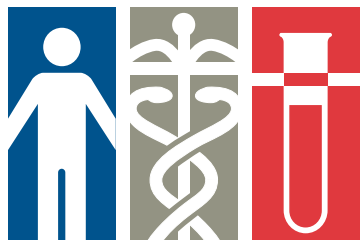


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# RESULTS

American Clinical Laboratory Association

## Lab Co-Pay: R.I.P.

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RESULTS is a monthly report to ACLA members companies

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### President's Message

It's nice to finally be able to say the lab copay provision is out of the Medicare prescription drug bill! The final bill passed the House on November 15th, the Senate is expected to pass it before Thanksgiving, and the President has said he will sign the legislation into law.

Not only is the copay out of the final bill, but conferees rejected a last minute proposal that was reportedly floated by at least one conferee to actually cut lab reimbursement between 1.5-2%. ACLA strongly opposed this cut.

The final bill freezes lab reimbursement rates (no CPI adjustment) for five years. This is an improvement over the seven year freeze that was in the bill until the final hours of negotiations. Of course, ACLA opposes any freeze in reimbursement rates as unjustified given how much we have been cut in the past. We will live to fight this battle another day.

Things could have been far worse given the threats we faced over the past four months. We were facing a lab copay, then a 2% cut in reimbursement, followed by a 10-year freeze, and, finally, a 7-year freeze.

Another major threat ACLA is fighting is the proposed rule by the HHS Office of Inspector General (OIG) on "excessive charges." We had tremendous input from our members on this issue, and we submitted comments on the proposed rule on November 14<sup>th</sup>. We are also beginning to work with other trade associations who oppose the rule, including those representing hospitals, doctors, medical device companies and others. Like our coalition efforts on HIPAA transactions, we are working to build a strong effort opposing this proposed rule.

Earlier in November I had the pleasure of speaking at the California Clinical Laboratory Association (CCLA) meeting in San Diego. There was some real excitement about the ACLA and CCLA working more closely together on our many issues of common concern.

We are already taking steps to share information and communicate better among our memberships.

Finally, if you have not already done so, please register for the ACLA annual meeting coming up on January 15, 2004 in Washington. We have already confirmed some great speakers. The registration form and preliminary agenda can be found on our web site, [www.clinical-labs.org](http://www.clinical-labs.org).

*Alan Mertz*

### **Lab Provisions of the Medicare Drug Bill**

1. Five year freeze (2004-2008) on Part B lab payments.
2. Competitive bidding demonstration project for laboratory tests.
3. Two year (2005-6) extension of the grandfather for certain physician pathology services.
4. Preventive Services
  - a. Coverage of initial preventive physical exam which would not include clinical lab tests, but does include coverage for screening PAP and PSA, cardiovascular screening blood tests and colorectal cancer screening tests.
  - b. Coverage of cardiovascular screening blood tests for cholesterol levels and other lipid and triglyceride levels not more than once every two years.
  - c. Coverage of diabetes screening tests including fasting plasma glucose tests for individuals defined as at risk for diabetes.

## ACLA Files Comments on OIG Proposed Rule

On November 14, 2003, ACLA submitted comments on the proposed rule of the HHS Office of Inspector General (OIG) clarifying the terms and application of Medicare program exclusion authority for submitting claims containing “excessive charges.” We argued that the proposed rule should be withdrawn for the following reasons: (1) the proposed rule is an inappropriate attempt by the OIG to set reimbursement policy instead of CMS, the agency that has the authority to set reimbursement policy; (2) the OIG is attempting to redefine the long-standing regulatory concept of “charges” in contravention of the plain language of the law and Congress’ intent; (3) the proposed rule is unnecessary because Congress has already acted to protect the Medicare program by establishing fee schedules; and (4) the proposed rule is based on a series of false premises, which will make it difficult to administer and ultimately lead to increased health care costs for all Americans.

ACLA’s comments are posted on the ACLA website. We have also exchanged our

comments with representatives of other affected provider groups who have expressed strong interest in working together to defeat the proposed rule. A brainstorming session is scheduled for the first week in December.

## FDA ASR Regulation

ACLA and representatives of ACLA member companies attended the quarterly meeting of the FDA IVD Professional Roundtable on November 6, 2003. The roundtable brings together representatives of laboratory associations and staff from the FDA Center for Devices and Radiological Health to discuss issues of mutual interest. The past several meetings have devoted considerable time to FDA’s concerns with the regulation of ASRs. A representative of the professional association working group, of which ACLA is an active member, recommended that the Federal agencies take an incremental approach in expanding oversight of “high risk” ASRs and genetic testing. During general discussion, FDA acknowledged the difficulty of trying to define a “genetic test” as well as trying to classify tests on the basis of risk. Participants agreed to continue the dialogue with FDA.

## CPT

Kaye Jones, Chair of the ACLA’s CPT Advisory Committee and Dr. Sundwall, represented ACLA at the CPT Editorial Board meeting in Tucson, AZ, November 6-8. Various clinical lab codes were considered by the panel, including proposals for new codes and revisions in existing codes that we had reviewed in advance of the meeting as members of the Pathology Coding Caucus (PCC). However, the importance of our attendance was underscored by the fact that a significant revision in coding for flow cytometry was “put on the table,” without our having any prior knowledge this topic was to be considered, and one of the proposals for a revised code that we had reviewed and approved was misrepresented to the Panel. By being present, we were able to review, on site, the flow cytometry proposal and make comment, and ensure the codes reviewed were presented as endorsed by the PCC. After years of feeling kept at arms length from the CPT coding process, it is a welcome development to be able to participate more fully with CAP and the AMA.

Another significant development at this meeting was the presentation by Dr. Mark Synovec, representing CAP’s Genetic Test Coding Workgroup, of a proposal to accommodate new codes for genetic tests within Category I CPT codes by using a modifier, coupled with a numeric-alpha numbering system. This could enable payers to identify both genes and disease categories tested. [This concept was initially proposed to the CAP workgroup by ACLA representatives] The Panel approved this concept and delegated AMA staff to seek review and opinions of the CPT Advisory Committee before it is officially considered at the next meeting of the Panel in February.

### ACLA Annual Meeting January 15, 2004 Marriott Metro Center, Washington, D.C.

8:30 a.m. – 3:30 p.m.

#### Expected Speakers Include:

Doug Badger, Assistant to the President  
Leslie Norwalk, Deputy CMS Administrator  
Dr. Mark McClellan, FDA Commissioner (*invited*)  
Dr. Julie Gerberding, Director, CDC (*invited*)  
Key Congressional Staff Panel (*invited*)  
John McManus, House Ways and Means  
Patrick Morissey, House Energy and Commerce  
Linda Fishman, Senate Finance  
Elizabeth Fowler, Senate Finance

Please return registration form to [chawk@clinical-labs.org](mailto:chawk@clinical-labs.org).  
Forms and agenda on ACLA website, [www.clinical-labs.org](http://www.clinical-labs.org)

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## Calendar of Events

<b>December 2</b>	Laboratory Health Care Coalition Meeting	Washington, DC
<b>December 2-4</b>	Alan Mertz tours Specialty Labs, US Labs, Quest Diagnostics, and LabCorp	LA/San Diego, CA
<b>December 5</b>	Coalition on OIG Proposed Rule Meeting	Washington, DC
<b>December 8</b>	CPT Advisory Committee Meeting	Conference Call
<b>December 10</b>	Meeting with NY State Officials	Albany, NY
<b>December 11</b>	Meeting with CMS Officials	Baltimore, MD
<b>December 12</b>	ESRD/Lab Open Forum	Baltimore, MD
<b>December 12</b>	Transaction Coalition Meeting	Washington, DC

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