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CMS Seeks Industry Views On Lab Competitive Bidding Demo

Though staunchly opposed by the clinical lab industry, competitive bidding could loom larger as Congress grapples with putting the brakes on soaring Medicare spending growth

A "special listening session" has been scheduled on Mar. 3 by the Centers for Medicare & Medicaid Services to get public input on the competitive bidding demonstration project the agency is required to conduct for Part B independent laboratory services, including colorectal cancer screening. Congress mandated the project as part of the Prescription Drug, Improvement and Modernization Act of 2003 (Public Law 108-173), with a report due by Dec. 31, 2005.

CMS is particularly interested in:

- ❑ What tests the demonstration should include.
- ❑ What bidding methods should be used.
- ❑ How many and what type of demo sites there should be.
- ❑ What administrative steps would smooth the demo process.

For more details, see *cms.hhs.gov/researchers/demos*.

The session will be held from 10 am-12 noon at CMS's Baltimore headquarters. Those wishing to attend must respond by Feb. 26 with an email to *Lab_BID_DEMO@cms.hhs.gov*, including name, organization, contact information and whether they wish to speak. Anyone wishing to speak, in person or by telephone, should send written comments to the e-mail address. To listen in by phone, dial 1-800-837-1935 and key in Conference ID 5674538.

Bidding Proponent To Lead Key House Panel

Laboratory lobbyists aren't sounding an alarm over the nomination of Rep. Joe Barton (R-TX) by House GOP leaders to succeed Billy Tauzin (R-LA) as chairman of the Energy & Commerce Committee, despite Barton's role in Congress as a champion for switching from Medicare fee schedule reimbursement to a competitive bidding payment alternative. Tauzin resigned as chairman effective Feb. 16, and the 12-term congressman said he would not seek reelection. He reportedly is being courted by pharmaceutical companies and other interests for major lobbying responsibilities.

Barton was the lead sponsor of provisions in last year's Medicare reform legislation that require a demonstration of competitive bidding for independent lab services, including colorectal cancer screening (with a report due to Congress by the end of 2005), and full-scale implementation of competitive bidding for selected durable medical equipment. Barton called for the DME payment method ➠ *p. 2*

INSIDE *NIR*

U.S. Rep. Joe Barton (R-TX) backed Medicare competitive bidding when he headed the Energy & Commerce oversight and investigations panel in 1995-1998. His probes of Medicare/Medicaid overpayments, fraud and abuse convinced him that an alternative to government-set fees would save money (NIR, 24, 21/Sept. 12, '03, p. 3)

Competitive Bidding, *from p. 1*

change after a demonstration he had earlier backed reported reductions in DME spending by 18% in Florida and 20% in San Antonio, TX. A favorable lab bidding pilot could prompt the government to switch lab payment from the Part B fee schedule to competitive bidding as well, something lab groups have vigorously opposed.

So why aren't labs up in arms over Barton's ascent? After all, as committee chairman, he clearly will be in a stronger position to pressure the Centers for Medicare & Medicaid Services to make the lab bidding pilot a priority. But lab groups remain hopeful he will retain existing committee staff, including lab issues veteran Patrick Morrisey, and they also take heart from assurances Barton gave a small group of lab lobbyists earlier this month. Don Lavanty, president of J.T. Rutherford & Associates, recalls Barton telling the group, in essence, "If competitive bidding is the answer, let's do it. If not, let's talk about it." Lavanty added, "I was convinced he wanted to do the right thing."

Even so, when the American Society for Clinical Laboratory Science, which Lavanty represents, and the Clinical Laboratory Management Association hold their legislative symposium on Mar. 22-23, they intend to press members of Congress to call on CMS to establish an advisory committee on competitive bidding for laboratories. The aim is to provide a venue for labs to explain the problems that bidding could cause, such as reduced access to care for some beneficiaries. For example, Lavanty points out, low bidders would likely find it uneconomical to provide services at nursing homes, because many facilities are so remote and the specimen collection fee is so low.

Medicare Gears Up For New Rural Lab Pay Rates

The new policy will generate about $100 million in additional reimbursement for affected labs during 2005 and 2006, the Congressional Budget Office has estimated

The Centers for Medicare & Medicaid Services has changed its manual for Medicare claims processing to allow certain rural hospitals to get paid for 100% of their reasonable costs (with no co-insurance or deductible applicable) for Part B clinical laboratory services furnished to outpatients during a two-year cost-reporting period that begins July 1, 2004. This exception to payment via the Medicare fee schedule was mandated by the Medicare reform law enacted last December (*National Intelligence Report, 25, 5/Dec. 15, '03, p. 6*).

The new policy expands on a similar provision for critical access hospitals in the 1999 Balanced Budget Refinement Act and applies to a limited universe of rural facilities—those hospitals that are located in "qualified rural areas" and have less than 50 beds.

The CMS central office will determine which rural areas qualify and identify the lowest 25% quartile population density areas. A file of eligible zip codes will be available to fiscal intermediaries on or about May 15, the agency said in Transmittal 100 (Feb. 13, 2004). Intermediaries are to use a "1" in position 138, the "Special Locality Indicator," of the provider-specific file to signify that the provider qualifies for reasonable-cost reimbursement.

CMS says that reasonable costs will be determined by using the ratio of costs to charges for the lab cost center times the billed charges for outpatient lab services for cost-reporting periods beginning after July 1, 2004, and before July 1, 2006. In deciding whether lab services are furnished as part of the hospital's outpatient services, the same rules now used for outpatient critical access hospital services will apply. The CMS contact is Linda Easter, 410-786-6978.

Govt. Urged To Pump Up Blood Supply, Establish Reserves

The HHS Advisory Committee on Blood Safety & Availability has called on Health & Human Services Secretary Tommy Thompson to take a number of steps to stabilize the blood system and to improve preparedness for natural disasters or terrorist acts. On Jan. 29, the panel:

- Advised a 5-7 day inventory of blood components in all collection centers.
- Urged the Department to approve whatever new funding would be necessary to support the goals of the 1974 national blood policy and to fully fund the HHS Blood Action Plan, particularly to monitor and increase the blood supply.
- Endorsed a proposal by an American Association of Blood Banks task force to establish a government-private sector partnership to form a blood reserve to improve the stability and security of America's blood system, and urged the HHS secretary to help get it funded. The reserve would be dispersed, so there would be enough blood within a four-hour drive in the event of an emergency.

The latter recommendation is based on a plan from the AABB Intergovernmental Task Force on Domestic Disasters and Acts of Terrorism, which Don Doddridge, CEO of Florida Blood Services, presented Jan. 28. It calls for a liquid reserve of some 10,000 units, dispersed among designated public and private storage sites around the country. The U.S. military's whole blood product labs would store 2,000; private-sector regional blood centers would control the other 8,000.

AABB estimated the blood reserve would entail $2.14 million in start-up costs and $5.2 million in annual operating costs for the private-sector regional blood centers. The Defense Department would have to spend $450,000 for start-up and $1.56 million for related annual operations. Perhaps another $10 million or more would have to be spent on a national awareness campaign to donate blood.

FDA To Fine Red Cross Again

The Food & Drug Administration warned the American National Red Cross on Feb. 6 that it intends to fine the not-for-profit agency an additional $450,000 for continued failure to improve its blood services management procedures as required by an Apr. 15, 2003 consent decree.

The Red Cross had submitted new standard operating procedures for problem management last June 6, but FDA rejected them, listing their deficiencies in a July 22 adverse determination letter. FDA later fined the Red Cross $518,500 in daily non-compliance penalties for the 61 days prior to Aug. 6, when it submitted a plan for revising the problem management SOP (*NIR, 24, 22/Sept. 29, '03, p. 7*).

The latest fine concerns the revised SOP, which Red Cross submitted last Oct. 28. FDA said it "continues to be inadequate to fulfill the requirements in Paragraph IV.B.1 of the decree" and concluded that the Red Cross "still has failed to correct significant deficiencies." The fine would consist of $7,500 in daily non-compliance penalties for 60 days beginning last Oct. 28, and ending Feb. 6 of this year, the date when FDA issued its second adverse determination letter, *www.fda.gov/ora/frequent/letters/ARC_ADLetter_2604.html*.

focus on: *CLIA Waived Testing*

CLIAC Tackles "Hot Potato" Issue For Labs & IVD Makers

The final outcome could drive POL market growth to new heights and encourage IVD makers to devote more R&D to expand the number and types of tests eligible for waived status

Breaking new ground in the controversy over how flexible the Food & Drug Administration should be in categorizing lab tests as waived under CLIA, the Clinical Laboratory Improvement Advisory Committee (CLIAC) has reached broad agreement on a set of criteria that the government should follow in issuing new waiver guidance to manufacturers of in vitro diagnostic devices (IVDs). Waived testing is the least regulated CLIA category, so expansion of the number and types of such tests on the market would be a major growth opportunity for both physician office testing (POL) and IVD makers (*NIR, 25, 8/Feb. 9, '04, p. 5*).

At its Feb. 11-12 meeting in Atlanta, GA, the panel, which advises the government on CLIA scientific and technical matters, endorsed a series of recommendations based on input from its waiver criteria workgroup, including pre- and post-analytical safeguards to ensure safe use of waived test kits.

Dueling Approaches

The statutory terms for waiving a test under CLIA are broad (*see below*) and federal agencies have applied them differently. From 1992 to early 2000, the Centers for Disease Control & Prevention handled waivers, relying on draft criteria it proposed in 1995 but never finalized. After the Food & Drug Administration took over this responsibility in 2000, it soon drew fire for waiving too many tests using its own criteria, which critics said were too "manufacturer-friendly" and not detailed enough on quality concerns. Reinforcing their arguments were government studies that uncovered major quality lapses in waived testing (*see p. 5*). The dispute bubbled to a boil after FDA waived OraQuick's rapid HIV-1 test and HHS Secretary Tommy Thompson pushed it through, over the objections of officials at CDC and the Centers for Medicare & Medicaid Services, CLIAC and other lab interests. FDA later sought to calm the waters by restricting sale of the test to licensed labs. The agency typically waives dozens of tests each year that are equivalent to existing waived test methods, but waiver of a new analyte/technology is rare.

IVD makers are especially anxious to get clear guidance on the waiver process. One product that has been in the pipeline for a year is Biosite's B-type natriuretic peptide (BNP) test, a cardiac marker used to diagnose and assess the severity of heart failure. For IVD companies like Biosite, waived status for a product paves the way to the lucrative market in physician office and alternate site testing. Users need only follow the manufacturer's instructions and are subject to only random inspection. High school graduates

CLIA Waived Testing
Statutory Requirements

Under CLIA (the 1988 Clinical Laboratory Improvement Amendments, Public Law 100-578), as amended by the FDA Modernization Act of 1997 (P.L. 105-115), the CLIA waived test category is designed for "laboratory examinations and procedures that have been approved by the Food & Drug Administration for home use or that, as determined by the [HHS] Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that:

(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly."

qualify to run the tests. For the other major CLIA categories—moderate and high complexity testing—users must satisfy detailed standards on quality, proficiency and personnel qualifications, and are subject to routine (biennial) inspection.

CLIAC Recommendations

The break in the logjam between CDC's approach, which lab professional organizations preferred, and FDA's approach, favored by IVD makers, came when the Advanced Medical Technology Association (AdvaMed, the main trade group for medical device makers) presented CLIAC with a new proposal for waiver criteria. The committee then appointed a workgroup, representing all the parties involved, to search for consensus, with AdvaMed's plan as a starting point.

Using the workgroup's recommendations as a guide, CLIAC agreed on the following regulatory framework for waived tests:

Waiver studies: Demonstrate likely test performance over time using evaluation methodologies such as NCCLS EP-12A or EP21-A and intended clinical testing sites, users and, where possible, actual patient specimens, while keeping in mind that contrived specimens are often necessary.

Specimen characteristics: Disallow waiving tests with specimen types that require "significant manipulation." This would include plasma and serum because they require centrifugation, but not tests that require relatively minor manipulation, like swabbing for strep throat samples.

Test system characteristics: Waived tests should either provide direct quantitative read-out of results or distinct qualitative positive/negative endpoints. For test systems with distinct color gradations, results should be comparable to a traceable reference method, not subject to interpretation, and unaffected by color-blindness.

Flex studies: These should show that waived tests are more robust than non-waived tests. They should identify potential sources of error and show that these have either been controlled or mitigated. Further, test makers should assess the risk of erroneous results and show what mitigation measures they have taken.

Labeling and test system instructions: Labeling should be standardized, identifying the test as waived and including results of waiver studies and a quick reference guide. Further, user instructions should be clear, easy to understand, and written, in a readable font, at a level no higher than the seventh grade. Also, they should address test performance, labeling limitations, fail-safe and failure-alert mechanisms and quality control. CLIAC agreed to caution against using tests in a clinical setting if they have been waived for home use, but to be sensitive in the wording so as not to infer that a home-use test was inferior.

Limitations and intended use: These should appear on the outside of test kits,

Quality Problems With Waived Testing

As CLIA waived testing has proliferated, government authorities have been spot-checking its quality—with disturbing results. When the Centers for Medicare & Medicaid Services surveyed 897 waived labs in 2002, it found that 2% were putting patients in "immediate jeopardy," which it defined as posing an "imminent and serious risk to human health." Several residents of a nursing home in Mississippi died because untrained people were testing their blood glucose with equipment that had not been properly calibrated, Judy Yost, CMS's top CLIA official, told CLIAC at its recent meeting.

A broader survey of 1,756 labs in 2003 found that 3% were in the "immediate jeopardy" category, including one POL that, based on Rh slide testing, was giving men Rhogam, a vaccine that protects Rh-positive fetuses from Rh-negative mothers.

Other key findings from both studies and a smaller one in 2000: one-third of waived labs did not have the test manufacturer's instructions, and one-third did not perform the quality control required by manufacturers. There also was a 44% turnover in staff. Notably, labs in states with licensure programs performed 10 times better than those in states without such programs.

"Often the person who does the point-of-care testing is the lowly person in the office. Most of the time, it is the blind leading the blind," said CLIAC member Anthony Hui, MD, medical director at Northwest Arkansas Pathology Associates in Fayetteville. Hui advocates requiring new users to download authority from manufacturers to use test systems after training with a CD-ROM.

and clearly indicate that only people with the appropriate CLIA personnel qualifications may use the test on others. CLIAC recognized that manufacturers can't limit sales to only waived testing facilities since most sales are handled through distributor networks. But the committee said it would work with the Health Industry Distributors Association to see how distributors can help.

Fail-safe, failure-alert mechanisms: Waived tests should include failure-alert mechanisms in lieu of fail-safes, which often are not possible with waived-test technologies such as urine dipsticks. Further, manufacturers should provide built-in checks or quality control materials whenever feasible. If some components of waived-test systems are not monitored internally, then electronic controls, where available, should be run at specified intervals. External QC should be tested to monitor operator performance, test system operation and environmental conditions such as temperature and humidity.

As technology advances lead to smaller and easier-to-use devices, more and more testing is expected to shift to POL settings. But this trend depends largely on the introduction of new CLIA-waived analytes, says industry consultant Sheila Dunn, who heads Quality America in Asheville, NC. The number of POLs has risen steadily since 1996, from 53,666 to 79,203 in 2003, and POLs now account over half of all waived facilities. Dunn thinks many more will switch to only waived testing because of new CLIA quality system rules for moderate complexity testing

Quality control: After considerable debate, CLIAC agreed that QC materials should be "provided with, preferably in, test kits to increase the likelihood of QC testing." Further, QC materials should be ready to use or require only simple preparation. If the manufacturer doesn't provide them, it must recommend sources for them in the package insert. Also, CLIAC wants QC instructions to be integrated with test procedure instructions, where they are more apt to be read.

CLIAC was also sensitive to the likelihood that manufacturers would be able to design out the QC problems associated with waived tests, unless encumbered by regulations predicated upon existing technologies and processes. Valerie Ng, MD, PhD, professor and interim chair of the Department of Laboratory Medicine at the University of California/San Francisco, suggested that manufacturers address QC for waived tests by developing instruments with lockout features and unitized devices (such as pregnancy tests) with QC built into them. CLIAC concurred and agreed to forward this recommendation to AdvaMed.

Sales restrictions: CLIAC supported promotion of "best laboratory practices" to guide waived testing labs, rather than reliance on sales restrictions like FDA imposed on OraSure. Judy Yost, the head of CMS's CLIA program, informed the panel that CMS has been working with the National Committee on Clinical Laboratory Standards to develop "best practices" for labs. CLIAC asked CDC to report on the feasibility of having "best practice" guidelines for waived labs.

Next Steps

CDC staff will work with CLIAC to establish final written recommendations over the next two months for presentation to HHS Secretary Tommy Thompson and FDA officials. FDA's Steven Gutman, MD, director of the Office of In Vitro Device Evaluation & Safety, told CLIAC that his agency is eager to establish a clear regulatory process for waived tests soon. Rather than finalize CDC's 1995 waiver criteria proposal or FDA's previous guidance, FDA intends to draft a new Level-1 guidance, Gutman said, using as a framework the CLIAC recommendations which, he noted, "transcend" the previous proposals. A Level-1 guidance is more tentative, with more opportunity for input, he added.

♦REGULATORY W·A·T·C·H

Lab-To-Lab Referrals: A new implementation deadline of July 1, 2004 has been set for Medicare carriers to switch to new procedures designed to make Part B payments for lab-to-lab referrals more uniform nationwide and speed up payments to labs that do business across carrier jurisdictions (Transmittal 85, Feb. 6, 2004). Each carrier is to have available to it all the local fee schedules nationwide, and beginning July 1, must pay claims based on the fees applicable to the zip code where the testing was performed. Carriers also must discontinue use of reference-only provider IDs for labs outside their jurisdiction. The changes were to have begun Apr. 1, but because only part of them would be ready by then, the Centers for Medicare & Medicaid Services decided to advance the start-date (*NIR, 25, 7/Jan. 26, '04, p. 7*).

Colorectal Cancer Screening: Effective July 1 of this year, Medicare fiscal intermediaries are to begin covering fecal occult blood tests performed for the purpose of annual colorectal cancer screening of beneficiaries age 50 or older who reside in skilled nursing facilities (Transmittal 80, Feb. 6, 2004). Tests include the guaiac-based FOBT (HCPCS G0107) and immunoassay-based FOBT (G0328). The transmittal also instructs intermediaries on extending to SNF residents the additional screening services covered under Medicare's colorectal cancer preventive benefit: flexible sigmoidoscopy (G0104) and barium enema (G0106).

No More Coding Grace Period: Labs and other providers billing Medicare will have to be ready at the start of each year to submit only codes that are active for that year. Medicare is eliminating the usual 90-day grace period allowed to accommodate CPT, HCPCS and ICD-9-CM coding changes. For CPT and HCPCS, this will begin Jan. 1, 2005; claims with discontinued codes will be returned as "unprocessable" (Transmittal 89, Feb. 6, 2004). For ICD-9 diagnosis codes, this will begin Oct. 1, 2004 (Transmittal 95, Feb. 6, 2004). CMS says it is scrapping the grace periods to comply with the HIPAA electronic transactions final rule, which requires usage of the medical code set that is valid at the time the service was provided.

To prepare for the various coding changes, CMS advises all providers to:
—Get a copy of the CPT codes for the upcoming year, available in print or electronic format from the American Medical Association (typically during October).
—Preview the alpha-numeric HCPCS changes which are typically posted at the end of each October at *cms.hhs.gov/providers/pufdownload.anhcpcdl.asp*.
—Check for ICD-9 updates in the annual hospital inpatient PPS rule or, after the rule is proposed, at c*ms.hhs.gov/medlearn/icd9code.asp*.

♦QUESTION *of the* M·O·N·T·H

I know from the literature that the most effective way to identify the organism that causes septicemia is with sets of two or three blood cultures. So when an outpatient presents with a physician order for "blood culture," should I collect and bill for two sets of cultures?

If the physician is clearly ordering one culture, just do one. If you find the order confusing, "you're obliged to go back to the physician and clarify what he or she is ordering," says coding consultant Diana Voorhees, who heads DV & Associates in Salt Lake City, UT. "It's not appropriate to assume you know what the physician needs to order."

FDA, SEC To Improve Data Sharing To Better Protect Investors

FDA said its staff "will not be expected routinely to police statements by publicly held, FDA-regulated companies"

In more fallout from the Wall Street accounting and investment scandals, the Food & Drug Administration has proposed a move that could make it harder for publicly held companies, including drug and medical device manufacturers, to mislead their investors. FDA aims to improve the way it shares information with the Securities & Exchange Commission, which oversees Wall Street. Explained FDA chief Mark McClellan, MD, PhD, "When we identify suspected misstatements, we have a new process to bring these to the attention of SEC staff as quickly and efficiently as possible."

Whenever FDA staff suspect that firms have misled investors on regulatory matters such as the likelihood of obtaining premarket approval, the staff can notify SEC via a new point of contact FDA is proposing to establish in its division of the top-level HHS Office of General Counsel. Further, in a Feb. 3 letter to SEC officials, FDA's associate chief for regulatory affairs, John Taylor II, said FDA would:

- ❑ Establish SEC contacts in its Office of Regulatory Affairs and each of its centers.
- ❑ Work with SEC to train staff in areas of mutual interest, such as FDA procedures for responding to requests for non-public information.
- ❑ Share non-public information more readily by giving staff designated as contacts on SEC matters "blanket" authority to share such information in response to requests from the SEC or its staff during a two-year period.

washington WATCH

Playing Political Football With Medicare

Medicare has always come under sharp partisan wrangling, but Democratic lawmakers say the Bush Administration is "out of bounds" in its ad campaign to inform 40 million beneficiaries of the new prescription drug benefit.

Testifying before the House Ways & Means Committee on Feb.10, HHS Secretary Tommy Thompson rejected charges that the campaign was political. By law, he said, HHS must conduct an educational effort to apprise seniors of the Medicare changes.

CBS announced it was pulling the Medicare ad, then relented after HHS made changes. Still ahead, however, is a Democratic-sought ruling by the General Accounting Office on the legality of using public funds to support the TV spot and distribute an HHS fact sheet.

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