ENGROSSED ORIGINAL

A BILL

20-289

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

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To amend the District of Columbia Health Occupations Revision Act of 1985 to establish an Advisory Committee on Clinical Laboratory Practitioners that shall develop and submit to the Board of Pharmacy guidelines to regulate the practices of cytotechnology, histotechnology, medical technology, practices by histologic technicians, medical laboratory technicians, and phlebotomists and to establish the minimum qualifications for licensure of cytotechnologists, histologic technicians, histotechnologists, medical laboratory technicians, medical technologists, and registration of phlebotomists.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Clinical Laboratory Practitioners Amendment Act of 2014."

Sec. 2. The District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.),* is amended as follows:

(a) The table of contents is amended as follows:

(1) Strike the phrase "Sec. 208. Board of Pharmacy." and insert the phrase "Sec. 208. Board of Pharmacy and Advisory Committee on Clinical Laboratory Practitioners." in its place.

(2) A new TITLE VIII-E is added to read as follows:

"TITLE VIII-E

"QUALIFICATIONS FOR LICENSUREE TO PRACTICE AS A CLINICAL

LABORATORY PRACTITIONER.

"Sec. 871. Qualifications for licensure.

"Sec. 872. Waiver.

"Sec. 873. Exemption from licensure for select clinical laboratory practitioners..".

"Sec. 874. Transition of licensed and registered clinical laboratory practitioners.".

(b) Section 102 (D.C. Official code § 3-1201.02) is amended as follows:

(1) A new paragraph (3A) to read as follows:

"(3A) "Practice of cytotechnology" means the microscopic study or examination of body fluids, tissues, or cells desquamated from a body surface or lesion for the practice of clinical laboratory science, including detecting malignancy and microbiologic changes and the measurement of hormonal levels.".

(2) The existing paragraph (6A) is re-designated as paragraph (6A-ii)

(3) A new paragraph (6A) is added to read as follows:

"(6A) "Practice by histologic technicians" means the preparation of human and animal tissue samples for microscopic examination.

(4) A new paragraph (6A-i) is added to read as follows:

"(6A-i) "Practice of histotechnology" means the preparation and processing of sections of body tissue for examination through the processes of fixation, dehydration, embedding, sectioning, decalcification, microincineration, mounting, and routine staining, and includes the identification of tissue structures, cell components, and their staining characteristics, and relating them to physiologic functions.

(2) New paragraphs (6B-i) and (6B-ii) are added to read as follows:

"(6B-i) "Practice by medical laboratory technicians" means performing tests on tissue, blood, and body fluids for the purpose of assisting in the diagnosis and treatment of diseases while working under the supervision of a medical technologist or physician. Such tests performed by medical laboratory technicians includes monitoring tests and procedures, and preparing blood, urine, and tissue specimens for analysis; using sophisticated laboratory equipment to look for bacteria, parasites, and other microorganisms; analyzing the chemical content of fluids; matching blood for transfusions; and testing for drug levels in the blood to show how a patient is responding to treatment.

"(6B-ii) "Practice of medical technology" means performing clinical laboratory tests and procedures in areas of a clinical laboratory, with the exception of cytotechnology, which require the exercise of independent judgment and responsibility.".

(c) Section 208 (D.C. Official Code § 3-1202.08) is amended as follows:

(1) The section head is amended to read as follows:

"Sec. 208. Board of Pharmacy and Advisory Committee on Clinical Laboratory Practitioners.".

(2) Subsection (b)(1) is amended to read as follows:

"(b)(1) The Board shall regulate the practice of pharmacy, the practice of pharmaceutical detailing, and the practice of clinical laboratory practitioners with guidelines approved by the Advisory Committee on Clinical Laboratory Practitioners."

(3) Subsections (i), (j), (k), (l), (m), and (n) are added to read as follows:

"(i) There is established an Advisory Committee on Clinical Laboratory Practitioners which shall consist of 5 members appointed by the Mayor.

"(j) The Advisory Committee shall develop and submit to the Board guidelines for the licensure of cytotechnologists, histologic technicians, histotechnologists, medical laboratory technicians, medical technologists, and the registration of phlebotomists.

"(k) The Board shall administer the examination required for cytotechnologists, histologic technicians, histotechnologists, medical laboratory technicians, and medical technologists.

"(l) Of the members of the Advisory Committee on Clinical Laboratory Practitioners, one shall be a pathologist certified by the American Board of Pathology or the American Board of Osteopathic Pathology; one shall be a medical technologist and supervisor; one shall be a medical technologist who is not a supervisor; one shall be a medical laboratory technician; and one shall be a consumer member with no direct affiliation with clinical laboratory practitioners or another health profession.

"(m) The qualifications for the professional members shall be as follows:

"(1) The pathologist, for at least 3 years preceding appointment, shall have been actively engaged as a pathologist in rendering professional services in pathology or in the education and training of medical personnel in pathology;

"(2) The medical technologist, for at least 3 years preceding the appointment, shall have been actively engaged as a medical technologist in rendering professional services in

medical technology or in the education and training of medical technologists;

"(3) The medical laboratory technician, for at least 3 years preceding the appointment, shall have been actively engaged as a medical laboratory technician in rendering professional services as a medical technician.

"(n) The initial appointees, with the exception of the pathologist and the consumer representative, shall become licensed immediately upon their appointment and qualification as members of the Advisory Committee.".

(d) Section 401(b)(2) (D.C. Official Code § 3-1204.01(b)(2)) is amended by striking the phrase "the audiologist and speech-language pathologist members initially appointed to the Advisory Committee," and inserting the phrase "the audiologist and speech-language pathologist members initially appointed to the Board, the clinical laboratory practitioner members initially appointed to the Board," in its place.

(e) Section 501 (D.C. Official Code § 3-1205.01) is amended by striking the phrase "chiropractic," and inserting the phrase "chiropractic, cytotechnology," in its place, by striking the phrase "dietetics," and inserting the phrase "dietetics, as a histologic technician, histotechnologist," in its place, and by striking the phrase "massage therapy," and inserting the phrase "massage therapy, as a medical laboratory technician, medical technology," in its place.

(f) Add a new Title VIII-E to read as follows:

"TITLE VIII-E
"QUALIFICATIONS FOR LICENSURE TO PRACTICE AS A CLINICAL LABORATORY PRACTITIONER.

"Sec. 871. Qualifications for licensure.

"(a) The Board of Pharmacy shall license as a cytotechnologist a person who, in addition to meeting the requirements of Title V, has:

"(1) At least a baccalaureate degree from an accredited institution that incorporates the academic coursework and minimum hours of supervised training required by the regulations adopted by the Board and whose program is accredited by an agency recognized by the U.S. Department of Education, or has qualified as a cytotechnologist under federal regulations; and

"(2) Passed a national certification examination given by the Board or from a body recognized by the Board.

"(3) Has a baccalaureate degree and training or experience as the Board determines is appropriate for cytotechnologist.

"(b) The Board of Pharmacy shall license as a histologic technician a person who, in addition to meeting the requirements of Title V, has demonstrated, to the satisfaction of the Board, that he or she possesses the medical laboratory education, training, or experience that is appropriate for medical laboratory technicians concentrating in histology.

"(c) The Board of Pharmacy shall license as a histotechnologist a person who, in addition to meeting the requirements of Title V, has:

"(1) At least a baccalaureate degree in biological sciences and chemistry from an accredited institution recognized by the Council for Higher Education Accreditation or

the Department of Education;

"(2) Successfully completed a histotechnology program accredited by an agency recognized by the U.S. Department of Education or one year of full-time laboratory work experience in histology deemed acceptable by the Board of Pharmacy; and

"(3) Passed a national certification examination given by the Board or from a body recognized by the Board."

"(4) Has a baccalaureate degree and training or experience as the Board determines is appropriate for histotechnologist.

"(d) The Board of Pharmacy shall license as a medical laboratory technician a person who, in addition to meeting the requirements of Title V, has:

"(1) Successfully completed a medical laboratory technician program accredited by an agency recognized by the U.S. Department of Education or a military medical laboratory specialists program;

"(2) Has obtained an associate degree or has at least 60 semester hours or 90 quarter hours from an accredited institution recognized by the Council for Higher Education Accreditation or the Department of Education, including a minimum of 6 semester hours or 9 quarter hours of biological science and 6 semester hours or 9 quarter hours of chemical science, and has 3 years of full-time acceptable medical laboratory work experience within the last 5 years; or

"(3) Has been previously qualified as a medical laboratory technologist under

federal regulations; and

"(4) Passed a national certification examination given by the Board or from a body recognized by the Board."

"(5) Has a baccalaureate degree and training or experience as the Board determines is appropriate for medical laboratory technician.

"(e) The Board of Pharmacy shall license as medical technologist a person who, in addition to meeting the requirements of Title V, has:

"(1) At least a baccalaureate degree from an accredited institution that includes courses in biological science, chemistry, and mathematics, and successfully completed a medical technology program accredited by an agency recognized by the U.S. Department of Education;

"(2) A baccalaureate degree from a regionally accredited institution recognized by the Council for Higher Education Accreditation or the Department of Education, including a minimum of 16 semester hours or 24 quarter hours of biological science, 16 semester hours or 24 quarter hours of chemical science, including 1 semester or 1 quarter in organic chemistry or biochemistry, 1 semester or 1 quarter of mathematics, and 3 years of full-time, clinical laboratory work experience in the major disciplines of laboratory practice deemed acceptable by the Board of Pharmacy, within the last 5 years and one of the following:

"(A) Certification as a medical laboratory technologist by a national certifying organization acceptable to the Board;

"(B) Successful completion of a medical laboratory technology program accredited by an agency recognized by the U.S. Department of Education; or

"(C) Successful completion of an advanced military medical laboratory specialist program;

"(3) A baccalaureate degree from an accredited institution, including a minimum of 16 semester hours or 24 quarter hours of biological science, 16 semester hours or 24 quarter hours of chemical science, including 1 semester or 1 quarter in organic chemistry or biochemistry, 1 semester or 1 quarter of mathematics, and 5 years of full-time clinical laboratory work experience in the major disciplines of laboratory practice deemed acceptable by the Board of Pharmacy, within the last 10 years. For the purposes of this paragraph, the term "major disciplines of laboratory practice" includes, but is not limited to, blood banking, chemistry, immunology, and microbiology.;

"(4) Has been previously qualified as a medical technologist under federal regulations; or

"(5) Has a baccalaureate degree and training or experience as the Board determines is appropriate for medical technologists concentrating in categories such as blood banking, chemistry, hematology, immunology, microbiology, and virology.

"(f) For the purposes of this paragraph, the term "major disciplines of laboratory practice" includes blood banking, chemistry, immunology, and microbiology.

"Sec. 872. Waiver.

"The Board shall waive the requirements specified in section 871 for any

cytotechnologist, histologic technician, histotechnologist, medical laboratory technician, or medical technologist who has passed an examination approved by the Board, and who has received a certification from a national certifying organization acceptable to the Board whose current eligibility requirements are equivalent to or exceed the qualifications established under the Clinical Laboratory Amendment Act of 2005, effective July 26, 2005 (D.C. Law 16-33; D.C. Official Code §44-201 *et seq*.),.

"Sec. 873. Exemption from licensure for select clinical laboratory practitioners.

"(a) Section 1001 of the District of Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1210.01), concerning the practice of a health occupation without a license shall not apply to any cytotechnologist, histotechnologist, medical laboratory technologist, medical technologist, histologic technician, or phlebotomist who is:

"(1) Licensed in the District of Columbia under any other act and who engages in the practice for which he or she is licensed or registered;

"(2) Employed by the United States government or any bureau, division, or agency thereof while in the discharge of the employee's official duties;

"(3) Engaged exclusively in education or research; provided, that the results of any examination performed are not used in the diagnosis, prevention or treatment of a disease, or assessment of a medical condition;

"(4) A student or trainee enrolled in a medical laboratory education program; provided, that the activities constitute a part of a planned course in the program, that the

person is designated by title such as intern, trainee, or student, and that the person works directly under a person licensed under section 871;

"(5) A person who exclusively performs laboratory tests, classified as waived pursuant to 42 CFR § 493, which are determined by the Secretary of the U.S. Department of Health and Human Services to have an insignificant risk of an erroneous result, including those which:

"(A) Have been approved by the United Stated Food and Drug Administration;

"(B) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

"(C) The Secretary of the U.S. Department of Health and Human Services has determined pose no reasonable risk of harm to the patient if performed incorrectly;

"(6) A pathologist or other licensed physician:

"(7) A laboratory manager who does not perform or supervise laboratory tests;

"(8) Personnel performing point-of-care testing; provided, that:

"(A) A laboratory director or other qualified, licensed person, if this duty has been so delegated by the laboratory director, who provides oversight and is responsible for ensuring the development and implementation of:

"(i) A protocol of implementation, including tests to be performed and

staff who will perform the tests;

"(ii) Criteria to be used in selecting the method of testing to be used for point-of-care testing;

"(iii) Minimum training and education requirements for those who will perform point-of-care testing;

"(iv) Documented in-service training, initial and ongoing competency validation of personnel performing point-of-care testing;

"(v) An appropriate internal and external quality control protocol; and

"(vi) Record keeping requirements; and

"(B) Processes are in place and are acceptable to the Board that ensure and document the continued competency of point-of-care testing personnel.

"(b) For the purposes of this section, the term

(1) "laboratory director" means:

"(A) A physician or dentist who is qualified and eligible to supervise and direct the technical and scientific operation of a medical laboratory by possessing the following:

"(i) Certification in anatomic or clinical pathology, or both, by the American Board of Pathology, the American Osteopathic Board of Pathology, or qualifications that are equivalent to those required for certification;

"(ii) Certification by the American Board of Pathology or the

American Osteopathic Board of Pathology in at least one of the laboratory specialties;

"(iii) Certification by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysts, or another national accrediting board in one of the laboratory specialties;

"(iv) Certification by the American Society of Cytopathology to practice cytopathology or qualifications that are equivalent to those required for certification;

"(v) Subsequent to graduation, 4 or more years of full-time general laboratory training or experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a licensed medical laboratory; or

"(vi) Subsequent to graduation, other documented clinical laboratory training and experience as the Board determines by regulation is appropriate, taking into consideration the complexity and diversity of the laboratory tests to be performed; or

"(B) A dentist, certified by the American Board of Oral Pathology for the specialty of oral pathology only, or qualifications which are equivalent to those required for certification. "point-of-care testing" means those analytical patient testing activities that are performed under the supervision of the laboratory director, that are provided within an institution but performed outside the physical facilities of the central medical laboratory that do not require permanent dedicated space, and include analytical instruments that are temporarily brought to a patient care location.

"(c) "Point-of-care testing" means analytical patient-testing activities that are performed under the supervision of the laboratory director within an institution, but are performed outside the physical facilities of the central medical laboratory and do not require permanent dedicated space, and include analytical instruments that are temporarily brought to a patient care location.

"Sec. 874. Transition of licensed and registered clinical laboratory practitioners.

"For a period of 2 years after the effective date of the Clinical Laboratory Practitioners Amendment Act of 2014, approved by the Committee on Health on November 12, 2014 (Committee print of Bill 20-289), all reference to clinical laboratory practitioners shall refer to persons meeting the requirements for licensure or registration in the District of Columbia, regardless of whether that person is licensed or registered.".

(g) A new section 912 is added to read as follows:

"Sec. 912. Phlebotomist.

"(a) For the purposes of this section, the term "phlebotomist" means an unlicensed person trained in the proper procedure for withdrawing blood by venipuncture or skin puncture for clinical laboratory test purposes.

"(b) A person who is engaged as a phlebotomist in the District of Columbia shall register with the Mayor, renew the registration as required by rule, and pay the required registration fee established by the Mayor.

"(c) Any person registered to practice as a phlebotomist shall work under the general supervision of a licensed physician, advanced practice nurse, or other licensed health

professional as the Mayor determines by rule.".

"(h) Section 1003 (D.C. Official Code § 3-1210.03) is amended by adding a new subsection (jj) to read as follows:

"(jj) Unless authorized to practice as a clinical laboratory practitioner under this act, a person shall not use or imply the use of the words or terms " "medical technologist", "cytotechnologist", "medical laboratory technologist", "histotechnologist", "histologic technician", "clinical laboratory scientist-generalist", "clinical laboratory scientist-specialist", "medical laboratory technician", "phlebotomist", or any similar title or description of services with the intent to represent that the person is a clinical laboratory practitioner.".

Sec. 3. Fiscal impact statement.

The Council adopts the fiscal impact statement in the committee report as the fiscal impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 4. This act shall take effect following approval by the Mayor (or in the event of veto by the Mayor, action by the Council to override the veto), a 30-day period of congressional review as provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of Columbia Register.