COUNCIL OF THE DISTRICT OF COLUMBIA

NOTICE

D.C. LAW 7-182

"Clinical Laboratory Act of 1988".

Pursuant to Section 412 of the District of Columbia Self-Government and Governmental Reorganization Act, P. L. 93-198, "the Act", the Council of the District of Columbia adopted Bill No. 7-373 on first and second readings, July 12, 1988, and September 27, 1988, respectively. Following the signature of the Mayor on October 13, 1988, this legislation was assigned Act No. 7-240, published in the October 28, 1988, edition of the D.C. Register, (Vol. 35 page 7718) and transmitted to Congress on January 23, 1989 for a 30-day review, in accordance with Section 602(c)(1) of the Act.

The Council of the District of Columbia hereby gives notice that the 30-day Congressional Review Period has expired, and therefore, cites this enactment as D.C. Law 7-182, effective March 16, 1989.

DAVID A. CLARKE Chairman to the Council

Dates Counted During the 30-day Congressional Review Period:

January 24,25,26,27,30,31

February 1,2,3,6,7,8,9,21,22,23,24,27,28

March 1,2,3,6,7,8,9,10,13,14,15

BATE MAR 1 6 1989

AN ACT

CODIFICATION, New Chapter 15 of title 32 (1989 Supp.)

D.C. ACT 7 - 2 4 0

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

OCT 1 3 1988

To license and provide standards for the operation of clinical and physician office laboratories in the District of Columbia.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "Clinical Laboratory Act of 1988".

Sec. 2. Definitions.

New, Section 32-1501

For the purposes of this act, the term:

(1) "Basic test" means a laboratory test that requires a series of steps, reagents, additions, or instrumentation, and the result of which is determined by a visual signal.

(2) "Board" means the Laboratory Advisory Board

established by section 7.

(3) "Clinical laboratory" means a facility for the microbiological, serological, chemical, hematological, biophysical, cytological, or pathological examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease, or the assessment of health. The term "clinical laboratory" shall include all independent, hospital, and District of Columbia government laboratories.

(4) "Complex test" means a laboratory test that requires sophisticated techniques, interpretation of multiple signals, or proven technical skill. Complex tests

may require:

(A) Highly skilled physical manipulation;

(B) Technique dependent steps in the testing, sampling, or reading of results;

(C) User programming of the device or

devices;

(D) Detailed calculation of the results;

(E) Dilution of samples with chemically reactive substances; or

(F) Preparation of reagents.

"Cytotechnologist" means a person who meets the qualifications for a cytotechnologist under 42 C.F.R. sec. 405.1315(c) (1987).

"Exempt test" means a laboratory test that (6) shall not be performed in a physician office laboratory including pap smear test and tests for drug abuse.

- (7) "Laboratory director" means the person responsible for administration of the technical and scientific operation of a clinical laboratory, including supervision of procedures and reporting of findings of tests.
- (8) "Laboratory reference system" means a system of periodic testing of methods, procedures, and materials of laboratories, including the distribution of manuals of approved methods, inspection of facilities, and cooperative research.
- (9) "Physician office laboratory" means a laboratory operated by a physician or a physician group that performs medical laboratory tests for the patients of the physician or physician group, and does not accept referral specimens.

(10) "Proficiency testing program" means an external program approved by the Mayor to monitor proficiency in the performance of medical laboratory tests.

(11) "Simple test" means a test that is noninstrumental in nature, and the result of which is determined by a visual signal.

(12) "Specimen" means materials derived from the human body.

Sec. 3. License requirements for clinical New, atories. Section 32-1502 laboratories.

(a) Except as provided in subsection (b) of this section, it shall be unlawful to operate a clinical laboratory in the District of Columbia, whether public or private, for profit or not-for-profit, unless licensed by the Mayor. The Mayor shall issue a license authorizing the performance of 1 or more of the following categories of laboratory tests: laboratory tests:

(1) Bacteriology; (2) Mycology; (3) Parasitology; Parasitology; Virology; Serology;

4)

5)

Blood Chemistry; Endocrinology; Toxicology; Urinalysis; 6)

(7)

8) 9)

Immuno-hematology;

(11)Hematology;

(12)Pathology; and

(13)Cytology.

Clinical laboratory licenses shall not be required of:

Clinical laboratories operated by the federal (1)

government; Any laboratory maintained and operated purely for non-clinical research purposes, the results of which are not used for clinical application;

(3) Any laboratory operated solely for teaching and conducting analyses, the results of which are not used

for clinical application; or

(4) A physician office laboratory licensed under

section 6.

- (c) Clinical laboratories that, prior to the effective date of this act, were not or would not have been subject to licensure in the District of Columbia may operate without a license until 6 months after the issuance of rules pursuant to section 14.
- (d) An application for a clinical laboratory license shall be made by the owner of the clinical laboratory on forms provided by the Mayor. The application shall contain the name of the owner, the name of the laboratory director, the categories of laboratory tests for which the clinical laboratory license is sought, an approved proficiency testing program in which the clinical laboratory plans to participate, the location and physical description of the facility at which tests are to be performed, and other information as the Mayor may require.

(e) A license shall be valid only for the premises

stated on the application.

(f) A license shall automatically become void 30 days following a change in the laboratory director, or 30 days following a change in ownership or location of the clinical laboratory. A new application for a license may be made prior to a change in the laboratory director, ownership, or location of the clinical laboratory, or prior to the expiration of the 30 day period, in order to permit the uninterrupted operation of the clinical laboratory.

(g) Unless already terminated or renewed, a clinical laboratory license shall expire 1 year from the date of initial issuance or the date of last renewal. application for a license shall be accompanied by a license fee determined by the Mayor that is commensurate to the cost

of inspection.

(h) A clinical laboratory license shall specify on its face the names of the owner and the director of the laboratory, the categories of laboratory tests authorized, and the location at which the tests may be performed. Each clinical laboratory licensed under this act shall post its license in a conspicuous place on the premises, and have its license readily available for inspection by the public.

(i) A license shall not be issued or renewed unless:

(1) A valid certificate of qualification in the procedures for which the license is sought has been issued to the laboratory director by a recognized personnel certifying agency as approved by the Mayor;

(2) The clinical laboratory is appropriately staffed with qualified personnel and properly equipped;

(3) The clinical laboratory has participated to the satisfaction of the Mayor in an approved proficiency testing program, pursuant to section 10; and

(4) The clinical laboratory is operated in the manner required by this act and rules issued pursuant to

this act.

Sec. 4. Laboratory director.

(a) A clinical laboratory shall be under the direct and personal supervision of a laboratory director.

(b) To qualify as a laboratory director, a person

shall:

 Hold a doctor of science degree or its equivalent in 1 of the basic sciences of chemistry, biology, or microbiology, including professional degrees in public health, medicine, osteopathy, pharmacy, dentistry, or veterinary medicine from a college or university recognized by the National Committee of Regional Accrediting Agencies; and

(2)(A) Have a minimum of 4 years of experience in

a clinical laboratory acceptable to the Mayor; or (B) Be certified by the American Board of Pathologists, the American Board of Osteopathic Pathology, the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other accrediting board acceptable to the

Mayor in 1 of the laboratory specialties.

The laboratory director shall be responsible for the proper performance of all tests in a clinical laboratory. The laboratory director shall direct and supervise the testing of specimens and be responsible for the continuous application of quality control procedures to the clinical laboratory work in accordance with the rules issued pursuant to this act. The laboratory director shall be responsible for the work of subordinates. Clinical laboratory records of all work performed shall indicate the name of the laboratory director and be signed by or otherwise indicate the person who actually performed the test.

New. Section 32-1503

- (d) The laboratory director shall be present for a reasonable period of each working day in each clinical laboratory for which he or she is director. If the laboratory director cannot be present on a short-term basis for a period of time to be determined by the Mayor, the laboratory director shall designate, in writing, a substitute laboratory director who meets the qualifications of subsection (b) of this section.
- (e) No person may serve as a director of more than 2 clinical laboratories.

Sec. 5. Qualifications of technical personnel. (a) A clinical laboratory shall employ a clinical laboratory technologist. A clinical laboratory technologist shall perform clinical laboratory tests with minimal supervision by the laboratory director while working in those areas in which he or she is qualified by education or experience. To qualify as a clinical laboratory technologist, a person shall hold a baccalaureate degree in medical technology or in a chemical, physical, or biological science and have at least 1 year of clinical laboratory experience or training acceptable to the Mayor.

(b) Technical personnel below the level of technologist shall be determined by the laboratory director to be fully qualified for all assigned technical duties. The bases for the determination shall be maintained in writing in the clinical laboratory's personnel files. technical personnel shall have clinical laboratory training that complies with the rules issued pursuant to this act.

Sec. 6. License requirements for physician office

laboratories.

(a) It shall be unlawful to operate a physician office laboratory in the District of Columbia, unless licensed by the Mayor. The Mayor shall issue a Level I, Level II, or Level III physician office laboratory license authorizing the performance of 1 or more of the following categories or subcategories of laboratory tests:

(1)Bacteriology;

(2) Mycology;

(3) Parasitology;

(4) Virology; (5) Serology;

- (6) Blood Chemistry;
- (7) Endocrinology; (8) Toxicology;
- (9) Urinalysis;
- (10) Immuno-hematology; and (11) Hematology.
- An application for a physician office laboratory license shall be made by the physician or physician group on

New. Section 32-1504

New. Section 32-1505 forms provided by the Mayor. The application shall contain the name of the physician or physician group, the name of the designated supervisory physician and, for physician groups, an assistant supervisory physician, the license level and the categories of laboratory tests for which the physician office laboratory license is sought, the location and physical description of the physician office laboratory, a proficiency testing program in which the physician office laboratory will participate, and other information as the Mayor may require.

(c)(1) A physician office laboratory applying for an initial physician office laboratory license shall first receive a probationary license valid for 90 days. During the 90-day period, laboratory tests performed by the physician office laboratory shall be subject to monitoring and supervision under a proficiency testing program as set

forth in section 10.

- (2) At the end of the 90-day period, the physician office laboratory shall submit a copy of the results of the proficiency testing program to the Mayor. If the physician office laboratory has achieved a satisfactory result in a category of tests as determined by the Mayor pursuant to section 10, the physician office laboratory shall be issued a 2-year provisional physician office laboratory license authorizing the performance of 1 or more of the categories or subcategories of tests listed in subsection (a) of this section.

(3) If the physician office laboratory fails to achieve a satisfactory result in a category of tests, the physician office laboratory shall be required to continue under the probationary license for an additional 90 days. At the end of the additional 90-day period, if the physician office laboratory has achieved a satisfactory result in a category of tests, the physician office laboratory shall be issued a 2-year provisional physician office laboratory license authorizing the performance of 1 or more of the categories or subcategories of tests listed in subsection

(a) of this section.

(4) A physician office laboratory that fails to achieve a satisfactory result in a category of tests during the additional 90-day probationary period shall cease to perform tests in that category. If the physician office laboratory meets the licensing requirements for clinical laboratories pursuant section 3(i) and employs a laboratory director and a medical technologist pursuant to sections 4 and 5, the physician office laboratory may apply for a new 90-day probationary license.

(5) A physician office laboratory that adds a category of tests to its office laboratory license shall apply for a 90-day probationary permit for the category of

tests. The physician office laboratory shall be required to qualify for the category of tests in the same manner as required for an initial 90-day probationary license, pursuant to paragraphs (1) through (4) of this subsection. If the physician office laboratory achieves a satisfactory result in the category of tests during the initial or additional 90-day period, the category of tests shall be added to the physician office laboratory license.

(d) A physician office laboratory shall designate a supervisory physician and, for physician groups, an assistant supervisory physician, who shall be responsible for the proper performance of all tests in the laboratory. The designated or assistant supervisory physician shall direct and supervise the testing of specimens and be responsible for the continuous application of quality control procedures to the laboratory work in accordance with the rules issued pursuant to this act. The designated or assistant supervisory physician shall be responsible for the work of subordinates. Laboratory records of all work performed shall indicate the name of the designated or assistant supervisory physician and be signed by or otherwise indicate the person who actually performed the test. The designated or assistant supervisory physician shall be present for a reasonable period of each working day in the physician office laboratory.

(e) A license shall be valid only for the premises stated on the application. A license shall automatically become void 30 days following a change in the designated supervisory physician, or 30 days following a change in the location of the physician office laboratory. A new application for a license may be made prior to a change in the designated or assistant supervisory physician, or the location of the physician office laboratory, or prior to the expiration of the 30 day period, in order to permit the uninterrupted operation of the physician office laboratory.

- (f) Unless already terminated, a provisional physician office laboratory license shall expire 2 years from the date of issuance. Upon expiration of the 2-year provisional physician office laboratory license, the physician office laboratory shall be eligible for a physician office laboratory license. Unless already terminated or renewed, a physician office laboratory license shall expire 1 year from the date of issuance or the date of the last renewal. An application for a license shall be accompanied by a license fee determined by the Mayor.
 - (g) A license shall not be issued or renewed unless:

 The physician office laboratory is appropriately staffed and properly equipped;

(2) The designated supervisory physician and any other personnel performing or supervising tests in the

physician office laboratory have successfully completed, on an annual basis, 5 hours of continuing medical education specific to the management, staffing, clinical procedures, or testing techniques of laboratory services, with proof of the completion of the continuing medical education submitted annually to the Mayor;

(3) The physician office laboratory has participated to the satisfaction of the Mayor in an approved proficiency testing program, pursuant to section 10; and

(4) The laboratory is operated in the manner required by this act and rules issued pursuant to this act.

(h) A physician office laboratory shall post its license in a conspicuous place in the premises and shall have its license readily available for inspection by the

public.

- (i) A Level I physician office laboratory may perform simple tests and may be subject to inspections. A Level II physician office laboratory shall be subject to the inspection provisions of section 8(a) and may perform simple and basic tests. A Level III physician office laboratory shall be subject to the inspection provisions of section 8(a) and (b) and may perform simple, basic, and complex tests. A new application for a license shall be required for a physician office laboratory prior to a change in testing level.
- (j) The Mayor may adopt rules pursuant to section 14 that set additional requirements or limitations for Level I, Level II, or Level III physician office laboratory licenses.

(k) A physician office laboratory shall not perform

exempt tests.

(1) Physician office laboratories may continue to perform laboratory tests without a physician office laboratory license until 6 months after the issuance of rules pursuant to this act.

Sec. 7. Mayor's authority to establish a Laboratory Advisory Board;

Section 32-1506

(a) The Mayor shall appoint a Laboratory Advisory

Board, which will advise the Mayor on:

 Classifying laboratory tests as simple, basic, complex, or exempt, for the purposes of this act;

(2) Developing additional requirements or limitations for Level I, Level II, or Level III physician office laboratory licenses;

(3) Proficiency testing programs and certifying institutions and organizations for the purposes of this act; and

(4) Developing rules and procedures for inspections of laboratories. (b) The Mayor shall appoint the members of the Board within 60 days of the effective date of this act.

(c) The Board shall transmit its written recommendations to the Mayor within 180 days of the date of the appointment of all members and shall then cease to exist.

(d) The Mayor may appoint a temporary board, at the Mayor's discretion, for whatever periods of time the Mayor deems necessary because of advancements in technology or other purposes consistent with carrying out the provisions of this act.

New, Section 32-1507

- Inspections. Sec. 8. (a) The Mayor shall conduct inspections of clinical laboratories and Level II and Level III physician office laboratories, methods, procedures, materials, staff, and equipment with an option to inspect Level I physician office labs as deem appropriate. Nothing shall prohibit an authorized District government official from entering the premises of any laboratory regulated by this act during operating hours for the purpose of conducting an announced or unannounced inspection consistent with constitutional guidelines to check for compliance with any provision of this act or rules issued pursuant to this act. conducting an inspection, the District government official shall make every effort not to disrupt the normal operations of the laboratory and its staff.
- (b) To ensure that each clinical laboratory and each Level III physician office laboratory is in compliance with the provisions of this act, and the rules issued pursuant to this act, the Mayor shall conduct an on-site inspection prior to the laboratory's initial licensure and before each license renewal. Temporary licenses or renewals may be granted for a period not to exceed 60 days to afford the Mayor sufficient time to conduct the on-site inspection. The Mayor may issue a provisional license for less than 1 year to a new clinical laboratory, pending satisfactory completion of additional follow-up inspections.

Sec. 9. Quality assurance.

(a) The Mayor shall operate a laboratory reference system and shall prescribe standards for the examination of specimens.

(b) The Mayor shall adopt rules pursuant to section 14 that:

(1) Prohibit payment to laboratory personnel based upon the number of tests performed; and (2) Limit the number of hours that laboratory personnel may work.

New, Section 32-1508 (c) The Mayor shall set standards for proficiency testing programs to determine a satisfactory result, a satisfactory level of overall performance, and a substandard level of overall performance.

Sec. 10. Proficiency testing programs.

New, Section 32-1509

(a) Each clinical or physician office laboratory shall participate in a proficiency testing program approved by the Mayor.

(b) A proficiency testing program shall include proficiency testing at least 4 times per year. Proficiency tests shall be conducted for each category of tests for which the clinical or physician office laboratory has obtained a license.

(c) The clinical or physician office laboratory shall demonstrate continuing satisfactory performance in the proficiency testing program. Continuing satisfactory performance shall include:

(1) A determination of a satisfactory level of overall performance on each quarterly proficiency test; or

(2) A determination of a substandard level of overall performance on 1 quarterly proficiency test, followed by completion of an approved course of education in proper laboratory techniques and procedures, and a satisfactory level of overall performance on the next quarterly proficiency test.

(d) Proficiency testing programs shall report the results of each proficiency test to the Mayor. Upon receipt of a determination of a substandard level of overall performance, the Mayor shall, within 30 days, inspect the clinical or physician office laboratory at any time during normal operating hours. For the purpose of this section, a substandard level of overall performance shall include intentional non-performance.

(e) Upon completion of the inspection, the Mayor shall determine if any deficiencies exist. Upon an affirmative determination of any deficiency, the Mayor shall notify the laboratory director or the designated supervisory physician in writing of the deficiencies. The clinical or physician office laboratory shall submit a written plan to correct the deficiencies and an appropriate course of remedial education and dates by which the corrections shall be made to the Mayor within 30 days of the receipt of the notice of the deficiencies.

(f) If the clinical or physician office laboratory does not submit a plan for corrective action that is approved by the Mayor, or if a clinical or physician office laboratory is determined by the Mayor after a subsequent inspection not to have corrected the deficiencies as specified in the plan by the expiration dates in the plan, the Mayor may take action to revoke, suspend, or limit the

laboratory license pursuant to section 13.

The analyses and reports of a proficiency testing program may be considered by the Mayor in proceedings under section 14.

New. Section 32-15.

Sec. 11. Cytology screening.

The Mayor shall adopt rules pursuant to section 14 that:

(1) Limit the number of slides a cytotechnologist

may examine per day;

(2) Prohibit cytotechnologists from examining slides at any building not owned or used by a licensed clinical laboratory;

(3) Require clinical laboratories to rescreen no less than 10% of all negative pap smears, and require that pap smear rescreening be performed by a supervisory level

cytotechnologist;

(4) Require clinical laboratories to rescreen all negative non-cervical smears, and require that non-cervical smear rescreening be performed by a supervisory level pathologist;

(5) Require clinical laboratories to reject improperly prepared smear specimens, make appropriate comments regarding the quality of the specimen, and maintain records on improperly prepared specimens for 5 years subject to review by the Mayor;

(6) Require clinical laboratories to maintain and store for 5 years from the date of examination any smear slide that was examined for disease or disease agents; and

(7) Require all smear specimen reports to be retained for at least 10 years.

Sec. 12. Confidentiality of test results.

(a) A patient may request, in writing, access to or copies of the results of the patient's own laboratory tests.

(b)(1) All requests for clinical or physician office laboratory services, the results of all clinical or physician office laboratory tests, and the contents of patient specimens shall be confidential.

(2) Persons other than the patient or the patient's physician may have access to the results of the

patient's laboratory tests if:

The patient has given written consent to (A) the person seeking access for the release of the records for a specific use; or

(B) The court has issued a subpoena for the results of the patient's laboratory tests, and except in a law enforcement investigation, the person seeking access has New. Section 32-151 given the patient notice and an opportunity to contest the

subpoena.

(c) All clinical laboratory results shall be reported to the requesting physician. When there is no requesting physician, the clinical laboratory shall report the test results to the patient and shall recommend that the patient forward the laboratory results to the patient's personal physician as soon as possible.

Sec. 13. Penalties and enforcement.

(a) A clinical or physician office laboratory license may be revoked, suspended, or limited by the Mayor on proof that the laboratory or 1 or more of its employees:

(1) Has made misrepresentations in obtaining the

license or in the operation of the laboratory;

(2) Has engaged or attempted to engage or represented the laboratory as entitled to perform any laboratory procedure not authorized by the license;

(3) Has rendered a laboratory report actually performed in another laboratory without designating the fact that the examination or procedure was performed in another laboratory;

(4) Has failed to submit a plan for corrective action or failed to correct deficiencies as required in

section 10; or

(5) Has failed to file a report required by the provisions of this act or the rules issued pursuant to this act.

(b)(1) If the Mayor determines, after investigation, that the conduct of a licensee presents an imminent danger to the health and safety of the residents of the District, the Mayor may summarily suspend or restrict, without a hearing, the license of laboratory employee.

(2) The Mayor, at the time of the summary suspension or restriction of a license, shall provide the licensee with written notice stating the action that is being taken, the basis for the action, and the right of the

licensee to request a hearing.

(3) A licensee shall have the right to request a hearing within 72 hours after service of notice of the summary suspension or restriction of license. The Mayor shall hold a hearing within 72 hours of receipt of a timely request, and shall issue a decision within 72 hours after the hearing.

(4) Every decision and order adverse to a licensee shall be in writing and shall be accompanied by findings of fact and conclusions of law. The findings shall be supported by, and in accordance with, reliable, probative, and substantial evidence. The Mayor shall provide a copy of the decision and order and accompanying

New, Section 32-15 findings of fact and conclusions of law to each party to a

case or to each party's attorney of record.

(c)(1) When the Mayor, after investigation, but prior to a hearing, has cause to believe that any laboratory or laboratory employee is violating any provision of this act and the violation has caused or may cause immediate and irreparable harm to the public, the Mayor may issue an order requiring the alleged violator to cease and desist immediately from the violation. The order shall be served by certified mail or by personal service.

(2) The alleged violator may, within 15 days of the service of the order, submit a written request to the

Mayor to hold a hearing on the alleged violation.

(3) Upon receipt of timely request, the Mayor

shall conduct a hearing and render a decision.

(4)(A) The alleged violator may, within 10 days of the service of an order, submit a written request to the Mayor for an expedited hearing on the alleged violation, in which case the alleged violator shall waive his or her right to the 15-day notice.

(B) Upon receipt of a timely request for an expedited hearing, the Mayor shall conduct a hearing, pursuant to title 1 of the Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1204; D.C. Code, sec. 1-1501 et seq.), within 10 days of the date of receiving the request and shall deliver to the alleged violator at his or her last known address a written notice of the hearing, at

least 5 days before the hearing date.

(5) The Mayor shall issue a decision within 30 days after an expedited hearing. If a request for a hearing is not made, the order of the Mayor to cease and desist is final. If, after a hearing, the Mayor determines the alleged violator is not in violation of this act, the Mayor shall revoke the order to cease and desist. If any person fails to compy with a lawful order the Mayor issued pursuant to this section, the Mayor may petition the court to issue an order compelling compliance or take other action authorized by the act.

- (d) Except as provided in this subsection, no license shall be revoked, suspended, or limited without a hearing pursuant to title 1 of the District of Columbia Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1204; D.C. Code sec. 1-1501 et seq.). If a license is revoked or limited for failure to demonstrate continuing satisfactory performance, reinstatement of the license shall require demonstration of proficiency over a testing period, not to exceed 6 months.
- (e) Any laboratory director, laboratory owner, or designated supervisory physician who willfully and knowingly participates in the unlawful operation of a clinical or

physician office laboratory in the District of Columbia, and any person who intentionally impedes a District of Columbia official or employee in the performance of his or her authorized duties under this act or any rules issued pursuant to this act, shall be guilty of a misdemeanor and, upon conviction, shall be subject to a fine not exceeding \$1,000 per day until the violation ceases, imprisonment for not more than 90 days, or both. Prosecution shall be in the Superior Court of the District of Columbia upon information by the Corporation Counsel or 1 of his or her assistants.

(f) A violation of this act shall be a civil infraction for purposes of the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, effective October 5, 1985 (D.C. Law 6-42, D.C. Code, sec. 6-2701 et seq.) ("Civil Infractions Act"). Civil fines, penalties, and fees may be imposed as sanctions for any infraction of the provisions of this act, or the rules issued under authority of this act, pursuant to title I-III of the Civil Infractions Act. Adjudication of any infractions shall be pursuant to titles I-III of the Civil Infractions Act.

(g) Notwithstanding the availability of any other remedy, the Corporation Counsel or 1 of his or her assistants may maintain, in the name of the District of Columbia, an action in the Superior Court of the District of Columbia to enjoin any person, agency, corporation, or other entity from operating a clinical or physician office laboratory in violation of the terms of its license, the provisions of this act, or any rules issued pursuant to this act.

Sec. 14. Rules.

(a) The Mayor shall, pursuant to title 1 of the District of Columbia Administrative Procedure Act, approved October 21, 1968 (82 Stat. 1204; D.C. Code, sec. 1-1501 et seq.) ("APA"), issue proposed rules, including a schedule of civil fines, to implement the provisions of this act.

(b) The Mayor may issue emergency rules, which shall be effective no more than 90 days and which shall be

consistent with the APA.

Sec. 15. Effective date.

This act shall take effect after a 30-day period of Congressional review following approval by the Mayor (or in the event of veto by the Mayor, action by the Council of the District of Columbia to override the veto) as provided in section 602(c)(1) of the District of Columbia Self-Government and Governmental Reorganization Act, approved December 24, 1973 (87 Stat. 813; D.C. Code, sec. 1-233(c)(1)), and publication in either the District of Columbia Register, the District of Columbia

New, Section 32-151

Anrelled Original

Statutes-at-Large, or the District of Columbia Municipal Regulations.

Council of the District of Columbia

Mayor

District of Columbia APPROVED: October 13, 1988



COUNCIL OF THE DISTRICT OF COLUMBIA Council Period Seven

RECORD OF OFFICIAL COUNCIL VOTE

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CERTIFICATION RECORD