GAC Report to ASCLS Region II Members

Kim Przekop, GAC Region II Liaison

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Government Affairs Committee (GAC) Report:

- Legislative Symposium 2015: A total of 134 people from 34 states attended the Symposium this year. Out of the 134, 20 were students (2 were from ASCLS-NJ). Five organizations work together and all of them take part in teaching us the "How To's" of lobbying and the current issues: ASCLS, CLMA (Clinical Laboratory Management Association), ASCP our certification organization, AGT (Association of Genetic Technologists), and AMT (American Medical Technologists). We stand as a united front while we are in Washington. We discussed these topics with our representatives while educating them on who we are and what our issues were: funding the education grants in Title VII and VIII, our personnel shortage, and stopping cuts to our Medicare reimbursements. Next year, we need many more laboratorians and students to attend! Start raising money now so more can go in 2016. It costs approximately $500 per person to go, if someone drives their own car with several people in the car, and everyone shares a room.

- Kim Przekop spoke at the New Jersey state Spring Seminar 4/16 on Government Affairs. Many students and currently-practicing MLS were present. If anyone would like to give this speech to their own state members, she will gladly send it to you!

- PAMA (Protecting Access to Medicare Act): Laboratories must submit how much they are paid for each test and by each payer. The deadline is January 2016. This is important- need all labs to submit the data so that real reimbursements can be established from the pool of laboratory data. CMS is revising the Laboratory Fee schedule; we are nominating someone from ASCLS to be on the advisory committee. CMS will be publishing the final rule very soon; the original goal date has passed, and there will be a shorter comment period. The new reimbursement rates go into effect January 1, 2017.

- There were many comments to the FDA on Laboratory Developed Tests (LDTs) from many organizations. There may be an advisory committee, and we will nominate someone. Labs who run tests for transplants, like the Sharing Network here in New Jersey, and forensics labs will continue to have CLIA governance with no FDA oversight. All other LDTs will be classified into Low Risk, Moderate Risk, and High Risk. ASCLS has suggested a model for the processes to

determine clinical validity, and asked that the definition of LDT's not include small changes to FDA-approved tests, such as adding another body fluid as an acceptable source. Of some concern is the time it takes to get anything approved in the FDA now- having hundreds of LDTs to approve every year could slow down innovation and backlog assays that companies want to get approved. The final guidance, or withdrawal, isn't expected until later this year. Laboratorians would like to make sure that the FDA understands laboratory testing, CLIA, and high-complexity laboratories so that they target the companies that are developing these in-house tests without the regulations of CLIA.

- Nebraska is starting to look at licensure. Missouri is rewriting their licensure bill and will be resubmitting it. Idaho held a legislative symposium last week; they will introduce a licensure bill in 2016. Washington D.C. licensure bill died at the end of the last Congress. No bills have been re-introduced yet. If any state in Region II has decided to start pushing for licensure, please let Kim know so she can report it to the GAC.

- Just last month, a new bill passed the House that would change the antiquated SGR (sustainable growth rate) formula for reimbursing physicians for Medicare patients so that quality, efficiency, and innovation were rewarded. Now, we have to wait for the Senate to pass a similar bill, but it has a 79% chance of passing according to the congress.gov website. This will strengthen Medicare and the payment system of reimbursements to physicians and prevent Congress from cutting clinical laboratory reimbursements (which they have in the past) to pay for inefficient patches to this formula.

- The Affordable Care Act (ACA) contained a 2.3% medical device tax, which manufacturers of instruments have to pay (and pass on to laboratories to pay). There is good news, though- the Senate Finance Committee is getting ready to hear arguments to repeal this tax. Bills have been introduced in the House and Senate, so we will see how it goes.

- Here is the list of cuts to our Medicare reimbursements over the last 2 decades:
    - ACA: 9% (through 2015)
    - Productivity adjustment- across the board reimbursement cut of 11% over the ten years beginning in 2011
    - Another 2% cut to pay for the patch of the SGR in 2012, and another 2% cut across the board cuts as part of balancing the federal budget.
    - It is estimated that our Medicare reimbursements have been slashed up to 40% over the past 20 years.

  The part we don't understand is that less than 2% of all Medicare spending goes to clinical laboratory tests.

Respectfully Reported by Kim A. Przekop

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