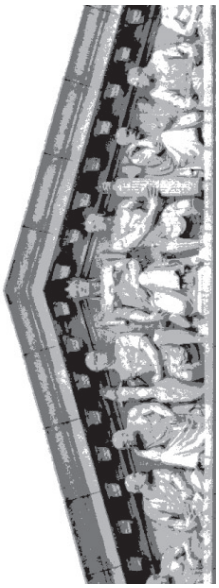

G-2 Compliance Report

WASHINGTON G-2 REPORTS

Vol. VII, No. 9, October 2005

For Hospitals, Laboratories and Physician Practices

FDA Draft Guidance On Waived Testing Toughens Test Evaluation Standards

Much-anticipated draft guidance from the Food and Drug Administration (FDA) on CLIA-waived testing reflects recommendations from the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Advisory Committee (CLIAC) on more demanding test evaluation standards.

Waived tests are the least regulated test category under CLIA and generally are those that are simple to use and which pose no unreasonable risk of harm to a patient if used incorrectly.

The draft guidance, issued Sept. 7, 2005, replaces earlier guidance issued in March 2001 and includes changes to respond to several major issues raised by the laboratory community—in particular, quality and accuracy when tests are performed outside traditional lab settings. Among the changes compared with the previous document:

- Greater emphasis on scientifically based flex and validation studies, linked to the hazard analysis for each device.
- Recognition that reference methods may not be available for every device type. (However, devices should be traceable to true reference methods of known accuracy, when such methods are available.)
- Additional emphasis on use of quality control procedures.
- Greater emphasis on intended users, which may include medical assistants, nurses, doctors, or lay people, during studies testing the device.
- Updated study recommendations with emphasis on use of patient specimens, in an intended use environment, over time.

➥ *p. 9*

Inside this issue

CLIAC To Review Cytology PT Testing

In response to myriad concerns raised by the laboratory industry, the Clinical Laboratory Improvement Advisory Committee (CLIAC) has decided to establish a workgroup to review cytology proficiency testing (PT).

The College of American Pathologists (CAP) was among those pressuring for reconsideration of Medicare's cytology PT requirements, which were created by the 1992 final rule for the Clinical Laboratory Improvement Amendments of 1998 (CLIA), but not carried out until the start of 2005.

"We believe that [the Centers for Medicare & Medicaid Services] is implementing a testing program based on a flawed grading system that ignores a significant evolution in the practice of gynecologic cytology in the many years since the regulation was first issued," wrote CAP in testimony presented to CLIAC September 7.

➥ *p. 2*

The rollout of cytology PT enforcement is expected to affect some 3,800 laboratories that are CLIA-certified in this subspecialty.

Cytology PT Testing, *from p. 1*

CAP and a coalition of pathology groups argue that the PT regulations have fallen far behind modern science and practice and unfairly single out pathologists for competency testing that no other physician specialty faces.

The coalition sent a letter to Health and Human Service Secretary Michael Leavitt June 3 asking him to review the cytology PT regulations in light of current practice. The coalition also is working with key members of Congress to win House members' signatures on a congressional letter to Leavitt, urging him to immediately suspend the cytology PT program and to re-evaluate it.

CMS Plans To Move Forward

CMS responded to the June 3 coalition letter to Leavitt, agreeing that further review is needed for certain aspects of the cytology PT regulations, including its grading scheme and testing frequency. But the agency said the coalition's concerns did not persuade it to delay the continued rollout of testing.

"The college is deeply disappointed that . . . [CMS] is resolute on moving forward with the cytology PT regulations, despite an overwhelming consensus within the laboratory and pathology profession . . . that the program requires a prompt and thorough review," CAP wrote in its testimony. "CMS continues down the very path we believe will lead to diminished patient access to gynecologic cytology services and a costly and ineffective regulatory burden on providers."

CAP notes that CLIAC itself said in February that "consideration be given to revising the cytology PT regulations, basing the revisions on updated comments from the professional organizations and the public to reflect current practice, evidence-based guidelines, and anticipated changes in technology."

CAP also testified that CMS' decision to re-evaluate cytology PT frequency based on the first two years of experience with the program is unnecessary, given that the many other long-standing CLIA quality requirements for laboratories argue against the need for annual testing.

"These important measures guarantee countless hours devoted to quality assurance associated with Pap tests," the college wrote. "Given the preponderance of regulatory oversight in this area, we believe a proficiency test administered to pathologists and cytotechnologists every year is excessive."

In addition, CAP also rebutted the agency's contention that the cytology PT regulations mention individual testing and, therefore, require it.

"[I]t is equally important to note that language also specifies that the Secretary of Health and Human Services should establish quality assurance standards that 'assure consistent performance by laboratories of valid and reliable cytological services . . . with such testing to take place, to the extent practicable, under normal working conditions.' In our estimation, 'normal working conditions' can be reflected in this examination only by including the collaborative team approach that is a fundamental aspect of pathology practice and the laboratory environment. The regulation's premise that individuals conducting laboratory work are doing so in isolation and making determinations alone is false," CAP testified.

Currently, the only approved provider of cytology PT is the Midwest Institute for Medical Education (MIME), based in Indianapolis. CAP and the American Society for Clinical Pathology have formally applied to become CMS-approved cytology PT providers, but the earliest they could qualify to begin testing would be 2006.

HHS IG To Keynote Lab Institute

Daniel Levinson, the new Inspector General of the Department of Health and Human Services, will discuss his top priorities for the healthcare sector, including labs, at G-2 Report's 23rd annual Lab Institute: *Transformational Forces Reshaping Labs*.

Lab Institute will be held October 19-22 in Arlington, VA. G2 subscribers pay just $875. For more information, go to *www.g2reports.com*.

There are four easy ways to register:

1. WEB: *www.ioma.com/labinstitute05*
2. CALL: 1-800-401-5937, ext. 2
3. FAX: 212-564-0465
4. MAIL: G2/IOMA, 3 Park Ave., 30th Floor, New York, NY 10016-5902

Competitive Bidding Proposal Draws Fire

The draft design for the Medicare clinical laboratory competitive bidding demonstration incorporates some recommendations from the lab industry but still fails to reflect an in-depth understanding of the complexities associated with the lab business, say industry groups.

The Centers for Medicare & Medicaid Services (CMS) released the draft design August 24 during an open-door forum featuring CMS officials and researchers from Research Triangle International, the contractor for the project.

> ***"It is hard to conceive how CMS will be able to make fully informed comparative decisions to select the winning bidder based on HCPCS code bids that can reflect very disparate testing services."***
>
> ***—ACLA***

While lab groups continue to oppose the basic premise of competitive bidding, they acknowledge that Congress has required a demonstration and are working to ensure lab interests are fairly represented.

The demo will run in a single state, at two sites, with a staggered start date (the demo at the second site will begin a year after the first). By law, the demo is restricted to lab services that don't involve a face-to-face encounter with the beneficiary. This has raised questions about how CMS would treat labs that send phlebotomists to draw stations in the community. CMS projector director Linda Lebovic told the forum that CMS will deal with this issue through claims processing.

Bids On All Tests

As recommended by the Clinical Laboratory Coalition, the demo will require bids on all tests on the Part B lab fee schedule, rather than just the top 100 or 200. The draft design also incorporates other changes advocated by the coalition, including the recommendation to exclude end-stage renal disease beneficiaries and include hospital outreach in the scope of the project. It also contains the recommendation to use a fee-for-service basis for bidding and to allow bidders to use subcontractors.

However, the draft design falls short in other key areas, the coalition maintains. For example, it proposes that bidders will be required to submit a bid price for each HCPCS code in the demo test menu of more than 1,000 tests.

"What is not accounted for is the standard business practice to bill multiple laboratory tests under one HCPCS code," writes the American Clinical Laboratory Association (ACLA). "Indeed, many laboratory tests are unique and are developed by the laboratory itself—another factor that will complicate a competitive bidding process. It is hard to conceive how CMS will be able to make fully informed comparative decisions to select the winning bidder based on HCPCS code bids that can reflect very disparate testing services."

What's more, labs and third-party payers typically negotiate all terms of a contract, including non-fee components, notes ACLA. When a lab agrees to a fee schedule with a private insurer, it has also negotiated and reached agreement on other non-fee schedule components, which have a material, financial impact on the lab economics and, therefore, fees.

"Thus, the competitive bidding demonstration should open the RFP/bidding process to include bids on terms and components that impact the proposed fees," writes ACLA. "This is even more important for doing business with Medicare because Medicare has requirements beyond what private payers typically have."

These include requirements for Advance Beneficiary Notices, medical necessity limitations, frequency limitations, stat charges, limiting the number of CPTs paid when multiple units are billed, and bundling of payment of one CPT into payment of another CPT. These additional components affect the cost of testing and should be negotiated as part of a competitive bidding program, says ACLA.

Quality Measures

The Lab Coalition also is concerned about the proposed multiple performance and access

reporting requirements, which it says will negate the ability of labs to competitively price services at fees below current Medicare reimbursement rates.

The administrative cost to collect, submit, and analyze performance and access data—either incurred by the labs, CMS, or a third-party—needs to be accounted for and factored into the bidding process. Further, the measures of quality should be in place and reviewed for all bidders in advance of the bidding process, rather than enforced only on the winning bidders, the group believes.

Find out more about the lab competitive bidding demonstration at this year's* Lab Institute, *October 19-22, in Arlington, Virginia. To register or for more info, go to www.g2reports.com.

In addition, ACLA and the Lab Coalition recommend that the design should require that as part of the bidding process, a laboratory be required to include a detailed accounting of its record on providing high-quality lab services (including turnaround time and other factors listed on the design).

The groups also maintain that the draft design does not address the equal playing field issue potentially created by excluding physician office laboratories (POLs), which perform many of the same lab tests as hospital and independent laboratories.

"ACLA has previously commented that POLs should be included in the demonstration project," the group writes. "If they are not included in the bidding, we recommend that POLs receive the same reimbursement as those who are subject to the competitive bidding scheme."

Resources

- Competitive bidding draft design: *www.cms.hhs.gov/researchers/demos/clinicallabdemo.asp*
- ACLA: 202-637-9466

Feds Relax Compliance Rules In Hurricane Zone

Healthcare providers supplying medical services to those affected by Hurricane Katrina, but unable to comply with certain Medicare and Medicaid program requirements because of the hurricane, will still be paid for their services provided in good faith and will be exempt from sanctions, the Centers for Medicare & Medicaid Services (CMS) says.

CMS said it will also relax requirements under the State Children's Health Insurance Programs, the Health Insurance Portability and Accountability Act, and the Emergency Medical Treatment and Active Labor Act to accommodate the healthcare needs of beneficiaries and providers in the affected regions. CMS administrator Mark McClellan on September 9 said states serving hurricane evacuees would be granted emergency section 1115 demonstration waivers to provide temporary eligibility for all Medicaid eligible groups.

Meantime, the Department of Health and Human Services has issued guidance to industry and an enforcement statement for health records privacy regulations in light of the large-scale evacuation. The document, *Hurricane Katrina Bulletin No. 2*, was issued by the HHS Office for Civil Rights, which enforces privacy requirements under HIPAA.

The new bulletin builds on a September 2 guidance in which the department emphasized how the HHS privacy rule under HIPAA "allows patient information to be shared to assist in disaster relief efforts, and to assist patients in receiving the care they need." For example, health plans and healthcare providers could disclose prescription and other health information to healthcare providers at shelters to facilitate treatment of evacuees, it said.

Both bulletins are available at *www.hhs.gov/ocr/hipaa/EnforcementStatement.pdf*. Additional information is available at *www.cms.hhs.gov/katrina/*.

COMPLIANCE PERSPECTIVES

Laboratory Strategies For Improving Physician Compliance

Christopher Young is president of Laboratory Management Support Services, a consulting firm based in Phoenix

Trying to get physicians to comply with medical necessity information requirements while not violating some law or regulation has been one of the all-time toughest challenges laboratories have faced. It is a topic that has plagued the industry since the early to mid-1990s and still draws heated debate and discussion at laboratory conferences and around meeting tables in labs today.

Laboratories have lost untold thousands, maybe millions, of dollars because of physician noncompliance. The losses come not only in denied claims but in costs associated with resources that are employed trying to get the information; financial losses associated with claims being held for 30, 60, or 90 days before they can be filed; resubmitting the same claim two or three times; and requisition redesign and investment in software or other assets to solve the problem.

Since I want to spend as much time as possible on solutions, I'm not going to spend much time describing the problem. I expect that the audience for this newsletter already knows the problem in great detail.

Suffice to say that the complexities that surround the issues of medical necessity, limitations on financial liability, and legal and regulatory constraints on laboratories are the contributing factors that make the problem so difficult to resolve. Couple this with an unwillingness by the government to hold physicians responsible, in a meaningful way, for not complying with their responsibilities for supplying the information and you end up with a problem that seems unsolvable.

Yet, some laboratories have improved, and tools are becoming available to help with the problem. Physicians are starting to come around. There really is light at the end of the tunnel, and it's not an oncoming train.

One additional thing to consider is the change in focus for medical necessity. Initially, when medical necessity began costing laboratories significant amounts of money, the emphasis was on getting ABNs (advance beneficiary notices) more than on getting correct codes. The fact is, physicians don't like to explain to their patients why they have ordered a test that is not medically necessary so the natural course is to avoid that discussion.

Most of the audits I have conducted in the last two years clearly indicate that physicians are complying with the requirements to provide diagnosis information, and labs are getting diagnosis information and ICD-9 codes on the majority of their requisitions or orders. The problem now is getting valid codes, codes allowable for limited coverage tests, and/or translating narrative diagnosis information. Many laboratories today employ trained ICD-9 coders, or they train their own.

But success requires effective commitment of both energy and resources. Success requires a comprehensive strategy and process that is ongoing and continuously improving and includes all of the pieces involved, both internal and external. Success requires gathering data, information, and facts to use in making decisions, not anecdotal information, speculation, and rumors.

This article will discuss strategies laboratories can employ to improve physician compliance. If a lab is going to be successful at all in improving physician compliance, it must employ several strategies. There is no single approach a laboratory can take that will work, or be financially reasonable to deploy, for all of its customers. The laboratory also needs to

keep compliance issues firmly in focus as it works to resolve these problems. There are risks associated with medical necessity solutions, and risky behavior or corner cutting can be tempting.

Start With Your Own Employees

The last place an incomplete requisition or an order that does not meet medical necessity requirements should come from is the lab's own employees. Examine the outcomes and error rates for patient service centers and sites where a laboratory employee is placed in a client's office. These error rates should be near zero. If not, the laboratory needs to figure out why and correct the problems.

If the lab can't get the correct information when its own employee is directly involved at the time the order is placed or the sample is collected, the chances of getting others to do it are even poorer. Laboratories must learn how to get their own house in order and use that knowledge to help their clients comply.

One of the techniques laboratories use to help solve medical necessity problems is to place an employee in a physician office. This strategy is expensive and has compliance risks that limit it to larger clients but, if the laboratory is going to spend the money, it must make sure the employee is properly trained and has the tools to keep error rates down to near zero.

Before The Order Is Ever Placed

Every laboratory has to go through some kind of a client set-up process when a new physician begins to refer specimens to it so that it can, at a minimum, be sure the samples get to the laboratory and the reports get back to the correct physician. It is an important piece of the medical necessity success chain.

The laboratory needs to find ways to ensure that new physicians know its policies concerning such things as supplying medical necessity information like ICD-9 codes, billing information, and how and when ABNs should be used. Physicians need to be instructed from the start on how to complete a requisition for both government and non-government patients. An evaluation needs to be made at this time about what are the proper tools, manual or electronic, for this particular client, and those tools should be provided and the client trained for those specific tools.

This is not too hard when a new physician is set up in a formal way during which a sales or service representative actually goes into the office and delivers the supplies and forms to get the client started. Initial training of the office staff should occur during this first visit. Do not miss this opportunity. Make sure employees who set up these clients have some kind of check list that must be completed and signed attesting that they covered the material with the client.

If the laboratory has a Web site, the compliance policies and medical necessity requirements should be prominently displayed and/or easily accessible. New clients can be directed to the Web site for the information.

Some laboratories may try to get the client to attest to receiving the information or require clients to sign an agreement that includes consequences if they do not complete the forms properly. If the laboratory chooses to employ such a strategy, it must decide what it will do if the client refuses.

If the client is set up without such a formal visit, as happens with some frequency in laboratories because many labs receive specimens from doctors who are not already set up in their computers, the lab needs to have some kind of strategy to follow up to ensure this new client gets the information needed to comply with the lab's policies on medical necessity. This can be done by having a mechanism to notify the sales or service representatives responsible for the client to visit the physician's office to deliver the information.

Another approach is to have packages of information, prepared in advance and sent to

these clients immediately, that explain the policies and requirements. They should also include the basics necessary to submit, like a batch of requisitions, a laboratory manual, specimen submission bags, a cover letter pointing them to the medical necessity information, and a contact for more information if they need it.

If the laboratory has a Web site, the compliance policies and medical necessity requirements should be prominently displayed and/or easily accessible. New clients can be directed to the Web site for the information.

Requisition Design & Laboratory Manuals

Another important piece of the lab's strategy to improve compliance is to design its requisition to make it easy for the physician and staff to comply. The requisition needs to include adequate space for diagnosis information. It should identify tests that need special attention like NCD and LCD tests so the user has a better chance to comply. It should also contain instructions on supplying valid ICD-9 codes or photocopies of insurance cards and directions on submitting an ABN if a test is not covered by Medicare. The requisition should also include information about medical necessity. The back of the requisition is valuable space that can be used to supply this kind of information. Although space is limited on the requisition, a lab is better off providing this kind of instruction instead of a few additional tests that are not used with great frequency.

One of the best tools the laboratory can employ is an electronic order system that has flags and edits built into it to notify the person using the system when medical necessity or billing requirements have not been met.

Laboratories have tried a variety of techniques to improve compliance beyond those already mentioned like providing lists of "most used ICD-9 codes" on the form or including an ABN, either on the reverse side of the form or as an additional copy bundled in the form. Listing ICD-9 codes is risky from a compliance perspective and problematic from a logistics perspective because it can be difficult to keep them current. In addition, the lab could be accused of code steering.

Laboratory manuals are another good tool to help improve compliance by physicians. Whether electronic or paper, the manuals should include medical necessity information both in a specific section at the beginning of the manual and for every test where it is applicable, like limited coverage test and non-FDA approved tests. Electronic manuals have the additional benefits of lower cost, the ability to provide more information, and the ability to employ electronic tools like hyperlinks and pop-up reminders.

In addition to the laboratory manual, a laboratory should also provide a medical necessity manual or instructions to clients about how to access medical necessity information electronically on their own. These manuals include lists of all the applicable NCD and LCD tests for a client's carrier or fiscal intermediary. These manuals should contain the complete text of the NCD or LCD listing and not simply lists of HCPCS and allowable ICD-9 codes (again, because of compliance concerns).

One of the problems with this is the NCD and LCD policies are constantly being updated, which requires a process to keep the books updated. Providing the information through the laboratory's Web site eliminates some of these problems.

Electronic Order Systems & Internet Connectivity

One of the best tools the laboratory can employ is an electronic order system that has flags and edits built into it to notify the person using the system when medical necessity or billing requirements have not been met. These systems give the laboratory another opportunity to educate and guide their clients to improve compliance with the lab's policies

and procedures. Electronic order systems usually do not have the space limits found on paper order forms so the lab has an opportunity to provide lots of information about the tests being ordered. Further, the electronic systems reduce miscues and other errors that the human-based system is prone to.

That said, placing computers and/or software can be expensive and present unique compliance problems of their own. For the laboratory to get maximum benefit from these systems they must be easy to use, sophisticated enough to be beneficial without being difficult, and cannot pose a compliance risk by being too helpful.

A good system will employ error messages that are complete, not cryptic or too general. For example, every claim for a laboratory test(s) must include a currently valid ICD-9 code, and every claim for a test that has a coverage policy for it, whether national or local, must include valid codes and those codes must be included in the coverage policy. The best system knows the difference and provides error messages that are helpful rather than cryptic. This results in fewer frustrations for the user and encourages use and compliance. Laboratories should survey their clients concerning ease of use and make changes accordingly.

Not all customers will use electronic systems or are large enough to warrant placement of them. The laboratory must also have and maintain an effective manual system for those clients as well. Don't believe for a moment that purchasing an electronic system will solve all or most of these problems. It is just one strategy the lab should employ.

A Strategic Approach: Data Collection & Tracking

The most effective approach to resolving the problems of physician compliance while not violating any laws or regulations is to use a global approach to process improvement, such as quality improvement techniques, teamwork, or Six Sigma. Further, whatever is done along these lines must include a continuous monitoring and improvement component. The use of data gathering and analysis, making fact-based decisions, and continuous improvement will bring cost-effective improvement and success. One-time efforts may have short-term impact but often are not cost effective and certainly do not guarantee long-term improvement.

It is important to know which physicians are not complying and what the nature of their noncompliance is.

It is important to know which physicians are not complying and what the nature of their noncompliance is. Directed training and education by representatives armed with facts and data is more effective than shotgunning the client with general information about all of the "mistakes" they have made.

It is also good practice not to harass noncompliant docs, but to reward clients who are not making mistakes. These clients also afford the laboratory an opportunity to find out what works and what doesn't in the physician office so the lab can use that information to make suggestions to other clients who may be struggling with compliance issues. Further, meaningful feedback to clients actually helps them as they work to meet your requirements.

You will always have clients who are just not going to be compliant or who need extra assistance with their compliance efforts. It is important to identify these clients as early as possible so they can be taken out of the routine process and handled in a separate way. The only way to effectively handle these physicians is through a focused, one-on-one effort with laboratory employees working directly with the client to find solutions to the problem. Ultimately, because this is a drain on resources and presents a compliance risk, the laboratory has to decide if a client in this category is worth the cost and effort to bring them into compliance.

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FDA Draft Guidance, *from p. 1*

The FDA says it has taken "the least burdensome approach" in determining that a test is simple and poses an insignificant risk of erroneous result, both key waived criteria specified in the CLIA statute.

According to CAP, the changes contained in the new draft guidance track recommendations the college made during the process to revise the original 2001 guidance, including increased use of quality control and focus on users of a device.

"It is our belief that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect test result is 'risk free' or inconsequential with regard to potential harm," CAP wrote in testimony submitted to CLIAC in February 2004. The college maintains that all tests, including those designated as 'waived' under CLIA, should be subject to documented quality control measures and proficiency testing, when available.

Definition Of "Simple"

According to the draft guidance, the following are characteristics of a simple test:

- ❖ Is a fully automated instrument, or unitized or self-contained test.
- ❖ Uses direct, unprocessed specimens, such as capillary blood (fingerstick), venous whole blood, nasal swabs, or urine.
- ❖ Needs only basic, non-technique-dependant specimens and reagent manipulation (such as "mix reagent A and reagent B").
- ❖ Needs no operator intervention during the analysis steps.
- ❖ Needs no technical or specialized training with respect to troubleshooting or interpretation of multiple, or complex, error codes.
- ❖ Needs no electronic or mechanical maintenance.
- ❖ Produces results that require no operator calibration, interpretation, or calculations.
- ❖ Produces results that are clear to read, such as "positive or negative," a direct readout of numerical values, the clear presence or absence of a line, or obvious color gradations.
- ❖ Provides instructions and materials for obtaining and shipping specimens for confirmation testing, in cases where such testing is clinically advisable.
- ❖ Has test performance comparable to a traceable reference method, as demonstrated by studies in which intended operators perform the test. If a reference method is not available for a test being proposed for a waiver, the manufacturer is advised to contact the OIVD to discuss the proposed plan prior to submitting the application.
- ❖ Contains a quick reference instruction sheet that is written at no higher than a seventh-grade reading level.

Further, FDA says a test that is simple should not have the following characteristics:

- ❖ Sample manipulation is required to perform the assay. (For example, tests that use plasma or serum are not considered simple.) Sample manipulation includes processes such as centrifugation, complex mixing steps, or evaluation of the sample by the operator for conditions such as hemolysis or lipemia.
- ❖ Measurement of an analyte could be affected by conditions such as sample turbidity or cell lysis.
- ❖ Results need to be reported to a public health department at the state or local level (e.g., tests for sexually transmitted diseases) since this is not a requirement that would be explained in the device labeling.

Fail-Safe Mechanisms

Generally, the FDA notes, waived tests should be more robust than non-waived tests. Test manufacturers "should demonstrate that sources of error are controlled or mitigated by fail-safe or failure alert mechanisms."

In addition, whenever feasible, manufacturers should include external control materials in the test kit. The kit should include Quick Reference Instructions (QRI), which should be laminated and attached to the test system, easy to understand, in a readable font of 12 point or greater, and include pictures wherever possible. Instructions for quality control should be integrated with procedural steps for performing the test.

The kit should also provide a toll-free telephone number for technical help with quality

*Join us for a special audio conference: "*CLIA-Waived Testing: Understanding the Impact of FDA's New Guidance," *on September 29, 3:00-4:30 p.m. (Eastern). To register or for more information, visit our Web site,* www.g2reports.com.

control problems, says the FDA. Users should be warned that failure to follow all instructions is an "off-label" use, which changes the test's CLIA categorization to high complexity, subject to more stringent standards.

Demonstrating Accuracy

To demonstrate that a device or test is "accurate" in the hands of the intended operator, the FDA recommends that manufacturers perform prospective clinical studies of the device proposed for waiver, using patient samples collected in the intended testing environment. "In this way, the studies will demonstrate, as closely as possible, how the device performs on actual clinical specimens by intended operators under the conditions of intended use."

Test performance should be evaluated in a setting designed to replicate, as closely as possible, the actual intended clinical use setting, says the FDA. The clinical study should be conducted at a minimum of three intended use sites at different demographic locations (e.g., outpatient clinic, physician's office) representative of the type of sites where the device will be used.

Manufacturers should provide the intended operators who participate in the study with only the proposed package insert and/or quick reference instructions. "Study participants should receive no training, coaching, prompting, or written or verbal instruction beyond the written test procedure," says the guidance. "They should have no opportunity to discuss the test with, or otherwise coach or observe each other."

Erika Ammirati, president of Ammirati Regulatory Consulting, believes that test manufacturers are likely to find the clinical study criteria overly burdensome and unrealistic. "Sales reps don't normally drop off the test kits and run away," she notes. "There is usually some element of training involved."

The deadline for comments on the FDA draft guidance is December 6.

Resources

- FDA draft guidance on waived testing: *www.fda.gov/cdrh*.
- CAP: 800-323-4040
- Erika Ammirati: 650-949-2768

HHS Extends Interim Rule On HIPAA Violations

The Department of Health and Human Services (HHS) is extending for six months an interim final rule establishing procedures for imposing civil money penalties on covered entities found to have violated federal healthcare information standards.

The procedural rule, which applies to regulations HHS issued under the administrative simplification provisions of the Health Insurance Portability & Accountability Act (HIPAA), was set to expire on September 16.

In a notice published in the September 14 *Federal Register*, HHS says the action extends the expiration date to March 16, 2006, to avoid the disruption of ongoing enforcement actions, while HHS completes rule making to develop a more comprehensive enforcement rule.

The procedural rule applies to enforcement of the HIPAA administration provisions by both HHS's Office for Civil Rights, which is charged with the privacy regulation, and the department's Center for Medicare & Medicaid Services, which is responsible for administering all other aspects of the title.

AdvancePCS To Pay $137.5 Million In Fraud Settlement

AdvancePCS, one of the nation's largest pharmacy benefit managers, has agreed to pay $137.5 million to resolve civil allegations it solicited and received kickbacks from drugmakers and paid kickbacks to potential customers.

The civil settlement, announced September 8, resolves claims under the False Claims Act and Public Contract Anti-Kickback Act, according to a statement from the office of U.S. Attorney for the Eastern District of Pennsylvania Patrick Meehan.

AdvancePCS, a wholly owned subsidiary of Caremark Rx Inc., was charged with soliciting and receiving kickbacks from pharmaceutical manufacturers in exchange for preferred treatment of drugs in contracts with health plan providers, including those that administer plans for the Federal Employees Health Benefits Program and Medicare+Choice organizations.

In addition, the PBM was charged with accepting lump-sum and flat-fee percentage rebate contracts from drugmakers for certain highly used drugs, in return for favorable treatment of those drugs in health plan contracts.

AdvancePCS was acquired in March 2004 by Caremark. Both companies have denied any wrongdoing. They said in a September 8 statement to investors that nothing in the settlement should be construed as inappropriate actions on the part of any pharmaceutical manufacturer, customer, or other entity that had a contract with AdvancePCS.

"Caremark and the marketplace were aware of this situation prior to our acquisition of AdvancePCS. We evaluated the issue during the acquisition process, and we already have provided for it in the company's financial statements," said Caremark Chairman, Chief Executive Officer, and President Mac Crawford. "We are pleased with the settlement with the federal government as it allows us to avoid the expense, uncertainty, and distraction of potentially time-consuming litigation."

Resources

Settlement and consent order: *www.usdoj.gov/usao/pae/News/Pr/2005/sep/sep05.html*.

OIG Okays Donation Of Medical Office Building

A for-profit owner of a hospital would not face sanctions for a proposed donation of a medical office building to a state-affiliated medical school, the Department of Health and Human Services Office of Inspector General (OIG) said in a recent advisory opinion (No. 05-11).

Although the proposed donation could violate the anti-kickback statute, the OIG said it would not impose administrative sanctions on the owner of the hospital proposing to donate the medical office building to the medical school. The building is located on the hospital's campus.

In the letter requesting an advisory opinion, the hospital's owner said the medical school, which is a college within the state university, would use the donated building to relocate the medical school's existing family medicine clinic.

The university is an agency of the state that oversees facilities, programs, and policies related to students, staff, and faculty of the university system. The medical school was established 30 years ago to operate primary care residency programs.

When the medical school was formed, the hospital and other hospitals in the area stopped operating residency programs and the medical school began operating nine different residency programs through affiliation agreements with the area hospitals. The hospitals remit funds to the university to support graduate medical education program costs from the medical school's residency programs.

The medical school offers residents education in outpatient care through the operation of its outpatient family medicine clinic. According to the requestors, the current clinic's two sites are outdated and inconveniently located. Closer proximity to a hospital would facilitate the provision of care to the clinic patients, the requestors said.

The requestors also noted that the clinic provides a significant amount of care to a medically underserved population. The clinic is the largest provider of Medicaid and uncompensated care in the city.

Under the proposed donation, the building would be transferred back to the hospital and the ground lease terminated if the medical building is not used for the stipulated purpose. Once the university receives the building, it would assume full responsibility for the building's operating costs and would not be involved in any decisions related to the building, including the nature of the services offered in the clinic.

Drug Companies Sued: California, joining a dozen other states, has filed a lawsuit charging 39 major pharmaceutical companies with artificially inflating the price of drugs and costing the state's Medicaid program, known as Medi-Cal, hundreds of millions of dollars. The lawsuit, which is an amended complaint to one Attorney General Bill Lockyer filed against two companies in 2003, adds more than three dozen companies to the list of defendants charged with inflating the average wholesale price (AWP) of drugs. Medi-Cal used AWP to determine drug reimbursement rates to providers.

Fraud Perpetrator Gets Prison Time: The co-owner and operator of an ambulance company used in a massive scheme to defraud Medicare and the Internal Revenue Service was sentenced September 2 to 108 months in federal prison and ordered to pay more than $2.4 million in restitution to Medicare. Boris Shpirt, who along with partner Gregory Plotkin owned and operated Greybor Medical Transportation, was also fined $50,000. At the same time, Boris's wife, Jenny Shpirt, was sentenced to 18 months in prison for two counts of filing false tax returns and was ordered to pay a $15,000 fine.

Discovery Halted: The Department of Justice has asked a Missouri federal judge to halt discovery in a whistleblower lawsuit over allegations of Medicare fraud at the Lester E. Cox Medical Center in southwestern Missouri, making public for the first time that it was conducting a criminal investigation aimed at the hospital system. The civil lawsuit, filed June 8, charges that two employees of the hospital system were fired in retaliation for cooperating with the criminal investigation. In its motion, the government said that ongoing discovery in the civil lawsuit could threaten its criminal investigation by giving targets of the investigation access to information and possible testimony being developed by the government.

Medicare Guidance Urged: Medicare providers need better guidance from the Centers for Medicare & Medicaid Services about how to properly bill for cardiac rehabilitation services, the Health and Human Services Office of Inspector General said in a recent report. CMS had asked the OIG to review hospitals' compliance with Medicare's coverage requirements for cardiac rehab because CMS is considering expanding coverage for such services, stated the report, "Review of Medicare Outpatient Cardiac Rehabilitation Provided by Hospitals." The OIG found there appears to be confusion about how to bill for the services, which are supposed to be provided with direct physician supervision and "incident to" a physician's services. The report is available at *www.oig.hhs.gov/oas/reports/region5/50300102.pdf*.

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G-2 Compliance Report (ISSN 1524-0304) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Website: www.g2reports.com.

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