Chapter 438

1979 REPLACEMENT PART
(1981 reprint)

Clinical Laboratories

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GENERAL PROVISIONS

438.010 Definitions. As used in this chapter, unless the context requires otherwise:

(1) "Clinical laboratory" or "laboratory" means a facility where the microbiological, serological, biochemical, hematological, immunohematological, biophysical, exfoliative cytological, pathological or other examinations are performed on materials derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.

(2) "Clinical laboratory specialty" or "laboratory specialty" means the examination of materials derived from the human body for the purpose of diagnosis and treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans, employing one of the following sciences: Serology, microbiology, biochemistry, hematology, immunohematology, biophysiology, exfoliative cytology or pathology.

(3) "Dentist" means a person licensed to practice dentistry by the State Board of Dental Examiners.

(4) "Director of clinical laboratory" or "director" means the person who plans, organizes, directs and participates in any or all of the technical operations of a clinical laboratory, including but not limited to reviewing laboratory procedures and their results, training and supervising laboratory personnel, and evaluating the technical competency of such personnel.

(5) "Laboratory evaluation system" means a system of testing clinical laboratory methods, procedures and proficiency by periodic performance and reporting on test specimens submitted for examination.

(6) "Owner of a clinical laboratory" means the person who owns the clinical laboratory, or a county or municipality operating a clinical laboratory or the owner of any institution operating a clinical laboratory.

(7) "Physician" means a person licensed to practice medicine by the Board of Medical Examiners for the State of Oregon.

(8) "Division" means the Health Division of the Department of Human Resources.

(9) "Specimen" means materials derived from a human being or body. [1969 c 685 §2]

438.030 Policy. It shall be the declarative purpose of this chapter to insure the quality of medical laboratory work in order to protect the health and welfare of the people of the State of Oregon by establishing a regulatory program for clinical laboratories. [1969 c.685 §1]

438.040 Laboratory license required; director to be qualified. On and after July 1, 1970, it shall be unlawful:

(1) For any owner or director of a clinical laboratory to operate or maintain a clinical laboratory without a license issued under ORS 438.110 or without a temporary permit issued under ORS 438.150 or to perform or permit the performance of any laboratory specialty for which the laboratory is not licensed except as specified under ORS 438.050.

(2) For any person to serve in the capacity of director of a clinical laboratory without being qualified as a clinical laboratory director under ORS 438.210. [1969 c 685 §3]

438.050 Application of chapter; exceptions. (1) This chapter applies to all clinical laboratories and laboratory personnel within the State of Oregon, except:

(a) Clinical laboratories operated by the United States Government.

(b) Clinical laboratories operated and maintained purely for research or teaching purposes, and that involve no patient or public health services.

(c) Clinical laboratories operated by less than five physicians and used exclusively for the diagnosis and treatment of their own patients.

(d) County health departments performing emergency public health laboratory procedures as approved by the division.

(2) Laboratories operated by the State of Oregon and by county health departments are exempt from licensing fees, but all other provisions of this chapter shall apply.

(3) Nothing in this chapter is intended to confer on any licensed practitioner of the healing arts any authority he would not otherwise possess under his license. [1969 c 685 §§4, 20; 1973 c 829 §54; 1979 c 193 §1]

LABORATORY LICENSE

438.110 Standards for issuance and renewal of laboratory license. The Health Division shall issue and renew annual licenses for any or all clinical laboratory specialties to the owners of clinical laboratories who demonstrate to the satisfaction of the division that:

(1) The clinical laboratory is in compliance with this chapter and the rules of the Health Division promulgated under ORS 438.450.

(2) The laboratory is adequately equipped to perform proficiently within the scope of its license.

(3) The clinical laboratory has facilities for retaining and does retain complete laboratory records for an appropriate length of time as the Health Division by rule may require.

(4) The clinical laboratory meets the standards of the Health Division for safety, sanitary conditions, plumbing, ventilation, handling of specimens, maintenance of equipment and requirements of general hygiene to insure protection of the public health. [1969 c 685 §5, 1971 c 650 §18]

438.120 Standards for licensing specialties. (1) In determining the specialties that are authorized to be performed in a clinical laboratory, the Health Division shall consider laboratory personnel, with particular emphasis on the qualifications of the director, laboratory equipment and any other relevant factors affecting the ability of the laboratory to perform different laboratory specialties.

(2) No laboratory shall be licensed to perform examinations in the fields of surgical pathology, autopsy pathology, exfoliative cytology, or immunohematology, except as the Health Division may establish exemptions from the requirements of this subsection in the field of immunohematology, unless its director is a physician or dentist specifically qualified in these fields. [1969 c 685 §6]

438.130 License application; fees; expiration and renewal. (1) The application for a license for a clinical laboratory shall be made on forms provided by the Health Division and shall be executed by the owner or one of the owners or by an officer of the firm or corporation owning the clinical laboratory, or in the case of a county or municipality, by the public official responsible for operation of the laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the owner, the director or directors of the clinical laboratory, the location and physical description of the clinical laboratory, the laboratory specialties for which a license is requested and such other information as the Health Division may require.

(2) The application shall be accompanied by an annual, nonrefundable license fee of $70 for laboratories employing one person, $175 for laboratories employing two to five persons, $350 for laboratories employing six to 10 persons, and $550 for a laboratory employing 11 or more persons.

(3) Unless sooner voided, suspended or revoked, all licenses issued under this section expire on June 30 next following the date of issuance and shall be renewable in the manner prescribed by the Health Division. [1969 c 685 §7, 1977 c 284 §3; 1979 c 696 §2]

438.140 License content; display; nontransferability; voidability; special permit when director changes. (1) A license issued to the owner of a clinical laboratory shall show on its face the names of the owners and directors, the location of the laboratory and the clinical laboratory specialties authorized under the license. The license shall be displayed at all times in a prominent place in the laboratory.

(2) A license issued to the owner of a clinical laboratory is not transferable. The license of the laboratory is voided 30 days after a change in its director if it has only one director or if all directors change or a change in the ownership or in the location of the laboratory. In case of death of a director, immediate notification to the Assistant Director for Health or his designee who shall be empowered to issue a special temporary permit of 30 days' duration issued to a designated substitute director is required. If a license is voided or a special temporary permit is issued under this section, a new license application, accompanied by the nonrefundable license fee prescribed in ORS 438.130, shall be filed with the Health Division. [1969 c 685 §8]

438.150 Temporary permit; conditions and limitations. (1) In lieu of the license of a clinical laboratory required by ORS 438.040, the Health Division may issue a temporary permit valid for a six-month period from the date of issuance in any or all clinical laboratory specialties upon payment of the respective required fees as described in ORS 438.130 (2). The temporary permit may be issued only when it appears that:

(a) The clinical laboratory is not qualified for a license but meets standards sufficient to protect the health and safety of the public; and

(b) The clinical laboratory can comply with all applicable laws and rules within a period of six months from the date of issuance of the temporary permit.

(2) In issuing the temporary permit, the Health Division may require that:

(a) Plans for compliance with applicable laws and rules be submitted with the application for the temporary permit; and

(b) During the period in which the temporary permit is in effect periodic reports be submitted on the progress of the plans for compliance; and

(c) Special temporary provisions specified by the Health Division upon application of the temporary permit be maintained for the protection of the public.

(3) If at any time the Health Division determines that the clinical laboratory can no longer operate in a manner which protects the public health and safety or that the requirements imposed under subsection (2) of this section are not being maintained, the Health Division shall cancel the temporary permit.

(4) One renewal of the temporary permit may be granted if deemed to be in the best interest of public health by the Health Division. The fee for renewal is the respective required fee as described in ORS 438.130 (2). [1969 c 685 §9]

438.160 Refusal to issue or renew or suspension or revocation of license. Subject to ORS 183.310 to 183.550, the Health Division may refuse to issue or renew the license or may suspend or revoke the license of any clinical laboratory, if it finds that the owner or director has:

(1) Intentionally made false statements on an application for a clinical laboratory license or any other documents required by the Health Division, or made any misrepresentation in seeking to obtain or retain a license.

(2) Demonstrated incompetence as defined pursuant to regulations promulgated after public hearing.

(3) Intentionally falsified any report.

(4) Referred a specimen for examination to a nonlicensed or an unlicensed clinical laboratory in this state unless the laboratory is exempt from the application of this chapter.

(5) Misrepresented the scope of laboratory service offered by the clinical laboratory or the clinical laboratory specialties authorized by the license.

(6) Rendered a report on clinical laboratory work actually performed in another clinical laboratory without designating the name and address of the clinical laboratory in which the test was performed.

(7) Knowingly had professional connection with or permitted the use of the name of the licensed clinical laboratory or its director by a clinical laboratory that is required to but has not obtained a license.

(8) Failed to perform or cause to be performed within the time specified analysis of test samples as authorized by ORS 438.320, or failed to report on the results of such analysis within the specified time.

(9) Failed to permit within a reasonable time the entry or inspection authorized by subsection (1) of ORS 438.310.

(10) Failed to continue to meet requirements of ORS 438.110 and 438.120.

(11) Violated any provision of this chapter. [1969 c 685 §10]

LABORATORY DIRECTOR

438.210 Qualifications of a laboratory director. A person is qualified to act as a laboratory director of a clinical laboratory if:

(1) He is a pathologist certified in clinical or anatomical pathology by a national organization or organizations recognized by the Health Division, or is a physician who possesses qualifications equivalent to those required for such certification;

(2) He is a physician who possesses special qualifications that enable him to perform as a laboratory director, or is directing a laboratory on January 1, 1970;

(3) He has an earned degree of Doctor of Science or Doctor of Philosophy, or an acceptable degree as determined by the Health Division, from an accredited college or university, with a major in the chemical, physical, or biological sciences and possesses special qualifications as described in the administrative rules of the Health Division that enable him to perform as a laboratory director;

(4) He is the member of a group of five or more physicians who operate a laboratory performing work only on their patients and

who is designated by the group to be the director; or

(5) He was responsible for the direction of a clinical laboratory for at least 12 months within the five years preceding January 1, 1970, and has had at least two years of pertinent clinical laboratory experience, as determined by the Health Division. [1969 c 685 §12]

438.220 Special qualifications for laboratory director at chiropractic college. Notwithstanding ORS 438.210, a person is qualified to act as the laboratory director of the clinical laboratory at any accredited chiropractic college in this state for the benefit of chiropractic patients if that person is a chiropractic physician licensed by the State Board of Chiropractic Examiners, and possesses special qualifications, as determined by the State Board of Chiropractic Examiners, that enable that person to perform as a laboratory director. [1979 c 303 §2]

INSPECTION AND EVALUATION

438.310 Inspection of laboratory premises; owner to submit reports and findings on communicable disease; information confidential. The Health Division or its authorized representative may:

(1) At reasonable times enter the premises of a clinical laboratory licensed or subject to being licensed under this chapter to inspect the facilities, methods, procedures, materials, staff, equipment, laboratory results and records of the clinical laboratory.

(2) Require the owner or director to submit reports on the operations and procedures of the laboratory.

(3) Require the owner or director to submit initial laboratory findings indicative of communicable disease as defined by law or by rule. Each report shall include the name of the person from whom the specimen was obtained, if the name was reported to the laboratory, and the name and address of the physician for whom such examination or test was made. Such reports shall not be construed as constituting a diagnosis nor shall any laboratory making such report be held liable under the laws of this state for having violated a trust or confidential relationship.

(4) The Assistant Director for Health or his designee, the Health Division, or any employe thereof, shall not disclose information contained in reports on communicable diseases submitted to the division under subsection (3) of this section except as such information is made available to employes of the division and to local health officers for purposes of administering the public health laws of this state. However, information contained in such reports may be used in compiling statistical and other data in which persons are not identified by name or otherwise. [1969 c 685 §13]

438.320 Laboratory evaluation system; internal quality control system; consultants for systems. (1) The Health Division shall institute a laboratory evaluation system, as defined in ORS 438.010, and shall make such rules as are necessary to insure quality control of laboratory work.

(2) As part of this system, the division may require each laboratory to:

(a) Participate in on-site inspection and testing,

(b) Analyze test samples submitted by the division prior to, during or subsequent to the inspection, and

(c) Contract with, at the laboratory's own expense, a division-approved source of test samples for such test samples to be submitted periodically to the laboratory and to be returned to that source for grading after testing. The test results shall be made available to the advisory committee and the division.

These procedures shall be referred to as external quality control. The samples are to be tested by regularly assigned personnel using routine methods. The test samples shall be confined to the specialty of the laboratory as indicated on the license. A specified time shall be allowed for such testing and reporting of the results and shall be the time required under conditions of normal operation.

(3) In addition to external quality control, each clinical laboratory shall establish an internal laboratory quality control system pursuant to rules of the division including but not necessarily limited to the testing of reference or control sera and other biological samples, verifying concurrent calibration standards and control charts recordings, and reporting on its control system as required by the division.

(4) For laboratories doing 250,000 or more tests per year a special team consisting of at least two pathologists conversant with laboratories of this magnitude shall be used, on a

consultative basis, for such inspection and testing. [1969 c 685 §14]

MISCELLANEOUS

438.410 [Formerly 433 310, repealed by 1971 c 650 §51]

438.420 Communicable disease reports to be from licensed laboratory. When the control or release of a case contact or carrier of a communicable disease is dependent on laboratory findings, the health officer may require such findings to be obtained by a clinical laboratory licensed by the Health Division. [Formerly 433 325]

438.430 Specimens taken from and reports made only to persons authorized to use results. (1) Except as otherwise provided in this chapter, a clinical laboratory shall examine specimens only at the request of a physician, dentist, or other person authorized by law to use the findings of laboratory examinations.

(2) No person shall report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease except to a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of his practice or in the fulfillment of his official duties. Reports shall not be issued to the patient concerned except with the consent of the physician or other authorized person. [1969 c 685 §21]

438.440 Disposition of fees. All moneys received by the Health Division under this chapter shall be credited to the Health Division Account and shall be used for payment of the expenses of the Health Division in administering the provisions of this chapter. [1969 c 685 §16]

438.450 Rules. The Health Division shall make such rules as are necessary for carrying out this chapter in accordance with ORS 183.330. [Formerly 433 335]

438.510 Prohibited acts. It is unlawful for the owner of a clinical laboratory or the director of a clinical laboratory to:

(1) Operate or maintain a clinical laboratory unless the laboratory is under personal supervision of a director who is qualified to supervise the laboratory.

(2) Advertise or solicit the general public.

(3) Violate any provision of this chapter [1969 c 685 §11]

PENALTIES

438.990 Penalties. Violation of any provision of ORS 438.040 or 438.510 is a Class A misdemeanor. Each day of continuing violation shall be considered a separate offense. [1969 c 685 §22, 1977 c 582 §45]

CHAPTER 439
[Reserved for expansion]