



April 19, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Brett Guthrie
Chair, Health Subcommittee
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
Ranking Member, Health Subcommittee
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

SENT VIA ELECTRONIC DELIVERY

RE: Health Subcommittee Legislative Hearing: “Examining Existing Federal Programs to Build a Stronger Health Workforce and Improve Primary Care”

Dear Chairwoman McMorris Rodgers, Ranking Member Pallone, Health Subcommittee Chairman Guthrie and Health Subcommittee Ranking Member Eshoo:

The American Clinical Laboratory Association (ACLA) appreciates the opportunity to provide comments in advance of your legislative hearing, “*Examining Existing Federal Programs to Build a Stronger Health Workforce and Improve Primary Care*” on April 19, 2023. ACLA is the not-for-profit association representing the nation’s leading clinical and anatomic pathologic laboratories, including national, regional, specialty, end-stage renal disease, and nursing home laboratories. Laboratories are experiencing shortages across their workforce. While ACLA members are striving to grow, attract, and retain laboratory professionals, a long-term public-private collaboration is essential to ensure a robust laboratory workforce in the years ahead. As you review and reauthorize public health programs to support health care workforce education and training, ACLA welcomes the opportunity to offer recommendations to mitigate shortages experienced by the nation’s laboratories.

Laboratory workforce is foundational to the U.S. healthcare delivery system

The laboratory workforce is foundational to the U.S. healthcare delivery system. As 70% of all clinical decisions are informed by laboratory services¹ – the nation’s laboratory workforce is delivering for patients and providers every day across the country. From patient sample collection, sample transport, and analysis of samples, to delivering test results, the laboratory workforce provides patients and their clinicians with vital information for the prevention, diagnosis, treatment, and management of disease.

¹ Centers for Disease Control and Prevention, Division of Laboratory Systems: <https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html>

Growing workforce shortage in laboratories

Like many other health care professions, laboratories are facing a declining number of accredited education programs to meet state and federal regulatory requirements for personnel, as laboratory professionals exit the workforce through planned retirements, or, in part as a response to the exceptional pressures on the laboratory workforce during the Covid-19 public health emergency (PHE). From the earliest days of the PHE, laboratory professionals heroically met the challenge of unprecedented demand for testing services across the country and continued to deliver during peaks of infection, while also continuing to provide screening and diagnostic services for all diseases and conditions.

Current workforce shortages are widespread and significant, with some laboratories operating at shortages from 10-25% vacancy rates. High vacancy rates contribute to employee “burnout” as there is too much work for too few existing staff, further exacerbating personnel shortages. The most significant shortages are among highly specialized laboratory technicians and technologists including cytotechnologists, histotechnologists, and microtechnologists, as well as molecular technologists and histotechnologists in esoteric laboratories. Qualified personnel are in such short supply that ACLA members find it can take up to six months to fill a position in these fields.

The need for additional personnel is acute and structurally persistent. For example, there are approximately 500 unfilled cytotechnology positions in the United States at any given time and 16% of the current practicing cytotechnologists expect to retire within the next 5 years.² Not enough new cytotechnologists are being trained to meet this need. In fact, only an average of 134 new cytotechnologists are taking the national registry exam and entering the workforce each year.³ Similarly, the shortage of medical technologists and technicians is also predicted to get worse in the coming years. Even before the pandemic’s negative impact on staffing levels, CNN predicted that by 2025, the US will likely face a shortage of 98,700 medical technologists and technicians.⁴ According to the U.S. Bureau of Labor Statistics (BLS), clinical laboratory technicians and technologist occupation shortages are projected to increase by 7% between 2021 and 2031⁵, about as fast or faster than all other healthcare occupations. Further, the BLS reports employer demand for skilled phlebotomists who collect patient blood samples in physician offices, clinics, and in laboratory patient services centers, is projected to increase by 10% between 2021 to 2031.⁶

Genetic counselors and medical geneticists, critical to results interpretation and patient and provider engagement to inform the best care pathway for patients, are also in shortage, most acutely in rural areas and other underserved communities. These professionals tend to live in or close to urban areas and academic medical centers. Further, southern states in addition to certain

² American Society of Cytopathology, Barbara A. Crothers, DO, *Statement to the Clinical Laboratory Improvement Advisory Committee (CLIA) on the topic of technology workforce in the United States* (March, 2018).

³ *Id.*

⁴ Kavilanz, Parija, “The US can't keep up with demand for health aides, nurses and doctors.” CNN Money (May 2018).

⁵ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Clinical Laboratory Technologists and Technicians, at <https://www.bls.gov/ooh/healthcare/clinical-laboratory-technologists-and-technicians.htm> (visited March 03, 2023).

⁶ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Phlebotomists, at <https://www.bls.gov/ooh/healthcare/phlebotomists.htm> (visited March 06, 2023).

midwestern and western states tend to have a lower number of medical geneticists and genetic counselors per 500,000 people. For example, in one study, three states, West Virginia, Mississippi, and Wyoming had less than one genetic counselor per 500,000 people.⁷ A 2017 workforce study noted that it may be as late as 2030 before the supply of genetic counselors meets the current demand for their services in the United States.⁸

It is imperative that we invest in the clinical laboratory workforce to meet the current and future needs of our healthcare systems.

Recommendations

ACLA members are making efforts within their companies and communities to support increasing the pipeline of individuals from high school level and onward who might enter a career in laboratory sciences. For example, one ACLA member has invested in a local nonprofit program that develops after school and summer programs for students interested in STEM, incorporating a laboratory science component to the curriculum, and increasing awareness about this future profession. Another ACLA member has focused efforts on retainment and career advancement for current employees through internal training, mentorship, and tuition reimbursement to get advanced degrees needed for certain laboratory personnel roles.

While ACLA members are individually contributing to efforts to address workforce challenges, we are pleased for the opportunity to make recommendations for how public-private collaboration can address this challenge.

Education, Training and Licensure

ACLA encourages policymakers to advance legislation to establish requirements for states to institute reciprocity for licensure requirements, thereby decreasing burden and cost for providers and increasing patient access. Licensing is an important part of ensuring quality care, though it can also be burdensome to those trying to provide such care. For one ACLA member offering genetic testing, each of their genetic counselors held an average of 12 state licensures, which together cost an average of \$3000 and required 52 hours of administrative work for each counselor to establish. Multiplied by the thousands of genetic counselors offering services across state lines through telehealth results in hundreds of thousands of dollars and thousands of hours of administrative work to comply with state licensure requirements. Often, licensing requirements do not differ materially among states. Allowing licensed healthcare practitioners to practice across state lines in the appropriate instances would help to address the shortage, including of genetic specialists, among others.

ACLA recommends that policymakers consider requiring the Clinical Laboratory Improvement Advisory Committee (CLIAC) to update educational and training

⁷ United States Government Accountability Office, *Genetic Services, Information on Genetic Counselor and Medical Geneticist Workforces* at <https://www.gao.gov/assets/gao-20-593.pdf> (July, 2020).

⁸ Hoskovec, Jennifer M et al. "Projecting the Supply and Demand for Certified Genetic Counselors: a Workforce Study." *Journal of genetic counseling* vol. 27,1 (2018): 16-20. doi:10.1007/s10897-017-0158-8

requirements considering the workforce shortages for these professions. More training opportunities are needed to open the talent pipeline to meet applicable personnel requirements, but the personnel requirements may be more stringent than necessary to ensure quality in some cases. For example, CLIA requires a Masters degree for cytotechnologists in addition to certain other training. Where training and educational requirements can be reduced without sacrificing quality, it would help resolve the workforce shortages. To the extent that training requirements can be shifted from being a pre-condition for employment to being an on-the-job training arrangement, that would also help to mitigate challenges with finding qualified workforce.

ACLA encourages the establishment of federal support for clinical laboratory educational programs. For some clinical laboratory scientists and technicians to meet federal and state licensure requirements, they must take specialized courses in the clinical laboratory sciences. Clinical laboratory education programs can be expensive given the costs of maintaining up-to-date equipment in laboratories to meet modern requirements and workforce demands. Increased federal programs to augment institutional funding for laboratory sciences education programs would help to improve increased enrollment in existing and future laboratory sciences curricula to meet the increasing need for workers with four-year degrees, such as histotechnologists and medical laboratory scientists⁹.

ACLA recommends the establishment of a federal loan repayment program for laboratory professionals. As with other healthcare professionals, funding this education can be a burden and barrier to those entering the field. Programs such as the National Health Service Corps for physicians and other programs that support loan repayment for nurses could serve as models for the establishment of a federal program for loan forgiveness and repayment for laboratory professionals.

Remote Review

ACLA recommends that all relevant laboratory professionals be permitted to remotely review laboratory data and slides, which experience during the COVID-19 PHE has demonstrated is effective, appropriate, and high quality. Early in the course of the COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS) and Food and Drug Administration (FDA) recognized the importance of ensuring that laboratory operations could safely continue amidst the personnel and travel limitations that were put in place within communities across the country. These Agencies put forth guidance that enabled laboratory professionals (i.e., pathologists, cytogeneticists, laboratory technologists) to review laboratory data and slides from an alternative site, such as their home office, without a separate Clinical Laboratory Improvement Amendments (CLIA) certificate and expanded the availability of devices to enable home review of laboratory data and slides.^{[1],[2]} These policies were set to run

⁹ Garcia E, Kundu I, Kelly M, Guenther G, Skillman SM, Frogner B. *The Clinical Laboratory Workforce: Understanding the Challenges to Meeting Current and Future Needs*. American Society for Clinical Pathology (Washington, DC) and Center for Health Workforce Studies, University of Washington (Seattle, WA), April 2021

^[1] Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health

Emergency (March 26, 2020), available at <https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>.

^[2] Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19)

Public Health Emergency (April 24, 2020), available at <https://www.fda.gov/media/137307/download>.

through the end of the COVID-19 public health emergency (PHE). These actions enabled laboratories to continue operations by allowing appropriate personnel to work from remote locations via secure connection to their information systems. This resulted in significant changes to the landscape and work location of laboratory professionals who, in many cases, worked from their home offices at a significant distance from the primary laboratory.

While CMS has notified laboratories that they will continue enforcement discretion for pathologists with respect to the policy to require a separate CLIA certificate when reviewing laboratory data and information from a home office, this enforcement discretion policy will not be extended for other laboratory personnel. This narrow application of enforcement discretion would either require many non-pathologist laboratory professionals to return to the primary laboratory site, which may not be at a reasonable distance to their home, or obtain a separate CLIA certificate for their home office, which carries additional challenges from an operational perspective. Given the current working landscape and challenges with recruiting and retaining laboratory employees, it is critical that laboratories can continue offering remote working capabilities to all qualified personnel.

Telehealth

ACLA recommends the permanent extension of telehealth coverage. In addition to remote review of laboratory information and data, one of the ways to mitigate some of the impacts of workforce shortages is by expanding virtual access to care across geographically separated patients and providers. Providers can meaningfully engage with patients during such sessions, order laboratory testing following a telehealth visit, and later leverage telehealth to relay laboratory testing results. Telehealth can help ease provider burden and as appropriate expand testing access to patients across the country.

Developments in Digital Health

Finally, developments in digital pathology and digital cytology products could offer improvements to patient care as we face a shortage of these critically needed professionals.

ACLA recommends that Congress encourage the Administration to consider workforce challenges when prioritizing review of *in vitro* diagnostics (IVD) technologies that could ameliorate worker shortages.

Expanded Recruitment of Foreign Laboratory Workers

While ACLA fully supports efforts to expand educational and training opportunities as well as remote review to increase the numbers of qualified laboratory personnel in the United States, expanding opportunities for recruitment of foreign workers could also help alleviate critical staffing shortages. There is a strong international pool of qualified laboratorians, but ACLA members find it difficult to access the number of workers they need. Foreign lab personnel can be recruited through either an H1-B visa or EB-3 Permanent Resident visa. However, labs face challenges with both programs.

There are a limited number of H1-B visas available in any year and the current lottery system is problematic. Under the current system, initial applications are due in March or April every year. These applications go into a lottery. Full visa applications are then submitted for candidates who

are successful in the lottery. Finally, if a candidate's full application is approved, they may be cleared to begin work October 1. However, ACLA members have noted that recent immigration processing delays have pushed back start dates to December or January. This H1-B process is not aligned with how businesses actually hire and operate. Labs cannot always foresee what their staffing needs will be six months or a year in advance. Moreover, labs cannot anticipate how many applicants will make it through the lottery. For example, for one ACLA member, approximately 20% of applications were successful in 2022, whereas in previous years up to 50% were. It would be helpful to eliminate the lottery and have H1-B applications considered monthly or on a rolling basis instead of annually. Increasing the number of H1-B visas available for healthcare workers in general, and laboratorians in particular, would also be helpful. Finally, amending the educational requirements for an H1-B visa could also be considered. Currently, candidates are required to have a bachelor's degree to qualify for H1-B visas. This requirement limits the available pool of foreign workers for laboratory roles in the United States. Reducing this requirement and permitting work experience or certifications to substitute for bachelor's degrees would increase the number of qualified foreign candidates.

Pursuing permanent resident visas for laboratory personnel is also challenging due to per country caps and long processing times. To increase the number of foreign candidates available to fill critical lab roles, we suggest exempting healthcare workers from per-country caps on immigrant visas and making the processing of healthcare worker visas a priority to reduce delays. It may also be worthwhile to consider the creation of a non-immigrant visa program for healthcare workers.

ACLA stands ready to engage with lawmakers on proposals to address the root causes and mitigate challenges associated with healthcare workforce shortages. Thank you for your consideration of these comments. If ACLA may be of further assistance, please contact Holly Grosholz at hgrosholz@acla.com

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association