American Society for Clinical Laboratory Science
Voice, Value, Vision

Government Affairs Committee (GAC)
e-newsletter

Issue #6 – November 2010

One of the strategic goals of our committee for 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.

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Health Care Reform Update

With the results of the recent mid-term elections, the future of the recently passed healthcare reform legislation is in question. As we have been witnessing in the media, the House Republicans are calling for repeal of the legislation. While the Senate is still controlled by the Democrats, the majority is much smaller and unless the party sticks together, the reforms may be in jeopardy. President Obama still has veto power, but the reality is likely that we will see changes in healthcare reform but that outright repeal is unlikely.

The laboratory industry had hoped to have the opportunity to introduce modernization of the laboratory fee schedule through negotiated rulemaking in the lame duck session between the election and the holidays. With the significant political change in Washington DC, we are unlikely to get that opportunity.

Your government affairs committee will work with Don Lavanty, Legislative Consultant, at our November and December meetings to determine our next steps. Stay tuned!

Physician Signature requirement on laboratory requisitions

On Tuesday, November 1, CMS released the final rule noting policy and payment changes to the Medicare Physician Fee Schedule (MPFS) that will go into effect on January 1, 2011

The final rule announces a reduction to payment rates for physicians' services (including pathology professional fees) in 2011 under the sustainable growth rate (SGR) formula. You may recall that the Medicare Preservation Act of 2010 held the mandated 21% reduction and provided a 2.2% increase in rates from June 1 through November 30, 2010. MPFS rates are currently scheduled to be reduced under the SGR system on December 1, 2010, and then again on January 1, 2011 under current law. The total reduction in MPFS rates between November and January under the SGR system will be -24.9 percent. While Congress has provided temporary relief from these reductions every year since 2003, a long-term solution is critical. As of today, we are not aware of a bill moving forward that would address this issue. We may see CMS hold claims for a short period of time or go forward to implement the reductions with retroactive rate changes if a "fix" passes

Among the other notable changes in the rule is the following issue which directly impacts the laboratory.

Clinical Laboratory Fee Schedule (CLFS) - Signature on Requisition: CMS finalizes its proposed policy to require a physician's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS. This policy does not affect physicians who choose not to use requisitions to request lab tests. Such physicians can continue to request such tests by other means, such as by using annotated medical records, documented telephonic requests or electronically. **If you recall, ASCLS submitted comments on this proposed rule in August.**

- It appears to be that CMS is finalizing the rule as published initially with no modifications. Although additional comments are being requested for parts of the rule, it does not appear to apply for this requirement. It says physicians can order by other means, inc. annotated medical record, documented telephonic requests, or electronically.
- The laboratory industry appears to have lost the battle to prevent this requirement.

The 2,023 page rule is very dense, but the specific section pertaining to physician signature requirements is on pages 1021-1035. Here is the link to the preview rule: http://www.ofr.gov/OFRUpload/OFRData/2010-27969_PI.pdf

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FDA Open Meeting on Laboratory Developed Tests

On Monday, November 22 the FDA is holding an open meeting in Washington DC on the topic of Laboratory Developed Tests (LDT). The meeting has open registration and is open to 250 people. Elissa Passiment is on the steering committee to plan the agenda and Rick Panning is going to attend as the chair of GAC and in his role as a laboratory administrator for a large integrated health system. FDA is proposing that they have oversight for the

regulation of LDTs - a very broad, heterogeneous group of tests either developed or modified in your own laboratory. First, we have a concern about FDA's ability to do this given their limited resources and secondly while we may believe that a tests developed by a lab, completely from scratch may need additional regulatory oversight, we do not believe that a test where the lab basically made a change of allowing to perform it on an addition specimen source (for which the test was not FDA approved) requires the same level of regulation.

The goal of the meeting is to define LDTs, discuss the structure of a list of LDTs and whether anything that is on the list makes the laboratory a medical device manufacturer, and what regulations from other agencies currently exist that might have oversight over LDTs. There will likely be a follow-up meeting to compare CLIA's Quality system to the FDA QSR regs.

MAKE A DIFFERENCE WITH ASCLS, CLMA, ASCP & AMT!

Legislative Symposium 2011

March 21 - 22, 2011
Washington, D.C.

ASCLS IS PROUD TO WORK WITH CLMA, ASCP, and AMT on the 2011 Legislative Symposium. Joining an ASCLS tradition since 1989, CLMA, ASCP and AMT members will meet with their Representatives and Senators on Capitol Hill as a unified front on behalf of our profession. We need you!! – committed laboratory professionals and leaders – to come to Washington to provide a visible and informed voice and make our concerns known inside Congress!

This event is one of the premier meetings on the ASCLS calendar. Legislative advocacy is an important benefit of ASCLS membership. We urge each constituent society to send at least one member to this event. It is a great way for first-timers, new professionals, students and seasoned ASCLS members (notice I did not say "old") to become engaged in the profession, and as Past President Mary Ann McLane would ay, provide the face for our profession.

Look for registration materials after the holidays!

Your ASCLS Government Affairs Committee looks forward to seeing you in Washington DC!

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