

GAC Report to ASCLS-NJ Members

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Government Affairs Committee (GAC) Report:

- PAMA (Protecting Access to Medicare Act 2014): The laboratory private payor reimbursement data being collected by CMS is being filtered to remove acute care hospitals and other healthcare providers with less than 50% current Medicare reimbursement. CMS is making it clear that they only want to use the lowest reimbursement rates from reference labs in updating the Laboratory Fee Schedule. After adjusting down to the mean of all the rates CMS collected, the final reimbursement numbers will be much lower than they are now. This is of great concern for all laboratories who process specimens from Medicare patients; ASCLS sent a letter to CMS to state our concerns. Elissa will be having meetings with ACLA (American Clinical Laboratory Association). We may need to reach out to Congress to protest that CMS missed all of the deadlines on this guideline and is not using most of the labs in its calculations.
- ASCLS and AMT sent letters to the Rhode Island legislature to repeal the recent ruling that MLS licensure be removed. We are waiting for a hearing date.
- On October 27, 2015 the *New York Times* reported that the FDA recently inspected Theranos and found some major deficiencies. The California company, which claims to be able to produce dozens of test results from a drop of blood, has one FDA-approved assay: Herpes Simplex virus I. Previous CLIA and local inspections did not report deficiencies. The company is valued at more than \$9 billion.
- In September, the Marymount lab of the Cleveland Clinic was closed and fined \$650,000 for sloppy record keeping and poor procedures in the Blood Bank and for proficiency testing and other regulatory violations. A dozen employees, including the lab director, were terminated. So far, no proof of patient harm has been uncovered.

Respectfully Reported by Kim A. Przekop

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