



Labvocate

Amplify Your Voice for Your Profession
and Your Patients

April 25, 2023

Objectives

Upon conclusion of this webinar, the participant will be able to:

1. Identify the differences between legislative and regulatory advocacy at both the state and federal level
2. Explain how legislation and regulation impact the practice of medical laboratory science
3. Discuss the best approach to engage with elected leaders, legislative staff, and other stakeholders to maximize their impact

Overview



Advocacy

- To promote a cause or principle
- To work to change the policies that affect our lives
- Involves actions that lead to a selected goal
- Influencing the decisions or legislation that affects the future

Why Should We Be Advocates?

- We are the experts in the clinical laboratory, so we know how legislation will impact us
- What happens to the laboratory impacts healthcare
- The issues matter to our practice
- If we don't speak up for ourselves, no one will be speaking for us



Minnesota Senator Amy Klobuchar working with ASCLS-MN delegation

Branches of the Federal Government

LEGISLATIVE	EXECUTIVE	JUDICIAL
Makes Laws	Carries Out Laws	Evaluates Laws
<ul style="list-style-type: none">➤ Congress<ul style="list-style-type: none">➤ Senate (Two Senators per state)➤ House of Representatives (435 based on state populations)	<ul style="list-style-type: none">➤ President<ul style="list-style-type: none">➤ Vice President➤ Cabinet (nominated by the President and must be approved by the Senate)	<ul style="list-style-type: none">➤ Supreme Court (Nine justices with lifetime appointments nominated by the President and approved by the Senate)➤ Other Federal Courts

Branches of State Government

- Similar to Federal Government except:
 - Governor instead of President
 - Lieutenant Governor instead of Vice President
 - Nebraska is the only state that has a unicameral legislative branch (Senate only)
 - All other states have a bicameral legislative branch (State Senate and House of Representatives or Assembly)

Federal & State Government

FEDERAL GOVERNMENT

- Make (print or coin) money
- Declare war
- Manage foreign relations
- Oversee trade between states and with other countries
- Examples: CLIA, CLFS, PAMA

STATE GOVERNMENT

- Ratify amendments
- Oversee trade within the state
- Manage public health and safety
- Example: Licensure, funding for special state programs

Both may provide special funding opportunities, such as scholarships

How Is Advocacy Different?

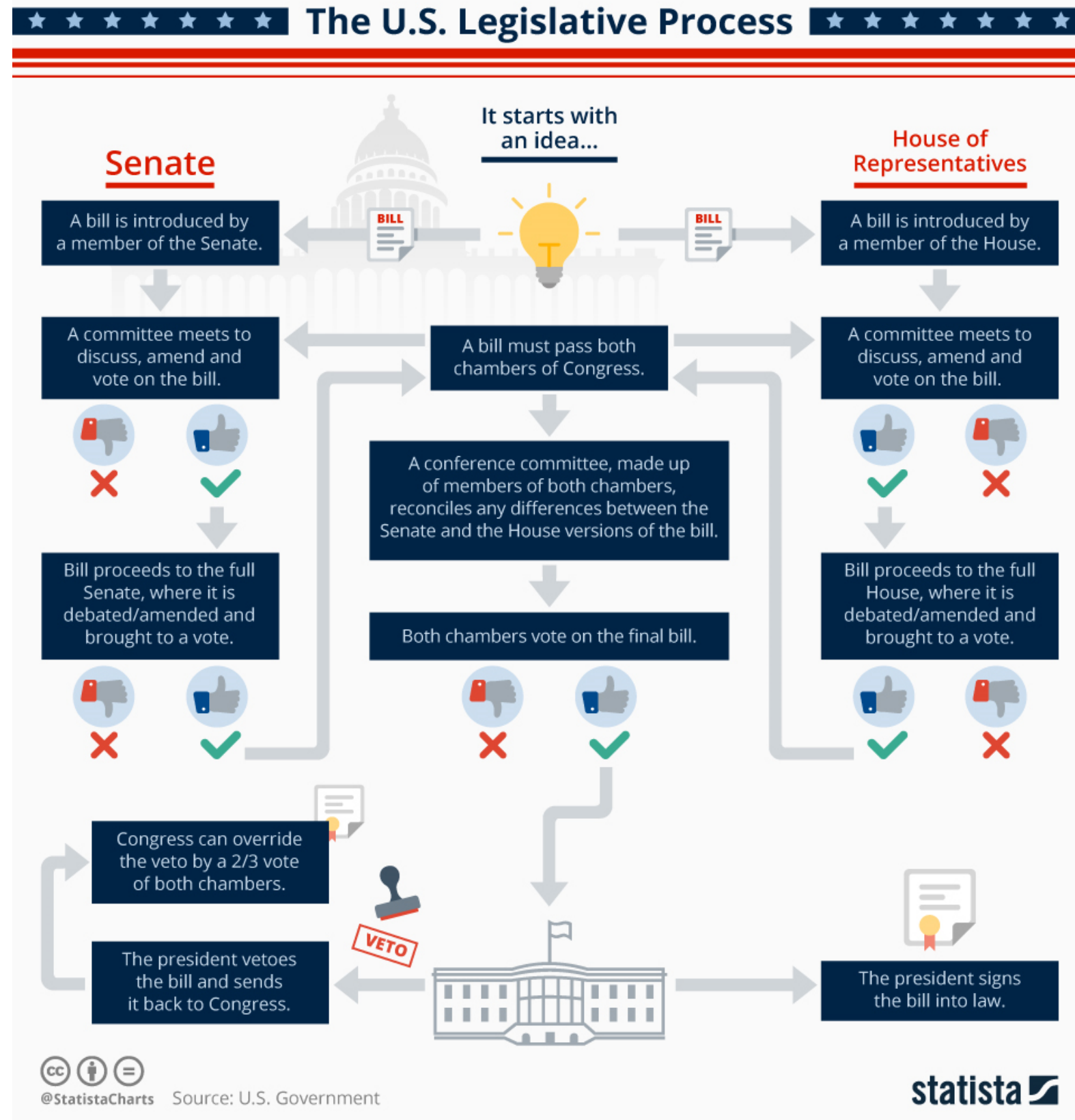
- Easier to get opportunities to meet with State Senators and Representatives
 - Visits to State Capitols
 - Town Hall meetings
- Shorter legislative sessions
 - Bills move quickly
- Stay in touch with professional organizations to learn about issues
- For the most part, advocacy is advocacy



Meeting with Minnesota State Senator John Marty

Legislation vs. Regulation

Diagram of The U.S. Legislative Process by statistaCharts



How can I influence legislation?

- Vote
- Talk to your representatives about model legislation
- Speak at a legislative hearing

Regulation



FEDERAL REGISTER

The Daily Journal of the United States Government

Friday, May 4th



Current Issue

146 documents from 48 agencies (302 Pages)

117 Notices 6 Presidential Documents 9 Proposed Rules 14 Rules 2 Significant Documents



Public Inspection

Special Filing

updated on 04:15 PM, on Thursday, May 3, 2018

10 documents from 6 agencies


4 Notices 5 Proposed Rules 1 Rule

Regular Filing

updated on 08:45 AM, on Friday, May 4, 2018

117 documents from 46 agencies

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Text to 42 CFR Part 493 CLIA 88 Proficiency Testing Regulations



1536

Federal Register / Vol. 84, No. 23 / Monday, February 4, 2019 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3355-P]

RIN 0938-AT55

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update proficiency testing (PT) regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. This proposed rule would also make additional technical changes to PT referral regulations to more closely align them with the CLIA statute.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 5, 2019.

ADDRESSES: In commenting, please refer to file code CMS-3355-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX)

Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sarah Bennett, CMS, (410) 786-3531; Caecilia Blondiaux, CMS, (410) 786-2190; or Nancy Anderson, CDC, (404) 498-2741

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

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- IV. Response to Comments
- V. Regulatory Impact Analysis
 - A. Statement of Need
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 - E. Accounting Statements and Table
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which the laboratory is certified under CLIA. PT referral was further addressed by enactment of the Taking Essential Steps for Testing Act of 2012 (Pub. L. 112-202, December 4, 2012) (TEST Act) and our implementing regulations (79 FR 25435 and 79 FR 27105). As of January 2017, there were 246,143 CLIA-certified laboratories, of which 36,777 Certificate of Compliance and Certificate of Accreditation laboratories were required to enroll in a U.S. Department of Health and Human Services (HHS)-approved PT program and comply with the PT regulations.

Testing has evolved significantly since 1992, and technology is now more accurate and precise than the methods in use at the time the PT regulations became effective for all laboratories in 1994. In addition, many tests for analytes for which PT was not initially required are now in routine clinical use. For example, tests for cardiac markers, such as troponins, and the hemoglobin A1c test commonly used to monitor glycemic control in persons with diabetes, were not routinely performed prior to 1992. Recognizing these changes, we are proposing revisions to our existing PT regulations in this proposed rule.

As part of the process for developing our proposals to revise the PT regulations, HHS requested input from the Clinical Laboratory Improvement Advisory Committee (CLIAC) regarding appropriate revisions to the regulations. CLIAC is the official federal advisory committee charged with advising HHS regarding appropriate regulatory standards for ensuring accuracy, reliability and timeliness of laboratory testing. Questions posed to CLIAC at the September 2008 CLIAC meeting and

Example

- Legislation

“(a) REPORTING OF PRIVATE SECTOR PAYMENT RATES FOR ESTABLISHMENT OF MEDICARE PAYMENT RATES.—

“(1) IN GENERAL.—Beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary, applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

“(2) DEFINITION OF APPLICABLE LABORATORY.—In this section, the term ‘applicable laboratory’ means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, section 1833(h), or section 1848. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

Example

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- Legislation

- Regulation

- CMS defined an “applicable laboratory” as

- An entity that bills Medicare Part B under its own National Provider Identifier (NPI)
 - Has more than \$12,500 in Medicare revenues from laboratory services on the CLFS
 - Received more than 50% of their Medicare revenues from laboratory and physician services


How can I influence regulation?

- Make a comment



PA -- Noblit, Stephanie

This is a Comment on the **Centers for Medicare Medicaid Services (CMS) Proposed Rule: [Requests for Information: Revisions to Personnel Regulations, Proficiency Testing Referral, Histocompatibility Regulations and Fee Regulations Under Clinical Laboratory Improvement Amendments of 1988](#)**

For related information, [Open Docket Folder](#) 

Comment

As a clinical laboratory professional dedicated to providing the highest standard of care to my patients, I am writing to urge the Centers for Medicare and Medicaid Services (CMS) to use this once-in-a-generation opportunity to update CLIA personnel regulations to reflect the current and future practices in clinical laboratories that support clinical decision-making in an ever-evolving healthcare system.

The Agency must focus on strengthening laboratory personnel standards and ensuring the ongoing, invaluable contributions of laboratory professionals in the healthcare system. Updates to the personnel regulations must address the following principles.

Nursing Degrees Are Not Equivalent to Biological Sciences Degrees: In April 2016, CMS released a memo updating its interpretation of the personnel regulations allowing surveyors to consider a bachelor's degree in nursing as equivalent to a bachelor's degree in a biological science for high complexity testing personnel. This was inappropriate and puts the lives and health of patients all across the country at risk.

In both scope and depth, the natural science coursework required for a biological sciences degree vastly outweighs the natural science coursework required as part of a nursing degree. Typical coursework requirements for a bachelor of sciences degree in biological sciences includes a total of at least 63 hours of natural sciences, including at least 39 hours of major requirements in the biological sciences and 32 hours of prerequisites. In contrast, nursing degrees include only a quarter of the course hours in the natural sciences.

While I have great respect for our nursing colleagues and believe that existing educational programs in nursing provide outstanding training for professionals in the nursing field, the nursing degree is not intended to be, nor should it be viewed as adequate to direct moderate complexity or perform high complexity diagnostic testing.

Non-Laboratory Personnel Qualifications Should be Based on Coursework, Not Degree Label: For those holding nursing degrees or those with a bachelor's degree in a "physical science," CMS should not focus on specific degree labels, which may not be entirely descriptive of the coursework. Rather, CMS should define the educational requirements for non-laboratory science bachelor degree holders instead of defining requirements by degree.

Approaches to maximize impact

Engage and Advocate Effectively

————— . . .

Laboratory professionals advocate in many ways and for many reasons.

Determine your why?



1 Better work conditions?

- DRAW ATTENTION to all the work you and your co-workers do in the laboratory by sharing data with each other and management

2 Increase visibility of the laboratory?

- Make your role KNOWN within your organization so other healthcare team members will recognize you and understand your value

3 Recruit into the profession?

- Outreach to schools and in-house training and visiting opportunities to SHOWCASE the clinical laboratory as a career option

4 Support efforts at the State level?

- Issues like:
- Licensure
 - Minimum wage
 - Housing
 - Funding for education
 - Affordable health care and insurance

5 Make an impact nationally?

- LEARN about and SUPPORT efforts from professional organizations

Things you can do

When advocating for the laboratory profession, no action is too small

Improve your workplace

- Communicate with your colleagues about problems and creative ways to address them
- Use staff meetings or one-on-ones with managers to brainstorm solutions
- Choose one thing and DO IT!

Visibility of the laboratory

- Participate in workgroups and committees in your organization
- Meet with patients (as your role permits it) and tell them about US
- Go ALL OUT during NATIONAL MEDICAL LABORATORY PROFESSIONALS' WEEK!

Recruitment into the lab

- Volunteer with professional societies and science education programs
- Become a mentor to LPs in training
- “You are an ambassador for our profession.”
(Stanger, 2023)

Connect with policy resources

A lot of time and effort goes into breaking down and understanding policy that affects the clinical lab

Strategies

- Research and analysis of policy and issues
- Oversight of regulations and monitoring new policies that are being implemented
- Awareness through public awareness media advocacy
- Organizing grass roots efforts
- Building coalitions and networks of like-minded professionals/organizations
- Taking legal action to prevent/minimize effects of laws/regulations
- Increase influence with policy-makers through lobbying

(Raynot, J., York, P., & Sim, S-C., 2009).



Leading the News

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Congress Approves Bill To Effect Immediate End To COVID-19 Pandemic National Emergency

The [Washington Post](#) (3/29, Paybarah) reports the United States Senate has “passed a resolution ending the national emergency declaration that was announced three years ago by President Donald Trump at the start of the coronavirus pandemic.” Even as “House Democrats overwhelmingly voted against the measure last month, Senate Democrats moved ahead with it on Wednesday.” The bill, “under the Congressional Review



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Legislation Significant to Medical Laboratories, Introducing CDC OneLab™, Register for the 2023 Emerging Laboratory Managers Collaborative Conference, Submit Award Nominations, and more.

Two Pieces of Legislation Significant to Medical Laboratories Could Pass this Month

Watch for Verifying Accurate, Leading-edge IVCT Development (VALID) Act and Saving Access to Laboratory Services Act (SALSA)



PAMA and has bipartisan support in

medical laboratories and patient safety.



AMERICAN
SOCIETY FOR
MICROBIOLOGY

Home / Press Releases / 2023 / March / [ASM Statement in Response to COVID-19 Hearing](#)

ASM Statement in Response to COVID-19 Hearing

March 8, 2023

Statement from the American Society for Microbiology
in response to the
House Select Subcommittee on the Coronavirus Pandemic Hearing:
“Investigating the Origins of COVID-19”

March 8, 2023

On behalf of our 30,000 members in the United States and around the world, the American Society for Microbiology (ASM) shares the following points in response to the House Select Subcommittee on the Coronavirus Pandemic’s hearing to discuss the origins of COVID-19, the disease caused by the SARS-CoV-2 virus.

HOME | [NEWS & RESOURCES](#) | ABB NEWSFEED

NEWSFEED

AABB’s Newsfeed is an essential resource offering the latest news, analysis, commentary and updates on critical topics for the blood and biotherapies community.

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Topics	
<input checked="" type="checkbox"/> Public Policy (156)	+
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<input type="checkbox"/> Blood Donation & Collection (12)	+
<input type="checkbox"/> Regulatory & Compliance (11)	+
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<input type="checkbox"/> Patient Transfusion (5)	+
<input type="checkbox"/> Quality (1)	+

Search



Viewing 1 to 10 of 136 (with filters applied)

Blood Community: Emergency Preparedness Legislation Must Include Blood Supply

3/28/2023

AABB, ABC and ARC urged policymakers to incorporate the safety of the blood supply into legislation to reauthorize the Pandemic and All-Hazards Preparedness Act (PAHPA).

AABB Urges Congress to Include Laboratory Workforce in Health Care Workforce Legislation

3/21/2023

AABB urged leaders of the U.S. Senate Committee on Health, Education, Labor and Pensions to include medical and public health laboratory professionals when developing legislation to strengthen the health care workforce.

Blood Community Urges Congress to Center the Blood Supply in Disaster Response Legislation

3/15/2023

AABB, America’s Blood Centers and the American Red Cross urged members of the U.S. House Energy and Commerce Committee to prioritize the availability of blood when developing legislation to reauthorize the Pandemic and All-Hazards Preparedness Act.



You have a unique perspective that nobody else in healthcare has

Share your story

- Write to your representatives during advocacy campaigns
 - Letters and emails are popular choices
 - Through the ASCLS Labvocacy Action Center. Calls for grass roots support: <https://ascls.org/labvocate/>
- Call your representatives, especially when they are in session, and tell others to do the same!
 - Call (202) 224-3121 (U.S. Capitol Switchboard) and ask for your Senator's/Representative's office
- Participate in research that generates data on the needs of laboratory professionals
 - ASCP Wage and Vacancy surveys
 - @LabWOHS

Other ways to share your Laboratory Journey:

Letters to the Editor

- Lookup your local newspaper at www.50states.com/news

Podcasts:


- Off the bench
- eLABorate Topics
- Inside the Lab
- Lab Culture
- Blood Advances Community Conversations

Lab newsletters


- Your organization's newsletter
- ASCLS Today
- Critical Values
- Today's Clinical Lab
- Medical Laboratory Observer
- Other society-specific newsletters

Podcast series / clinical laboratory


From sources across the web




Lab Medicine Rounds




Off the Bench




Answers from the Lab




Inside the Lab




LabMind



eLABorate Topics



Clinical Chemistry Podcast



JMAEvidence The Ratio...

ASCLS Today

ASCLS Today is the membership newsletter of the American Society for Clinical Laboratory Science.

To submit an article for ASCLS Today,

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To Lab (Week), or not to Lab (Week), that is the Question



Professional Visibility: Tips for Achieving Your Professional Goals

Volume 37 Number 2 | April 2023 Benjamin Galvan, MEd(ASCP), CIC, CDB, ASCS



Developing Medical Laboratory Science



Creating Partnerships: The Key to Increasing Visibility in Clinical Laboratory Science

Volume 37 Number 2 | April 2023 Jolene Le, MLS(ASCP), ASCLS Developing Professionals Forum Councilor Ivann Martinez, PhD, MEd(ASCP), ASCS Developer



News > All > ASCP NEWS -- April 2023

NEWS

ASCP NEWS -- April 2023

Apr 3, 2023, 00:19 AM by Susan Montgomery

Show Your Team Spirit: Join ASCP's 2023 Lab Week Photo & Video Contest

Lab Week is just around the corner, April 23-29, 2023. In honor of Lab Week, ASCP is celebrating the laboratory team and their impact in the diagnosis of diseases with the 2023 Saved by the Lab Photo & Video Contest! How do you and your team work together to affect patient care? Now is the time for your entire laboratory team to come together and be creative in coming up with ideas for your video or photo contest entries!

To get started, upload your photo or video by 2 p.m. CDT on Friday, April 7, 2023. Vote for your favorites during Round One of voting by 2 p.m. CDT on Thursday, April 13, 2023. The five entries in each category (photo or video) receiving the highest number of votes will move on to Round Two of voting, which begins at 2 p.m. CDT on Monday, April 17, 2023, and ends at 2 p.m. CDT on Thursday, April 20, 2023.

Alloantibody Exchange Receives HHS Equity Award

The U.S. Department of Health and Human Services (HHS) has announced that the Alloantibody Exchange, which has been promoted by ASCP and others in the blood bank community, has received

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Air National Guard Captain Carolyn Gill: Serving Both Patients and Country

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Submit your idea to criticalvalues@ascp.org and include "Story Pitch" in the subject line.

Labvocate Action Center

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The American Society for Clinical Laboratory Science
11107 Sunset Hills Road, Suite 100 | Reston, VA 20190-5376
Ph. 571.748.3770 | Email ascls@ascls.org

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Object to Lowering Personnel Standards for High Complexity Laboratory Testing

The Centers for Medicare and Medicaid Services has proposed a regulation under "§ 493.1489 Standard; Testing personnel qualifications" to allow individuals with bachelor's degree in nursing as a qualifying degree for high complexity testing personnel without any additional...

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Get SOCIAL!

- Create and communicate through a professional social media account
- Look up your State or Federal Senator/Representative and explore issues they support that impact the lab
- Connect with other laboratory professionals (and influencers) and engage with them
- Support laboratory professional societies and content related to advocacy and policy



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Beware -- always make sure that any content you read about, learn about, or share, comes from reliable sources

Step outside the laboratory and from behind the screen

Meet people, network, show you are human

- Look for the “Congressional schedule” - <https://www.congress.gov/calendars-and-schedules>
- Find the dates when your Senator/Representative will be participating in events in your district
- Go to Town Hall meetings
- Schedule a meeting in local office

Visit and engage with
your elected officials



2021 Annual Legislative Symposium
ASCLS-Kansas delegation (left to
right, Heather Santaniello, Jennifer
Jones, and Letycia Nuñez-Argote)
visiting Rep. Tracey Mann (District 1).

References

Special thanks to all authors in the ASCLS Today Professional Visibility Issue, April 2023.
Available from: <https://ascls.org/ascls-today/> YOU are INSPIRING!

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Thank you. Questions?

Thank you to Cardinal Health for this opportunity

Connect with us at:

Donna Spannaus-Martin | spann003@umn.edu

Stephanie Noblit | snoblitmls@gmail.com | Twitter and LinkedIn @StephanieNoblit

Letycia Nuñez-Argote | lety7273@gmail.com | Twitter & LinkedIn: @LeNA4LoveandLab

