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Labs Up the Ante in Drive to Stop Medicare Bidding Demo

The CMS project officer for the demo, Linda Lebovic, is scheduled to present a demo update and outlook at Lab Institute 2007 on October 11. To register for the Institute, go to www.g2reports.com

Members of Congress are coming under renewed pressure from lab lobbying groups and their own lab constituents to block Medicare's planned competitive bidding demonstration project for independent laboratory services.

The Centers for Medicare & Medicaid Services is developing the demo, in accord with a requirement in the 2003 Medicare reform law, and has announced a planned launch for the spring of 2008 (*NIR, 28, 20/Aug 13 '07, p. 1*). The project's purpose is to see if competitive bidding can be used to pay for Part B lab services at rates below the current lab fee schedule.

At press time, lab groups were reportedly close to getting a Senate sponsor for demo repeal legislation similar to that introduced in the House (H.R. 3453). They also are at work mustering more co-sponsors for the House bill.

Here's a rundown of other major efforts to block the CMS demo: The American Association of Bioanalysts' National Independent Laboratory Association is sponsoring a "March on Washington" on October 9-10 to lobby Congress to repeal the demo, *Continued on p. 2*

Medicare Lab, Physician Fee Update

At press time, the Centers for Medicare & Medicaid Services was expected soon to release tentative fees for new lab test codes to be added to the Part B fee schedule as of January 1. CMS had set September 7 as the target to unveil the initial fee decisions. Once released, the agency will allow another round of comment before establishing final fees in the 2008 lab fee schedule.

On the physician fee front, Congress is expected to prevent a scheduled Medicare cut of 10% in 2008 and grant a modest increase, but the questions are: "When?" and "How?" A fee fix, plus reduced payments for Medicare managed care plans, is included in the House-passed reauthorization of the popular State Children's Health Insurance Program (SCHIP), which expires September 30. The Senate version is a SCHIP-only bill, with no Medicare provisions.

At press time, House Democratic leaders were signaling they could scrap some or all of the Medicare changes to get SCHIP reauthorized and take them up in other legislation later this year. The compromise may be necessary, observers note, to get enough votes to override the President's threatened SCHIP veto.

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Medicare Bidding Demo, *from p. 1*

says AAB/NILA administrator Mark Birenbaum. The event immediately precedes Lab Institute 2007. Participants will gather at the Crystal City Marriott Hotel (Arlington, VA), where the Institute is being located, for an orientation dinner on October 9, and the next day, go to Capitol Hill for meetings with members of Congress and their staff. AAB/NILA will arrange transportation and appointments. To participate, contact AAB/NILA, 314-241-1445, or at *www.aab.org*.

Nearly 300 community and regional labs from across the country voiced their opposition to the demo in a September 5 letter to House Small Business Committee Chairwoman Nydia Velázquez (D-NY), who introduced H.R. 3453. They expressed strong support for the bill, saying that "rather than creating competition, [the demo] will result in fewer labs, less competition, and the government picking winners and losers. The experiment is scheduled to last three years. However, the impact on local community labs will be long lasting." The letter also warned that nursing home beneficiaries are particularly at risk since the large labs typically avoid this service-intensive market, leaving only local labs to fill the gap.

The bidding demo re-emerged in the political spotlight earlier this year, after months in the shadows inside CMS, when the agency announced a July 16 public forum to discuss a draft bidder's package and unveil the project's timeline (*NIR, 28, 18/Jul 16 '07, p. 1*). That sparked a lab lobbying surge against the project. The Clinical Laboratory Coalition immediately fired off a letter calling on Health & Human Services Secretary Michael Leavitt to stop, and Congress to repeal, the demo. On July 25, lab groups got a hearing before the House Small Business Committee to air their concerns over the demo's impact on small business labs and beneficiaries served by nursing homes and home health agencies (*NIR, 28, 19/Jul 30 '07, pp. 1, 4-6*). Chairwoman Velazquez followed up August 4 by introducing H.R. 3453 to repeal the statutory requirement for the demo. Three days later, the chairman of the House Energy & Commerce Committee, John Dingell (D-MI), raised his own concerns over the demo's impact on lab quality and access in a letter to Secretary Leavitt. And on August 14, Reps. Jim Matheson (D-UT) and Anna Eshoo (D-CA), members of the Energy & Commerce health subcommittee, urged Dingell and health subpanel chairman Frank Pallone (D-NJ) to hold hearings to discuss the demo issues further.

Demo Details for Lab Bidding

- ❑ Scheduled to run for three years in two Metropolitan Statistical Areas within a single state.
- ❑ Covers independent lab services, excludes tests by physician office labs (POLs) and by hospitals for their patients. Outreach and/or non-patient services provided by a hospital or a POL would be covered where the lab is functioning, in effect, as an independent lab.
- ❑ Includes 358 "demo tests," excludes Pap smears, colorectal cancer screening, and tests added to the lab fee schedule during the project.
- ❑ Requires bidders to submit bid prices for all demo tests, whether done in-house or sent to reference labs.

The contractor for the project is Research Triangle Institute, International (RTI).

CMS contends it has made changes to accommodate the above concerns. In testimony at the July 25 hearing, Timothy Love, director of the agency's Office of

Research, Development & Information, said that "to assure that smaller labs are treated fairly in the bidding process," the project would:

- ❑ Choose multiple winners (no winner-take-all).
- ❑ Not require bids from small labs with less than $100,000 in annual Medicare revenue from demo tests.
- ❑ Not require bidders to provide services to the entire demo area.
- ❑ Allow bidders not selected as winners to continue to provide lab services in areas outside the competitive bidding area.

ACLA, CAP Advocate Separate 'Lab Seat' in New E-Health Entity

HHS plans to award a contract this fall to one or more parties to develop and run the AHIC successor entity by the fall of 2008. Leading contenders reportedly include EHI (the Electronic Health Initiative) and NAHIT (the National Alliance for Health Information Technology).

As the Department of Health & Human Services prepares to shift responsibility for development of a nationwide exchange system for personal e-health records to a new public-private partnership, the American Clinical Laboratory Association and the College of American Pathologists are urging that laboratory services be given a separate seat in the entity that will succeed the American Health Information Community (AHIC).

This is a chance to "correct the wrongs of the past," Jason DuBois, ACLA vice president of government relations, told *NIR*. He noted that labs had sought their own representation on AHIC before its primary members were chosen, but in the end were lumped with pharmacy under "ancillary services."

AHIC is a federally chartered advisory committee, formed in 2005, to provide guidance to HHS on how to make health records digital and interoperable, and how to assure that the privacy and security of those records are protected (*NIR, 27, 15/May 22 '06, pp. 4-5*). The charter requires that its responsibilities be transferred to a public-private entity. HHS invited comment on this transfer in an August 2 *Federal Register* notice and issued a final white paper on August 7 describing its expectations for the member-supported partnership.

In comments submitted September 10, ACLA emphasized: "Lab data are the 'keystone' to the medical record—electronic or otherwise. … With 60% of data in medical records derived from lab test results, every community that is trying to launch some health IT infrastructure is looking at labs as the first element they need." Labs also confront unique liability issues that require expertise on CLIA rules and state law that impose restrictions on use and disclosure of protected health information that no other healthcare sector faces, ACLA added.

In its comments submitted September 10, CAP said a separate membership sector for clinical labs, like that proposed for pharmaceuticals and devices, would permit a vital interface with other physicians. "Pathologists have an important perspective and indispensable role to play in identifying what information from diagnostic testing should be included in e-health records and how that information should be transmitted to maximize its use in clinical decision-making."

The AHIC successor entity will include representatives from federal and state governments and from the private sector. But getting some of its costs underwritten by federal departments and agencies like HHS, CMS, CDC, the FDA, and others will be crucial, DuBois said. "It won't have the impact intended if it's just private."

FDA Clarifies Rules for Analyte-Specific Reagents

The FDA also has reopened the comment period on its controversial guidance that would, for the first time, require premarket review of certain lab-developed tests, known as In Vitro Diagnostic Multivariate Index Assays (Federal Register, *September 17). Citing industry requests for more time to submit comments, the FDA has extended the deadline to October 17. The original comment period ended August 27, and CAP and ACLA continued to challenge the FDA's authority to expand oversight in this area* (NIR, 28, 21/ Sep 10 '07, p. 3).

In industry guidance published in the September 14 *Federal Register*, the Food & Drug Administration announced the availability of updated Frequently Asked Questions about commercially distributed analyte-specific reagents (ASRs). A draft of the guidance was issued September 7, 2006.

The latest version clarifies certain ASR rules and "eliminates confusion about particular marketing practices among ASR manufacturers," said the FDA's Center for Devices & Radiologic Health in releasing the revised guidance.

The FDA specifically noted that the guidance is not intended to cover the role of clinical laboratories in developing in-house an array of genetic and other tests. As noted in the guidance, "ASRs are building blocks of lab-developed tests."

The FDA alerts ASR manufacturers to two practices it sees as inconsistent with the marketing of an ASR:

- ❑ Combining, or promoting for use, a single ASR with another product such as other ASRs, general purpose reagents, controls, designated lab instruments, software, etc.
- ❑ Promoting an ASR with specific analytical or clinical performance claims, instructions for use in a particular test, or instructions for validating a specific test using the ASR.

When an ASR falls outside the definition in the rules, the FDA views the product as another type of in vitro diagnostic device (IVD) or device component not covered by the ASR rules and, therefore, not necessarily exempt from premarket requirements.

Major Revisions

In response to public comments on the earlier draft guidance, the FDA said it has revised the document to clarify that:

- ❑ The agency views ASRs as being intended to detect a single ligand or target.
- ❑ Oligonucleotide primer pairs and polyclonal antibodies can meet the definition of an ASR when properly marketed, because they are for the identification of a single target or ligand (*e.g.*, used to detect a single protein, a single nucleotide change, a single epitope).
- ❑ When manufacturers provide labs with information describing use of their product in a specific test, the product would fall outside the definition of an ASR.

The labeling for Class I, exempt ASRs must bear the statement, the FDA says: "Analyte Specific Reagent. Analytical and performance characteristics are not established." Class II or III ASR labels must state: "Analyte Specific Reagent. Except as a component of the approved/cleared test (name), analytical and performance characteristics are not established."

To assist makers of Class II or III IVDs that are currently being inappropriately labeled and marketed as ASRs to come into regulatory compliance, the FDA intends to exercise enforcement discretion with respect to premarket approval and clearance requirements for 12 months.

The revised guidance is on the CDRH Web site at *www.fda.gov/cdrh/oivd/guidance/1590.html*.

California Expands Pathology Direct Billing Law

A California bill that would require direct billing for anatomic pathology services, not just cytopathology, recently passed the state legislature and is currently on the desk of Republican Gov. Arnold Schwarzenegger, who has 30 days to sign or veto the measure. If he does not act by then, the bill automatically becomes law.

Schwarzenegger is expected to sign it, Robert. J. Achermann, executive director of the California Society of Pathologists, told *NIR*, noting that it has broad bipartisan support despite some opposition. The Society led the drive to get the legislation passed, and the College of American Pathologists supported the effort. The bill, SB 661, cleared the California Senate unanimously on September 10 and the Assembly by a vote of 86-2 on September 4.

The bill would prohibit clinicians from billing patients and third-party payers for anatomic pathology services not performed or directly supervised by the clinician. Current state law prohibits direct billing for cytopathology, including Pap smears, and also bars physicians from marking up other clinical lab services.

The definition of anatomic pathology services in SB 661 is consistent with model CAP legislative language, including histopathology, cytopathology, hematology, subcellular pathology, surgical pathology, and blood banking services performed by a pathologist, noted Gretchen Schaefer, CAP's vice president for communications in advocacy, in the September 13 issue of *Statline*.

According to CAP data, 13 states have direct billing statutes for pathology services: Arizona, California, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Louisiana, South Carolina, Tennessee, Iowa, Montana, and Kansas. In addition, six states have anti-markup provisions: California, Florida, Michigan, Oregon, Utah, and Washington. Fourteen states require disclosure of physician charges: Arizona, Connecticut, Delaware, Florida, Louisiana, Maine, Maryland, North Carolina, Pennsylvania, Texas, Vermont, New Jersey, Tennessee, and Utah.

New Acting CMS Chief Pledges 'Even Keel' with Providers

In his first press briefing since being named acting administrator of the Centers for Medicare & Medicaid Services, Kerry N. Weems said he would take a hands-off approach with healthcare providers and other industry partners to dispel any perception that the agency's decisions are slanted toward any one group.

But Weems said little about two highly controversial issues—reauthorization of the State Children's Health Insurance Program (SCHIP) and prevention of scheduled Medicare physician payment cuts. He acknowledged that his was a political nomination and said he expects to be a "spokesman for the Administration for health policy."

Weems was named acting CMS administrator by Health & Human Services Secretary Michael Leavitt on September 5. In appointing Weems, Leavitt said he wanted "solid leadership in place" at the agency that serves millions of Medicare and Medicaid beneficiaries. Having the title of acting administrator gives Weems the same authority as an administrator, noted an HHS spokeswoman.

Weems, a 24-year career veteran with HHS, was nominated as administrator May 3 by the Bush Administration (*NIR, 28, 15/May 21 '07, p. 7*). The nomination is pending in the Senate Finance Committee and requires approval by the full Senate.

Weems Outlines CMS Priorities

During his September 12 press briefing, Weems noted the following priorities for CMS resources:

- ❑ Getting competitive bidding for durable medical equipment on a sound footing.
- ❑ Greater transparency in communications with trading partners.
- ❑ Emphasis on quality via value-based purchasing.
- ❑ Continuing health information technology initiatives in both public and private sectors, particularly affecting personal e-health records.
- ❑ Expanded consumer education through outreach to low-income beneficiaries.

While a strong proponent of e-prescribing, Weems said the agency is "not yet at a point to use the payment system as a measure of coercing it."

The Finance panel held a hearing on the nomination on July 25. Senators from both parties admonished Weems that one expectation they had if he were confirmed in the role is that he mend CMS's relationship with congressional oversight panels by responding promptly and fully to requests for information about provider payment decisions that impact their constituents.

Prior to his nomination, Weems had been deputy chief of staff to Leavitt. An expert in finance, he has served as advisor to several HHS Secretaries and as HHS budget director. Leavitt said Weems' budget credentials will be "a valuable asset to CMS … He understands the large fiscal challenges facing Medicare and Medicaid and what it will take to strengthen and sustain those programs in the future. Further, he has been a leader in HHS's efforts to accelerate adoption of health information technology and better financial management systems."

If confirmed by the Senate, Weems will succeed Mark McClellan, MD, who resigned in October 2006. After McClellan's departure, Leslie Norwalk served as acting CMS head, but she told Leavitt early on she did not want to be considered as a permanent successor and departed in July.

On September 5, Leavitt also appointed Herb B. Kuhn to be permanent deputy administrator at CMS, a post Kuhn has filled in an acting capacity. "Having served nearly a year as acting deputy administrator, as part of the CMS management team for more than three years, and in senior roles in healthcare before that, Herb knows the in-and-outs of Medicare and Medicaid policy," Leavitt said.

Lab Value Educational Campaign Marks More Milestones

Dovetailing with intensified lobbying on Capitol Hill against Medicare's competitive bidding demonstration for laboratory services, the *Results for Life* campaign, spearheaded by the American Clinical Laboratory Association, is moving ahead with its effort to continue to educate lawmakers and the public about the value of lab testing in diagnostic and preventive medicine. One goal is to make lawmakers "think twice" about any further cuts in Medicare fees for lab services.

Results for Life has sent a communication package to staff of members of Congress, explaining how lab tests contribute to quality, cost-effective care. This will be followed, says ACLA's newsletter *Results* in the September issue, by meetings with members, in particular those who have an ACLA member headquartered or a *Results for Life* supporting sponsor in their district. The initiative also continues to recruit and train lab professionals as "ambassadors," ACLA said, to spread the word to decision-makers and community leaders in their locale.

For more on the Results for Life *campaign, go to* www.labresultsforlife.org *or visit the ACLA Web site at* www.clinical-labs.org.

Most recently, Alan Mertz, ACLA president, accepted an award from the National Cervical Cancer Coalition on behalf of ACLA members and the *Results for Life* campaign. The coalition promotes grassroots efforts to educate the public about cervical cancer prevention and outreach. In accepting the award, Mertz said, "I certainly do not have to impress on any of you the value of lab testing. You have firsthand knowledge of the importance of the Pap test and HPV testing, which allow physicians to identify cervical cancer early, thus 'changing the course of disease.'"

ACLA officially rolled out *Results for Life* at a Capitol Hill special event earlier this year, with Rep. Charles Rangel (D-NY), chairman of the House Ways & Means Committee, as a featured speaker. Rangel's panel has key jurisdiction over lab payment and policy issues (*NIR, 28, 12/Apr 9 '07, p. 8*).

The campaign also recently released a new consumer fact sheet pointing to gains in testing children for blood lead levels. Use of a $17 lab test, the brochure noted, has led to a 98% drop in blood lead levels in children over the past 30 years, making this one of the most significant public health achievements of the 20th century.

Lead poisoning destroys brains and causes mental retardation, nerve damage, and reduced IQ, but lab tests allow doctors to identify lead poisoning and stop it. In particular, notes the brochure, the blood lead test has been a key factor in saving the lives and minds of countless youth. By protecting a child from the harmful efforts of lead, their IQ and mental capacity are preserved, allowing for success in school, personal esteem, and employment.

Other lab tests that provide vital information include:

- ❑ Iron deficiency tests that evaluate the level of iron in the blood and the cells of the body. Lead can disrupt absorption of iron.
- ❑ Hemoglobin and hematocrit tests that indicate whether a patient has anemia, which can be caused by iron deficiency.
- ❑ Zinc Protoporphyrin, which evaluates the level of zinc in red blood cells, which can suggest iron deficiency caused by lead poisoning.

Additional brochures in the education series have highlighted the role of lab testing in HIV diagnosis, treatment, and monitoring ("From Killer to Chronic Disease") and in diabetes care management ("Changing the Course of Diabetes").

Dr. Marc Grodman is scheduled to speak about the campaign at Lab Institute 2007 on Saturday, October 13, during the session, "Selling the Value of Lab Services: Defining a Strategic Vision & Direction."

Results for Life is especially important, ACLA president Alan Mertz has noted, as healthcare is being transformed by scientific advances in gene- and protein-based testing. While lab tests make up only a small portion of overall healthcare spending, they influence as much as 60% of the patient's medical record. The initiative is structured as a 501(c)(3) educational entity, facilitating partnering with other organizations, ACLA notes, including Bayer, Roche, Sysmex, the College of American Pathologists, the American Society for Microbiology, and the American Association for Clinical Chemistry, and others are in the wings.

The campaign is important, ACLA board member Marc Grodman, MD, told *NIR* as the campaign was getting underway. Grodman, who is president of Bio-Reference Laboratories, Inc., in Elmwood Park, NJ, noted that the messages are conveyed in real-life stories that can strike a "resonant chord" with legislators and the public. Labs have nothing to apologize for by doing good work, he emphasized, but need to get the "value" message across at the local level and have it filter up to the national scene. Response has been very positive to date, he said.

CMS Releases Quick Guide to Medicare Preventive Services

Be sure you are billing Medicare correctly and getting paid appropriately for laboratory and pathology screening services included as benefits in the Part B preventive services package. To help with this, the Centers for Medicare & Medicaid Services announced that the 2nd Edition of the *Guide to Medicare Preventive Services for Physicians, Providers, Suppliers, and Other Health Care Professionals* is available in downloadable format from the CMS Medicare Learning Network.

The purpose of the updated materials to give clinicians and their staff the information they need in recommending Medicare-covered preventive services that are right for their Medicare patients and in billing Medicare for services furnished.

The 2nd Edition is a comprehensive guide for fee-for-service healthcare providers and suppliers, CMS says, with coverage, coding, billing, and reimbursement information for Part B preventive services.

To view online, go to *www.cms.hhs.gov/MLNProducts/downloads/mps_guide_web-061305.pdf*.

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