Greetings ASCLS-Michigan Members!

I hope you are now finally enjoying the fall color change of the season. The state of things of recent still brings uncertainties for the laboratory professions and healthcare at large. But know that ASCLS continues to be involved in these conversations that will impact you.

Last week, the ASCLS-Michigan Government Affairs committee members attended the Legislative Symposium. They attended both virtually and in person. I know they are moving forward and will be announcing their next steps in the near future. Please see their update in this edition of Newslinks.

I know that many of you continue to face challenges through the COVID-19 pandemic whether you are a student navigating courses back in person, an MLS who are doing the work focused on patient care, an administrator who are managing the workflow, know that we as the ASCLS-MI community thank you for your hard work and perseverance. Please make sure you take time for you!
Save the Date!

Mark your calendars for these important 2022 events

- January 10-17: Pride-Respect-Inclusion-Support-Momentum (PRISM)
  https://ascls.org/prism/
- January 14-15: Emerging Lab Managers Collaborative Conference (ELMC2)
  https://ascls.org/elmc2/
- April 10-13: ASCLS-MI Spring Conference
- ASCLS National Meeting, June 26-30 in Grand Rapids, Michigan
  https://ascls.org/annual-meeting/

ASCLS-Michigan Newslinks
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ASCLS-MI Leadership: Visit our web site at www.ascls-michigan.org for a complete listing and contact information for all ASCLS-MI board members and a wealth of other information on the Society.

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In years past, many laboratory professionals have descended on Washington, D.C. to participate in the annual Legislative Symposium. Due to delays caused by the COVID-19 pandemic, Legislative Symposium attendees traded the spring cherry blossoms of March for the fall foliage of October. The COVID-19 pandemic has caused us all to adapt to certain changes on how we go about our daily lives and how we conduct business. After a year hiatus, this year’s Legislative Symposium adapted a hybrid attendance model, allowing participants to attend either in person at the Hilton Old Town Alexandria or virtually. ASCLS again shared a partnership sponsoring the meeting with Clinical Laboratory Management Association (CLMA), American Society for Clinical Pathology (ASCP), Association of Genetic Technologists (AGT, American Medical Technologists (AMT), National Society for Histotechnology (NSH), and the Philippine Association of Medical Technologists-USA (PAMET-USA). In all this year’s Legislative Symposium had approximately 86 in-person attendees and 45 virtual participants.

The two-day event held Monday and Tuesday October 25th and 26th, comprised of Monday’s informational sessions where Capitol Hill insiders provided details on legislation and other issues the White House and Congress have been dealing with in respect to the clinical laboratory. Three main issues were discussed during Monday’s session: How PAMA reimbursement rates are hurting the laboratory’s bottom line, clinical laboratory workforce shortages, and the VITAL and VALID Acts and how they relate to laboratory developed tests (LDTs). The second day of the Symposium provided a different strategy from past events. Typically, we put on our lobbying caps and march to Capitol Hill and visit our Representatives’ and Senators’ staff. Due to COVID protocols, many Congressional offices could only meet in a virtual capacity. Many attendees had to juggle virtual meetings with in-person meetings with Congressional staff. Michigan’s delegation was no exception with meetings with our Senators virtually and meetings with Congressional offices in-person.

**PAMA**

In 2014, Congress passed the Protecting Access to Medicare Act (PAMA). The intention of PAMA was to update the clinical laboratory fee schedule (CLFS) using a market-based system to collect payment data from laboratories across the country. The initial data collection was flawed. New reimbursement rates were established based off data collected from roughly 1% of US laboratories with 90% of the data coming from large laboratories like Quest and LabCorp. Due to high test volumes, these labs can charge a lot less for testing than a smaller community hospital lab or private lab. These large cuts in reimbursement rates have hurt...
budgets of laboratories across the country. With continuing rate cuts coming, mounting labor costs, and increasing workload caused by the pandemic, we have asked Congress to forestall additional cuts until the pandemic is over. We also request that the Centers for Medicare and Medicaid (CMS) do a new collection of private-payer rates from a proportional sample of the entire laboratory industry. This will create rates that are fairer and from a true market-based system.

**Work Force Shortage**

Across the entire country, all industries are facing workforce shortages. The clinical laboratory profession has been no stranger to workforce shortages. This issue has plagued the profession for nearly 20 years. The COVID-19 pandemic has served to heighten the concerns with workforce shortages as workload continues to increase. This has led to burnout, causing many laboratory personnel to look for employment elsewhere. Congress has acted by introducing H.R.5602, The BIO Preparedness Workforce Act of 2021. The bill was introduced on October 15th by Rep. Lori Trahan (D-MA). The bill would do two things: Make clinical laboratory technologists and technicians (mentioned in the bill by that name) eligible for student loan repayment up to $50,000 and establish a federal grant program to assist schools with allied health programs in recruiting and retaining clinical laboratory students and faculty. To be eligible for the loan repayment program, the laboratory professional would have to be out of school within 10 years and devote at least 3 years of service to an underserved area related to bio-preparedness and infectious disease. The federal grant program would assist schools in recruiting and retaining students, assist programs to recruit faculty and provide the necessary clinical training required to graduate and enter the profession.

**VALID Act**

The third issue brought to our attention was ASCLS’s endorsement of the Verifying Accurate Leading-edge IVCT Development Act of 2021 or simply the VALID Act. Reintroduced in June 2021 by Rep. Diana DeGette (D-CO) and Dr. Larry Bucshon, M.D. (R-IN), the VALID Act establishes a risk-based method for the regulation of laboratory developed tests (LDTs). The VALID Act would do the following things:

- Create a risk-based oversight of LDTs regulated by the FDA, risk categories being high risk, low risk, or no risk.
- CLIA will continue to provide oversight on the processing side of LDTs, whereas the FDA will focus on the risk, stability, and the product itself.
- Medical device user fees still need to be established under the legislation.

A competing bill introduced by Senator Dr. Rand Paul (R-KY), Verified Innovative Testing in American Laboratories Act of 2021 or VITAL Act, in a nutshell, put the oversight of LDTs completely under the purview of CLIA. The AACC has endorsed the VITAL Act.

The attendees at this year’s Symposium also got to express our concerns with the supply chain to White House COVID Supply Chain Coordinator, Tim Manning. The laboratory professionals at this meeting got to address Mr.
Manning with our concerns about basic supplies on back-order like collection tubes, instrument reagents and basic consumables.

During our Congressional meetings, our Michigan delegation of Stephanie Mabry, Caitlyn Crone, Kyle McCafferty, Michelle Russell (virtual) and Billie Ketelson (virtual) met virtually with members of both Senator Stabenow and Senator Peters staff. Observing our virtual meeting were members of PAMET from Michigan, California, and New York. Our PAMET counterparts were very impressed with how the meeting was conducted. It gave them extra confidence in their own meetings with other Congressional staff.

Stephanie, Caitlyn and I had the pleasure of spending about 20-30 minutes with Congresswoman Lisa McClain (R-MI-10) and staff member Nick Seelinger. See excerpt below from the Congresswoman’s newsletter. It was a rare meeting for us ASCLS members having never sat for a meeting with a member of Congress. Rep. McClain was very concerned about PAMA reporting. As a businesswoman, she understands the need for a fair, market-based reporting system for reimbursement rates. She was quite concerned with how low reimbursement rates effect a laboratory total operating cost. With the BIO Preparedness Workforce Act, she was concerned as to where the money for the loan repayments would come from. On the flipside, she was extremely enthusiastic about supporting a federal grant program for allied health programs. As a member of her district, I have provided my expertise about the lab profession to their office. When we departed, Nick, told me he would like to speak to me personally about future issues.

The energy was electric and all of us were fired up. We all got our point across to Congress and this administration that the laboratory profession is vital to this pandemic and the healthcare of all Americans. I encourage all to reach out to your member of Congress to express your concerns. There is power in numbers.

We all can be a Labvocate!

Hearing from Constituents

I also met with a group of constituents on Tuesday from the American Society for Clinical Laboratory Science. Meighan Sharp, President-Elect of the society, spoke about workforce shortages in laboratories across Michigan and how medicare reimbursement is negatively affecting the industry.
Expressing Our Thanks to Carey Loveland

Stephanie Mabry

On the chilly afternoon of October 16, a group of ASCLS-Michigan members visited Carey Loveland, ASCLS-MI Executive Secretary from 2002-2021, to recognize her for her achievements and dedicated years of service to the organization. Most recently, in addition to her capacity as ASCLS-Michigan Executive Secretary, Handbook Chair, and Audit Committee Member, she has also participated on the Bylaws Committee at the National level.

Carey is a passionate advocate for the profession, and has received nearly every award that ASCLS-Michigan bestows, and she has been recognized for her dedicated and outstanding contributions to the profession through membership in the Alpha Mu Tau Fraternity. She has been an invaluable resource for every ASCLS-Michigan president for the past 20 years, as evidenced by her numerous Presidential Recognition Honors.

As a former President of ASCLS-Michigan, I can truthfully say I could not have done it without the guidance and mentorship of Carey. Carey Loveland has been the heart and soul of the ASCLS-Michigan family for many, many years, and she is truly deserving of recognition. As Carey transitions from Executive Secretary to new roles with ASCLS and ASCLS-Michigan, please join us in our gratitude for her invaluable service to our organization!

Thank you, Carey!