



American
Clinical Laboratory
Association

RESULTS

August 2008

SPECIAL EDITION

***CONGRESS REPEALS LAB COMPETITIVE BIDDING, EXTENDS
'TC GRANDFATHER,' AVERTS PHYSICIAN FEE CUTS!
Labs to Receive 4.5% Update in 2009***

President's Message

This is the message I've been looking forward to writing for four years: The Medicare laboratory competitive bidding demonstration is repealed. Dead. Gone!

As most readers know by now, Congress voted overwhelmingly on July 15th to override the President's veto of Medicare legislation that included a total repeal of the laboratory competitive bidding demonstration project. The new law also extended the so-called "TC Grandfather clause" for 18 months and reversed the 10.6% reduction in the Physician Fee Schedule.

While I called the new law a "triple play" for laboratories, I could not use that metaphor for long. The day after the bill was enacted, a fourth win for laboratories occurred when the government announced that the June 30th inflation figure on which the next year's laboratory update is based will be 5%, not the 1.9% we had expected. This means that the Clinical Laboratory Fee Schedule will receive a 4.5% increase on January 1, 2009. [It is .5% less than the full CPI because laboratories took a small reduction in the increase in order to repeal competitive bidding]

The repeal of competitive bidding was one of the most difficult advocacy battles I've witnessed in my nearly 30 years in and around government. Success in this case required not only enacting a bill into law, but actually repealing an existing program that was statutorily required. I can recall only two or three times this has been achieved.

The repeal is the culmination of years of work by the entire laboratory community. In a July 23rd ACLA "LabLine," Jason DuBois and I explained in detail how this "textbook" advocacy campaign was successful. Critically important was strong leadership, a broad-based coalition, effective grassroots advocacy, the development of champions in Congress, and, of course, the lawsuit in San Diego that stopped the project long enough to allow Congress time to repeal it.

There are strong lessons learned from this effort that can be applied to future battles. First, when the laboratory community is focused and works together, we can achieve great results. Also, the broader participation of the laboratory community, including independent, hospital, and esoteric laboratories, and beyond (nursing homes) the more likely we will see success. In addition, the intense advocacy in Congress that educated members of Congress and their staff about the value of laboratory services to patients, and the complexity of laboratory diagnostics, will pay dividends for years to come.

Space does not permit me to list all of the people who deserve thanks for this effort. However, I do want to give a special thanks to the Jason DuBois of ACLA's staff who headed the laboratory community's advocacy in Congress, JoAnne Glisson, David Mongillo, Cheryl Hawkins, Kim Bernet, Peter Kazon, Dean Rosen, and Stacey Rampy from ACLA's staff, counsel and consultants.

And, of course, thanks to ACLA Board of Directors, and ACLA's member companies who supported ACLA and worked so hard with us in repealing this project.

Before I close, a reminder that ACLA has moved to its new offices at 1100 New York Avenue, NW, Suite 725 West, Washington, DC 20005. Our email addresses and telephone numbers stay the same. If you are in Washington, DC, please stop by and see our new digs! The new office is less than a block from our old office. We have an extra office for visitors, and better conference room capabilities.

Medicare Changes a BIG Plus for Labs

On July 15th, critically important legislation for the laboratory community was enacted into law. The new law includes issues of particular importance to the laboratory community -- repeal of the Medicare demonstration project to competitively bid clinical laboratory services, an 18-month extension of the pathology technical component (TC) grandfather provision and positive updates to the Medicare Physician Fee Schedule in 2008 and 2009.

The American Clinical Laboratory Association was a leader with others in the laboratory community in a two year unprecedented advocacy campaign that culminated in the passage of landmark Medicare legislation for laboratories.

Lab Industry Gains From 2008 Medicare Bill

- Total repeal of the competitive bidding demonstration project
- Lab fee schedule updated by 4.5 percent in 2009
- Reversal of 10.6 percent reduction in physician fee schedule
- Extension of TC grandfather clause for 18 months

The following articles best describe the specifics of the Medicare law and ACLA's efforts in having the legislation signed in to law.

Laboratory Industry Report – August 2008

Medicare Bill Delivers 4.5% Lab Fee Update in 2009, Repeals Competitive Bidding Demo

The laboratory industry has multiple reasons to celebrate the passage of the recent Medicare bill, which was pushed through by an overwhelming Congressional override of President Bush's veto, notably the repeal of the competitive bidding demonstration project for lab testing services, the reversal of the 10.6 percent reduction in the physician fee schedule, as well as extension of the technical component (TC) grandfather clause for anatomic pathology services for 18 months. But what may be the most astonishing development is the boost the bill gives to the lab fee schedule, over 4 percent for 2009, explained Alan Mertz, president of the American Clinical Laboratory Association (ACLA) at a July 23 LabLine audioconference.

Throughout their negotiating of the Medicare bill with lawmakers on Capitol Hill, ACLA and other industry leaders agreed to take a half of one percent reduction in the lab fee schedule over five years—which would save the Centers for Medicare & Medicaid Services (CMS) \$600 million—as long as the competitive bidding demonstration project was repealed in the Medicare bill. During the negotiations, it was predicted that the lab fee update would be about 2 percent. With the .5 percent reduction proposed by industry leaders, this would net a 1.5 percent lab fee schedule increase in 2009. “We thought this might give us some level of protection against further cuts in our update—we could say that we’ve already taken a little cut every year,” said Mertz. “This turned out to be a great strategy because the day after competitive bidding was repealed, the Department of Labor put out the inflation statistics, on which they are going to base the update for labs in January, and it’s not 2 percent, but it’s now 5 percent. So we are going to get about a 4.5 percent update in January 2009.”

Challenges Ahead

When Congress initially mandated CMS to conduct a competitive bidding demonstration project for laboratory services, it included a provision known as “conforming language” that gave the agency the authority to rebase the entire fee schedule on bids submitted in the demo, according to Mertz. While this conforming language was repealed in this recent legislation, ACLA is concerned that those bids might be used by CMS in future initiatives, explained the group's chief counsel, Peter Kazon, on the audioconference. “One of the key issues that everyone is concerned about is that the government not be able to use the bids that were submitted as part of the preliminary bid process,” he said adding that attorneys working with labs in San Diego—the first demonstration site—are discussing with the government how to protect this bid information. “We expect there will be some determination of that in early August if not before,” Kazon added.

Another issue is the physician payments, which averted an over 10 percent cut but will continue to be a target, according to another audioconference speaker, Denise Bell, director of federal affairs for the College of American Pathologists. “There have been predictions that over the next 10 years, physicians could see a cumulative cut of about 40 percent in their payment rates, while practice expenses are expected to go up about 20 percent during that same time period,” she said.

National Intelligence Report – July 28, 2008

Labs Score Big With Repeal of Medicare Bidding Demo

For the clinical laboratory industry, it was the long desired outcome of a four-year lobbying campaign. The Part B competitive bidding demonstration for independent clinical lab services was repealed when Medicare legislation (H.R. 6331) became law after Congress overrode the president's veto on July 15. The government had planned to launch the demo July 1 in San Diego, but a court order stopped the project earlier this year.

Repeal of the demo, coupled with the first increase in Medicare lab fees in five years, represents the most significant victory for the lab industry in decades, a Washington insider told NIR.

Labs and pathologists also gained from provisions in the new law that:

- Extend, through 2009, the TC "grandfather" protection that expired July 1. This allows qualified independent labs to continue to bill separately for certain anatomic pathology services to hospital patients.
- Reverse the cut in physician fees that took effect July 1 and replace it with a 0.5 percent increase through the rest of this year and a 1.1 percent increase for 2009.

Lab, Pathology Priorities Enacted After Final Medicare Showdown

Congress this month overrode President Bush's veto of Medicare legislation and enacted major program changes advocated by clinical laboratory and pathology organizations. The changes include a physician fee fix and extension of the "grandfather" protection through next year, plus repeal of the lab competitive bidding demonstration and a delay in introducing competitive bidding for durable medical equipment suppliers. The Medicare Improvements for Patients and Providers Act of 2008 became law July 15. The votes to override the veto were well above the two-thirds required. In the House, the vote was 383-41, with 153 Republicans joining 230 Democrats. In the Senate, the vote was 70-26, with 21 Republicans joining 42 Democrats and two independents.

President Bush has vetoed bills nine times but has been overridden only three times before. The president said he did not oppose the physician fee increase but rejected paying for it in part by reductions in Medicare managed care funding. The reductions target Medicare Advantage indirect medical education payments and include new provider network requirements for private fee-for-service plans, saving \$12 billion over five years, according to Senate Finance Committee estimates.

Competitive Bidding

Competitive bidding has been touted by the Bush administration as a fee-for-service alternative intended to inject more market forces into the Medicare program. For clinical laboratory services, this effort is now at a dead end. The new Medicare law repeals the authority of the Centers for Medicare and Medicare Services to conduct a Part B lab bidding demonstration, as was required under the 2003 Medicare reform law passed by the GOP-controlled Congress. The law also puts a halt on the national rollout of competitive bidding for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), which CMS began July 1. It imposes an 18-month delay in Round 1 involving 10 communities throughout the country and requires a corresponding 18 to 24 months' delay in subsequent rounds. National competitive bidding for DMEPOS was mandated by the GOP-run Congress, following reports of savings this payment method achieved in two pilot projects in Texas and Florida.

Pathologist/Physician Fees

Congress has replaced the cut of 10.6 percent in Medicare physician fees that took effect July 1 under the SGR (Sustainable Growth Rate) update formula with a 0.5 percent increase, retroactive to July 1 and effective through Dec. 31. For 2009, fees will rise an additional 1.1 percent.

The day after the veto override, CMS announced that physicians should begin to receive payment at the 0.5 percent update rate in 10 business days or less, noting that Medicare contractors are working to incorporate the new rates in their payment system. To avoid disruption to claims payment, contractors will continue to process claims that have been on hold on a rolling basis (first in/first out) for payment at the -10.6 percent level, CMS said. After contractors begin to pay claims at the 0.5 percent rate, they will automatically reprocess, to the extent possible, any claims already paid at the lower rates.

Claims with dates of service July 1 and later billed with a submitted charge at least at the level of the Jan. 1 to June 30, 2008 fee schedule amount (reflecting a 0.5 percent increase in effect over that period) will be automatically reprocessed, CMS said. Any lesser amount will require providers to contact their local contractor for direction on obtaining adjustments. Nonparticipating physicians who submitted unassigned claims at the reduced nonparticipation amount also will need to request an adjustment, the agency said. The new law also extends through Dec. 31, 2010, the Physician Quality Reporting Initiative (PQRI), which authorizes bonus payments for reporting on CMS-approved quality performance measures. Moreover, the bonus is increased to 2 percent in 2009 and in 2010. Meantime, CMS has announced that physician bonuses for the 2007 program topped \$36 million and payments should be received no later than August. More than 56,700 physicians and other health professionals satisfactorily reported quality information. The highest incentive totals went to providers in Florida (\$3 million) and Illinois (over \$2 million).

Laboratory Services Reimbursement

For the first time in five years, the Part B lab fee schedule will get a positive update starting Jan. 1, 2009, though it will not be the full

Consumer Price Index update currently projected to be 5 percent. Congress reduced the CPI update to the lab fee schedule by 0.5 percent, for a net gain of 4.5 percent. Also, critical access hospitals serving rural areas will receive 101 percent of reasonable costs for clinical lab services to beneficiaries, regardless of whether the lab specimen was taken in the hospital or off-site at another facility operated by the hospital.

Pathology TC “Grandfather” Protection

The new law extends for 18 months, from July 1, 2008 through Dec. 31, 2009, the “grandfather” provision that allows qualified independent clinical laboratories to bill Medicare Part B separately for the technical component (TC) of anatomic pathology services to hospital inpatients and outpatients. The protection affects hospital-lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end such billings on grounds that the TC is reimbursed as part of Medicare’s Part A inpatient payment and that labs should seek TC payment from the hospital, not Part B. The “grandfather” protection applies to the hospital, not the lab, CMS has noted. Hospitals may switch labs without losing the protection; however, independent labs cannot switch hospitals and still be protected. CMS also has defined the TC of pathology services to include not only anatomic services, but also cytopathology and surgical pathology.

Expanding the Preventive Services Benefit

Until now, coverage of Part B preventive services required an act of Congress, but in the new law, CMS is given authority to cover new services, via the Medicare national coverage decision process, that are recommended by the U.S. Preventive Services Task Force. Moreover, Congress modified the “Welcome to Medicare” physical exam by waiving the deductible and extending coverage from six months to one year after enrollment in Part B.

ACLA Staff

Alan Mertz, *President*

JoAnne Glisson, *Senior Vice President*

David Mongillo, *Vice President for Policy & Medical Affairs*

Jason DuBois, *Vice President, Government Relations*

Cheryl Hawkins, *Membership Coordinator*

Kimberly Bernet, *Executive Assistant*

Peter Kazon, *Legal Counsel*

202-637-9466
www.clinical-labs.org

Calendar of Events

August 7	GeneDx Site Visit	Rockville, MD
August 7	Health IT Data Standards Meeting	Conference Call
August 7	Weekly IOAS Coalition Meeting	Conference Call
August 8	ACLA Weekly Member Call	Conference Call
August 11	CCM Audioconference	Conference Call
August 13	CPT Committee Meeting	Conference Call
August 14	FDA Committee Meeting	Conference Call
August 21	Billing & Reimbursement Committee Meeting	Conference Call
August 21	Weekly IOAS Coalition Call	Conference Call
August 22	Results for Life Committee Meeting	Conference Call
August 26	Ionized Calcium Meeting	TBD
August 29	ACLA Weekly Member Call	Conference Call

Please note ACLA's new address:

**ACLA
1100 New York Avenue, NW
Suite 725 West
Washington, DC 20005**

**202-637-9466 (phone)
202-637-2050 (fax)**

www.clinical-labs.org