AGENDA

ASCLS/CLMA/ASCP/AMT/AGT/NSH LEGISLATIVE SYMPOSIUM

March 19 - 20, 2018 | Hilton Old Town Alexandria

MONDAY, MARCH 19

7:30 – 8:00 am	REGISTRATION AND CONTINENTAL BREAKFAST
8:00 – 8:15	**Welcome from the Partners**
8:15 – 8:30	**Meeting Overview** Jim Flanigan, ASCLS
8:30 – 9:15	**Overview of the Political Environment in Washington**
9:15 – 10:00	**Addressing Laboratory Workforce Shortages**
10:00 – 10:15	BREAK
10:15 – 11:15	**PAMA – Advocacy After Implementation**
11:15- 12:00	**CMS Personnel Regulation Request for Action Briefing**
1**2:00**	**Political Action Committee** ASCLS PAC Board of Trustees
12:15 – 1:30	**LUNCH** (Washington/Jefferson Room and Foyer)
1:30 – 2:15	**Preparing for Congressional Visits** • Review of Issues, Leave Behinds and "Talking Points" • Walk Through Feedback on Visits • How Congressional Offices Work • How Legislative Staff View Your Visit • How to Communicate Your Message Effectively

2:15 – 3:00	**The Diagnostic Accuracy and Innovation Act (DAIA)** Sarah Killeen, Legislative Director in the Office of Rep. Larry Bucshon (R-IN)
3:00 – 3:45	**Advocacy Perspectives Outside the Laboratory Profession** Cynthia K. Morton, MPA, Executive Vice President National Association for the Support of Long Term Care
3:45 – 4:15	BREAK
4:15 – 5:00	**Congressional Update** Representative Mike Bishop (R-MI) Committee on Ways and Means
5:00 – 5:30	**Practicing Your Message/Making a Difference** • Developing your personal advocacy message • Breakouts and Role-Playing
6:00 – 7:00	RECEPTION

TUESDAY, MARCH 20

6:30 – 8:30 am	**Breakfast** (Washington/Jefferson Room and Foyer)
8:00	**Begin traveling to Capitol Hill** **Appointments (on your own)**

Flawed Attempt to Set "Marketing Pricing" Fails and Jeopardizes Access to Quality Care

Position

The entire clinical laboratory community urges Congress to fix the flawed implementation of Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014, which will restrict access to quality clinical laboratory services, especially for patients living in nursing homes and rural areas. The law required CMS to establish a market-based payment system for laboratories paid on the Clinical Laboratory Fee Schedule (CLFS). However, regulatory requirements included in the final PAMA regulation do not comply with the statute as the data collected reflects just a small sector of the clinical laboratory market. Full implementation of these cuts will cause an irreversible, market shift that threatens access to essential laboratory tests. Congress must step in to mitigate this risk.

1. **Make a statutory adjustment to CLFS payments that provides short term relief and allows time to revise the rate setting process conducted by CMS.** Any adjustment would not be more than the original 2014 PAMA CBO 10-year baseline for the statute. A 10 percent per year cut to a majority of the tests on the CLFS will eliminate testing in small and mid-size clinical laboratories, hospitals and physician office labs currently serving Medicare beneficiaries
2. **Ensure a valid stratified random data sample is collected by CMS that represents all segments of the laboratory market.** The sample strata are: hospital laboratories, physician office laboratories, large independent laboratories, and small independent labs, further stratified to assure representation across geographic areas, e.g. MSA, and including urban and rural regions.
3. **Require that data collection requirements streamline collection to reduce the burden on participating laboratories by focusing on data specific to the private market.** Data collection and reporting requirements must be applied only to private payment rates paid after implementation rules and guidance documents are finalized. Medicaid managed care data that are a result of federal or state budgetary or statutory requirements, which is not reflective of market rates, must be excluded. Laboratories should be allowed to exclude data from paper, manual and non-electric claims that collectively constitute no more than 10 percent of a lab's private market claims.
4. **Revise PAMA statutory requirements to calculate final CLFS payment rates per code as a weighted mean proportionate to laboratory-type, market share, and geography.** Annual test fee reductions caps should be put in place, lowering the 10 percent-15 percent limits in the current statute, and spread over a 10-year period.

Rationale

PAMA required "applicable laboratories" to report private payor payment rates and the associated test volume for those laboratory services defined by CMS. The intent of PAMA was to ensure true market-based pricing by setting the fee schedule to a weighted median of the collected data. Unfortunately, by manipulating the definition of the "applicable laboratory,"

CMS intentionally skewed the data collection and artificially lowered the weighted median of payment rates.

In its 2016 report, the OIG estimated that 3,500 laboratories would report, but actual reporting entities number barely half that. **Paired with the fact that the proposed fee cuts exceed the Congressional Budget Office estimated savings from PAMA by more than 300 percent, it is clear this implementation fails to maintain alignment with Congressional intent.**

After defining "applicable laboratory" in the narrowest possible terms, the Agency collected 90 percent of reported data from independent laboratories. Hospitals and physician office laboratories, which provide 44 percent of laboratory services under Medicare, represented just 8.5 percent of the reporting entities. Less than one percent of hospitals and physician office laboratories reported data. CMS admits that just 1.85 percent of data was collected from laboratories serving rural areas.

Hospital laboratories represent 24 percent of the laboratory billing from the CLFS, but data was collected from just 21 of the 6,994 hospital laboratories. Physician office laboratories represent 20 percent of the laboratory billing for Medicare, but only 1,106 out of approximately 236,000 POLs reported. (OEI-09-16-00040)

Impact

Smaller, local, independent, physician office and hospital laboratories, functioning closest to the patient and clinician, provide services for nursing home residents, patients requiring frequent testing for management of chronic conditions like diabetes and hypothyroidism, same day information for oncologists to treat their patients undergoing chemotherapy or those suffering from infections that require rapid detection and identification for proper monitoring and treatment.

To serve the needs of their patients, local laboratories provide more rapid results drawn from more specialized test menus without economies of scale. The methods used by CMS to collect and interpret an incomplete dataset without validation excluded the possibility of measuring those differences. Laboratories are responding by reducing staff and cutting back on capital investment, leaving clinicians without important tools to quickly diagnose and treat patients. Access to care for both the community and nursing homes served by the community-based, hospital laboratory outreach programs will be compromised.

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Growing Crisis in the Clinical Laboratory Workforce

Position

To ensure access to quality health care services the healthcare system must have an adequate supply of clinical laboratory personnel. Today that supply is in already seriously short of what is needed and estimated to become critical. This shortage hampers the ability of clinical laboratories to meet the growing need for appropriate testing, hampering the ability of clinicans to diagnose and treat patients. A growing patient population and the number and complexity of medical laboratory tests are putting strains on a profession whose numbers are barely growing.

We call upon Congress to address this concern within the Veterans Health Administration and to begin to address the concern throughout our nation's health care system.

Congress must do the following:

- ✓ Enhance recruitment and retention efforts within the Veterans Health Administration by providing resources to host clinical rotations from clinical laboratory science and technology programs.
- ✓ Authorize and appropriate funding for a program to within the Public Health Service Act to ensure training for citizens seeking to enter the clinical laboratory workforce.
- ✓ Authorize the Government Accountability Organization (GAO) to study the shortage of clinical laboratory personnel and the impact on the healthcare system, and make recommendations to Congress.

Rationale

The Bureau of Labor statistics anticipates needed growth of 12,000 new medical laboratory professionals per year to meet growing demand. However, academic programs produced just 6,300 graduates in 2017; a number that has not grown in the last five years.

A 2016 survey by the American Society for Clinical Pathology of more than 1,300 laboratory managers overseeing 51,586 employees across the United States found current vacancy rates of more than seven percent in many key laboratory positions including the core laboratory, blood bank, hematology, toxicology and specimen processing. In most cases, those vacancy rates are worse than the results of a similar study conducted in 2014. Another cause for concern is the average age of the laboratory workforce, which has been increasing steadily. Results also show that 15 percent of all clinical laboratory professionals are expected to retire in the next 5 years. This is more than double the rate in 2012.

For the fourth straight year, in 2017 the VA Office of Inspector General (OIG) listed Medical Technologist (clinical laboratory personnel) as one of the five largest critical need occupations

for the system. By expanding clinical sites, clinical laboratory science educational programs, which now limited the number of graduates they can produce, would expand. By exposing the VA to a wider range of professionals in training, the VA will have greater opportunity to successfully recruit them.

This crisis is the result of a decades-long decline in MLS and MLT producing academic programs. From 1970 the number of accredited programs declined from nearly 1,000 to less than 450 in 2006. Since 2008, the number of programs has rebounded modestly from 427 to 478 in 2017. That increase has not been nearly enough to address the increasing demand, and the shortage exacerbates the challenge in securing clinical sites for training.

Background

Clinical laboratory personnel are critical to our nation's health care. They provide a wide-range of diagnostic, technical, therapeutic and direct patient care and support services. These professionals are critical to physicians and nurses with whom they work and to the patients they serve. In total, clinical laboratory personnel and other allied health professions account for an estimated 60 percent of the entire health care workforce.

More than 4 billion medical laboratory tests are performed each year in the United States, the single highest volume medical activity. Approximately 70 percent of physicians' patient interactions are influenced by laboratory test data.

Owing to the sequencing of the human genome and a focus on precision medicine, new laboratory tests are being developed constantly to improve early detection and diagnosis of diseases, more accurately monitor conditions and better protect outcomes. Molecular diagnostics detect and measure the presence of genetic material or proteins associated with a specific health conditions or diseases, helping to uncover the underlying mechanisms of disease and enabling clinicians to take care at an individual level, facilitating the practice of "personalized medicine."

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