



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care
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October 5, 2023

The Honorable Jason Smith
U.S. House of Representatives
1011 Longworth House Office Building
Washington, DC 20515

Submitted electronically via email to WMAccessRFI@mail.house.gov.

Dear Chairman Smith:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide input to the Committee as it explores ways to address chronic disparities in access to care in rural and underserved communities. AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

AMP was particularly pleased to see the RFI's focus on healthcare workforce shortages. Clinical laboratories are facing challenges with maintaining adequate workforce and staffing to provide timely laboratory results, challenges which were further exacerbated by the COVID-19 pandemic. The need for laboratory professionals is expected to grow by 11% between 2020 and 2030, which is higher than the average growth rate for any other health profession.¹ We are pleased that under your leadership, the Committee intends to address workforce issues and we are grateful for the opportunity to provide these solutions for your consideration.

Enable Qualified Doctoral Scientists to Bill Medicare for Interpretive Services

A strong incentive for pursuing a career in laboratory medicine would be to ensure that these professionals are able to bill payers for their services, allowing their institutions to receive adequate reimbursement which then enables them to appropriately compensate their medical laboratory scientists. AMP believes that medical professionals should be able to practice at the top of their licenses to increase access to care and achieve healthcare savings. This currently is not the case in molecular medicine, which creates obstacles to efficient and improved patient care.

¹ Leber AL, Peterson E, and Dien Bard J. "The Hidden Crisis in the Times of COVID-19: Critical Shortages of Medical Laboratory Professionals in Clinical Microbiology." *Journal of Clinical Microbiology*, Vol 60 issue 8 August 2022.

When a treating physician orders a molecular or genetic test on a patient, the sample is sent to a clinical pathology or molecular pathology laboratory for testing. Molecular pathology procedures (e.g., multigene panel test to assess a patient’s tumor) involve multiple steps including preparation of the patient sample; performing the molecular diagnostic test; interpreting the results in the context of the patient; and ultimately preparing a comprehensive report for the treating physician and patient. The evaluation and interpretation of test results require specialized professional training, certification, and expertise, and the medical professionals performing these services have a doctoral degree, either medical (MD/DO) or scientific (PhD). However, under current law and CMS billing practices, only physicians are allowed to bill Medicare directly for evaluation and interpretation services.

While molecular pathology services, including genomic sequencing procedures, are housed in the Clinical Laboratory Fee Schedule (CLFS), billing codes that represent interpretation and reporting services reside on the Physician Fee Schedule (PFS). Since qualified PhD doctoral scientists who perform and interpret molecular pathology procedures are not currently considered Qualified Healthcare Professionals under the Social Security Act, these individuals are not allowed to bill directly for these services on the PFS. Thus, while the laboratory is reimbursed for the procedure under the CLFS, reimbursement for the interpretation and development of the test report is limited to physicians (MD/DO) billing the PFS. AMP believes that appropriately trained and board-certified non-physician doctoral scientists who have the required qualifications to interpret and report molecular pathology tests should also be eligible to bill Medicare directly for these services.

As molecular pathology procedures become increasingly more complex, and the value and the need for these tests continue to increase as the promise of precision medicine is realized, it is even more critical for these services to be interpreted by trained molecular laboratory professionals, who may include both physicians and qualified PhDs. Allowing both qualified doctoral scientists and physicians to bill directly for interpretive services will expand access to care throughout the United States with the added benefit of helping to recruit and retain these health professionals. Thus, we encourage you to explore legislation to enable qualified doctoral scientists to bill Medicare directly for their professional services and stand ready to work with you on such an effort.

Expand Training Programs for Laboratory Professionals

While policy related to training of laboratory professionals may fall outside the jurisdiction of the Ways and Means Committee, we still offer it here as a solution to address the ongoing workforce shortage within clinical laboratories. One of the challenges to maintaining an adequate laboratory workforce is that there are fewer graduates than vacancies for medical laboratory professionals. The number of medical laboratory scientist training programs declined by 57.2%, from 638 to 273, in the 16-year period between 1983 to 1999. In 2021, it declined even further to 240 training programs accredited by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS).² Over the next 5 years, the field anticipates a 14.5% rate of retirement, resulting in an even higher number of vacancies.³ Taking into

² Ibid.

³ Ibid.

account that the number of qualified applicants will remain woefully low, we anticipate the shortage of these critical professionals will continue to worsen.

For this reason, we encourage Congress to invest resources in expanding training programs for medical laboratory scientists via grants to academic institutions to expand existing training programs and create novel ones. To encourage increased enrollment, we recommend funding a public awareness campaign to generate interest in these professions as well as a loan repayment program to help students complete the needed training. The American Society for Clinical Pathology and the Center for Health Workforce Studies at the University of Washington found that a lack of awareness about clinical laboratory careers constrains the pipeline of potential new entrants and AMP believes that such a public awareness campaign will significantly raise the visibility of these professionals, especially in light of the public's newfound understanding of the importance of molecular testing from the COVID-19 pandemic.⁴

Thank you again for the opportunity to submit these recommendations as you continue to work to address healthcare workforce issues that contribute to chronic disparities in access to care for rural and underserved communities. If AMP may be of further assistance, please do not hesitate to contact Annie Scrimenti, Associate Director of Public Policy and Advocacy at ascrimenti@amp.org.

Sincerely,

Laura J. Tafe, M.D.
President, Association for Molecular Pathology

⁴ https://familymedicine.uw.edu/chws/wp-content/uploads/sites/5/2021/05/Siemens_Clinical-Laboratory-Workforce_Report_042721.pdf