COLLEGE of AMERICAN PATHOLOGISTS

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BILL 24-764, the "Clinical Laboratory Practitioners Amendment Act of 2022"
Committee on Health, D.C. City Council
1350 Pennsylvania Ave., N.W., Washington, D.C. 20004

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Thank you, Chairman Gray and members of the Health Committee for the opportunity to testify this morning on Bill 764, the "Clinical Laboratory Practitioners Amendment Act of 2022." I am Don Karcher, President-Elect of the College of American Pathologists and Professor and Immediate Past Chair of Pathology at George Washington University here in the District of Columbia. I'm here representing both GW and the CAP, the world's largest board-certified pathologists' organization and the leading laboratory accreditation and proficiency testing program provider. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

In 2015, our D.C. CAP membership previously opposed the D.C. clinical laboratory personnel licensure law based on the CAP's longstanding position that local regulation of clinical laboratory personnel is unnecessary and does not guarantee quality assurance in the laboratory. In recent years, multiple states have recognized the redundant nature of these laws, in addition to the administrative and financial burdens on the clinical laboratory. As our members have worked tirelessly to respond to the needs of patients throughout two public health emergencies, COVID-19 and Monkeypox, the workload in our laboratories has been unprecedented.

D.C. clinical laboratories are already subject to robust federal oversight which require rigorous quality assurance standards under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). While it is our position that D.C.'s laboratory personnel licensure law is superfluous, we are requesting several amendments to improve the current law and ensure excellence in the clinical laboratory. We have previously submitted our recommended amendments in writing to the Committee. I'd like to briefly mention some of our recommendations this morning.

First, we believe all clinical laboratory personnel should be under the "general supervision and direction" of a physician or clinical laboratory director to guarantee quality laboratory practices are upheld for testing under CLIA. The current law omits supervision and direction for certain personnel and should be corrected to provide supervision across medical technology, cytotechnology, and histotechnology personnel classes.

Second, "physician supervision" of medical laboratory technicians should not be omitted from the law and should also include an option for supervision by the clinical laboratory director. This change is consistent with our prior amendments to subject personnel to supervision under the clinical laboratory director.

Third, the scope of histologic technicians should remove reference to "animal" tissues and clarify tissues used for "patient diagnosis and treatment." The current law could incorrectly apply to non-CLIA testing and research without this statutory fix.

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Fourth, we advocate for the Advisory Committee on Clinical Laboratory Practitioners, of which I'm currently a member, to have discretion on the necessity for rule development for personnel licensure and registration, recognizing that any regulations must meet federal standards under CLIA.

Lastly, we request minor grammatical changes. We also strongly support the proposed transfer of the regulatory authority from the Board of Pharmacy to the Board of Medicine and see this as an appropriate fix.

In closing, as diagnostic experts we recognize the important work to guarantee quality assurance in the clinical laboratory and proper safeguards to provide timely and accurate care to patients. We urge the committee to re-evaluate the need for D.C.'s clinical laboratory licensure law. If the repeal of the licensure law cannot be considered, we urge the committee to include our recommended amendments to bolster clinical laboratory practice while ensuring that laboratory operations are not undermined or encumbered by DC-specific regulations that could also conflict with Federal CLIA law.

Thank you for the opportunity to testify today and for your consideration.

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