



American Society for Clinical Laboratory Science
Voice, Value, Vision

Government Affairs Committee (GAC)

E-newsletter

Issue #12 –Fall 2012

One of the strategic goals for our committee is to improve communication to the broader ASCLS membership and to provide a more consistent face to our members. The GAC e-newsletters are also available on the *ASCLS Advocates for You* section of the ASCLS website.

In this issue...

- **Current issues:**
 1. CLIA proficiency testing legislation proposed
 2. Physician signature regulation
- **Update from the Annual Meeting GAC committee meeting**
- **GAC strategic action plan highlights for 2012-2013**

CLIA proficiency testing legislation proposed

In July, two companion bills were introduced in the House and Senate. Both have the intent to change language related to the automatic revocation of a laboratory's CLIA certification for referral of proficiency testing from one clinical laboratory to another. Although we all understand that the intent of this regulation was to prevent a laboratory from working with another laboratory to confirm or verify results, the practice of laboratory medicine has changed significantly since the regulations were implemented and it is now not uncommon for one laboratory in a system to perform part of a test and need to refer to another laboratory in the same system to perform another part of the same reportable test. In other cases the referral is accidental and inadvertent, and usually is the result of a clerical or paperwork error. Now Health and Human Services and CMS has to revoke the laboratory's license and bar the laboratory director from directing a laboratory for two years, even if the referral was accidental. The TEST bills would give CMS the flexibility to use some judgment in determining the penalty.

The legislation amends the Public Health Service Act to revise sanctions and would change the language from "**shall** be suspended" and to "**may** be suspended". It would allow CMS to substitute intermediate sanctions where warranted, including a directed plan of correction, civil money penalties and costs for on-site monitoring, or any

combination of these.

The two bills are as follows:

- House bill H.R. 6118, Taking Essential Steps for Testing Act of 2012 (TEST). It was introduced on July 12, 2012, by Rep. Michael Grimm (R-N.Y.). It has 13 co-sponsors and in July was referred to the Committee on Energy and Commerce and the subcommittee on Health. It has now gone back to the full committee. A mark-up session for the bill occurred on September 11.
- Senate bill S. 3391, Taking Essential Steps for Testing Act. It was introduced on July 17, 2012, by Senator Amy Klobuchar (D-MN). It has 6 co-sponsors and has been referred to the Committee on Health, Education, Labor and Pensions (HELP). There has been no action since July.

On September 18, ASCLS sent an advocacy alert on this topic to all members. **ASCLS urged you to contact your members of Congress and ask them to co-sponsor or vote for these two bills.**

Suggested Talking Points

Essential laboratory services could be jeopardized as laboratories try to comply with the requirement to test/process PT samples as patient specimens yet not inadvertently send a PT sample to another laboratory even though such a referral would be part of the process for a patient specimen.

- There is bipartisan agreement that these changes need to be made to help CMS and the nation's clinical laboratories
- CMS has expressed a need for more flexibility when considering sanctions for proficiency testing referrals.
- If you know of an accidental mishandling of a PT specimen, share it.
- **I ask that you vote for this important and necessary legislation that will continue appropriate oversight of clinical laboratories while ensuring appropriate and reasonable sanctions when necessary.**

How to Call Your Members of Congress:

1. You can call the Capitol Switchboard and asked to be connected to your Members' offices. The phone number is (202)224-3121.
2. You can also go to <http://www.congress.org> to find the office's direct line and to look up your Members of Congress.

How to Email Your Members of Congress:

1. To locate the emails of Members Congress, please visit <http://www.contactingthecongress.org/> and click on your state. A list of your Senators and all of the Representatives in your state will appear with all of their contact information.
2. If you do not recognize your representative, please visit <http://www.congress.org/news/> and enter your zip code under "Join the conversation" on the right.

UPDATE: As of Friday, September 21, H.R. 6118 had been passed by the House. S. 3391 was not voted on by the Senate before they adjourned on Saturday. According to the information posted on the website this bill has been placed on the Senate Legislative Calendar. Hopefully after the elections this bill can get passed during the lame duck session before the new Congress takes its place in January. We want to thank all of our members who contacted their Senators or Representatives in support of these bills.

Physician Signature Requirement

GAC is also following a potential regulatory proposal to require a physician's signature on laboratory test requisitions. While this had been proposed in late 2011 in the form of Proposed Rulemaking, we have been waiting for the final rule based on comments received from the industry. CMS has told the laboratory industry that the inclusion of this requirement was inadvertent and that the language will be removed. GAC will keep you posted on this development to make sure that this requirement does not go into effect.

GAC committee update from Annual Meeting (July 17, 2012)

Don Lavanty updated the committee on legislative initiatives. Highlights included:

- Now that the Supreme Court has ruled on the constitutionality of the Healthcare Reform legislation, full implementation (assuming it is not ultimately repealed) will take 8-10 years.
 - State buying cooperatives for healthcare coverage must be fully operational by January 2014.
 - The "super board" (much like the Federal Reserve Board) to be responsible for limiting increases in healthcare costs will be appointed.
 - Filling the "donut hole" in the Prescription Drug benefit
 - The proposal to eliminate the proposed technology tax (\$30B) has been introduced in the House and the Senate.
 - Cannot require the states to abide by the Medicaid revised poverty formula.
- Legislation was introduced to address the revoking of CLIA certificates related to referral of proficiency testing (see item below). Our discussion centered around whether this could open the door to making other changes in CLIA and about giving CMS more flexibility in terms of the enforcement of this CLIA requirement.

Elissa Passiment updated the committee on regulatory issues. Highlights included:

- The publication of FDA proposed regulations on Laboratory Developed Tests (LDTs) and the final rule on Patient Access to Laboratory Results are not expected until after the November elections.
 - The proposed funding for workforce initiatives did not include funding for the AHECs (Area Health Education Centers).
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Following are highlights of the GAC strategic action plan for 2012-2013:

- 1) Communications: Publish five articles in ASCLS today and publish month e-newsletters.
 - 2) Create a database for those attending the Legislative Symposium to track visits, feedback and follow-up from Hill visits.
 - 3) Work closely with the Membership Committee, the Administrative Scientific Assembly and the Product Development Committee
 - 4) Implement and evaluate the effectiveness of the regional and state GAC liaisons expectations document. Regional committee liaisons were assigned.
 - 5) Support the ASCLS Executive Vice President (Elissa Passiment) and the Legislative Consultant (Don Lavanty) in responding to legislative and regulatory initiatives.
 - 6) Continue to work with the Association of Genetic Technologists (AGT) to integrate their organization into our GAC committee.
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Rick Panning, GAC e-newsletter editor (2012-2013)