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FDA Issues New Draft Guidance On CLIA Test Waivers

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 get more information, visit our Website,* www.g2reports.com

After years of controversy both within and outside government, the Food & Drug Administration has issued new draft guidance for medical device makers seeking waived status for their test kits under CLIA (the Clinical Laboratory Improvement Amendments of 1988). Waived status is the least regulated CLIA test category and thus is a vital entrée to the physician office and point-of-care testing markets and other alternative testing sites.

The FDA says the document, which replaces its 2001 draft guidance, includes changes to respond to several major issues raised by the laboratory community—in particular, quality and accuracy when tests are performed outside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.

The guidance gives greater emphasis, the FDA says, on studies to show that there is insignificant risk of an erroneous result when the device operator has limited or no training or hands-on experience with lab testing. The studies also must include ➥ *p. 2*

Lab Groups Still Critical Of Bidding Demo

Clinical laboratory and pathology groups saw some key changes they have advocated picked up in the latest retooling of the draft design for the Medicare competitive bidding demonstration for lab services. But they also saw that other big concerns were not addressed, especially the issue of an "unequal playing field."

The latest draft design was unveiled for public comment at the recent open-door forum held by the Centers for Medicare & Medicaid Services in Baltimore, MD. On the panel for the "listening session" were CMS officials and researchers from Research Triangle International, the contractor for the CMS demo project.

In one major change urged 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, though it's acknowledged that this puts a special burden on smaller labs. They'll have to bid on some 1,100 tests, many of which they send out or don't offer at all, and there's the risk that reference labs could jack up the price for tests the smaller labs need to offer to compete. More on the design was featured at the forum, such as the bidding process, selection of winners, payment, quality, and access. For details, see the *Focus*, pp. 4-6.

INSIDE *NIR*

FDA Issues New Draft Guidance, *from p. 1*

The new draft guidance does not address test systems cleared or approved by the FDA for over-the-counter or prescription home use. These tests are automatically waived under the CLIA statute

easy-to-understand information for such operators as physicians, medical assistants, and nurses at the point of care and laypersons.

In other differences from the previous draft guidance, the agency says there's greater emphasis on flex studies and validation studies linked to the hazard analysis for each device. There's also 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.

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

A simple test should have characteristics such as:

- ❑ Is a fully automated instrument or a unitized or self-contained test.
- ❑ Uses direct unprocessed specimens.
- ❑ Needs only basic, non-technique-dependent specimen and reagent manipulation. (A test would not be simple, for example, if sample manipulation includes processes such as centrifugation, complex mixing steps, or evaluation for conditions such as hemolysis or lipemia.)
- ❑ Needs no operator intervention during the analysis steps, no troubleshooting training, and no electronic or mechanical maintenance.
- ❑ Produces results that require no operator calibration, interpretation, or calculations and 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.

Generally, the FDA notes, waived tests should be more robust than non-waived tests. "Device makers should demonstrate that the sources of error are controlled or mitigated by fail-safe or failure-alert mechanisms and conduct validation studies to test these mitigations." Studies should demonstrate as closely as possible "how the device performs on actual clinical specimens by intended users under the conditions of intended use, and over time." The guidance recommends specific validation designs for quantitative and qualitative tests.

The deadline for comments on the FDA guidance is December 6. To download the document and the procedures for submitting comments, go to www.fda.gov/cdrh

The waived test kit should include Quick Reference Instructions (QRI). The QRI should be laminated and attached to the test system, easy to understand (written at no higher than a 7th grade reading level), in a readable font of 12 points 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 control problems. 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 the most stringent standards.

Controversy has flared for many years over the CLIA waiver criteria as the number of waived tests continues to proliferate and government studies continue to find quality problems in waived labs. The controversy was aggravated by a jurisdictional tug-of-war among federal agencies that was settled last year when the HHS Secretary affirmed that the FDA had sole authority over CLIA test complexity rankings.

Labs, CMS Mobilize For Hurricane Katrina Relief

While it will take time to assess the scale of damage to the clinical laboratory infrastructure along the Gulf Coast that was devastated by Hurricane Katrina, there's already been an outpouring of aid offers from across the lab spectrum. Here's a snapshot:

Katrina Lab Relief Bulletin Board

The American Association for Clinical Chemistry created this site at *www.aacc.org* to help coordinate clinical lab-related relief for victims. Volunteers are from all parts of the country. Many lab professionals volunteer to help out in any way possible. Regional hospitals have offered help with routine testing, and several pathology and independent labs have said they'll do the routine work at no charge with regular pickups in the affected areas. One lab said it can coordinate molecular hematopathology testing for labs in the affected areas and can do some of the testing itself, if needed. Many labs also list potential job opportunities for displaced lab personnel. Diagnostics manufacturers and distributors also are offering help with equipment and reagents.

HHS Calls For Volunteers

The U.S. Department of Health & Human Services wants to identify lab technicians, physicians, and other healthcare professionals who can help with Katrina relief. The Website: *https://volunteer.hhs.gov*; the toll-free number, 1-866-KAT-MEDI.

CMS Relaxes Rules For Providers, Beneficiaries

To speed emergency services to the elderly, children, and the disabled, most normal operating procedures of Medicare, Medicaid, and the State Children's Health Insurance programs will be relaxed. Many beneficiaries have been evacuated to neighboring states where the receiving healthcare facility has no record of them. In these circumstances, the normal burden of documentation will be waived and the beneficiary will be presumed to be eligible.

Providers that furnish medical services in good faith, but can't comply with normal operating procedures because of Katrina will be paid for these services and will be exempt from non-compliance sanctions, unless it is discovered that fraud or abuse occurred.

Certain HIPAA privacy rules will be waived so that providers can talk to family members about a patient's condition even if that patient is unable to grant that permission to the provider. Information can be shared to provide treatment and, as necessary, identify, locate, and notify family members, guardians, or other responsible individuals as to the patient's location, general condition, or death.

Public Health Labs Mostly Okay

At press time, the Association of Public Health Laboratories reported on the status of member state public health labs (*www.aphl.org*):

—*Louisiana:* the central state lab in New Orleans was out of commission and the condition of the facility was unknown. Operations have been diverted to branch public health labs in Shreveport, Lake Charles, and Amite.

—*Mississippi:* all labs, branch and central, are operating, and the state health department is assessing the clinical lab situation in the state. The state of Florida has deployed a team of microbiologists, their mobile lab, equipment, and reagents to the affected area.

➥ *p. 7*

focus on: Lab Competitive Bidding

What Shape Is Medicare Demonstration Likely To Take?

The demo is required by the Medicare Modernization Act of 2003, but the law sets no specific implementation timetable, requiring only that a progress report be delivered to Congress by December 31, 2005

Clinical laboratory and pathology groups got a preview at the August 24 open-door forum convened by the Centers for Medicare & Medicaid Services. On center stage: a reworked design for a Medicare competitive bidding demonstration for Part B lab services. It incorporated several major changes sought by these groups, but not some other big ones, as noted at the forum and in later interviews with *NIR*.

Medicare competitive bidding is opposed across the laboratory spectrum—from large to small labs to associations of pathologists, lab managers, scientists, and other personnel. Its basic flaw in their eyes: It emphasizes the best price to the detriment of quality and access. It also puts smaller labs at unfair risk, especially in niche markets like nursing homes and rural areas. Opponents say it threatens the ready access to lab services that Medicare beneficiaries currently enjoy. Lab services are only 1.6% of Medicare spending, but they impact an estimated 70% of medical decisions, so risking quality and access would be penny-wise and pound-foolish, warns the American Clinical Laboratory Association.

But Congress has required a demo, lab and pathology interests acknowledge that CMS must act, and they "want to be part of the process," Vince Stine, head of government relations at the American Association for Clinical Chemistry, told *NIR*. ACLA president Alan Mertz said labs must stay involved to make sure the demo is fair.

Background on the Demo

The 2003 Medicare Modernization Act (P.L. 109-173) requires the HHS Secretary to pursue a Part B lab bidding demo restricted to lab tests provided without a face-to-face encounter, excluding Pap smears and colorectal cancer screening. The demo must be budget-neutral (result in no spending increase).

The CMS project has two phases: design and implementation (*NIR, 26, 1/Oct 11 '04, p. 1*). The contractor for the project, Research Triangle International, has assembled a technical expert panel to advise on the work (*NIR, 26, 5/Dec 16 '04, p. 2*). CMS and RTI held a previous open-door forum on the lab bidding demo on March 3, 2004. The project has an ongoing dedicated e-mail box (*lab_bid_demo @cms.hhs.gov*) that lets the public contact CMS directly.

RTI is no stranger to lab bidding. Back in 1997, it designed a pilot for CMS, but the effort got sidelined when CMS shifted its resources to making provider payment reforms required under the Balanced Budget Act (*NIR, 26, 1/Oct 11 '04, p. 1*).

Changes Urged by Industry

CMS and RTI responded to industry concerns in several main areas, Mertz told *NIR*. The demo design now includes all tests payable under the Part B fee schedule (except for Pap smears and colorectal cancer screening, which are statutorily excluded); it encompasses hospital outreach testing in addition to independent lab work; it excludes ESRD beneficiaries in the demo sites and allows for multiple winning bidders. The demo also assures that quality (turnaround time and other factors) will be assessed retrospectively in the process of determining winning bidders. It's important that labs be evaluated on their record, Mertz said, not just on what's promised.

But ACLA still faults the design for not reflecting how labs and third-party payers do business. They negotiate, Mertz told *NIR*, and all terms of the contract, including non-fee components, are part of it.

These components are especially important when doing business with Medicare, because Medicare has requirements beyond what private payers typically have—for example, Advance Beneficiary Notices, curbs on medical necessity and frequency, stat charges, and bundling, among others. For all these components, labs incur costs which should be negotiated as part of competitive bidding, ACLA contends.

"Unequal Playing Field"

The demo will run in a single state, in two sites (22 candidates identified so far), with a staggered start date (the demo in 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 project director Linda Lebovic told the forum that in defining "face-to-face encounter," the agency has followed legislative intent and limited the demo to any lab work performed by an independent facility, including reference work by a hospital when it is, in effect, functioning as an independent lab. "We sought to avoid the sticky business of phlebotomy arrangements," she said. "We stayed away from [that] and worked with claims processing," noting that CMS has modifiers to help pay and track lab work that will be part of the demo.

Getting Paid Under The Demo

- ❑ There will be multiple winners. Winning bidders will be paid for all Medicare tests; losers will get no payment.
- ❑ Composite bids from individual bidders will be arrayed from lowest to highest; the array will be used in conjunction with other criteria to determine the "pivotal" composite bid that will determine the winners. Those bidding less than or equal to the "pivotal" will be winners; those bidding above it will be losers.
- ❑ CMS will set a maximum acceptable composite bid, or "reservation bid." Labs whose composite bids exceed the reservation bid will automatically be losers.
- ❑ All lab firms with over $100,000 in annual Medicare payment for demo tests must bid or they'll get no Medicare payment. The threshold applies to the entire lab firm, including all affiliates.
- ❑ Non-required bidders will have the option to bid, but don't have to. Labs under the $100,000 threshold don't have to bid and will be reimbursed for Medicare work as long as they don't exceed the threshold. Once it's reached, they will get no further Medicare payment for tests covered by the demo.
- ❑ Winning labs will have relatively few restrictions on subcontracting and referrals as long as the performing lab is CLIA-certified.
- ❑ CMS reserves the right to conduct follow-up investigations or a second round of bidding.
- ❑ Collusion or price-fixing is prohibited. Bidding consortia allowed, subject to FTC review.

Critics say that by exempting physician office labs (POLs) from the demo, CMS is creating an unequal playing field. Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science, drove this point home when she told the forum panel that POLs aren't always limited to the physician's practice, and it's not uncommon to find a large group practice POL doing reference work—in effect, acting as an independent lab. If they're not in the demo, they have an unfair market advantage over labs that must bid to get Medicare payment, she said. In ACLA's view, if POLs remain outside, they should get the same payment as the others—the composite bid price, not lab fee schedule amounts.

Threat To Niche Markets

Several individuals at the forum came from labs serving nursing homes in Cleveland and Cincinnati, Ohio. They were alarmed over the impact that the demo could have on their market. Smaller labs typically serve this market; larger labs opt out, citing costly and intensive service demands.

"If competitive bidding eliminates the small labs that have taken on the added

In the past, lab groups have persuaded Congress to block a competitive bidding demo, and CMS has given greater priority to other payment changes. This time, lab representatives warn, there's a greater commitment on the Hill and at CMS to see a pilot through and settle the issue.

To AACC's Vince Stine, a key question is the time frame: Is the demo on the fast track?

burdens of serving this market, who will meet the testing needs?" they asked. "If larger labs don't want to serve nursing homes and we can't compete and go out of business, who will take care of [this] population?" Even if the market is corrected, there are significant barriers to re-entry, the American Association of Bioanalysts has previously pointed out.

The forum panel replied that the law allows working to protect smaller businesses and to use multidimensional criteria, not just price, in the bidding process. CMS officials said nursing homes will be a big consideration as the project goes forward. One possibility, Lebovic mused, is that labs serving niche markets could be defined as "passive" labs—they would not have to bid but would be eligible to get paid at demo rates.

In the best of all possible worlds, ACLA would like the CMS report to Congress to conclude that competitive bidding won't work for lab services. But if the demo goes ahead, ACLA wants to make sure it's a fair test. Mertz thinks the outcomes for quality and access will override the amount of savings to Medicare. What you risk, he argues, is you select a few winners and drive all the others out of business.

What's Next?

A lot has to happen before CMS reports to Congress, says one CMS source. The demo project will study public comments, make modifications where appropriate, and submit the work to CMS for clearance. It then goes up the line to the HHS Secretary and the Office of Management & Budget.

A lot of operational questions remain, says AACC's Vince Stine. There will be multiple winners, but how many? RTI has said winners will have no guarantee of volume, but volume is a big influence on bid prices, he notes. To him, the overarching question is: after we do the demo, how do we apply it? Nationwide? Will that lead to multiple fee schedules based on providers? When you get down to the lowest price, how do you get lower? He thinks the more information the project gets, the more flaws will be exposed.

It will become a whole different ballgame, Stine notes, when concrete decisions are made and the demo goes from the abstract to an actual project, impacting providers, beneficiaries, and their elected representatives in the selected sites. Then it will be like what has happened with recent military base closings, he thinks. Local groups will get mobilized, the economic impact will be debated, and politics will kick in.

Note: We're featuring a special session on the lab bidding demo at Lab Institute 2005, October 19-22. Panelists include key players cited in the *Focus*: Linda Lebovic from CMS, Donna MacMillan from the project's advisory panel, and Alan Mertz from ACLA. To register or get more information on the Institute, go to *www.g2reports.com.*

Maintaining Quality

To ensure quality at winning labs, the demo will rely on many existing mechanisms, Donna MacMillan, MT(ASCP), told the forum audience. She is director of operations for the pathology department at Massachusetts General Hospital and chairs the technical expert panel to the RTI project.

Mechanisms include CLIA regulation, quality assurance, proficiency testing, inspections, log-in error rates, physician satisfaction, and number of specimens found to be unusable or lost.

To monitor quality, the project will require winning labs to report data on six different measures of turnaround time.

To measure access, these labs will be monitored for five different rates of lab tests per beneficiary, with special attention to patients with diabetes, coronary heart failure, and coronary artery disease (CAD).

The project will monitor three different rates of lab tests by clinical guidelines for the percent of diabetics with one LDL cholesterol test per year, the percent with one HbA1c test per year, and the percent of CAD patients with one lipid profile per year.

Hurricane Katrina Relief, *from p. 3*

—*Alabama:* all lab facilities reported in working order.

Quest Diagnostics Aids Employees, Other Victims

Quest Diagnostics (Lyndhurst, NJ) tracks its Katrina relief efforts at *www.questdiagnostics.com*. At press time, in the greater New Orleans area alone, Quest had more than 300 employees and a laboratory in Metairie, which was not operating. All New Orleans and Mississippi employees are urged to contact the Human Resources Department at the Houston lab, 713-877-6114.

"Our immediate focus," said Surya N. Mohapatra, PhD, Quest's chairman and CEO, "has been to locate all employees in the region and provide direct financial assistance and help find housing options for those who have been displaced."

Quest has pledged $50,000 to the American Red Cross Katrina relief fund. Quest employees have set up a special relief fund to aid their fellow employees along the Gulf Coast. The company has pledged to match employee contributions in the special fund as well as to the American Red Cross, up to $200,000.

♦CODING A·D·V·I·S·O·R·Y

Effective October 1, 2005, Medicare will add and delete a number of ICD-9-CM diagnosis codes covered under National Coverage Determinations (NCDs) for specific laboratory tests. ICD-9 codes must be used on Part B lab claims to document that the testing is medically necessary.

LAB NCD	ICD-9 CODE ADDED	ICD-9 DELETED
Blood counts*	443.82, 525.40-525.44, 525.50-525.54, V26.31-V26.33, V49.84, V59.70-V59.74, V62.84	V26.3
Blood glucose	276.50-276.52	276.5
Digoxin	276.50-276.52, 426.82, 585.1-585.9	276.5, 585
Fecal occult blood	287.30-287.39	287.3
GGT	291.82, 567.21-567.29, 567.38, 567.39, 567.81-567.89, 585.6	567.2, 567.8, 585
HIV (diagnosis)	287.30-287.39	287.3
Lipids	278.02, 585.4-585.9	585
Partial thromboplastin time	287.30-287.39, 585.4-585.9	287.3, 585
Prostate specific antigen	599.60, 599.69	599.6
Prothrombin time	287.30-287.39, 443.82, 585.4-585.9	287.3, 585
Serum iron studies	287.30-287.39, 585.4-585.9	287.3, 585
Thyroid testing	327.00, 327.01, 327.09, 327.29, 327.52, 327.8	—
Urine culture	585.6	585

*This lists only codes that do *not support* medical necessity; the other negotiated lab NCDs list codes that *do support* medical necessity.

Source: CMS Change Request 4005, August 19, 2005. Note: To the list of codes not covered by Medicare for the negotiated lab NCDs, CMS is adding V17.81, V17.89, and V18.9, and deleting V17.8.

CMS Calls Off Lab Pay-For-Performance Forum

CMS says there are no detailed plans for a lab P4P initiative at this time but "welcomes input on quality improvement and other policy issues"

The special "listening session" on Medicare use of clinical laboratory pay-for-performance (P4P) programs, set for September 6, has been put off till a later, unspecified date by the Centers for Medicare & Medicaid Services. The reversal came five days after CMS first publicized the forum on August 25. The agency said it had heard that lab interests needed more time to prepare comments.

The initial announcement came out of the blue, said several lab representatives. CMS gave no hint of a lab P4P forum at the forum held the day before on lab competitive bidding, said Jeff Jacobs, vice president for public policy at the American Society for Clinical Pathology. Thus far, Medicare's interest in P4P has targeted hospitals, physicians, and nursing homes (*NIR, 26, 18/Jul 11 '05, p. 1*).

The Medicare Payment Advisory Commission has recommended that lab data be required on all Medicare claims, saying it could be useful in setting quality incentives for physicians. If so, lab groups say they should get paid for the added reporting costs (*NIR, 26, 10/Mar 7 '05, p. 1*). There are substantial shortfalls in lab reimbursement already, said Alan Mertz, president of the American Clinical Laboratory Association. If you're looking at lab pay differentials, he said, it should be noted that labs are indirect providers. "It's hard to measure labs by outcomes. We don't have control over how the test results are used. We inform treatment decisions; we don't make them."

washington WATCH

Hurricane Katrina Revamps Legislative Agenda

When Congress returned on Labor Day from a month-long recess, relief from Hurricane Katrina's devastation left key GOP legislative priorities either dead or in doubt.

Social Security overhaul is likely moribund this year, say Washington analysts, and certain tax breaks are problematic. Senate Majority Leader Bill Frist (R-TN) has put off, at least for now, a vote on permanent repeal of the estate tax.

With the federal deficit already soaring, Katrina relief will push it even higher. How that will impact the budget resolution is unclear. It calls for $70 billion in tax breaks and $35 billion in entitlement spending cuts, including $10 billion from Medicaid. However, a bipartisan group in the Senate is urging that Medicaid be spared since it's the sole source of healthcare for many hurricane victims.

Meantime, Congress has made an initial down payment of $10.5 billion for Katrina relief and recovery.

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