



RESULTS

American Clinical Laboratory Association

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President's Message

Advocacy takes patience.

I was reminded of this principle this month when the HHS Office of Inspector General (OIG) withdrew its so-called "excessive charges" proposed rule. I had been on the job at ACLA less than three months in September 2003 when the rule was proposed. At that time, ACLA was already fighting a mighty battle to defeat the Medicare laboratory co-pay in Congress.

Back in 2003, ACLA led the efforts to oppose the OIG rule. We marshaled our membership, conducted an important survey, reached out to other health care providers impacted by the proposed rule, met with the OIG office, and developed detailed comments raising objections.

Now, almost four years later, some of those same concerns we raised were cited by the OIG in withdrawing the proposed rule.

Will we be writing a similar story four years from now about the Medicare laboratory competitive bidding demonstration project? I cannot predict the outcome. This is our most difficult battle ever.

It can take years of work to turn the giant ship of government in a different direction. On competitive bidding, we will have met many times with every member of Congress on key committees, organized dozens of grassroots lobbying campaigns, had studies done, met with CMS, reached out to interests beyond laboratories, and employed many other tactics. And then, we will do all of these things time and time again.

In this edition of Results, we discuss the many other issues with which ACLA is engaged, including Results for Life, MUEs, Health IT, and ABNs. We expect the proposed Physician Fee Schedule rule to be issued in July and will be watching for this important announcement.

OIG Withdraws "Substantially in Excess" Proposal

On June 18, the HHS Office of Inspector General (OIG) announced in a Federal Register notice that it was withdrawing its 2003 proposed rule interpreting the substantially in excess provision of the Social Security Act. The OIG stated that it did not have sufficient information to establish a single, fixed benchmark that would serve as a "bright line standard." The OIG also expressed its concerns that implementing the rule might increase healthcare costs for other payers. However, it would continue to evaluate billing practices on a case by case basis and "use all tools available to OIG to address instances where Medicare or Medicaid are charged substantially more than other payers, without good cause."

ACLA strongly opposed the proposed rule, met with OIG representatives after the proposed rule was issued to discuss the issues it created, and formed a coalition of other laboratory organizations and other providers opposed to the proposed rule. ACLA also commissioned a survey of ACLA members comparing reimbursement by third party payers versus Medicare and Medicaid that found that Medicare and Medicaid pay less on average for laboratory testing than other comparable third party payers.

Competitive Bidding Update

The clinical laboratory industry's push to repeal the demonstration project to competitively bid laboratory services in Medicare has been making some progress. First and foremost, ACLA has been meeting with congressional staff to pursue a hearing in three different congressional committees to raise awareness about the demonstration project. The committees under consideration are the House Small Business Committee, the House Energy and Commerce Subcommittee on Health, and the

RESULTS is a monthly report to ACLA member companies

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Senate Special Committee on Aging. A hearing in any one of those committees could happen as early as July.

ACLA continues to hold meetings with Members of Congress in potential MSA areas to pursue a sponsor of legislation to repeal the demonstration project in the House and Senate. ACLA is also working with Member's offices to include legislative language to repeal the demonstration in bills being considered in the House and Senate to reauthorize the State Children's Health Insurance Program (SCHIP). In the Senate ACLA and the Clinical Laboratory Coalition have been working with Members of the Finance Committee in potential MSA areas for the competitive bidding demo, including Senators Maria Cantwell (D-WA) and Ken Salazar (D-CO).

SCHIP provides a capped amount of funds to States on a matching basis for Federal fiscal years 1998 through 2007. Federal payments to states will stop unless the program is reauthorized by Congress before October 1, 2007, the beginning of the 2008 fiscal year. The Senate Finance Committee and the House Energy and Commerce & Ways and Means Committees have been drafting legislation to address the issue. A mark-up of the SCHIP bill is expected in the Senate Finance Committee as early as the week of July 9th.

ACLA Urges "Status Quo" on Medicare Laboratory ABN

In comments filed with the Office of Management and Budget on June 25, ACLA urged OMB to reject CMS' proposal to replace the existing Advance Beneficiary Notice of Noncoverage for laboratory services (ABN-L) with a new ABN form to be used for laboratory services. ACLA argued that CMS has provided no justification for eliminating the existing ABN-L that was specifically developed with input from beneficiaries, laboratories and physicians. ACLA contended that replacing it with a new form without justification will result in confusion for beneficiaries and physicians who are familiar with ABN-L as well as substantial and unnecessary costs for laboratories to implement the new form. Other laboratory organizations have also provided com-

ments to OMB urging, at the very least, that the existing ABN-L be retained.

CMS had initially proposed to eliminate all provider specific ABNs and replace them with a single, generic ABN. ACLA met with CMS officials in April to convince them that a generic ABN would not work for laboratory services and advise them of our long history working with CMS to develop the ABN-L that is now in use. ACLA asked that, even if they chose to replace the general ABNs, that they retain ABN-L. Apparently, CMS recognized the need for a laboratory ABN, but, rather than retain ABN-L and without further justification, chose to provide a completely new optional lab ABN form.

Results for Life Launches Ambassador Program

The *Results for Life* campaign, which highlights the value of laboratory services, has added a new dimension to its outreach activities. An active effort is underway to recruit and train laboratory professionals to communicate the key messages of the *Results for Life* program to decision makers and community leaders within the Ambassador community.

Results for Life will recruit Ambassadors at national laboratory professional meetings such as the Executive War College, the AACC Annual Meeting, and the G-2 Institute. Volunteers will be asked to participate in a brief telephone conference training program to gain familiarity with the key *Results for Life* messages as well as the print materials, power point presentation, DVD and web site. All *Results for Life* communication tools will be available to the Ambassador.

We will ask the Ambassador to try and hold at least one educational session at their laboratory promoting the *Results for Life* campaign and message. We will also look for feedback about how well the topic was received by the audience and for suggestions for program improvement. Volunteers who complete the training program will be recognized with a certificate and be listed as an Ambassador on the *Results for Life* web site.

Look for more information about the program and the sign-up form which will be posted on the *Results for Life* web site – www.labresultsforlife.org.

Phase V MUEs Under Review

CMS has initiated a complete review of all CPT/HCPCS codes to determine the maximum units of service that a provider would report for a code for a single beneficiary on a single date of service. An example for laboratory coding is an MUE of 4 for CPT code 82784 – Gammaglobulin; IgA, IgD, IgG, IgM, each. The review is being implemented in quarterly phases. CMS is not publishing the final MUE list but did publish CMS Change Request 5495 that describes the quarterly update process at <http://www.cms.hhs.gov/transmittals/downloads/R1202CP.pdf>.

ACLA's CPT Committee most recently submitted comment on over 250 laboratory codes in Phase IV and identified over 60 codes for which ACLA proposed an alternative, higher MUE. In all cases the alternative was supported by a clinical or coding justification. ACLA is waiting for a response to the comments.

On June 15, ACLA received the proposed MUEs for Phase V for review and comment. The proposed MUE file contains 173 pathology and laboratory services codes for review. ACLA will submit comments by the August 17 deadline. Phase V edits are scheduled to be implemented in January 2008.

As future phases of MUEs are released over the next year, ACLA will continue to ensure that input from the laboratory community is fully considered.

ACLA LabLine on Gene Patents for Laboratory Tests

ACLA's continuing series of audio conferences presented the topic "Gene Based Patents for Clinical Laboratory Tests: Why You Should Care" on June 21st. Two leading experts presented their views. Dr. Debra Leonard, Vice Chair of Laboratory Medicine at Weil Cornell Medical College, and Claire Driscoll, the Director of the National Human Genome Research Institute (NHGRI)'s Technology Transfer Office at NIH, provided the participants with interesting and timely information.

Recently there has been renewed interest in the topic of gene based

patents. In early 2007 Congressmen Xavier Becerra (D-CA) and Dave Weldon (R-FL) introduced legislation (H.R. 977) that would prohibit the patenting of human genetic material. In addition, the Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health and Society is finalizing a report on the impact of gene patents on clinical practice. There have also been articles on the subject in some nationally prominent newspapers.

Both presentations provided insight as to who is patenting genes and how gene patents interact with clinical laboratories ability to perform genetic tests. The impact of exclusive licensing and excessive royalties was discussed as was the recognition that the investment of resources needed for research and discovery would not occur but for the financial incentives and market protections of the patent system. A number of possible legal, policy and other options were presented that are aimed at ensuring that clinical laboratories are allowed to continue to provide these important diagnostic services without appreciably changing the patent laws. A CD of the program is available by contacting CherylHawkinsatchawk@clinical-labs.org.

Please look for the next ACLA LABLine offering.

ACLA Part of New York State Kidney Disease Prevention Task Force

ACLA was invited to be a member of a newly formed New York State Chronic Kidney Disease Task Force. The Task Force is charged with developing a New York State strategic plan for chronic kidney disease detection, control and prevention to be coordinated by the New York State Department of Health.

The first meeting on June 22 was an opportunity to share ideas and concepts on how best to bring visibility to this serious health problem. There was full recognition of the important role the clinical laboratories can and do play in identifying individuals at risk of chronic kidney disease. It was suggested that a clinical laboratory sub-group be formed to provide more insight as to how labs can pro-

mote interventions that can prevent chronic kidney disease progression and complications. Follow up meetings of the Task Force are planned.

ACLA to Present at Annual Fee Schedule Meeting

ACLA will present pricing recommendations to the CMS for new lab codes in 2008 at the July 16 public meeting. The objective of the meeting is to receive recommendations from clinical laboratory, pathology, and other interested parties on how to price the new codes using one of two approved methods—crosswalk or gap-fill.

Crosswalk is the process used to link payment for a new test to a similar existing code and pay at that code's rate. Gap-fill is a method used when there is no comparable existing test. Local carriers set the fee for the first year then CMS sets a fee for the following years.

The July 16 meeting can be accessed by telephone conference call by dialing 888-889-1954 and using conference pass code "AMBULATORY S." Registration is not required for audio listening. The public forum will run from 10 a.m. to 2:00 p.m. Eastern time.

The list of new codes can be found on the CMS web site at <http://www.cms.hhs.gov/ClinicalLabFeeSched/Downloads/ClinicalLabMeeting71607.pdf>.

Health IT Update – No ICD-10 in HELP Committee Bill

On June 26, the Senate Committee on Health, Education, Labor and Pensions approved the "Wired for Health Care Quality Act" (S. 1693). Chairman Edward M. Kennedy (D-MA) and Senators Mike Enzi (R-WY), Hillary Clinton (D-NY) and Orrin Hatch (R-UT) are the bill's sponsors. The legislation creates a series of funding mechanisms to encourage the adoption of qualified health IT to improve the quality and efficiency of care. The bill also creates a demonstration program to integrate qualified health IT in the clinical education of health professionals and encourage the use of decision support software to reduce medical errors. The bill establishes a public-private partnership, known as the Partnership for Health Care Improvement, to provide recommendations to the Secretary regarding technical aspects

of interoperability, standards, implementation specifications, and certification criteria for the exchange of health information. Importantly, the legislation does not include a provision mandating transition to ICD-10.

ACLA has been working with groups including the American Medical Association and the Blue Cross Blue Shield Association to oppose efforts to include legislative language mandating a rapid transition to ICD-10. A copy of a coalition letter sent to Health and Human Services Secretary Michael Leavitt is available at the ACLA web site – www.clinical-labs.org.

ACLA Asks CMS to Continue Issuing UPINs During NPI Transition

On June 27, ACLA wrote to CMS Administrator Leslie Norwalk urging the agency to rescind Change Request 5584 and continue to issue UPINs and maintain access to the UPIN registry through May 23, 2008. CR 5584 would discontinue issuance of new UPINs after June 29, 2007, and close the UPIN registry on September 30, 2007. Because many health plans and clearinghouses that have used UPINs are not able to process NPIs at the present time, failing to issue UPINs will create a "provider identification gap" that will complicate administrative transactions. ACLA suggested that the registry be maintained until May 23, 2008, with the stipulation that a UPIN only be issued if the provider has obtained an NPI. We also asked that the UPIN registry be accessible through May 23, 2008 since the registry is the most efficient tool currently available to gather information required for electronic billing.

During a conference call with CMS officials on June 29, ACLA learned that, through May 23, 2008, Medicare will permit laboratories to use surrogate UPIN OTH000 as the qualifying number for physicians that have not obtained NPIs, are unable to obtain UPINs because of the June 29 issuance cutoff, or in instances where clearinghouses are unable to process NPIs. CMS also stated that they are seriously considering maintaining access to the UPIN registry after September 30, 2007.

ACLA in the News

National Intelligence Report - June 11, 2007

Genetic Testing Study Approved in Senate FDA Bill

“Neither of two genetic testing oversight bills got on the fast track as the Senate took up legislation reauthorizing Food & Drug Administration user fees for drug and device makers. But the final measure the Senate passed by a vote of 93 to 1 (S. 1082) included an amendment calling for an Institute of Medicine study to assess the safety and quality of genetic testing and to make recommendations to improve federal oversight and regulation of such tests. The amendment mirrors a provision in the bill that Sen. Barack Obama (D-IL) introduced. **But as Jason DuBois, vice president for government relations at the American Clinical Laboratory Association explained to NIR, it was modified at the request of the office of Sen. Orrin Hatch (R-UT) to focus the study on the ‘overall safety and quality of genetic tests.’ It also requires that the study ‘take into consideration relevant reports by the [HHS] Secretary’s Advisory Committee on Genetic Testing and other groups.’”**

National Intelligence Report - June 25, 2007

MUEs Moving Ahead, But Without Advisory Panel

“Medicare is set to implement Phase III of its controversial ‘medically unlikely’ edits (MUEs) of Part B claims, including claims for pathology and laboratory services, on July 1 and has already gotten comments on Phase IV to begin October 1... In comments on Phase IV proposed edits, **the American Clinical Laboratory Association and CAP** noted that certain methodology CPT codes, not analyte-specific, and pathology consultation codes should not be subject to any MUE. Many of these codes are used to detect antibodies of infectious agents, and as ACLA noted, CPT guidelines specify: ‘When multiple tests are done to detect antibodies to organisms classified more precisely than the specificity allowed by available codes, it is appropriate to code each as a separate service.’”

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Laboratory Economics - June 2007: Volume 2, Number 6

What’s this Mean for Competitive Bidding for Lab Services?

“... **Alan Mertz, president of the American Clinical Laboratory Association**, thinks CMS may soon release the final design and demonstration site for the lab competitive bidding project ACLA’s lobbying efforts to repeal the demonstration project have been focused on House and Senate members in those states.”

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Senate Bills Call for Oversight Of Laboratory-Developed Tests. Could New Requirements Overwhelm Labs and the FDA?

“Both of these bills, in particular Sen. Kennedy’s bill, are significant for the lab industry, because they have the potential to bring laboratory-developed tests to a level of regulation that they have never been subject to before,” explained Peter Kazon, an attorney with Alston & Bird LLP (Washington, DC), who specializes in laboratory testing regulation. He spoke at an April 3rd audioconference, “Sens. Kennedy and Obama Introduce Legislation on Laboratory Developed Tests,” sponsored by **the American Clinical Laboratory Association (ACLA)**.”

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Calendar of Events

July 6	ACLA Member Weekly Call	Conference Call
July 9	Clinical Laboratory Coalition Meeting	Washington, DC
July 12	Fundraiser: Senator Ken Salazar (D-CO)	Washington, DC
July 13	ACLA Member Weekly Call	Conference Call
July 13	ACLA Board of Directors Meeting	Conference Call
July 16	CMS Laboratory Public Meeting: <i>Payment for New Clinical Laboratory Tests for 2008</i>	Baltimore, MD
July 18	ACLA CPT Committee Meeting	Conference Call
July 19	ACLA Billing and Reimbursement Committee Meeting	Conference Call
July 20	ACLA Member Weekly Call	Conference Call
July 27	U.S. House of Representatives Health Fair	Washington, DC
July 27	ACLA Member Weekly Call	Conference Call
July 27	ACLA PR Committee/Results for Life Committee Meeting	Conference Call
