G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Legal Issues In Lab Outreach

While outreach testing offers hospitals significant market opportunities, there are also multiple legal concerns that must be addressed for an outreach program to be successful, including how to market services across state lines and how to collect specimens. Hope Foster, an attorney with Mintz Levin (Washington, DC), discussed these issues during Washington G-2 Reports' annual lab outreach conference, held March 31 to April 1 in Atlanta.

Medicare rules can vary depending on whether a lab is dealing with inpatients, outpatients, or nonpatients, explains Foster. While most healthcare professionals know what an inpatient is, some are still confused by the difference between outpatients and nonpatients. A person who is not admitted as an inpatient and is registered in a hospital as an outpatient and receives services is an outpatient. A nonpatient is everyone else, explains Foster.

"For Medicare purposes, a nonpatient is the outreach patient," she says. "A nonpatient is one where a specimen is collected from the patient (who is not registered in the hospital) by personnel who are not employed by the hospital, and that specimen is sent to the hospital for tests. The tests are nonpatient hospital services; in other words, outreach services."

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Inside this issue

Medicare Proposes Changes To Hospital CoPs

Revisions Expected To Ease Regulatory Burden

Proposed changes to Medicare's conditions of participation (CoPs) for hospitals should alleviate some of the regulatory burden on physicians and nurses, say industry experts.

The proposed rule, announced March 24, would revise CoP requirements for completion of history and physical examinations, authentication of verbal orders, securing of medications, and completion of post-anesthesia evaluations.

The Centers for Medicare & Medicaid Services (CMS) first proposed these changes in a notice of proposed rule making (NPRM), published Dec. 19, 1997. That proposal contained extensive revisions to the entire set of hospital CoPs. Delays within the agency prompted CMS to "carve out" specific CoPs as separate final rules. To date, CMS has finalized CoP requirements for organ, tissue, and eye procurement; patients' rights; anesthesia services-CRNA supervision; fire safety; and quality assessment performance improvement.

"These proposals respond to concerns in the medical community that the current Medicare hospital CoPs are contrary to current practice and are unduly burdensome," says CMS. "The changes specified

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Hope Foster, Esq.

Legal Issues, *from p. 1*

Hospital labs that offer outreach services must receive expanded certification and accreditation, Foster notes. A lab that collects specimens from patients in other states may also have to be licensed in those states. The following states require such licensing: California, Florida, Maryland, New Jersey, New York, Pennsylvania, and Rhode Island. The state of Kentucky requires licensure unless the lab is accredited by the College of American Pathologists (CAP) or another accrediting body that the state deems equivalent. Nevada requires licensing depending on what tests are performed.

Many states also have licensing requirements for outreach labs that want to include surgical pathology services in their expanded menu of tests offered or that expand the geographic area they serve through the provision of surgical pathology services, adds Foster. These include Alabama, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, Tennessee, Texas, Utah, and West Virginia.

Specimen Collection

Outreach labs must also consider legal issues that affect how specimens are collected, notes Foster. "There are lots of ways to obtain them," she says. "You can send couriers to physician offices to get them, in which case you'd better ensure that the couriers are licensed and that you have adequate insurance. You can maintain collection facilities where your own employees collect these specimens, in which case you have to determine whether these are outreach patients and whether the state is going to license those collection activities."

Outreach labs also can hire phlebotomists, who will work either in the lab's collection facility or draw specimens at physician offices. However, Foster warns that placing phlebotomists in physician offices can create legal risks if not done properly. "In some states it's prohibited," she explains. "In some states this would be viewed as a kickback. You have to be very careful. If you're thinking about that model, absolutely talk to your lawyer."

Outreach labs must also address issues that arise in performing the tests, such as ambiguous orders. "Do not perform a test and bill for it if you don't know what's really being ordered," cautions Foster. "That will get you in trouble with the feds and potentially state regulatory authorities as well. You need to develop a mechanism for figuring out what you're going to do when you get a test order you can't understand. I recommend a telephone call along with good documentation as to who has been spoken to, when the conversation occurred, and what the test was they really ordered – something that gives you a trail so you can go back and prove you clarified an ambiguous test order."

If you aren't able to get clarification quickly and you have a specimen that's going to deteriorate, Foster advises performing the test most commonly ordered on that type of specimen, and then verifying whether or not it is the correct test after the fact. "If you guess wrong, you'll have to get a new specimen," she says. "But if you guess right, you save everybody a lot of expense and wear and tear." In either case, you should not bill for the test until you've clarified what the correct test is.

Reimbursement

With regard to Medicare, outreach testing is reimbursed in the same way as outpatient testing, notes Foster. It is not subject to the hospital outpatient prospective payment system, but is reimbursed under the Medicare fee schedules. Anatomical services are reimbursed under the physician fee schedule.

When it comes to outreach testing, the three-day rule is particularly important, says Foster, who advises having a system to identify and match outreach services provided to patients who are later admitted to the hospital.

"What are you doing to make sure that you have mechanisms in place to know whether or not that patient is admitted to the hospital within three days of performance of the outreach service?" she asks. "It's easier with outpatients, but you still have the same requirements. You're going to have to bundle the outreach services with the inpatient payment [if the patient is admitted within three days of testing]. It's a logistical issue."

Resources

❖ Hope Foster: 202-661-8758

This is part one of a two-part discussion of legal issues in lab outreach. See part two in the next issue of G-2 Compliance Report.

OIG Settles Largest Ever Kickback CMP Action

Institutional pharmacy company PharMerica Inc. (Tampa, FL) has agreed to pay nearly $6 million to resolve allegations it paid illegal kickbacks during the purchase of a Virginia pharmacy in exchange for Medicaid and Medicare referrals. The settlement is the most ever paid in a civil monetary penalty kickback case, according to the Health and Human Services Office of Inspector General (OIG).

The OIG brought an administrative action against PharMerica under the civil monetary penalties law (CMPL) on June 17, 2004, alleging that the company paid an excessive amount of money for a small Virginia pharmacy in return for a commitment from the seller to refer its Medicaid and Medicare pharmacy business for the next seven years. The seller also owned 17 nursing homes and eight assisted living facilities with approximately 2,800 residents. The purchase price for the pharmacy, Hollins Manor 1, which had virtually no operating history, was $7.2 million.

The OIG initially issued a demand letter to PharMerica, stating that the agency sought as much as $21.8 million in civil monetary penalties and a 10-year exclusion from participating in federal health programs. Under terms of the settlement, PharMerica will pay $5.975 million and enter into a comprehensive five-year corporate integrity agreement.

PharMerica is owned by AmerisourceBergen Corp. (Valley Forge, PA), one of the largest pharmaceutical services companies in the United States. In a March 29 statement, AmerisourceBergen said the 1997 purchase predated the acquisition of PharMerica by Bergen Brunswig and the subsequent merger that created AmerisourceBergen in 2001.

William Shields, president of PharMerica, says the settlement will allow the company to "put this matter from the past behind us." The settlement's emphasis on corporate integrity "is consistent with PharMerica's policies and its overriding commitment to quality, compliance, and ethical conduct and does not affect any ongoing business with any customer or payer, including the federal government," he adds.

Resources

- HHS OIG: *www.oig.hhs.gov/publications/docs/press/2005/032905release.pdf*
- PharMerica CIA: *www.oig.hhs.gov/fraud/cia/agreements/Pharmerica.pdf*

CMS Outlines HIPAA Enforcement Procedures

Entities covered by the HIPAA rules include providers, payers, and clearinghouses that conduct certain healthcare transactions electronically.

The Centers for Medicare & Medicaid Services (CMS) has outlined procedures for the enforcement of all rules issued under the administrative simplification provisions of the Health Insurance Portability & Accountability Act (HIPAA), except the healthcare privacy regulations.

The notice, published in the March 25 *Federal Register*, sets forth procedures for filing complaints about violations of the following rules: transactions and code sets (TCS), security, national identifier number, national provider identifier, and the national plan identifier. It also outlines how CMS is instructed to investigate and resolve these complaints.

According to the notice, complaints must meet the following requirements:

- They must be filed in writing, either on paper or electronically. CMS will not accept faxed complaints.
- They must describe the acts of omission believed to be in violation of the applicable administrative simplification provisions.
- They must provide contact information, including name, address, and telephone number for the complainant and the subject of the complaint.
- Complaints must be filed within 180 days of when the complainant knew or should have known the action that is the subject of the complaint took place. CMS can waive the time limit for good cause.

Resource

March 25 *Federal Register* notice: *http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-5795.pdf*

Levinson Gets Committee Clearance As OIG

Daniel Levinson, acting inspector general for the Department of Health and Human Services, has received clearance from the Senate Finance Committee, which has forwarded his nomination to the full Senate.

The committee voted 20 to 0 to favorably report Levinson's nomination. The committee's vote, initially delayed, came after Levinson responded to a number of written questions posed by lawmakers. Levinson appeared before the Finance Committee in February and was asked specifically how he would improve management problems that had evolved over the past few years in the Office of Inspector General (OIG).

In written responses to questions from Senate Finance Committee Chairman Charles Grassley (R-Iowa), Levinson said that chief among his immediate goals for the office is filling senior management vacancies, many of which are occupied with individuals serving in acting capacities. He also noted that management issues remain key challenges for the OIG.

"I think more than anything, the office needs stable and focused leadership, which can have the beneficial effect of energizing staff to build on its existing record of accomplishments," said Levinson.

OIG Funding

Levinson said the OIG also faces challenges as it takes on added duties and responsibilities mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), while also working with flat funding levels from its primary source of funding, the Health Care Fraud and Abuse Control Fund. By law, HCFAC funding – provided by the Health Insurance Portability and Accountability Act of 1996 – was capped at 2003 levels. The FBI and the Department of Justice also receive HCFAC funds for healthcare fraud enforcement efforts.

OIG officials long have said the cap effectively amounted to a reduction in program dollars because of inflation. The problem has been compounded by MMA duties, Levinson said. The OIG receives about 80% of its funding from the HCFAC program.

"Since HCFAC funding has remained flat, the OIG faces challenges in how best to maintain enforcement and oversight responsibilities," Levinson told the committee. "Flat funding has naturally resulted in an attrition of staff."

Levinson also called it "unfortunate timing" that the capped HCFAC funding came when the OIG was given added responsibilities under MMA. He said he recognized that Congress authorized an additional $25 million for MMA-related activities and that the president's budget subsequently has requested it be available in 2005 and 2006, but that the new money is only short-term.

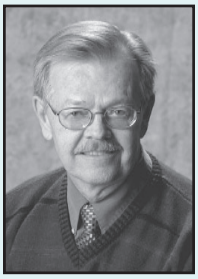
"Given the uncertainty of funding levels for years beyond 2005, hiring staff for the long term is problematic," he said. "Even with the [expanded use of the $25 million through 2006], it will be a challenge to utilize declining resources to efficiently and effectively protect expanding HHS programs."

Resource

❖ Acting OIG Daniel Levinson: 202-619-1343

COMPLIANCE PERSPECTIVES

Equivalent Quality Control: Back to the Future



James O. Westgard, Ph.D., is a professor in the Department of Pathology and Laboratory Medicine, University of Wisconsin Medical School, and president of Westgard QC Inc., both in Madison, Wisconsin.

The Clinical Laboratory Standards Institute (CLSI), formerly known as NCCLS, held a workshop on "QC for the Future" on March 18, 2005, in Baltimore, Maryland. This workshop was also promoted under the name of "Equivalent QC," suggesting that equivalent quality control is the QC for the future. I found the two themes to be contradictory because EQC is so seriously flawed (see previous discussion in *G2 Compliance Report*, April 2004, p. 5.) However, the outcome of the workshop was a proposal for "alternative QC" that will be developed as EQC Option 4 by a new CLSI committee.

I've always had some questions about the consensus process and how it works, but this is a particularly interesting example – organize a workshop, invite people to participate and contribute to the future of QC, then show them the outcome of the process, which was determined months earlier. Fortunately, this outcome has the potential to have a positive impact because it reintroduces the QC clearance process that was eliminated in the last draft of the Clinical Laboratory Improvement Amendment (CLIA) regulations.

Filling The QC Hole

Joe Boone, Ph.D., from the Centers for Disease Control and Prevention (CDC) was upfront in explaining that CLIA left a big hole in the laboratory world of QC when the final rule eliminated the requirement for Food and Drug Administration (FDA) clearance of manufacturer's QC instructions. Remember that the original CLIA rules were published Feb. 28, 1992, and contained a phase-in period of two years for the QC requirements. During this phase-in period, FDA was to develop a "QC clearance process" to approve a manufacturer's QC instructions, which would allow laboratories simply to follow those instructions and fully satisfy the CLIA QC requirements. This phase-in period was to end Sept. 1, 1994, but was extended to May 12, 1997, then till Oct. 14, 1998, then till Dec. 29, 2000, and then again until publication of the CLIA Final Rule on Jan. 24, 2003 (see "CLIA QC Clearance Postponed Again & Again & Again & Again," *www.westgard.com/essay38.htm*).

When the Final Rule finally appeared, the provision for QC clearance had been deleted from the regulations (see "Final CLIA Rule: Part I. Key Changes," *www.westgard.com/essay50.htm*). This left a "hole" in the regulations, which CMS then tried to fill by providing options for "equivalent QC procedures" (EQC). Such options are needed to provide flexibility for new technology, particularly analytic systems that have built-in internal QC checks. Depending on the completeness of the internal QC checks, CMS prescribes different validation protocols:

- **Option 1. Internal QC checks everything.** User must test two levels of external controls for 10 days. If neither the internal nor the external controls flag any problems, then the user can reduce daily QC to monthly QC.
- **Option 2. Internal QC only checks part of the operation.** User must test two levels of external controls for 30 days. If neither the internal nor the external controls flag any problems, the user can reduce daily QC to weekly QC.
- **Option 3. No internal QC.** User must test two levels of external controls for 90 days. If no problems are identified, user can reduce daily QC to weekly QC.

CLIA & EQC Options For The Future

During the workshop, Judy Yost, director of the Division of Laboratory Services at CMS, discussed the history of CLIA and the finality of the rule. Any flexibility to meet the CLIA regulations for QC must now come through new EQC options that are described in the *State Operations Manual* (SOM). The SOM provides "interpretative guidelines" through which CMS can accommodate the needs of technology and changes in the field.

Unfortunately, there are shortcomings in the EQC interpretative guidelines and they will not provide the "equivalent quality testing" specified in the regulations (see "Equivalent" Quality Testing," *www.westgard.com/cliafinalrule7.htm*). I believe it is obvious to everyone that a 10-day evaluation period cannot provide evidence of 30-day stability, yet that is the protocol that allows implementation of EQC Option 1, which leads to reduction of daily QC to monthly QC. CMS and CDC defend this evaluation protocol by citing an existing NCCLS standard M2-A: Performance Standards for Antimicrobial Disk Susceptibility Tests (see "A Rationale for EQC," *www.westgard.com/cliaeqc.html*). While one might challenge the transfer of a practice from microbiology to quantitative measurement procedures in chemistry and other areas, it turns out that M2-A doesn't have any provision for 10-day testing and reduction to monthly QC. M2-A calls for 20 or 30 days of testing and, if everything is acceptable, allows reduction of daily QC to weekly QC (see "An Analysis of the Rationale for EQC," *www.westgard.com/cliaeqc2.html*).

Of course, EQC Option 1 is the option users would most want to implement because it minimizes the amount of QC that needs to be done. But even some of these potential users are unhappy with Option 1 because it requires too much data; *i.e.*, they consider the 10 days of testing for Option 1 to be too much. The real difficulty for CMS is that those laboratories that are deficient in QC (which is 5% to 10% by CMS's own estimate) don't find the EQC options acceptable either. Everyone is confused and unhappy with the current situation, including the accreditation organizations that are left with the difficult task of uniform implementation of poorly defined and poorly designed EQC guidelines.

At the Baltimore meeting, CMS came close to admitting that the EQC options were a bust, hence the need for a new Option 4 to accommodate new technology where traditional external statistical QC may not be applicable, or necessary, particularly if internal instrument QC checks are exhaustive. CMS definitely equates "QC for the Future" with the new proposed Option 4 for EQC. However, the agency hasn't taken Options 1, 2, and 3 off the table and it should.

EQC Option 4

Luann Ochs from Roche Diagnostics, chair of the Evaluation Protocols Area Committee, presented the proposal for EQC Option 4, under which this new guideline will be developed. Ochs presented this proposal on behalf of AdvaMed, an industry trade group that represents diagnostic manufacturers. In May 2004, AdvaMed met with representatives from CMS, FDA, and CDC to discuss EQC and propose another EQC option. As presented at the Baltimore workshop, here is the proposal for "EQC Option 4":

- Manufacturers may validate an alternative quality control procedure.
- If FDA agrees that the validation shows that the alternative is equivalent to traditional QC, then
- Labs may use the alternative QC instead of the CLIA-mandated QC.

This sounds much like the original CLIA rule that called for FDA to review a manufacturer's QC instructions as part of the 510K approval process. There is a significant difference, however. CLIA originally called for QC clearance for all new measurement procedures, whereas the proposed EQC Option 4 will apply only to those manufacturers who voluntarily claim an alternative QC procedure as part of their product labeling. This should minimize the resources required for the Food and Drug Administration (FDA) to implement a QC clearance process. Steve Gutman, M.D., director of the FDA Office of In Vitro Diagnostic Device Evaluation and Safety, says that the FDA is willing to consider this new QC clearance option, but a final decision may still depend on the resource issue.

A Risk Assessment Approach To QC

The approach for developing alternative QC procedures is to be based on a risk assessment analysis whereby individual risk factors

are identified, controls are put in place to mitigate the risk, and a study is performed to document that the risk is adequately controlled. As part of the workshop program, Don Powers, Ph.D., discussed approaches to risk management for manufacturers and the clinical laboratories. Dr. Powers is the chair of the group that developed ISO 15198, "Clinical laboratory medicine—In vitro diagnostic medical devices—Validation of manufacturer's recommendations for user quality control." This ISO document proposes the use of Failure Mode Effect and Critically Analysis (FMECA) and/or Fault Tree Analysis (FTA). This is a "high-level document," meaning it provides no practical guidelines, just identifies principles and approaches (see "ISO Says So: Recommendations for validation of user QC," *www.westgard.com/essay54.htm*). Therefore, there is a need for another committee to develop a document that provides practical guidelines.

This committee will be chaired by Greg Cooper from Bio-Rad and includes the following members: George Brotea from Ortho Clinical, Fred Lasky from Genzyme, Dai J. Li from FDA, Gregory Makowski from University of Connecticut, Curtis Parvin from Washington University, George Plummer from Dade Behring, Jeffrey Vaks from Beckman Coulter, and Rhonda Whalen from CDC.

Back To The Future

So, here we are in May 2005 getting ready to finally implement a QC clearance process, as called for in the 1992 CLIA rules. The expected timetable for development and approval of the new CLSI document is two years. Assuming no problems or delays, that will make it 2007 before the CLIA rules finally get implemented in the way they were intended.

Some may call this progress, and it certainly happens in mysterious ways. I recall a conference organized by FDA in April 1992 to discuss the original QC clearance provision and to discuss guidelines for implementation. FDA even issued a draft guidance document in December 1992. And I also recall that the Health Industry Manufacturers Association (HIMA) mounted vigorous opposition to the proposed QC clearance guidelines. HIMA later became AdvaMed, which is now sponsoring EQC Option 4. What goes around comes around, and sometimes it almost makes one dizzy. While I applaud the manufacturers present support for QC clearance, this issue could have been resolved many years ago if they had supported it back then.

What's The Quality Of CLIA QC?

In the past decade under CLIA, what has happened to the quality of laboratory testing? Has CLIA really been effective – so effective that we can now reduce QC to only weekly or even monthly? CMS offers no data to support this. To raise this issue, I presented an assessment of the quality of a few selected tests based on data from proficiency testing surveys, using sigma-metrics that were calculated from the group and subgroup statistics:

- National Test Quality (NTQ) is calculated as TEa/SD_{group}, where TEa is the CLIA requirement for acceptable performance in proficiency testing surveys and SD_{group} is the observed SD for the group of laboratories participating in the survey;
- National Method Quality (NMQ) is calculated as a weighted average of the sigmas for method subgroups, i.e., Sigma = $TEa-bias_{subgroup}/SD_{subgroup}$;
- Local Method Quality (LMQ) is calculated as a weighted average of the sigmas for the method subgroups without taking bias into account, *i.e.*, Sigma = $TEa/SD_{subgroup}$.

Of these metrics, NTQ and NMQ are appropriate indicators of quality when national test interpretation guidelines are being followed; *e.g.*, the National Cholesterol Education Program (NCEP) guidelines for cholesterol, the ADA guidelines for glucose. The LMQ measure is applicable if tests are interpreted against local reference limits or cutoffs (see "Quality of Laboratory Testing: Touchstone Methodology," *www.westgard.com/essay72htm* for more detailed discussion of these measures and their calculations).

For these commonly performed tests, the table shows the different estimates of quality.

Test	Number Labs	NTQ	NMQ	LMQ
Cholesterol	9258	2.88 sigma	3.02 sigma	3.67 sigma
Calcium	9786	2.84	3.00	3.86
Glucose	10722	2.95	3.34	4.00

If these results are typical of the quality of laboratory testing today, they indicate that the average quality is only 3 to 4 sigma. For reduced QC to apply, test quality should be at least 5 to 6 sigma.

The relationship between sigma-quality and QC is shown in the figure below, where the probability for rejection is plotted on the y-axis vs. the sigma-metric on the x-axis (top scale) or the critical systematic error that must be detected (on the bottom scale). The curves represent the power or probability of rejection of the different QC rules and numbers of measurements (N), as shown in the key at the right. The curves top to bottom match up with the list of QC procedures in the key top to bottom.

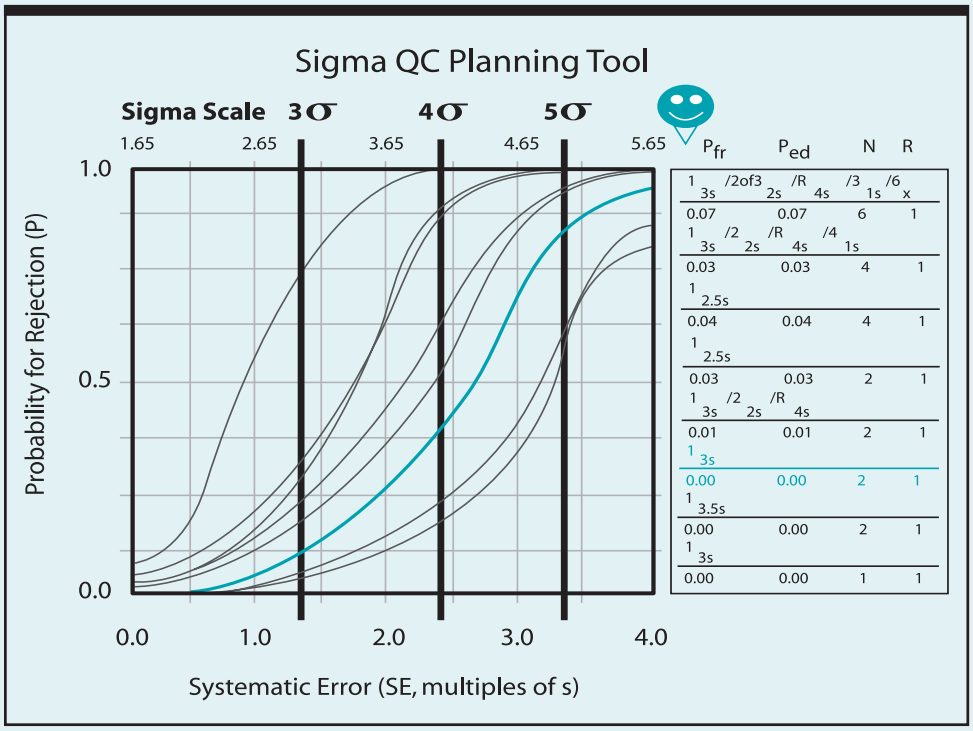
For example, the third curve from the bottom represents a QC procedure such as a Levey-Jennings chart with 3SD limits and two control measurements per run (*i.e.*, the CLIA minimum of two levels per day). If test quality is 4 sigma, then there will be a probability of 0.5 or a 50% chance of detecting a medically important error. If test quality is 3 sigma, there is less than a 10% chance of detecting a medically important error. For a 3 sigma method, even a multirule procedure with N = 6 (top curve) would provide only 75% detection of medically important errors.

Now look at a sigma of 5.2 (the fine line to the right of the 5 sigma bold line), where the chance of detecting a medically important error is 90%, which should be the minimum guarantee for the quality of test results. Thus, if the CLIA minimum QC is to apply, laboratory methods should be at least 5 sigma quality or better. If reduced QC is to apply, it follows that methods should be 6 sigma quality or better so that a minimum amount of QC will still be effective (that's slightly offscale at the right of the graph at the location shown by the happy face with the pointer).

QC In The Future Should Mean Better QC

Since the 1992 regulations, the quality of laboratory testing processes has suffered due to the CLIA minimums for QC becoming laboratory maximums. Getting laboratories to run even two levels of control per day has become difficult, and QC deficiencies are still commonly found during laboratory inspections, particularly in the small laboratories that CMS finds itself inspecting. In the face of these difficulties, it is hard to understand the rationale for the proposed CMS options for EQC that would reduce daily QC to weekly or even monthly QC.

It was heartening to see that some manufacturers also recognize that QC in the future must be better than the minimums under CLIA. Some recognize that a totally automated QC process is needed to guarantee that the quality of laboratory tests will satisfy medical requirements. Development and implementation of Option 4 will hopefully provide manufacturers with a path and process to improve laboratory QC.



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Medicare Proposes Changes, *from p. 1*

in the proposed rule are consistent with current medical practice and will reduce the regulatory burden on hospitals."

Physical Examinations

The proposed rule would expand the current requirement for completion of a medical history and physical examination (H&P) from "no more than seven days before or 24 hours after admission" to "no more than 30 days before or 24 hours after admission." The H&P exam would have to be placed in the patient's medical record within 24 hours of admission.

In addition, where an exam is completed before admission, any subsequent exams would have to be completed and documented in the patient's record within 24 hours after admission.

CMS also is proposing to expand the types of medical professionals who can conduct the H&P exam. Currently, the H&P exam must be conducted by a doctor of medicine, doctor of osteopathy, or, in limited circumstances, by an oromaxillofacial surgeon. The proposed rule would also allow an "other qualified individual," as designated by state law, to conduct the exam.

Authentication Of Verbal Orders

The proposed rule would require that all orders, including verbal orders, be dated, timed, and authenticated by a practitioner responsible for the care of the patient. However, during a five-year transition period from publication of the final rule, CMS would allow all orders, including verbal orders, to be dated, timed, and authenticated by the prescribing practitioner or another practitioner responsible for care of the patient. CMS believes the transition period "will allow sufficient time for the adoption of changes in healthcare information technology to make it easy for prescribing practitioners to authenticate all of their own orders in a timely fashion."

CMS also is proposing a time limit by which orders must be authenticated. Under the proposed rule, orders must be authenticated within the time frame designated by state law or within 48 hours, if there is no specific state law requirement. The rule would retain the current requirement that verbal orders be used infrequently.

Comments on the proposal are due May 24.

The proposal also would allow orders for drugs and biologicals, with the exception of influenza and pneumococcal polysaccharide vaccines, to be documented and signed by a practitioner "who is responsible for the care of the patient as specified under section 482.12(c) and authorized to write orders by hospital policy in accordance with state law." This would allow additional medical and nursing staff to administer some medications.

Securing Medications

The proposed rule eliminates the current blanket requirement that all drugs and biologicals must be kept in a locked and secure area. Under the proposal, those drugs and biologicals listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 would have to be kept secured, but noncontrolled drugs could be locked up "when appropriate."

This change would provide hospitals, and especially their anesthesia physicians and surgeons, more flexibility in securing medications while providing more patient-focused care.

Post-Anesthesia Evaluation

The current hospital anesthesia regulation requires the individual who administers the anesthesia to write the follow-up report. The proposed rule would allow the post-anesthesia evaluation of inpatients to be completed and documented by "any individual qualified to administer anesthesia."

The proposal would make the post-anesthesia requirements consistent with those of the pre-anesthesia evaluation, which can also be performed by any qualified individual. CMS says this provision "would give hospitals greater flexibility in meeting the needs of patients and impose less burden than the current requirement."

Resources

Hospital condition of participation proposed rule: *http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-5916.pdf*

Bill To Require FCA Settlement Details

Senate Finance Committee Chairman Charles Grassley (R-Iowa) has introduced legislation that would require the Department of Justice (DOJ) to report details about how it reached settlement agreements in False Claims Act (FCA) cases.

The bill, S. 636, proposes that the DOJ inspector general submit semiannual reports to Congress that include information about FCA settlements, such as estimated damages suffered by the government, the actual amount recovered through individual settlements, the multiplier used to calculate settlement amount, criminal fines imposed in connection with alleged illegal activities, and whether defendants had been liable in previous cases. The semiannual report also would include information about settlement dollars returned to states, such as in Medicaid fraud cases.

"State Medicaid budgets are stretched, and we need to make sure the federal program delivers every penny states are entitled to when they help recover dollars lost to fraud," Grassley said in a news release.

Congressional Authority

The proposed legislation would give Congress the ability to determine whether DOJ was properly handling FCA cases and how effectively it dealt with whistleblowers, said Grassley, author of the 1986 whistleblower amendments to the FCA. Grassley has been critical of some DOJ settlements in healthcare fraud cases, saying he is concerned that the agreements do not recoup enough money lost to fraud.

Specifically, he has questioned the $631 million settlement in December 2002 with HCA Inc., arguing that the amount was not adequate compared to the nature of the violations and did not represent Congress's intent under the FCA. The law allows for up to treble damages.

Grassley also criticized DOJ's application of the FCA during confirmation hearings for Attorney General Alberto Gonzales. "I believe that the inadequate use of the False Claims Act stems directly from the fact that [DOJ's] administration of the act is woefully inadequate," he said in written questions to Gonzales. "There are not enough cases taken on by the department. There are not enough resources allocated to the cases the department is pursuing, and this is very troubling in some cases, such as the cases involving drug-pricing fraud."

Furthermore, Grassley said DOJ does not provide adequate information so that Congress can carry out FCA oversight activities, citing DOJ practice to keep FCA cases under seal "for years."

"In a nutshell, I believe that the department's administration of the False Claims Act lacks vision, transparency, energy, authority, goals, and resources – almost everything a program should have to succeed," he said in the questions to Gonzales.

Gonzales responded to Grassley that he would evaluate how FCA cases were being handled but did not believe that reorganization or additional resources were warranted, as Grassley suggested. DOJ would not comment on the proposed bill.

Resource

Sen. Charles Grassley: 202-224-3744

CMS Issues Draft Guidance On NCD Process

The Centers for Medicare & Medicaid Services (CMS) has issued the first three drafts in a series of guidance documents that detail the process for determining whether an item or service is reasonable and necessary for coverage as a Medicare benefit.

The drafts represent an effort by CMS to open the national coverage determination (NCD) process to the public and to be more transparent about how it makes NCDs, say attorneys with the law firm of Foley & Lardner.

An NCD is a determination by the Secretary of Health and Human Services, regarding

whether a particular item or service is covered under Medicare. CMS's Coverage and Analysis Group, in the office of Clinical Standards and Quality, is responsible for the development of NCDs, which apply to Medicare beneficiaries nationwide. An NCD is binding on all Medicare contractors, Medicare Advantage plans, quality improvement organizations, and administrative law judges.

Factors CMS Considers In Opening An NCD

The first guidance document issued by CMS explains the initial step of the NCD process and what CMS considers to be a complete request necessary to start the formal review process.

A party interested in the submission of a formal request for an NCD may contact CMS on an informal basis to seek advice on how to request an NCD and the type of information to be submitted. CMS also encourages preliminary meetings with interested parties, either in person or by teleconference, to review, for example, the requestor's clinical trial data and supporting documentation.

Any party may initiate a request for an NCD, including a Medicare beneficiary who is an aggrieved party (i.e., who is in need of the item or service at issue). However, an aggrieved party request is subject to more stringent statutory time frames. A formal request for an NCD must: 1) be submitted electronically (unless there is good cause to submit a hard copy); 2) identify the request as a "Formal Request for an NCD"; 3) state the benefit, category, or categories of the Medicare program to which it applies; and 4) include adequate supporting documentation with the formal request letter.

In the course of CMS's review of an NCD request, the agency may refer the matter to the Medicare Coverage Advisory Committee (MCAC). The second guidance document explains the factors CMS considers to refer to the MCAC to obtain independent, expert advice and public input on specific clinical topics.

The third guidance document explains the factors CMS considers when determining when to commission an external Technology Assessment (TA) to evaluate the risks and benefits of a healthcare technology. In addition to the MCAC process, during the NCD process, CMS may determine that a TA is required. A TA also extends the timeline for completing NCDs. The six-month time frame for NCD decisions is extended to nine months when CMS requests a TA.

Resources

The three guidance documents are available online at *www.cms.hhs.gov/coverage/guidance.asp*.

Medicare To Speed Up Claims Appeals

Starting May 1, Medicare is implementing a major overhaul of the process that beneficiaries – and in certain circumstances, providers and suppliers – can use to appeal claims denial. Two laws mandated the restructuring: the Benefits Improvement & Protection Act of 2000 and the Medicare Modernization Act of 2003.

The time frame for handling fee-for-service appeals will be cut sharply – the process that now can exceed 1,000 days will be trimmed to 300. This, says the Centers for Medicare & Medicaid Services (CMS), has required a substantial revamping of all levels of the Medicare appeals process. The changes begin May 1, 2005, for Part A and Jan. 1, 2006, for Part B, which involves the bulk of Medicare appeals. CMS says it expects the changes to reduce appellants' concerns over the fairness and timeliness of Medicare appeals decisions, leading eventually to a reduction in later-stage appeals.

The overhaul establishes uniform appeals procedures for both Part A and Part B claims, forces quicker decisions on appeals, establishes Qualified Independent Contractors (QICs) to reconsider claims denials by Medicare contractors, uses QIC review panels that include medical professionals to handle all reconsiderations involving medical necessity, and requires appeals-specific data collection by CMS. In addition, the administrative law judge (ALJ) function will be transferred from the Social Security Administration to the Department of Health & Human Services no earlier than July 1, but not later than October 1 of this year.

RAC Demonstration: The Centers for Medicare & Medicaid Services (CMS) has launched a new demonstration project using recovery audit contractors (RACs) to search for improper Medicare payments that may have been made to healthcare providers and that were not detected through existing program integrity efforts. The present recovery audit contracts focus on Part A Medicare claims and excludes evaluation and management services. California, Florida, and New York have been chosen for the demo. Since current Medicare contractors will continue to review claims in the current fiscal year, each RAC will begin work on claims that are at least one year old.

Fraud Convictions: A federal jury in Miami has convicted five people, including two doctors, for their participation in a $5.5 million healthcare fraud scheme. The five defendants convicted are physicians Jose Garrido and Edgard Zamora, office manager Dalia Fernandez, and patient recruiters Antonio Pina and Deisy Aviles. Altogether, 20 people have been convicted in connection with the scheme, which involved Miami Health Medical Center, Exclusive Medical Supply Inc., and Hope Medical Supplies Inc. The defendants were charged with altering medical records, staging automobile accidents, paying bribes to the supposed victims to get them to complain of nonexistent injuries when they went to Miami Health, and submitting fraudulent claims to automobile insurance companies.

JCAHO Education: Effective July 1, all organizations accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), including laboratories, must educate their employees that if they have safety or quality-of-care concerns at an organization, they may report their concerns to the commission. This new Accreditation Participation Requirement (APR) also bars organizations from taking any disciplinary action against any employee who reports such concerns. For details, see the January 2005 JCAHO Perspectives, available at *www.jcaho.org*.

Hospital Compare: The Centers for Medicare & Medicaid Services April 1 launched an initiative to provide information to healthcare consumers on hospital performance on up to 17 clinical measures related to heart attack, heart failure, and pneumonia. The "Hospital Compare" program, available via the Internet and a toll-free telephone line, will allow individuals to better compare hospital quality performance, says CMS Administrator Mark McClellan. About 4,200 hospitals are participating in the voluntary initiative.

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