



# RESULTS

## American Clinical Laboratory Association

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RESULTS is a monthly report to ACLA member companies

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For more information regarding ACLA, please call 202-637-9466, or visit our website - [www.clinical-labs.org](http://www.clinical-labs.org)

### President's Message

This is my first report as President of ACLA after beginning my new role on June 2nd. I am excited about my new responsibilities and, thanks to ACLA's members and staff, have been able to hit the ground running.

We've already made progress in "taking ACLA up a notch" to effectively meet the tremendous challenges facing our industry. On several fronts – keeping the copay provision out of the House Medicare bill, creation of an ACLA-led provider coalition on the HIPAA Transaction Rule, meeting with Secretary Thompson on ACLA's key issues – we've had a successful and productive month.

If there was any doubt about the challenges facing our industry in Congress, the lab copayment provision in the Senate Medicare bill was a wake up call. It's been all hands on deck in our fight to keep a lab services copay out of the Medicare bill. Our efforts paid off as we were able to keep the provision out of the House-passed Medicare bill – critically important because had the House and Senate gone to conference with it in both bills it would have been virtually a "done deal." We have now shifted our focus to the House-Senate Conference Committee. This issue is our top priority. A full report on this battle follows the President's Message.

ACLA also has now created an effective provider coalition on another key issue for ACLA members, avoiding the potential disruption that could occur in October as a result of the HIPAA Transaction Rule. For the first time, all of the key provider groups are working together on the issue, issuing a joint letter to Secretary Thompson, and meeting with the key officials at CMS.

There are many other important issues we are working on, including competitive bidding (at the Federal and state levels), the FDA oversight issue, and others.

ACLA also had a timely and important Board meeting on June 26<sup>th</sup> which gave us an excellent opportunity to plan our strategy opposing the copay provision, as well as discuss moving ACLA "to the next level." The Board also spent the afternoon meeting with key members of Congress and staff, primarily on the copay issue.

We've expanded this edition of "Results" so we can more fully report on ACLA's activities. In the near future, we will be transforming "Results" into an electronic version that will be more informative and timely.

Again, I'm excited to be on board and look forward to working with all of you. Please do not hesitate to contact me if I may be of assistance.

**Alan Mertz**

### **Opposing Lab CoPay**

The Senate-passed version of the Medicare Rx legislation includes a 20% copayment on laboratory services. The provision was included almost entirely for budgetary reasons – it "pays for" more funding for rural health care providers.

ACLA has taken the lead in opposing this provision, and was instrumental in keeping the provision out of the House-passed Medicare bill. Keeping the provision out of the House bill was critically important because if the same provision is in both House and Senate bills it is generally a "done deal" and not subject to consideration in a House-Senate Conference.

ACLA took immediate action including:

- More than two dozen meetings be-

tween ACLA and key members of Congress and their staff

- Numerous meetings between ACLA member company CEOs and members of Congress and staff
- Development of data gathered from ACLA members to support ACLA's arguments and advocacy materials
- Creation of new advocacy one-pagers and other materials
- Contracting with Denise Henry with Strategic Health Solutions to assist in lobbying key members of Congress and staff
- Taking a leadership role with the clinical lab coalition
- Organizing positive advertising campaign to solidify support of key House members

ACLA is now focusing on the nine Senators appointed as conferees on the bill, and will continue working with those appointed from the House.

At press time for this report, it appears that the House-Senate conference committee will not come to any agreement on the Medicare bill this summer. Most likely, deliberations will drag on into the fall. However, ACLA will be lobbying aggressively throughout the summer to defeat the provision.

## **ACLA Takes Lead On HIPAA**

The coming October 16 compliance deadline for the HIPAA Transaction Rule is of serious concern to ACLA members as it could result in disruptions in processing and paying claims. To avoid such an outcome, ACLA has taken the lead in bringing these potential problems to the attention of HHS and CMS and making recommendations for actions they can take.

ACLA created and chairs a new provider coalition that includes some of the largest provider groups including the American Hospital Association, American Medical Association, Federation of American Hospitals, and the American Health Care Association (nursing homes). Members of the coalition have agreed on a set of principles for avoiding disruption in the health care system, signed a group letter to Secretary Thompson making specific suggestions for HHS/CMS action, and recently met with the top HIPAA officials at CMS who are overseeing the Transaction Rule implementation.

In the coming weeks, ACLA and the coalition will meet with the payer community and on a continuing basis with CMS on this problem. The Coalition is meeting weekly to try to avert disruption in October.

Thanks to ACLA's members for their active participation in this effort.

## **Successful Meeting with Secretary Thompson**

ACLA staff and representatives from ACLA member companies (Kenneth Freeman and Charles Silverman – Quest Diagnostics Incorporated; Brad Smith and Hawazin Faruki – Laboratory Corporation of America; Thomas Kosco – Specialty Laboratories, Inc.), had a very productive meeting with HHS Secretary Tommy G. Thompson on July 2<sup>nd</sup>. The Secretary invited senior staff to join this meeting to ensure clear communication of our issues and concerns, and to facilitate action being taken. They were: Dr. David Fiegel, Director of the FDA's Center for Diagnostics and Radiological Health (CDRH), and his Deputy, Dr. Steven Gutman; Don Shriber, Director of the CDC's Washington, DC Office; and Jared Adair, CMS's Director of HIPAA Standards.

ACLA discussed three topics of importance to the clinical laboratory industry: 1) improving the opportunities for independent clinical labs to collaborate with public health efforts to respond to threats posed by emerging biologic agents and bioterrorism; 2) request for relief from regulations and deadlines imposed for implementation of uniform "transaction codes" required under HIPAA; and, 3) ensuring collaboration with the development of revised regulations of ASRs (analyte specific reagents) by the FDA.

This meeting was pivotal — it provided a venue for the Secretary to learn more about the clinical laboratory industry and its role in quality health care, and gave us an opportunity to have input to the development of regulatory and payment policies at the highest levels of government.

The Secretary directed his staff to follow up on several "action items" to address our issues and/or concerns. The Secretary said he agreed that HHS should collaborate with ACLA on public health issues and directed that ACLA set up a meeting with the head of the CDC. The Secretary also asked CMS to meet with ACLA on the HIPAA issue.

## **Opposing Competitive Bidding**

The House-passed Medicare prescription drug legislation includes a provision requiring HHS to conduct a competitive bidding demonstration project for clinical laboratory services, other than those services provided by physician office laboratories. The Senate bill does not include any competitive bidding provisions. ACLA has, in face-to-face meetings with members of Congress and staff, expressed our opposition to competitive bidding. If the provision remains in the compromise version, ACLA has prepared report language to provide to committee staff that elaborates on the conditions for awarding any demonstration project and the items that should be included in evaluations of the project. ACLA is also becoming more active in opposing competitive bidding proposals in state Medicaid programs.

## **New Jersey Medicaid Visit**

On June 16, 2003, ACLA and representatives of ACLA member companies met with officials of the New Jersey Medicaid program to discuss the physician signature requirement and reference laboratory payment issues. We were concerned that the state remains unwilling to eliminate the requirement for an original physician signature as a condition for reimbursement. With the vast majority of Medicaid beneficiaries enrolled in managed care and most of the remaining fee-for-service enrollees Medicare dual eligibles whose lab services are paid by Medicare, which does not require signatures laboratories will find it even more difficult to remind physicians that New Jersey Medicaid – alone among payers – requires original signatures.

Changes were completed more than a year ago to the New Jersey Medicaid Management Information to allow a billing laboratory to directly request Medicaid payments for testing performed by an authorized laboratory within the same corporate structure. Providers were not told of the new policy. We asked them to provide us with written instructions for billing both

paper and electronic claims for reference testing in the form of a provider news-letter or alert.

## **CAP Genetic Test Coding Workshop**

ACLA participated in the first “in person” meeting of the Genetic Testing Workgroup in Chicago, on June 17<sup>th</sup>. ACLA reviewed the results of our efforts over the past year, via teleconference, to develop an approach to coding genetic tests that could accommodate the growing number of such tests, and at the same time provide payers with sufficient information to establish coverage policies. ACLA proposed that instead of using CPT categories I, II, or III, or HCPCS codes, we use CPT modifiers, based on a new numeric-alpha system. This could denote gene type and mutation, thus providing the “granularity” needed while retaining the use of the procedure-based nomenclature system. The workgroup endorsed this alternative approach and under the leadership of Dr. Mark Synovec will develop a proposal for the CPT Editorial Panel to consider at their meeting in November of this year.

## **ANNOUNCEMENTS**

### **ABN Brochure**

A revised version of ACLA's ABN Brochure, "Answers to Important Questions About Changes in Medicare Coverage of Laboratory Testing," is now available. For details, contact Cheryl Hawkins at 202-637-9466.

### **Electronic Results**

Future issues of Results will be mailed electronically. Please provide your e-mail address to Cheryl Hawkins at [chawk@clinical-labs.org](mailto:chawk@clinical-labs.org).

## AMERICAN CLINICAL LABORATORY ASSOCIATION

### **Lab Co-Pays Hurt Beneficiaries and Laboratories**

The proposal to charge Medicare beneficiaries a 20 percent copayment for laboratory services will shift costs to seniors, and further reduce reimbursements to clinical laboratories because of the high administrative costs of billing and collecting the co-pays.

- **Co-Pay Adds Billions To Beneficiary Costs**

A 20% co-pay would add billions of dollars to the ever-growing out-of-pocket costs borne by Medicare Beneficiaries. Seniors would pay either through direct payment of the copayment, or through higher medigap premiums.

- **The Added Administrative Cost of Billing and Collection Of Co-Pays Would Represent A Sizable Cut In Laboratory Reimbursement**

The administrative cost of billing and collecting lab co-pays is sizable – an estimated \$5 per claim if the beneficiary does not have supplemental coverage and \$2 if the beneficiary does – and would mean a net reduction in clinical laboratory reimbursement rates. Regardless of the total amount of the claim, laboratories will incur a fixed cost of collecting the co-pay. Medicare reimbursement rates do not account for such costs. In fact, clinical laboratories have seen their annual Medicare Part B CPI update reduced or eliminated in 11 of the past 18 years.

- **The Vast Majority of Private Sector Health Plan Arrangements Do Not Require Labs to Collect Co-Pays**

97% of private health plans in the under-65 market do not require laboratories to bill or collect copayments because of the administrative costs of doing so, and because the customary rationale for charging copays – to effect utilization – is not applicable to lab tests.

- **In 2000, The Institute Of Medicine Argued Against Requiring A Co-Pay For Outpatient Lab Services**

The Institute of Medicine (IOM) stated in its December 2000 report, Medicare Laboratory Payment Policy, Now and in the future, “(t)he current policy of not requiring beneficiary cost sharing for Medicare outpatient clinical laboratory services should continue. Cost sharing is unlikely to significantly reduce overuse or increase the detection of fraud and abuse; it could create barriers to access for the most vulnerable Medicare beneficiaries; and it would be financially and administratively burdensome for laboratories, patients, and the Medicare program depending on its design.”

- **Labs Have Paid More Than Their Fair Share**

Labs have seen their annual CPI update reduced or eliminated in 11 of the past 18 years. The ceiling on payments for each lab test has been reduced systematically over the past 18 years so that lab testing is being reimbursed at a lower level today that it was ten years ago. In fact, the 2003 Medicare Trustees' Report states that the estimated per beneficiary spending for 2003 of \$88.62 is less than the \$92.30 spent per beneficiary in 1993.

July 11, 2003

Dear Chairman Grassley:

I am writing on behalf of the American Clinical Laboratory Association (ACLA) which represents the leading national and regional clinical laboratories. ACLA strongly urges that the provision in the Senate version of the Prescription Drug and Medicare Improvement Act charging beneficiaries a 20 percent copayment for laboratory services not be included in the final conference bill.

First, the added administrative cost of billing and collecting copays from seniors would be, in many cases, as much or more than the amount collected. For our members, the typical copay per claim would be an estimated \$7. The administrative cost of billing and collecting each of these \$7 copays could range from \$5 for some of our larger members, to as much as \$15 or more for our smaller, regional/rural labs.

Moreover, these new administrative costs for billing and collection of the copay would represent a sizable cut in laboratory reimbursement. Medicare reimbursement rates do not account for such costs and, in fact, laboratories have seen their annual Medicare Part B CPI update reduced or eliminated in 11 of the past 18 years. Reimbursement rates have declined such that the estimated per beneficiary spending for lab tests in 2003 is *less* than it was in 1993 (\$88.62 v. \$92.30, respectively).

Also, the vast majority of private sector health plan arrangements (97%) do not require labs to collect copays because of the administrative costs of doing so, and because the customary rationale for charging copays – to effect utilization – doesn't apply. Patients don't order lab tests, their doctors do.

The Institute of Medicine looked at this issue as part of a 2000 report, concluding that copayments for lab services should not be required under Medicare.

Again, ACLA strongly urges that the lab services 20% copay provision not be included in the final Medicare legislation.

Sincerely,

Alan Mertz  
President

[Letter sent to all Senate Medicare Conferees]

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## Calendar of Events -- July 2003

<b>July 1</b>	ESRD Committee Meeting at CMS	<i>Baltimore, MD</i>
<b>July 2</b>	Meeting with HHS Secretary Tommy Thompson	<i>Washington, DC</i>
<b>July 8</b>	Meeting with Doug Badger, Assistant to President Bush	<i>Washington, DC</i>
<b>July 8</b>	Meeting with Jared Adair, Director of HIPAA Standards at CMS	<i>Baltimore, MD</i>
<b>July 10</b>	CPT Committee Meeting	<i>Washington, DC</i>
<b>July 10</b>	Billing Committee Meeting	<i>Washington, DC</i>
<b>July 10</b>	FDA IVD Roundtable Meeting	<i>Washington, DC</i>
<b>July 10</b>	Health Care Liability and Access Coalition (HCLA)	<i>Washington, DC</i>
<b>July 11</b>	HIPAA Transactions Coalition Meeting	<i>Washington, DC</i>
<b>July 12</b>	HIPAA Privacy Hill Briefing	<i>Washington, DC</i>
<b>July 14</b>	FDA SARS Meeting	<i>Rockville, MD</i>
<b>July 17</b>	CLIA Agenda Planning Meeting	<i>Atlanta, GA</i>
<b>July 17</b>	Quality Institute Steering Committee Meeting	<i>Atlanta, GA</i>
<b>July 18</b>	ESRD Committee Meeting	<i>Washington, DC</i>
<b>July 18</b>	CMS ESRD/Lab Open Forum	<i>Baltimore, MD</i>
<b>July 18</b>	HIPAA Transactions Coalition Meeting	<i>Washington, DC</i>
<b>July 28</b>	CMS Meeting on New Test Payment Determinations	<i>Baltimore, MD</i>
<b>July 31</b>	National Exploring Health Careers Exposition	<i>Bethesda, MD</i>

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