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New Senate Bill Boosts Drive Against Lab Bidding Demo

According to the last official word from CMS, a launch of the demo in at least one site is planned for the spring of 2008.

The lobbying campaign to stop Medicare's planned competitive bidding demonstration for independent lab services went into fast-forward late last month when a bipartisan bill was introduced in the Senate to repeal the pilot project. A similar bill was introduced in the House in August.

Both bills respond to concerns raised throughout the lab industry over the negative impact the bidding demo would have on small community labs and the niche markets of vulnerable Medicare beneficiaries they serve, such as nursing home and homebound patients.

The momentum against lab bidding on Capitol Hill has been fueled by swift reaction from national organizations and more than 300 community labs to the July 16 public forum where the Centers for Medicare & Medicaid Services said it was moving forward to launch the project and invited comment on a draft bidder's package (*see box, p. 2*).

The new Senate bill—S. 2099, the Preserving Access to Laboratory Services Act of 2007, introduced September 26—is sponsored by Ken Salazar (D-CO), with co-sponsors Pat Roberts (R-KS) and Maria Cantwell (D-WA). All serve on the Finance Committee, which has jurisdiction over Medicare and the bidding demo. *Cont. on p. 2*

Physician Fee Fix Put Off Till Later This Year

The Medicare physician fee fix and other pathology protections will have to find another legislative vehicle later this year. These provisions, contained in the original House-passed version of the bill reauthorizing the State Children's Health Insurance Program (SCHIP), were dropped from the final compromise measure that Congress sent to the President October 2.

Congressional Democratic health leaders have stated they recognize the need to address the scheduled 10% cut in Medicare payments to physicians as of January 1, 2008. And the Centers for Medicare & Medicaid Services said, in an October 5 *Federal Register* notice, that it expects Congress to step in, as it has repeatedly, to prevent fee cuts from going forward.

The final SCHIP bill approved $35 billion over five years to extend health insurance coverage to up to nine million children in low-income families. It would be paid for by higher tobacco taxes. *Cont. on p. 6*

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Lab Bidding Demo, *from p. 1*

The House counterpart, H.R. 3453, was introduced by Small Business Committee chairwoman Nydia Velazquez (D-NY) on August 4 and had five co-sponsors at press time—Reps. Diana DeGette (D-CO), Charles W. Boustany, Jr. (R-LA), Bart Gordon (D-TN), Jim Matheson (D-UT), and Bruce Braley (D-IA). DeGette, Gordon, and Matheson serve on the House Energy & Commerce health subcommittee, which has jurisdiction over Medicare and the demo.

CMS is developing the demo, in accord with a requirement in the Medicare Modernization Act of 2003. The 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. Under the current demo design, labs serving a demo site and having $100,000 or more in annual Medicare revenue would be required to bid on a range of 358 demo tests, whether done in-house or referred, or risk not getting paid by Part B.

National lab and pathology organizations were quick to applaud introduction of the Senate bill. Dr. Mark Birenbaum, administrator for the National Independent Laboratory Association (NILA) and the American Association of Bioanalysts, said it's a further sign of growing congressional sentiment against the demo.

"Both houses of Congress have made it clear that this government experiment must be stopped immediately before damage is done," he said. The demo "would be nothing but a program to put small labs out of business and lessen the competition for national, publicly traded labs. Rather than creating competition, it will result in fewer labs, less competition, and the government, in essence, picking winners and losers."

The College of American Pathologists, along with the American Society for Clinical Pathology, voiced similar concerns over the fallout on local labs and nursing home and homebound patients.

Medicare Lab Bidding Demo: Push-to-Repeal Timeline

July 16	After months of silence on the demo, CMS holds open-door forum on a draft bidder's package and announces plans to start the demo in the spring of 2008.
July 25	House Small Business Committee holds hearing on the demo's impact on small labs and beneficiary access to Part B lab services.
August 4	Small Business chairwoman Nydia Velazquez (D-NY) introduces House bill, H.R. 3453, to repeal the demo.
August 7	House Energy & Commerce Committee chairman John Dingell (D-MI) asks HHS Secretary Michael Leavitt to respond to specific questions about how the quality of services and beneficiary access will fare under the demo.
August 14	Reps. Jim Matheson (D-UT) and Anna Eshoo (D-CA) request an Energy & Commerce Committee hearing on the demo. Both are members of the committee's health subcommittee.
September 26	Senate bill, S. 2099, to repeal the demo is introduced by Sens. Salazar, Roberts, and Cantwell.

Commenting on the legislative momentum, Pat Lanza, chair of NILA, said: "We hope CMS takes note of the strong congressional action on this vital healthcare issue."

In hailing the Senate action, Alan Mertz, president of the American Clinical Laboratory Association, said, "It's time Congress pulls the plug on this unworkable and unfixable project … and adopts repeal legislation before the demonstration progresses any further … The clinical laboratory fee schedule is the wrong place to be looking for cost savings, given that lab services under Medicare have already been reduced 40% in real terms since 1984. Moreover,

lab services represent only 1.7% of Medicare spending, yet impact 70% to 80% of all medical decisions. Lab services are just what the name implies—services, not commodities. Ironically, the misnamed Medicare competitive bidding demo will mean *less* competition, not more."

Meantime, lab groups don't intend to let up in their drive to stop the demo. AAB/NILA is sponsoring a "March on Washington" on October 9-10 to enable local lab constituents to meet with members of Congress and air their opposition. ACLA is continuing its efforts on Capitol Hill to educate lawmakers and their staff on the value of lab medicine via its *Results for Life* campaign (*NIR, 28, 22/Sep 24 '07, p. 6*).

Coalition Follows Up with CLIAC on CLIA Cytology PT Changes

Questions about accountability and costs that were raised during discussion of CLIA cytology proficiency testing changes at last month's meeting of the Clinical Laboratory Improvement Advisory Committee were answered recently by the Cytology Proficiency Improvement Coalition, which includes 17 national organizations and all 50 state pathology societies.

The Coalition had briefed the panel on September 5 about why the vast majority of the pathology community supports a legislative solution (H.R. 1237) over a regulatory fix, despite what it acknowledged were good-faith efforts by CLIAC to prod CLIA officials to revise the rules (*NIR, 28, 21/Sep 10 '07, p. 1*).

In a follow-up letter to CLIAC on September 27, the Coalition noted, "While we recognize that CMS has instructed [you] that consideration of legislative alternatives is not within the scope of the committee's charter, we believe … several questions raised about H.R. 1237 should be more fully addressed."

The legislation, entitled the Cytology Proficiency Improvement Act of 2007, was introduced in the House earlier this year (*NIR, 28, 10/Mar 12 '07, p. 2; 28, 13/Apr 23 '07, p. 4*). It has bipartisan backing from 87 co-sponsors. (There is yet no Senate counterpart, but the Coalition is lobbying to get one introduced.) H.R. 1237 would:

- ❑ Suspend the current cytology PT program.
- ❑ Substitute a requirement that labs ensure that all individuals involved in screening and interpreting Pap tests participate annually in a continuing medical education (CME) program that tests their locator, recognition, and interpretive skills.
- ❑ Require that the CME program be approved by the Accrediting Council for Continuing Medical Education or the American Academy of Continuing Medical Education.
- ❑ Require the lab to maintain a record of the cytology CME results of each individual. Accrediting organizations will inspect these results during regular lab inspections required by CLIA.

The Coalition assured CLIAC that the requirements of H.R. 1237 do not "diminish" or "disturb" CLIA rules specifying the responsibility of the laboratory, and more specifically, the laboratory director, to ensure the competency of personnel hired to perform gynecologic cytology testing.

"Labs will still have to ensure that each individual who screens and interprets Pap tests is proficient," the Coalition said. "These individuals will still be required to

take part annually in a testing program, and their CME results will be utilized as another tool by the lab director to assess their continuing competence. CME test results will be retained by the lab and will be reviewed during the routine CLIA inspection process." On this point, the letter concludes by noting that the bill "provides assurance that Pap testing competency is carried out in a manner similar to the rest of the clinical lab."

CLIA cytology PT has been highly controversial since CMS began nationwide enforcement of the program in January 2005. Critics say the rules, written in 1992, don't reflect changes in cytology science and practice since then. The process of revising the rules began in 2006, and while CMS says it is still working on changes recommended by CLIAC, it has repeatedly postponed the deadline for publishing a proposed rule.

As to the costs associated with CME vs. current PT requirements, the Coalition said, "One only has to step back and look at the days prior to implementation of the current federal cytology PT requirements when most cytology labs were already participating in a CME program utilizing glass slides to improve their locator, recognition, and interpretive skills. With the introduction of CMS's cytology PT program in 2005, lab program costs in many cases doubled, due to the layering of the new federal program on top of existing CME programs. The Coalition believes that any objective analysis would have to conclude that the federal program has increased costs and that H.R. 1237 will relieve labs of these unnecessary additional costs or, at worst, be cost-neutral."

On the question of CME requirements for lab personnel who interpret slides, H.R. 1237 would apply to all individuals who screen or interpret Pap tests, the Coalition told CLIAC. "To the extent there is ambiguity about cytotechnologists' eligibility for CME vs. CE, this can be easily addressed through a technical correction to the bill, something we would expect to occur as the bill progresses through the legislative process."

The Coalition maintains that the regulatory process is neither a timely nor an effective way to keep up with evolving professional standards. As noted in its previous briefing, "By our projection, the process of revising the cytology PT rules that began in 2006 will likely not be completed until 2009, meaning at least five years will have elapsed since the profession began requesting changes to the regulations in 2004."

In addition to all 50 state pathology societies, the Coalition includes 17 national organizations, among them the American Medical Association, College of American Pathologists, American Society of Cytopathology, American Pathology Foundation, American Association of Bioanalysts, and the American Clinical Laboratory Association.

FDA Clears Genetic Lab Test for Warfarin Sensitivity

Each year in the U.S., two million people start taking warfarin to prevent blood clots, heart attacks, and stroke.

The Food & Drug Administration has cleared for marketing a new genetic test that will help physicians assess whether a patient may be especially sensitive to the blood-thinning drug warfarin (Coumadin), which is used to prevent potentially fatal clots in blood vessels.

One-third of patients on warfarin metabolize it quite differently than expected and experience a higher risk of bleeding. Research has shown that some of the unexpected response to warfarin depends on variants of two genes, CYP2C9 and VKORC1, the FDA noted.

The newly approved Nanosphere Verigene Warfarin Metabolism Nucleic Acid Test detects some variants of both genes, the agency said, approving it for use on the Verigene System, a clinical laboratory test system. Both products are manufactured by Nanosphere Inc., Northbrook, IL.

In announcing the approval in a September 17 statement, Daniel Schultz, MD, director of FDA's Center for Devices & Radiological Health, said, "Today's action offers physicians the first FDA-cleared genetic test for warfarin sensitivity, which is another step in our commitment to personalized medicine. With this test, physicians may be able to use genetic information along with other clinical information to treat their patients."

Warfarin can be a difficult drug to use because the optimal dose varies depending on many risk factors, including a patient's diet, age, and the use of other medications. Rapidly achieving the correct dose is important. Patients who receive doses that are higher than needed to correctly thin the blood are at risk of life-threatening bleeding. Those who receive doses that are too low may remain at risk of life-threatening blood clots. Warfarin is the second most common drug, after insulin, implicated in emergency room visits for adverse drug events.

Labeling Update

In August, the FDA approved updated labeling for Coumadin, the brand name version of warfarin, explaining that people with variations of the genes CYP2C9 and VKORC1 may respond differently to the drug and advising doctors to order genetic testing before prescribing the drug to patients. Manufacturers of generic warfarin are adding similar information to their products' labeling.

Physicians and other healthcare professionals who prescribe warfarin regularly check to see whether the drug is working properly by ordering the prothrombin time test that evaluates the blood's ability to clot properly. The results are measured in seconds and compared with the expected value in healthy people, known as the International Normalized Ratio or INR.

The Nanosphere test is not intended to be a stand-alone tool to determine optimum drug dosage, but should be used along with clinical evaluation and other tools, including INR, to determine the best treatment for patients.

FDA cleared the test based on results of a study conducted by the manufacturer of hundreds of DNA samples as well as on a broad range of published literature. In a three-site study, the test was accurate in all cases in which the test yielded a result; 8% of the tests could not identify which genetic variants were present.

The $35 billion in new SCHIP funding over five years, vetoed by the President, would have been added to the program's baseline funding of $25 billion. Mr. Bush, who sought a $5 billion addition over five years, said he's open to compromise, but Democrats are pushing to override the veto.

Physician Fee Fix, *from p. 1*

The President sought $5 billion instead and on October 3 vetoed the bill as too costly and too expansive of government involvement in healthcare. The legislation has a veto-proof majority in the Senate, but not in the House at press time. SCHIP meantime has been extended till mid-November under a stopgap funding measure.

Medicare provisions dropped from the SCHIP measure would have:

- Spared pathologists and other physicians from a 10% fee cut in 2008 and guaranteed at least a 0.5% increase in 2008 and 2009, costing an estimated $20 million over five years.
- Replaced the current SGR (sustainable growth rate) formula used to calculate annual physician fee updates with a new system of expenditure targets for six categories of physician services. Physician groups have long faulted the SGR for triggering negative updates throughout the decade, and CMS has acknowledged deeper cuts are ahead unless the formula is changed.
- Granted a two-year extension, through 2009, of the "grandfather" protection that allows independent labs to bill Medicare for the technical component (TC) of pathology services to hospital inpatients and outpatients. The protection expires at the end of this year, and CMS is again proposing to eliminate it, on grounds that the TC is reimbursed via the hospital's prospective payment, and the lab should seek payment from the hospital, not Part B. The protection applies to hospital-lab arrangements in effect as of July 22, 1999 (the date CMS first proposed to end separate TC billings).
- Loosened up the Part B preventive services package by eliminating beneficiary cost-sharing and by giving CMS the authority to act on its own, without waiting for Congress, to add to or otherwise change the benefit.
- Reduced Medicare managed care payments to 100% of traditional Part B fee-for-service. The Medicare Payment Advisory Committee told Congress that Medicare Advantage plans get 12% higher pay rates on average than traditional Medicare, but health plan groups disputed this, denying their rates are an overpayment.

N·P·I Update

NPI Registry Delay

The Centers for Medicare & Medicaid Services had announced that the National Provider Identifier (NPI) Registry would be operational September 4 (*NIR, 28, 21/Sep 10 '07, p. 5*). But in a September 24 notice, the agency said the Registry has been taken down due to "a period of instability." At press time, it was still unavailable.

Release of the NPI data, derived from the National Plan & Provider Enumeration System (NPPES), has been long awaited by providers who contend they need access to a centralized database to obtain NPIs and arrange for a smooth exchange of NPIs with trading partners. Otherwise, providers have to collect NPIs by going from one trading partner to another.

CMS said the NPPES will remain working while changes are made, but the Registry will stay down until all changes are made. CMS will announce when the Registry is up. The agency's NPI Web page is *www.cms.hhs.gov/NationalProvIdentStand*.

UPIN Registry 'Look-Up' Period Extended

Between September 3 and October 29, 2007, local Medicare contractors will begin to use edits that would reject claims where a provider's NPI/Legacy pairs don't match the Medicare NPI crosswalk (*NIR, 28, 21/Sep 10 '07, p. 6*).

To help with assuring a match, Medicare has announced that it will maintain the Registry Web site for UPINs (Unique Physician Identification Numbers) and its public "look up" functionality through May 23, 2008 (Change Request 5584, September 14, 2007). The functionality was scheduled to be discontinued September 30 of this year. The Registry is found at *www.upinregistry.com*.

Medicare stopped assigning UPINs last June 29, since UPINs, like other legacy identifiers, will be replaced by NPIs. Under Medicare's fee-for-service NPI implementation contingency plan (guidance issued April 2, 2007), for some time after May 23, 2007, Medicare fee for-service will allow, in addition to NPI-transactions only, continued use of UPINs and surrogate UPINs to identify ordering and referring providers and suppliers. The NPI contingency plan does not affect Medicare's plan to discontinue assigning UPINs and to disable the UPIN Registry and its "look-up" functionality. The effective date for providers to use only the NPI on claims and to cease entering UPINs will be officially announced at a later date, CMS said.

Next NPI Step in Medicare Fee-For-Service Coming in '08

Medicare issued an alert on October 1 to institutional providers that bill fiscal intermediaries (FIs) and A/B Medicare Administrative Contractors (MACs) of an upcoming "next step" in its fee-for-service NPI implementation plan at the start of 2008. The move is prompted by favorable results in the field, Medicare said, noting that the vast majority of institutional provider claims are being sent with an NPI, and the Medicare NPI crosswalk has been in successful operation for all such claims since June 2007.

"Effective January 1, 2008," CMS said, "your Medicare fee-for-service claims must include an NPI in the primary fields on the claim (*i.e.*, the billing and pay-to fields). You may continue to submit NPI/legacy pairs in these fields or submit only your NPI. Claims with only a legacy provider identifier for the primary fields will be returned as unprocessable. You may continue to include legacy only for the secondary fields, if you choose. Failure to submit an NPI in the primary fields will result in your claim being returned as unprocessable, beginning January 2, 2008."

CMS also advised: "If you already bill using the NPI/legacy pair in the primary fields and your claims are processing correctly, now is a good time to submit to your contractor a small number of claims containing only the NPI. This test will serve to assure that your claims will successfully process when only the NPI is mandated on all claims."

The **National Provider Identifier** is one of a series of identifiers required by HIPAA (the Health Insurance Portability & Accountability Act of 1996) to facilitate electronic healthcare data exchange. It replaces all existing legacy provider numbers. As of May 23, 2008, Medicare will recognize only NPIs in HIPAA standard electronic transactions.

CAP, ACLA Urge Public Release of 'Medically Unlikely' Edits

The edits are used by local contractors to weed out claims that exceed MUE limits and automatically reject them.

The College of American Pathologists and the American Clinical Laboratory Association have renewed their call for Medicare to disclose the "medically unnecessary" edits (MUEs) that limit the units of service that can be billed for a particular CPT/HCPCS code per beneficiary per day.

The groups were responding to a request from the Centers for Medicare & Medicaid Services for comment on its policy restricting MUE distribution. The agency has said this is necessary to prevent providers from "gaming" the system. ACLA and CAP said public disclosure is essential if providers are to submit accurate claims and avoid unwarranted denials. Otherwise, providers will not know when to apply an appropriate modifier to bypass the edit, and efforts to educate providers on MUEs and modifier use would be stymied.

ACLA said, "Having full knowledge of the MUEs will allow claims to be submitted per the rules established by CMS … We consider MUEs in the same category as National Correct Coding Initiative edits, which are fully disclosed to the public." ACLA further noted that there is no MUE-specific remark code, so those who process claims and denials will not know an MUE triggered the rejection until they have ruled out all other possibilities.

CLIA Watch

The State of Washington's CLIA-exempt program has been renewed until September 28, 2013, the Centers for Medicare & Medicaid Services announced. The program is run by the State Health Department's Office of Quality Assurance and covered 3,065 labs as of December 2006, according to CLIA data.

The CLIA statute allows states to run CLIA-exempt programs as an alternative to federal oversight if CMS deems the state's program to be equal to or more stringent than the federal CLIA program.

Only one other state, New York, runs a CLIA-exempt program (though some entities are excluded, such as physician office labs). New York covered 2,952 labs as of December 2006, according to CLIA data.

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