COLLEGE of AMERICAN PATHOLOGISTS

September 19, 2022

Via email: pmendelson@dccouncil.us
vgray@dccouncil.gov

Hon. Phil Mendelson
Chairman, Council of the District of Columbia
1350 Pennsylvania Avenue, NW, Suite 504
Washington, DC 20004

Hon. Vincent C. Gray
Chairman, Committee on Health
1350 Pennsylvania Avenue NW, Suite 406
Washington, DC 20004

Dear Honorable Mendelson and Honorable Gray:

On behalf of the College of American Pathologists (CAP), and our pathologist members in the District of Columbia, I am writing to convey our request for amendments to pending legislation before the D.C. City Council entitled, the "Clinical Laboratory Practitioners Amendment Act of 2022" (B24-764).

The CAP is the world's largest organization of board-certified pathologists and the leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. Our pathologist members practice in hospitals, independent clinical laboratories, and academic medical centers.

The CAP does not believe that local regulation of clinical laboratory personnel is necessary for, nor integral to quality assurance in the clinical laboratory. Accordingly, our members in D.C. opposed the enactment of the original D.C. licensure law (D.C. Law 20- 272; 62 DCR 6643) in 2015. Our position is based upon the rigorous quality assurance provisions embedded in the federal Clinical Laboratory Improvement Amendments (CLIA) law, and related regulations, that regulate all clinical laboratories. Of note, several states (GA, TN) in the last couple of years have since repealed their respective clinical laboratory personnel licensure laws, in deference to federal oversight, recognizing the redundant nature of state licensure laws.

Notwithstanding our position that D.C.'s laboratory personnel licensure law is superfluous, we submit the following recommendations to improve the law as follows:

I. The law should explicitly provide supervision requirements for all clinical laboratory personnel categories. Clinical laboratory personnel should be under the 'general supervision and direction' of a physician or clinical laboratory director. Our proposed amendments incorporate this oversight into the

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delineated scope and practice areas for cytotechnology, medical laboratory technology, and histotechnology.

The current D.C. law omits any reference to the "supervision and direction" of personnel for some of the categories. The oversight of personnel in the clinical laboratory, by CLIA-qualified directors, is crucial to ensuring that optimal, quality laboratory practices are adhered to in the conduct of CLIA testing.

II. "Physician supervision" should be included as an option for oversight of medical laboratory technician and not deleted, as proposed in the current legislation. In addition to retaining "physician supervision," the sentence specifying supervision should include "clinical laboratory director," consistent with our proposed physician supervision amendments.

III. The scope of histologic technicians should delete reference to "animal" tissues and instead clarify that the tissues are used for "patient diagnosis and treatment." The current language referencing "animals" and generically "human disease" could be erroneously construed to apply to non-CLIA diagnostic activity, including research related testing.

IV. The Advisory Committee on Clinical Laboratory Practitioners should reserve the right to as needed, develop, submit, and promulgate guidelines and rulemaking for the licensure and registration of cytotechnologists, histotechnologists, and medical technologists in accordance with the Committee's discretion. (We fully support statutorily transferring the reporting authority of this committee from the Pharmacy Board to the Medical Board, as it is proposed in the current legislation.)

V. The correction of typographic errors should be included in the definition of "medical laboratory."

The delineated amendments are detailed further on the attachment to this correspondence. We hope that the Council of the District of Columbia will see the merit in these amendments to ensure excellence in patient care and the clinical laboratory.

Thank you for your courtesies and consideration. If you would like additional information, or if we can further assist the Committee or the Council, please contact Barry Ziman at (202-453-7117), bziman@cap.org.

Sincerely,

Emily E. Volk, MD, FCAP
President, College of American Pathologists

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cc: Ronan Gulstone, Director, Office of Policy and Legislative Affairs, Office of the Mayor, Washington, D.C.
Donald Karcher, MD, CAP President-Elect, George Washington University
Barry Ziman, Director Legislation and Political Action, College of American Pathologists

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