduled to take effect Apr. 14, 2003, many are frustrated by the government's problems in proposing or finalizing a host of related rules required under the 1996 Health Insurance Portability & Accountability Act.

To date, the U.S. Department of Health & Human Services has finalized two of nine HIPAA standards—electronic transactions/code sets and privacy—but both have been or will be modified. Last December, Congress extended the date for compliance with the code set standards to Oct. 16, 2003. The privacy standards have undergone a series of "clarifications" by the Bush Administration, and HHS Secretary Tommy Thompson says more modifications will be proposed.

"There seems to be a lack of coordination [regarding] the provisions on transaction and code sets, security, privacy, provider identification and unique identifiers," says Peggy Burke, corporate director of internal audit and compliance for Novant Health (Charlotte, NC). "As each provision gets debated and implemented—sort of in isolation from the others—it makes it hard to build momentum."

Burke and several other compliance officers from major health systems shared their thoughts on HIPAA with *G-2 Compliance Report* during a roundtable conference call last December. One recurring theme was frustration with what they perceive as the government's disjointed approach to implementing HIPAA; that, in turn, makes it harder for them to do their jobs, they say.

"It's hard to align implementation and to schedule training when we have privacy rules taking effect before security rules," says Robert Footlik, lab compliance officer for Cedars-Sinai Medical Center in Los Angeles, CA. "It's sort of a piecemeal approach. We have a lot of information, but not enough clarification to mount our compliance effort."

HIPAA Regulations: *Where They Stand*

Standard	*Proposed*	*Final*	*Compliance Date*
Transactions, Code Sets	5/07/98	8/17/00	10/16/03
National Provider ID	5/07/98		
National Employer ID	6/16/98		
Security	8/12/98		
Privacy	11/03/99	12/28/00	4/14/03
Standards yet to be proposed			
National Health Plan ID			
National Individual ID (on hold)			
Claims Attachments			
Enforcement			

Source: HHS. Additional information at *www.reginfo.gov* and *http://aspe.os.dhhs.gov/admnsimp/pubsched.htm*

Certification Tricky

Complicating compliance efforts is the requirement that "covered entities" certify that they are HIPAA-compliant, says John Steiner, corporate compliance officer for the Cleveland Clinic Foundation in Ohio.

"Part of the ambiguity has to do with deciding who is best situated to do the certification when the underlying regulatory requirements are not easy to understand and implement. It's difficult to certify compliance when the rules are ambiguous or not yet tested. As organizations, we have to decide whether our own internal best efforts will satisfy the certification requirement or whether it's really wise to get some outside help."

HIPAA Coordination

One way of limiting the confusion that arises from having so many different pieces of the HIPAA puzzle incomplete or out of place is to designate a HIPAA officer. For example, at Intermountain Healthcare in Salt Lake City, UT, one person is responsible for coordinating HIPAA activities across the entire health system.

"Central coordination is very important," says Hyde Frederickson, compliance officer for IHC Laboratory Services. "If you've got one group working on privacy standards, another working on code sets, another working on security and none of them talk to each other, you don't know how you'll end up and you could be duplicating efforts."

Having an individual designated to handle HIPAA compliance is especially important in an integrated health system, he adds. "We have diverse service lines and multiple facilities. All of that has to be coordinated and work together."

Resources

- Peggy Burke: 704-384-7638
- Robert Footlik: 310-423-5335
- John Steiner: 216-444-1709
- Hyde Frederickson: 801-442-2860

Building An Audit Protocol For Internal Reviews
Eight Steps For Developing An Effective Plan

While there are no federal laws mandating that healthcare providers conduct internal reviews, self-auditing of your organization's operations is an important tool in protecting against charges of non-compliance, say experts.

"There is no law that says, 'Thou shalt do audits,' but there is a lot of information out there that suggests that audits are a very good idea," says Daniel Roach, vice president and corporate compliance officer for Catholic Healthcare West in San Francisco, CA.

Compliance guidance from the HHS Office of Inspector General as well as the federal sentencing guidelines cite effective auditing and monitoring as an important part of a compliance program, he notes.

Audit Plan Development

In developing an audit plan, it's important to tailor it to your organization's particular needs and to allow for some flexibility, advises Sheryl Vacca, vice president of the Health Care Compliance Association and director in the national healthcare compliance practice for Deloitte & Touche (Los Angeles and Sacramento, CA).

"It's an evolution," she observes. "You don't develop a plan today that necessarily stays intact until the year end. There should be some cushion in your plan that allows you to react to what's going on. If you know you're in crisis, you don't want to have to do 25 audits and not have time to respond to the crisis."

Vacca and Roach suggest the following steps in developing a plan:

1 Involve senior management and the governing board. Ultimately, it will be the organization's leaders who determine how information gleaned from the audit will be used, Vacca points out. Without explicit commitment to the process, the plan will likely fail.

2 Identify and prioritize risk areas. A good place to start is information published by the HHS OIG, including the annual work plan, fraud alerts and advisory opinions (online at *www.hhs.gov/oig*). Consider local risk areas as well. Next, look internally to determine what is most important for your organization and what you are actually capable of. Vacca recommends establishing five or fewer priorities so the organization does not become overwhelmed by too many audits.

3 Determine resources. Clearly, the more money and resources that are available for auditing, the more extensive your plan will be and the more often you will be able to conduct audits, says Vacca (higher risk areas should be audited more frequently). Available resources include staff and technology. In cases where there is limited staff for auditing, she suggests maximizing the efficiency of an auditor by pairing that person with a clinical expert in the area being audited.

4 Establish audit goals and objectives. Among the questions you should ask yourself, advises Roach: Will audits be used strictly for measurement or to drive educational activities? Should we look at processes or outcomes? Are we going to focus on substantive compliance or structural (procedural) compliance? "The balance in our protocol is about 50/50," he explains. "It's 50% substantive, 50% procedural or structural."

5 Determine what to do with audit findings. Legal counsel and risk management officers should be involved in making this decision. "If audit findings reveal an overpayment, is the organization willing to repay?" asks Vacca. "It's important to know that before you start auditing." It's also critical that one person have accountability for taking corrective action, she adds, noting that this person should not necessarily be responsible for solving problems, but should have oversight for making sure they get resolved.

6 Develop audit methodology. Will you use concurrent or retrospective review? Generally, concurrent review is preferable, says Roach, though it can be more difficult to generate results. Will you use sampling? Some attorneys might advise against this because of the potential downside of extrapolating to a larger universe of claims, he notes.

7 Decide how results will be reported. It's important to determine who will get the results, how they will be communicated and what benchmarks will be used. "You want to be able to communicate the information down in a way that impacts behavior," advises Roach. "The goal of an audit is not really to identify mistakes but to get us information that will allow us to educate people so mistakes aren't repeated."

8 Understand the limitations of attorney/client privilege. This privilege doesn't necessarily apply to every communication you have with a lawyer, says Roach. If the lawyer is giving advice but it's not legal or if the information is from inside counsel who has a variety of roles within the organization, the communication may not be protected. "It can be a double-edged sword. Sometimes we operate under the assumption that all communication with an attorney is protected, so we're not as careful as we should be. You should assume that virtually everything you say at one time or another may be looked at by a prosecutor."

Resources

- Sheryl Vacca: 714-436-7710 or 916-498-7156
- Daniel Roach: 415-438-5579

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News-At-A-Glance

JCAHO Survey Guidance: Joint Commission Resources, a subsidiary of the Joint Commission on Accreditation of Healthcare Organizations, has developed two publications to help laboratory leaders prepare for a JCAHO accreditation survey. *The Complete Guide to the 2002-2003 Laboratory Survey Process* (LSP-02) offers a detailed description of all survey activities, plus tips for success. *The 2002-2003 Self-Assessment Checklist for Pathology and Clinical Laboratory Services* (LBAC-02) offers tools to assess compliance, including a mock survey and self-assessment forms. The publications are available for $60 each, or $105 for the set (SPS-400). To order, call 630-792-5800.

SNF Code Information: As of Jan. 1, 2002, coding information for skilled nursing facility services included/excluded from consolidated billing (CB) may be found on the Centers for Medicare & Medicaid Services Website at *www.hcfa.gov/medlearn/refsnf.htm*. Four code files are available: codes for physician professional services (other than interpretation of diagnostic tests) not included in CB; codes for physician interpretation of diagnostic tests not included in CB; codes for ambulance services that will always be included in CB; and codes for physical, occupational and speech therapy services included in CB.

CLIA Lawsuit: The laboratory director is not liable for a lab's incorrect conclusion that a woman's Pap test was non-cancerous, an appeals court has ruled in the case of *Wood v. Schuen*. The court also reiterated that there is no private right to sue under CLIA (Clinical Laboratory Improvement Amendments). In a 2-1 decision, the Indiana Court of Appeals upheld a ruling by a trial court granting summary judgment to Ronald Schuen, MD, former director of cytopathology at Pathologist Associated Medical Laboratories (PAML).

Robyn Wood sued Schuen and others after she was diagnosed with cervical cancer following a Pap smear in February 1996. The smear had been sent to PAML, which reported it as normal. But the smear, it was later discovered, indicated that Wood had cervical cancer. In fact, PAML had misread the Pap smear, notes the appeals court.

Writing for the majority, Judge Ezra Friedlander said, "The director of a laboratory is not personally liable" to a claimant "merely by virtue of his or her position as director," especially where liability is alleged under CLIA. There must be a direct link between a director's actions and the negligence alleged in a case to establish liability, the court said.

Scrapping Local Codes: The Centers for Medicare & Medicaid Services has instructed fiscal intermediaries and carriers to eliminate unapproved local codes and modifiers by Oct. 16, 2002, and HCPCS Level III local codes and modifiers by Dec. 31, 2003. These changes are necessary under HIPAA, which requires standardized procedure coding (Transmittal AB-02-005, Jan. 18, 2002, *www.hcfa.gov/pubforms/transmit/memos/comm_date_dsc.htm*).

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