

CLINICAL LABORATORY SCIENCE
PRACTITIONERS BOARD LAWS
AS OF THE 2019 LEGISLATIVE SESSION

TITLE 37, CHAPTER 34
CLINICAL LABORATORY SCIENCE
PRACTITIONERS

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CHAPTER 34 CLINICAL LABORATORY SCIENCE PRACTITIONERS

Chapter Compiler's Comments

1993 Statement of Intent: The statement of intent attached to Ch. 345, L. 1993, provided: "A statement of intent is needed for this bill because it establishes a board of clinical laboratory science practitioners and gives the board rulemaking authority. The board is required to adopt rules to establish licensing and certification procedures, educational requirements for licensure, and continuing education requirements. The board is also required to establish rules for the renewal, suspension, and revocation of licenses. The board shall establish an investigation and hearing procedure for handling complaints and shall set fees for administration of the board's duties. The fees must be commensurate with the costs of administration. The board shall also adopt rules implementing the requirement that a supervisor of a clinical laboratory technician must be accessible at all times that testing is being performed in order to provide onsite, telephonic, or electronic consultation."

Severability: Section 14, Ch. 345, L. 1993, was a severability clause.

Part 1 General

37-34-101. Short title. This chapter may be cited as the "Clinical Laboratory Science Practice Act".
History: En. Sec. 1, Ch. 345, L. 1993.

37-34-102. Declaration of policy and purpose. The legislature finds and declares that because the practice of clinical laboratory science affects the public health, safety, and welfare of Montana citizens, it is the purpose of this chapter to provide for the common good by regulating and ensuring the qualified and professional practice of clinical laboratory science. The legislature further declares that because clinical laboratory science practitioners provide essential services to other health care providers by furnishing vital information that may be used in the assessment of human health and in the diagnosis, prevention, and treatment of disease or impairment, clinical laboratory tests must be performed by individuals who meet specific standards of competency.

History: En. Sec. 2, Ch. 345, L. 1993.

37-34-103. Definitions. As used in this chapter, the following definitions apply:

- (1) "Board" means the board of clinical laboratory science practitioners established in 2-15-1753.
- (2) "Clinical laboratory" or "laboratory" means any facility or office in which clinical laboratory tests are performed.
- (3) (a) "Clinical laboratory science practitioner" means a health care professional who performs clinical laboratory tests or who is engaged in management, education, consulting, or research in clinical laboratory science.
(b) The term includes laboratory directors, managers, supervisors, clinical laboratory scientists, clinical laboratory specialists, and clinical laboratory technicians who work in a laboratory.
(c) The term does not include:
 - (i) persons employed by a clinical laboratory to perform supportive functions not related to direct performance of laboratory tests; or
 - (ii) clinical laboratory trainees.
- (4) "Clinical laboratory scientist" means a person who:

- (a) performs clinical laboratory tests pursuant to established and approved protocols requiring the exercise of independent judgment and responsibility;
 - (b) maintains equipment and records;
 - (c) performs quality assurance activities related to test performance; and
 - (d) may supervise and teach within a clinical laboratory setting.
- (5) "Clinical laboratory specialist" means a person who:
- (a) performs laboratory testing in a specialized testing area, such as microbiology, chemistry, immunology, or hematology, according to approved protocols requiring the exercise of independent judgment and responsibility;
 - (b) maintains equipment and records;
 - (c) performs quality assurance activities related to test performance; and
 - (d) may supervise and teach within the specific area of the clinical laboratory.
- (6) "Clinical laboratory technician" means a person who performs laboratory tests pursuant to established and approved protocols that require limited exercise of independent judgment and that are performed under the supervision of a clinical laboratory scientist, laboratory supervisor, or laboratory director.
- (7) "Clinical laboratory test" or "laboratory test" means:
- (a) a microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical, immunological, cytogenetical, or other examination that is performed on material derived from the human body; or
 - (b) any other test or procedure conducted by a laboratory or facility that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease.
- (8) "Department" means the department of labor and industry provided for in 2-15-1701.
- (9) "License" means the clinical laboratory science license issued under this chapter.
- (10) "Practice of clinical laboratory science" means the performance and interpretation of microbiological, serological, chemical, hematological, radiobioassay, cytological, biophysical, immunological, cytogenetical, or other examination on material that is derived from the human body and that provides information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of a disease.
- History:** En. Sec. 3, Ch. 345, L. 1993; amd. Sec. 139, Ch. 483, L. 2001.

Compiler's Comments

2001 Amendment: Chapter 483 in definition of department substituted reference to department of labor and industry for reference to department of commerce and substituted "2-15-1701" for "2-15-1801". Amendment effective July 1, 2001.

Part 2 Board of Clinical Laboratory Science Practitioners

Part Administrative Rules

Title 24, chapter 129, subchapter 1, ARM Organizational rule.

Title 24, chapter 129, subchapter 2, ARM Clinical laboratory science practitioners — procedural rules.

- 37-34-201. Powers and duties of board — rulemaking authority.** (1) The board shall:
- (a) meet at least once annually, and at other times as agreed upon, to elect officers and to perform the duties described in Title 37, chapter 1, and this section; and
 - (b) administer oaths, take affidavits, summon witnesses, and take testimony as to matters within the scope of the board's duties.
- (2) The board has the authority to administer and enforce all the powers and duties granted statutorily or adopted administratively.
- (3) The board shall adopt rules to administer this chapter. The rules must include but are not limited to:
- (a) the development of acceptable certifications for each category of license;

(b) the establishment of criteria for educational requirements that, at a minimum, meet the standards set forth in 37-34-303; and

(c) a requirement that the supervisor of a clinical laboratory technician be accessible at all times that testing is being performed by the technician in order to provide onsite, telephonic, or electronic consultation.

History: En. Sec. 7, Ch. 345, L. 1993; amd. Sec. 96, Ch. 429, L. 1995; amd. Sec. 40, Ch. 271, L. 2003; amd. Sec. 91, Ch. 467, L. 2005.

Compiler's Comments

2005 Amendment: Chapter 467 in (1)(a) after "described in" inserted "Title 37, chapter 1, and"; in (3)(a) after "development of" deleted "a license application procedure and"; deleted former (3)(b) that read: "(b) the establishment of license fees commensurate with actual costs"; deleted former (3)(d) through (3)(f) that read: "(d) the development of procedures for the issuance, renewal, suspension, revocation, and reciprocity of licenses consistent with the provisions in 37-1-138;

(e) the adoption of disciplinary standards for licensees;

(f) the establishment of hearing procedures"; and made minor changes in style. Amendment effective July 1, 2005.

2003 Amendment: Chapter 271 in (3)(d) at end inserted "consistent with the provisions in 37-1-138". Amendment effective April 9, 2003.

Retroactive Applicability: Section 63, Ch. 271, L. 2003, provided: "[This act] applies retroactively, within the meaning of 1-2-109, to occurrences after December 31, 2002."

1995 Amendment: Chapter 429 in (3)(f), before "hearing", deleted "investigatory and" and after "procedures" deleted "for processing complaints received by the board"; deleted former (3)(g) that read: "(g) the establishment of continuing education requirements of at least 14 hours annually for license renewal for clinical laboratory practitioners"; and made minor changes in style.

Severability: Section 131, Ch. 429, L. 1995, was a severability clause.

Saving Clause: Section 132, Ch. 429, L. 1995, was a saving clause.

Applicability: Section 133, Ch. 429, L. 1995, provided: "[This act] applies to licenses applied for, complaints submitted, and proceedings begun after [the effective date of this section]." Effective October 1, 1995.

Effective Date: Section 16, Ch. 345, L. 1993, provided that this section was effective on passage and approval. Approved April 16, 1993.

Cross-References

Board — composition — allocation — quasi-judicial — compensation, 2-15-1753.

Part 3 Licensing

Part Administrative Rules

Title 24, chapter 129, subchapter 6, ARM Licensing.

37-34-301. License required. A person may not engage in the practice of clinical laboratory science or hold out to the public that the person is a clinical laboratory science practitioner in this state unless the person is licensed pursuant to this chapter.

History: En. Sec. 4, Ch. 345, L. 1993.

Administrative Rules

ARM 24.129.405 Inspections.

ARM 24.129.2101 Continuing education requirements.

37-34-302. Exemptions. (1) This chapter does not limit or regulate the practice of licensed physicians, including but not limited to pathologists.

(2) This chapter does not apply to:

(a) any other profession licensed under Title 37 to the extent that the applicable scope of that practice, as defined by statute, rules of the board or agency governing the other profession, or both the statute and rules, authorizes the performance of a clinical laboratory test;

(b) clinical laboratory science practitioners employed by the United States or by any bureau, division, or agency of the United States, while in the discharge of the employee's official duties;

(c) clinical laboratory science practitioners engaged in teaching or research, provided that the results of any examination performed are not used in health maintenance, diagnosis, or treatment of disease;

(d) students or trainees enrolled in a clinical laboratory science education or training program, provided that:

(i) these activities constitute a planned course in the program;

(ii) the persons are designated by a title, such as intern, trainee, or student; and

(iii) the persons work directly under an individual licensed by this state to practice clinical laboratory science;

(e) any person performing only waived tests as provided for in the federal clinical laboratory regulations set forth in 42 CFR part 493;

(f) a perfusionist or cardiopulmonary technician who, as part of a surgical team, performs laboratory tests in an operating room during surgery or during the perioperative and immediate postoperative period; or

(g) clinical laboratory science practitioners, employed by certified rural health clinics, who perform only those basic laboratory services required under federal regulations set forth in 42 CFR 491.9(c)(2).

History: En. Sec. 5, Ch. 345, L. 1993.

37-34-303. Standards for licensure. (1) The board shall issue a clinical laboratory scientist license to an individual who meets the qualifications as promulgated by rules of the board. At a minimum, a licensee must be a person who:

(a) has graduated with a baccalaureate degree, including a minimum number of hours in areas or disciplines established by rule by the board; and

(b) has passed a certifying examination approved by the board.

(2) The board shall issue a clinical laboratory specialist license to an individual who has graduated with a baccalaureate degree as described in subsection (1) and has passed a certifying examination covering those fields in which the applicant is eligible and approved by the board. The license must be issued as a clinical laboratory specialist license and must state the designation of the area of specialty.

(3) The board shall issue a clinical laboratory technician license to an individual who meets the qualifications promulgated by the board, including the following minimum qualifications:

(a) completion of an associate degree or 60 semester hours in a science-related discipline;

(b) completion of other equivalent formal education as approved by the board; and

(c) passing a certifying examination approved by the board.

History: En. Sec. 8, Ch. 345, L. 1993.

37-34-304. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 9, Ch. 345, L. 1993.

37-34-305. Licensure application procedures. (1) An applicant shall submit an application for a license to the board and shall pay an application fee set by the board.

(2) Upon receipt of the application and fee, the department shall issue a license for a clinical laboratory scientist, a clinical laboratory specialist, or a clinical laboratory technician to any person who meets the qualifications specified by the board as set forth in rules adopted by the board pursuant to 37-34-201 and 37-34-303.

History: En. Sec. 10, Ch. 345, L. 1993; amd. Sec. 97, Ch. 429, L. 1995; amd. Sec. 92, Ch. 467, L. 2005.

Compiler's Comments

2005 Amendment: Chapter 467 in (1) near middle after "board" deleted "upon the forms prescribed and furnished by the board"; in (2) near beginning after "fee, and" substituted "department" for

"board"; deleted former (3) and (4) that read: "(3) A license issued under this chapter must be renewed on or before the date set by department rule.

(4) Except for the assessment provided in 37-1-101(6), money paid for application, license, and license renewal fees must be deposited in the state special revenue fund for use by the board"; and made minor changes in style. Amendment effective July 1, 2005.

1995 Amendment: Chapter 429 at end of (3) substituted "on or before the date set by department rule" for "by May 1 of each year".

Severability: Section 131, Ch. 429, L. 1995, was a severability clause.

Saving Clause: Section 132, Ch. 429, L. 1995, was a saving clause.

Applicability: Section 133, Ch. 429, L. 1995, provided: "[This act] applies to licenses applied for, complaints submitted, and proceedings begun after [the effective date of this section]." Effective October 1, 1995.

37-34-306. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 11, Ch. 345, L. 1993.

37-34-307. Violation — penalties — injunction — manner of charging violation. (1) A person who violates a provision of this chapter or a rule adopted pursuant to this chapter is guilty of a misdemeanor and is punishable by a fine not to exceed \$500, by imprisonment in the county jail for a term of not more than 6 months, or both.

(2) Except as provided in 37-34-302, the board may maintain an action to enjoin a person from engaging in the practice of clinical laboratory science until a license to practice is obtained. A person who has been enjoined and who violates the injunction is punishable for contempt of court. The injunction does not relieve the person practicing clinical laboratory science without a license from criminal prosecution. The remedy by injunction is in addition to remedies provided for criminal prosecution of the offender.

(3) When charging a person in a complaint for injunction or in an affidavit, information, or indictment with a violation of law by practicing clinical laboratory science without a license, it is sufficient to charge that the person did, on a certain day and in a certain county, engage in the practice of clinical laboratory science while not having a license to do so, without specifying particular facts concerning the violation.

History: En. Sec. 12, Ch. 345, L. 1993.

Administrative Rules

ARM 24.129.405 Inspections.

37-34-308. Repealed. Sec. 128, Ch. 429, L. 1995.

History: En. Sec. 13, Ch. 345, L. 1993.