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Labs Ratchet Up Game Plan to Block Lab Bidding Demo

Under the timeline proposed by CMS, bids from labs in the San Diego demo site are due February 15 and winners are to be selected by April 11. Payments are to begin under the competitively bid fee schedule July 1.

At press time, a group of clinical laboratories in San Diego were close to filing a lawsuit to stop Medicare's competitive bidding demo from going forward, according to a key industry source. The demo is scheduled to get underway July 1 of this year in the San Diego-Carlsbad-San Marcos metro area and to run for three years. The area is the first of two sites to be selected for the lab bidding pilot.

The purpose of the demo, required by Congress, is to see if competitive bidding can be used to pay for independent lab services at rates below the current Part B lab fee schedule while maintaining quality and access to care.

In preparation for the initial launch, project officials from the Centers for Medicare & Medicaid Services and the project contractor, Research Triangle International, based in North Carolina, held a bidder's conference in San Diego last month to explain the demo to affected labs, though the meeting did little to assuage opponents' key concerns (*NIR, 29, 5/Dec 17 '07, p. 1*).

Meantime, lab lobbying groups are renewing their push to get Congress to repeal the bidding demo, said Mark Birenbaum who heads the American Association of Bioanalysts/ *Continued on p. 2*

Physician Fee Fix Issues in Flux

Unless Congress steps in, the 10.1% cut in Medicare fees to pathologists and other physicians under the SGR update formula will take effect July 1 of this year. Lawmakers late last year blocked the cut from starting January 1 and approved a 0.5% increase through June 30.

But as lawmakers reassembled this month for the final session of the 110th Congress, significant issues about another fix are unresolved, most importantly, how long to make a fix and how to pay for it. The Bush administration has signaled its opposition to any cuts in Medicare Advantage. That leaves the door open to cutbacks from other Medicare providers, including hospitals, nursing homes, and home health agencies—even potentially, labs—to pay for a physician fee increase.

Meantime, pathologists, while escaping the 10.1% cut at the start of this year, will see Medicare payments decline by 2% in 2008 due to revised work and practice expense values. However, revised overhead values for the technical component of flow cytometry and most in situ hybridization services will mean higher rates. For more on the Medicare payment outlook for 2008, see the *Focus*, pp. 4-6.

INSIDE *NIR*

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Lab Bidding Demo, *from p. 1*

National Independent Laboratory Association. Bills to do that are pending in the House (H.R. 3453) and in the Senate (S. 2099). "We are working on getting more co-sponsors," he told *NIR*, noting that the House bill, introduced by Nydia Velazquez (D-NY), now has 31 co-sponsors, roughly double the number who had signed on in early November last year (*NIR, 29, 3/Nov 5 '07, p. 6*).

The Senate companion bill, introduced by Ken Salazar (D-CO), has six co-sponsors, including key members of the Finance Committee, which has jurisdiction over Medicare matters, Alan Mertz, president of the American Clinical Laboratory Association, told *NIR*, adding that the Finance chairman and the ranking minority member are poised to approve repeal.

In the interview with *NIR*, Birenbaum said, "The merits of our case are well recognized on the Hill. Finding a legislative vehicle [for the repeal provisions] is the big obstacle now." The repeal language was not included in the compromise Medicare, Medicaid & SCHIP extension bill that Congress passed at the 11th hour before adjourning last December 21. But this year, with physicians spared a Medicare fee cut only through June 30, Congress will again have to address the issue, and lab groups will again lobby to get the demo repeal attached to Medicare legislation (*related coverage in this issue, p. 4*). The big question is how expansive such legislation is likely to be.

"The chances [for demo repeal] are better if Congress goes for a larger Medicare bill and not another stripped-down measure like the one passed as a stopgap last December," Birenbaum said, referring to the compromise bill that prevented a physician fee cut from taking effect January 1 of this year. "But Congress could opt again for a six-month block of a physician fee cut or an eight-month block and continue the 0.5% fee increase, pushing the issue into the next Congress and the next Administration," he cautioned.

Other industry sources note that legal action to halt the bidding demo from moving forward in San Diego would give lab lobbyists some "breathing room" to get legislative action to repeal the statutory authority for the project. But courts tend to be ill-disposed to intervene in regulatory matters, one source told *NIR*, especially when an agency is implementing a clear statutory mandate. Birenbaum agreed, noting that courts typically step in only when irreparable damage would otherwise result from regulatory action. "The court will want to see a lot of evidence before getting involved."

The time left to block the bidding demo is short, sources agree, and once the project gets going, it will be hard to stop. "The big concern, with us as an organization," Birenbaum told *NIR*, "is that the data due February 15 will be flawed because it is derived from a flawed demo design. The data won't reflect true market pricing. For example, a large lab with a small amount of Medicare business in the area would bid for the demo tests differently than a smaller lab with major Medicare business in the area. But even though flawed, the data could enter the wider debate over the Medicare lab fee schedule going forward."

This fear was echoed by another industry source who noted that once the bidding demo gets underway, CMS could go to Congress and say, "Here are actual prices for lab tests in certain regions, showing that labs are willing to go down in price to get the work." This could be used as an argument for lowering the current fee schedule or moving to nationwide lab competitive bidding, as the Bush administration has proposed.

Regulating IVDMIAs: A Closer Look at ACLA's Proposed Model

The model "can be implemented under current law through the MOU process and use of interpretive guidelines. If regulatory changes are needed, the industry would be committed to making consensus standards happen in a timely fashion" —ACLA comments to the FDA, posted on the association's Web site, www.clinical-labs.org

The American Clinical Laboratory Association has proposed, in comments to the Food & Drug Administration, a regulatory model addressing the continuing controversy over the FDA's decision to require premarket review for In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). *NIR* recently talked with David Mongillo, ACLA's vice president for policy and medical affairs, about the significance of the proposed model.

The FDA, in draft guidance to the lab industry, describes IVDMIAs as gene- or protein-based tests that combine assays and algorithms to produce results tailored to a specific patient. Examples include tests for breast and prostate cancer, cardiovascular disease, and Alzheimer's. What makes IVDMIAs different, the FDA contends, is that the algorithms are proprietary, making it difficult for physicians to interpret results and validate them independently. Lab and pathology groups have challenged what they regard as FDA overreach, saying it will stifle innovation and impede patient access to new and valuable tests. The HHS Secretary's Advisory Committee on Genetics, Health & Safety (SACGHS) has also registered its concern, urging the FDA to take a go-slow, broad-based consultative approach to the issue (*NIR, 29, 5/Dec 17 '07, pp. 3-6*).

At the heart of ACLA's model, Mongillo noted, is a Memo of Understanding (MOU) between the FDA and the Centers for Medicare & Medicaid Services that runs the CLIA lab regulatory program. The MOU would maintain CMS/CLIA as the exclusive regulatory authority for lab test services, while defining a major consultative role for the FDA on the clinical validity of specific IVDMIAs and their promotional claims. The MOU also would define an IVDMIA risk prioritization scheme and validation criteria for those deemed high risk.

No single agency has the infrastructure to handle the exploding field of genetic and genomic testing, Mongillo told *NIR*, and without interagency coordination, clinical labs are subject to duplicative and redundant oversight by both CMS and the FDA, something neither Congress nor the agencies intended. The MOU would clearly sort out and formalize the respective oversight responsibilities of these agencies, Mongillo said. Use of an interagency MOU for this kind of clarification is not unprecedented, he noted, citing the area of CLIA waived test categorization as one example.

For ACLA, as for SACGHS, the development of a risk-based IVDMIA regulatory framework built on industry consensus is crucial. The FDA made its own decision, Mongillo said, that certain IVDMIAs present increased risk, justifying tighter oversight. But on closer examination, ACLA found some well established tests do not merit this ranking, for example, estimated glomerular filtration rate to assess renal function and newborn screening for neural tube defects. In revising its guidance, the FDA agreed, saying it did not intend for all IVDMIAs to fall under premarket review. But this amounts to guidance by exclusion, Mongillo said, and that is not the way to go. "The FDA [focuses on] risk by technology platform," he added. "Why not also look at a test's intended use, as an adjunct to medical decision making, as part of a process of clinical decision points?"

Mongillo pointed out that the ACLA model envisions premarket review for IVDMIAs deemed high risk, but this would be done as part of CLIA enhancements to check clinical validity and promotional claims. All other IVDMIAs would have post-market review by CMS during CLIA inspections or as required by a CMS-FDA MOU.

Related:
Don't Miss the ***Molecular Diagnostics Regulatory Update*** by Steve Gutman, MD, Director of Invitro Diagnostic Device Evaluation and Safety, FDA, at G-2's ***Business & Financial Strategies for Molecular Diagnostics Conference***, April 30-May 2, Hyatt Regency Cambridge, MA.

focus on: *Medicare Policy Issues*

Legislative Outlook for Medicare Changes in 2008: *Key Priorities for Clinical Labs, Pathologists*

Medicare payment rates and other policy reforms are expected to top the healthcare agenda in Congress this year, and for clinical labs and pathologists, there is a lot of unfinished business left over from last year.

For pathologists, the key priorities are to get a Medicare fee increase beyond July 1 of this year, when a 10.1% physician fee cut is due, and to get an extension, beyond July 1, of the "grandfather" protection for certain pathology technical component billings. A broad pathology coalition also urges passage of legislation to overhaul the CLIA proficiency testing program for gynecologic cytology.

For clinical laboratories, the key priorities are repeal of the Medicare competitive bidding demonstration for Part B independent lab services and lobbying against any temptation by lawmakers to squeeze more savings from lab fees to fund other Medicare priorities, including a physician fee fix. In 2008, lab fees remain frozen for the fifth and final year of a zero update mandate in the 2003 Medicare Modernization Act (MMA).

A big question is how Congress will handle these priorities—whether it will opt for a "big" Medicare bill, a scaled-down version limited to a physician fee fix and a few other reforms, or an omnibus budget reconciliation measure that could incorporate a fee fix and other Medicare policy changes. The omnibus bill would face the least procedural hurdles. Under Senate rules, it could pass with only a simple majority, not a 60-vote supermajority.

Physician Reimbursement

Medicare fees for pathology and other physician services are due to be cut 10.1% as of July 1, 2008. Congress blocked the cut from taking effect January 1 and approved a 0.5% increase through June 30. Lawmakers now must address what to do about the 10.1% cut scheduled to be reinstated under the Sustainable Growth Rate (SGR) formula after the six-month reprieve expires, as well as an additional SGR cut looming January 1, 2009.

The main sticking points are the length of any fee fix and how to pay for it, given federal budgetary pressures and partisan jockeying in advance of the November presidential and congressional elections. Some legislative analysts speculate that lawmakers could opt to extend the 0.5% increase for another six to eight months or through 2009, leaving any SGR fix to the next Congress and Administration. Few analysts predict a comprehensive SGR overhaul this year.

But lawmakers still have to find a way to pay for a physician fee increase under congressional pay-as-you-go rules. Any fix will be costly. For example, a fix through 2009, as medical groups advocate, would cost an estimated $12 billion at a minimum. The White House has warned against any cuts in Medicare Advantage, so the money would have to come from other federal programs. Likely cutback targets include

Medicare providers such as hospitals, nursing homes, home health agencies, and potentially even labs.

Steep Medicare fee-for-service cuts are already expected to be proposed in the President's budget for fiscal 2009, due to Congress in early February. This is in accord with the 45% trigger established by the MMA. It requires the President to propose program cuts when general revenue spending exceeds 45% of Medicare financing within seven years. Medicare's board of trustees last year issued a report that put the 45% funding trigger in play for 2008. However, the law does not require Congress to pass the recommendations.

Pathology 'Grandfather' Protection

This protection expired at the end of calendar 2007, but Congress extended its life for six months, through June 30, 2008. The House had approved a two-year extension, through 2009. The protection allows independent clinical labs to bill Medicare Part B directly for the technical component of anatomic pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, the date when the Centers for Medicare & Medicaid Services first proposed to end such billings on grounds that the TC is reimbursed as part of Medicare's Part A inpatient payment.

House and Senate bipartisan bills are pending to extend the "grandfather" protection permanently:

- ❑ H.R. 1105, the Physician Pathology Services Continuity Act of 2007. *Introduced*: February 15, 2007. *Lead sponsor*: John Tanner (D-TN). *Co-sponsors*: 13. *Latest action*: Referred to the Subcommittee on Health.
- ❑ S. 458, the Physician Pathology Services Continuity Act of 2007. *Introduced*: January 31, 2007. *Lead sponsor*: Sen. Blanche Lincoln (D-AR). *Co-sponsors*: 8. *Latest action*: Referred to the Finance Committee.

Lab Competitive Bidding Demo

Bipartisan bills to repeal the statutory requirement for the Medicare Part B bidding demo are pending in the House and the Senate.

- ❑ H.R. 3453, Community Clinical Laboratory Fairness in Competition Act of 2007. *Introduced*: August 4, 2007. *Lead sponsor*: Nydia Velazquez (D-NY). *Co-sponsors*: 31. *Latest action*: Referred to the Subcommittee on Health.
- ❑ S. 2099, Preserving Access to Laboratory Services Act of 2007. *Introduced*: September 26, 2007. *Lead sponsor*: Ken Salazar (D-CO). *Co-sponsors*: 6. *Latest action*: Referred to the Committee on Finance.

CLIA Cytology Proficiency Testing

- ❑ H.R. 1237, the bipartisan Cytology Proficiency Improvement Act of 2007. *Introduced*: February 28, 2007. *Lead sponsor*: Bart Gordon (D-TN). *Co-sponsors*: 14. *Latest action*: Referred to the Committee on Energy & Commerce.

The bill would revise PT standards under CLIA (the Clinical Laboratory Improvement Amendments) to include requirements that each clinical lab (1) ensure that all individuals who screen and interpret cytological preparations participate annually in an approved continuing medical education program that provides each participant with gynecologic cytologic preparations designed to improve locator, recognition, and interpretive skills; and (2) maintain a record of program results. The bill would require termination of the CLIA individual PT program.

- ❑ S. 2510, Cytology Proficiency Improvement Act, similar to House version. *Intro-*

duced: December 18, 2007. *Lead sponsor*: Mary Landrieu (D-LA). *Co-sponsors*: 2. *Latest action*: Referred to Committee on Health, Education, Labor & Pensions (HELP).

Genetic Information/Non-Discrimination

- ❑ H.R. 493, the bipartisan Genetic Information Non-Discrimination Act of 2007. *Introduced*: January 16, 2007. *Lead sponsor*: Louise McIntosh Slaughter (D-NY). *Co-sponsors*: 224. *Latest action*: The bill as amended has cleared the committees of jurisdiction and is ready for House floor action.

The bill prohibits health insurers and employers from discriminating against individuals based on genetic information and establishes penalties for violations. It would bar employers from using genetic information when making decisions on hiring, firing, job placement, or promotion. It would prohibit group health plans and other health insurers in the group and individual market from using genetic information to deny coverage or set premium rates and from requiring that individuals undergo genetic testing. The prohibitions also would apply to employment agencies, labor unions, and Medicare supplemental policy plans.

- ❑ S. 358, the bipartisan Genetic Information Non-Discrimination Act of 2007, similar to the House bill. *Introduced*: January 22, 2007. *Lead sponsor*: Olympia J. Snowe. *Co-sponsors*: 28. *Latest action*: Reported out of the HELP Committee on April 10, 2007, ready for Senate floor action.

Lab Personnel Training

- ❑ S. 605, bipartisan Allied Health Reinvestment Act. *Introduced*: February 15, 2007. *Lead sponsor*: Maria Cantwell (D-WA). *Co-sponsors*: 8, including Edward Kennedy (D-MA). *Latest action*: Referred to the HELP Committee.

The bill authorizes funding for Title VII programs to promote careers in allied health and to educate and train allied health personnel, especially in critical shortage areas. Support would include grants to facilitate and expand student enrollment and to develop internship and resident programs; loans for faculty development; and scholarships for students who agree to provide service in rural and other medically underserved areas. S. 605 specifically includes clinical lab sciences, medical technology, and cytotechnology.

Alternatives to the Lab Fee Schedule

Bipartisan bills are pending in the House and the Senate to establish a demonstration project to evaluate new approaches to Medicare payment for clinical lab tests, including new molecular diagnostic tests. The bills also call for new rules on the gap-filling method used in determining fees, increased transparency in how fees are set for new tests, and advance notice of test fees being considered for adjustment under inherent reasonableness authority.

- ❑ H.R. 1321. Medicare Advanced Laboratory Diagnostics Act of 2007. *Introduced*: March 13, 2007. *Lead sponsor*: Bobby Rush (D-IL). *Co-sponsors*: 8. Backed by the Congressional Black Caucus. *Latest action*: Referred to Subcommittee on Health.
- ❑ S.2404, Medicare Advanced Laboratory Diagnostics Act of 2007. Similar to the House version. *Introduced*: December 3, 2007. *Sponsor*: Charles Schumer (D-NY). *Latest action*: Referred to the Committee on Finance.

The Clinical Laboratory Management Association and the American Society for Clinical Laboratory Science also advocate building on H.R. 1321 to devise a lab payment alternative that would set fees for new tests using a negotiated rulemaking process involving the lab industry, federal officials, and consumer groups.

FDA Okays 1st Test to Identify 12 Respiratory Viruses

The xTAG Respiratory Viral Panel is manufactured by Toronto-based Luminex Molecular Diagnostics.

The Food & Drug Administration earlier this month cleared for marketing a test that simultaneously detects and identifies 12 specific respiratory viruses from a single sample. The xTAG Respiratory Viral Panel is the first test to spot and differentiate influenza A subtypes H1 and H3. Influenza A is the most severe form of the flu for humans and has caused major epidemics. The panel is also the first test for human metapneumovirus (hMPV), newly identified in 2001.

The test amplifies viral genetic material in secretions taken from the back of the throat in patients with possible respiratory tract infections. In the test, specific beads, or microspheres, bind to the amplified viral genetic material. The beads are then sorted to identify the specific virus.

The xTAG panel is the first FDA-cleared test for infectious respiratory disease viruses that uses a multiplex platform, allowing several tests to be processed from the same sample. "Nucleic acid tests such as [this] panel utilize small amounts of genetic material and then replicate it many times," said Daniel G. Schultz, MD, director of FDA's Center for Devices & Radiological Health. "This speeds up the usual process of detecting and identifying respiratory viruses, which can take up to a week. And because this multiplex panel tests for 12 viruses at once, it uses less of a patient's specimen."

Other viruses pinpointed by the xTAG Respiratory Viral Panel include:

- ❑ Influenza B, one of three types of human flu, less severe than influenza A.
- ❑ Respiratory syncytial virus subtype A and B. Both are leading causes of infant pneumonia and bronchiolitis and often contribute to the development of long-term pulmonary disease.
- ❑ Parainfluenza 1, 2, and 3. All are key factors in the croup and the common cold.
- ❑ Rhinovirus, the most common viral infective agent in humans and a cause of the common cold.
- ❑ Adenovirus, a cause of respiratory tract infections often similar to strep throat or tonsillitis.

While the panel is faster than conventional tests, it is specific to the dozen viruses listed in the product, the FDA said, and should be used with other diagnostics such as patient data, bacterial or viral cultures, and X-rays. Positive results do not rule out other infection or co-infection, and the virus detected may not be the specific cause of the disease or patient symptoms, the agency further cautioned.

♦ Pathology Claims *Advisory*

On December 29, 2007, President George W. Bush signed into law legislation that blocked a 10.1% cut in Medicare payments to pathologists and other physicians scheduled to start January 1, 2008 in accord with the statutory update formula and replaced it with a 0.5% increase for the first six months of this year, through June 30. The revised conversion factor for this period is $38.0870 vs. $34.0682 under the cut.

Since then, the Centers for Medicare & Medicaid Services has been asked whether physicians should take any special action to get paid at the increased rate. The answer is no. According to CMS, Medicare contractors are able to process physician claims under Part B at the correct rate, and no adjustments should be necessary.

CMS to Adjust Payment for New Metabolic Panel Code

In response to an inquiry from the American Clinical Laboratory Association, an official of the Centers for Medicare & Medicaid Services has clarified a payment change due for the new CPT code 80047, basic metabolic panel (ionized calcium), added to the 2008 lab fee schedule (*NIR, 29, 6/Jan 14 '08, pp. 5-6*).

In the business requirement section of the CMS memo announcing the 2008 schedule, the agency advised contractors to pay for the new panel at the sum of the rate for a seven-test automated panel and the rate for 82330 (ionized calcium), resulting in a fee of $30.51 at the maximum. The fee schedule files published on the CMS Web site included this payment determination. However, in a separate section of the memo, CMS said it was establishing the fee by a crosswalk to 80048, which, though not subject to a fee cap, is paid by most carriers at $11.42.

Now, the CMS official said, the plan is to pay for 80047 via a crosswalk to the lower rate for 80048 as of July 1 of this year, noting that "because of a delay in updating our systems, we were not able to make the change as of January 1." The change will not be retroactive, the official said, adding that the agency will post a notification about the payment delay on its Web site.

Correction:

Physician Quality Reporting Program Extended for Full Year 2008

In the January 14 issue (p. 2), we incorrectly reported that Congress had extended Medicare's Physician Quality Reporting Initiative (PQRI) through June 30, 2008. In fact, Congress continued the program for all of calendar year 2008.

This year, for the first time, pathologists can participate following Medicare approval last year of reporting measures for breast and colorectal cancer (*NIR, 29, 4/Nov 19 '07, p. 6*).

The PQRI offers a financial incentive for eligible physicians and practitioners who successfully report on a range of 119 quality measures during 2008. The bonus is 1.5% of total allowed charges for covered services payable under the Medicare physician fee schedule. It will be paid in mid-2009 from the Part B Trust Fund. The bonus amount and its funding source for 2008 are the same as for 2007.

Pathologists and other eligible professionals who want to report for the 2008 PQRI and are not already submitting quality data codes on Part B claims with 2008 dates of service should start doing so as soon as possible. For details on the 2008 PQRI measures and reporting specifications, go to *www.cms.hhs.gov/pqri*.

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