

BEFORE THE BOARD OF CLINICAL LABORATORY SCIENCE PRACTITIONERS
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of)
ARM 24.129.401 fees, 24.129.402) NOTICE OF AMENDMENT AND
supervision, 24.129.603 minimum) ADOPTION
standards for licensure, 24.129.605)
military training or experience,)
24.129.612 temporary practice)
permits, and 24.129.2301)
unprofessional conduct and the)
adoption of NEW RULE I nonroutine)
applications)

TO: All Concerned Persons

1. On November 10, 2016, the Board of Clinical Laboratory Science Practitioners (board) published MAR Notice No. 24-129-17 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 2040 of the 2016 Montana Administrative Register, Issue No. 21.

2. On December 2, 2016, a public hearing was held on the proposed amendment and adoption of the above-stated rules in Helena. Several comments were received by the December 9, 2016, deadline.

3. The board has thoroughly considered the comments received. A summary of the comments and the board responses are as follows:

COMMENT 1: All the commenters opposed increasing the active and inactive renewal fees. The commenters stated that the proposed increases will be a hardship on licensees for one or more of the following reasons:

- (a) the increase to \$100 is nearly double the current \$60 active renewal fee;
- (b) the increase to \$50 is double the current \$25 inactive renewal fee;
- (c) even if the board hasn't increased licensing fees since 2008, the proposed increases work out to an increase of 8% to 12% per year;
- (d) licensees pay their renewal fees and are not reimbursed by their employers;
- (e) many licensees did not receive a pay increase last year and their wages have not kept pace with inflation and/or the cost living;
- (f) health care reimbursement rates are going down, not up; and
- (g) the average salary for a clinical laboratory scientist in Montana is \$59,120 and the national average salary is \$61,860.

RESPONSE 1: All licensing boards are statutorily mandated by 37-1-134, MCA, to set licensing fees related to its program area that provide the amount of money usually needed for the operation of the board for services. Each licensing board is required to fund its own operations through its licensure fees.

The board cannot set fees according to inflation, cost of living, or the current salaries of licensees. Over the last several years, the board has been operating at a deficit resulting from a decrease in the number of licensees combined with inflationary increases in costs such as rent, supplies, and electricity and a change in the department's method of allocating costs to boards. Roughly 70% of the board's budget is a fixed cost allocation to the board for computer systems, web site support, staff salaries, phone and mail service, etc.

Under 17-2-302, MCA, licensing boards may build a cash reserve for operating expenses, but the cash reserve may not exceed twice the annual appropriation for that year. If a board's cash reserve exceeds twice the annual appropriation, the board will abate renewal fees pursuant to ARM 24.101.301.

The board also notes that both the department and the board continually seek and implement ways to reduce costs associated with board functions. Examples of this are the recent shift to using electronic board books instead of paper ones and having some board meetings by telephone conference instead of in-person attendance.

COMMENT 2: Several commenters asserted that the fee increases will be a hardship because licensees must pay other licensure expenses including those associated with completing annual continuing education (CE), maintaining national certification, and licensure in other jurisdictions. The commenters stated that CE is not always provided by employers and these expenses are not always reimbursed by employers. One commenter stated that complying with multiple CE requirements can cost licensees \$300 to \$500 in registration fees annually.

RESPONSE 2: While the board requires licensees to complete 14 hours of CE annually, licensees have a significant amount of control over their CE expenditures. Licensees may obtain CE through approved online courses and webinars which usually cost less than live, classroom-style courses. Additionally, the board notes that there are many opportunities for licensees to obtain CE at no charge such as membership in ASCP (American Society of Clinical Pathologists), which includes the opportunity to complete up to six hours of no-cost CE through ASCP. Additionally, CAP (College of American Pathologists), CACMLE (Colorado Association for Continuing Medical Laboratory Education), and LEND (Laboratory Education of North Dakota) offer CE opportunities for clinical laboratory personnel at no charge.

Any licensing, certification, or continuing education requirements imposed by another regulatory entity, and the costs associated therewith, are outside the board's authority. Individual licensees and their employers decide whether additional certification or licensure is necessary and who bears the costs associated with obtaining and maintaining those additional qualifications.

COMMENT 3: Several commenters stated there is currently a workforce shortage and increasing licensing fees will deter future graduates from choosing this profession and working in Montana compared to states that only require national certification. Two commenters also stated that increasing the fees will make it more difficult to find the support to defend licensure and the integrity of the profession.

RESPONSE 3: While recognizing a current workforce shortage, the board does not believe that anticipated future licensure fees are a significant factor for individuals when considering a course of study in college and a future profession.

The board is required under 37-1-134, MCA, to set licensing fees that provide the amount of money usually needed for the operation of the board for services. Each licensing board is required to fund its own operations through its licensure fees. See RESPONSE 1 for more information.

COMMENT 4: One commenter suggested that the board move from annual to biennial renewals, like the Board of Nursing, to reduce paperwork and costs. The commenter further noted the license renewal fee for nurses is \$50 per year.

RESPONSE 4: The board has not proposed rule changes to move from annual to biennial license renewal and accordingly will take no action regarding the license renewal cycle.

Additionally, all licensing boards are statutorily mandated by 37-1-134, MCA, to set licensing fees related to its program that provide the amount of money usually needed for the operation of the board for services. Licensure fees are directly impacted by the number of licensees regulated by a board, and boards with fewer licensees generally charge higher licensure fees than boards with more licensees. The board licenses approximately 876 individuals which includes clinical laboratory scientists, clinical laboratory specialists, and clinical laboratory technicians. In contrast, the Board of Nursing licenses approximately 20,000 individuals.

COMMENT 5: One commenter disagreed with a statement during the last board meeting that the board had been fiscally responsible historically. After reviewing the budget information provided by board staff, the commenter stated the board has not had a balanced budget for the last five years. The commenter asked why board personnel costs increased 33% in the last year and asserted that the board's budget and expenses should be more transparent. Specifically, the commenter stated the \$50,000 "other expenses" budget line item should be explained in more detail.

The commenter further opined that the fee increases do not benefit the licensees and the board should get back to its core purpose of licensing clinical laboratory personnel and look for ways to do so within a reasonable budget.

RESPONSE 5: The board acknowledges the budget deficit over the last five years and notes that the deficit demonstrates the need for the fee increase.

The increase in personnel costs over the last year resulted from increased time spent by new department staff on board business including licensing, compliance, and legal work. Additionally, the database used by the department to manage the records of all the licensing boards required programming updates and the personnel costs for these updates are shared by all the boards proportionally based on time distribution and number of board licensees.

The board reviews and discusses the budget in open session at every full board meeting. The other expenses item in the budget includes expenses for information technology services staff and legal staff. If the commenter had

requested additional information regarding the other expenses item, department staff would have provided specific components and associated amounts.

The fee increases will benefit the licensees by allowing the board to operate without running a deficit. The board and department continually seek and implement ways to reduce costs associated with board functions.

COMMENT 6: A commenter noted that the board's inspection rules may be redundant because CLIA inspects the clinical laboratories and the CLIA inspector is given a list of lab personnel. The commenter stated that the board's contracted inspector also visited this year and asked for the same list. The commenter complained that, just in the past year, he provided a list of lab personnel to three different state government entities.

RESPONSE 6: Clinical laboratory facilities in Montana are inspected by CLIA every two years. Other government entities have regulatory authority over the clinical laboratory facilities, including the Centers for Medicaid and Medicare of the Department of Health and Human Services (CMS) which certifies clinical laboratory facilities. These regulatory authorities may conduct inspections of clinical laboratory facilities including the licensure of laboratory personnel.

The board contracts with an individual to inspect licenses at every clinical laboratory facility in Montana annually. This inspector also performs inspections for other licensing boards and combines trips to keep costs down for all boards. The inspector has found unlicensed individuals performing clinical laboratory tests.

While the board's rule regarding inspecting licenses at ARM 24.129.405, is not at issue in this rule notice, the board will consider whether to revise its approach to on-site inspections of licenses of clinical laboratory personnel to reduce costs while still safeguarding the public.

COMMENT 7: A commenter stated it is unnecessary for the board to conduct on-site inspections of clinical laboratory personnel licenses because the information is available to the department and board through their licensing records and database. The commenter suggested the board could save a lot of money by eliminating the inspection of licenses entirely, or only conducting on-site inspections of a small sample (e.g., 10%) of clinical laboratories or those having a negative history.

RESPONSE 7: The board notes that the inspector has found unlicensed individuals performing clinical laboratory tests and without an inspection, the unlicensed practice would not have been discovered.

While the board's rule regarding inspecting licenses at ARM 24.129.405, is not at issue in this rule notice, the board will consider whether to revise its approach to on-site inspections of licenses of clinical laboratory personnel to reduce expenses while still safeguarding the public.

Additionally, under 37-1-134, MCA, the board is required to set licensing fees to provide the amount of money usually needed for the operation of board regulatory services. In providing administrative services to the board, the department has advised that the board must increase fees to cover its operating expenses. See RESPONSE 1 for more information.

COMMENT 8: One commenter stated that the board should return to its mission of licensing clinical laboratory personnel and not set inspection rules.

RESPONSE 8: The board protects the public safety, health, and welfare by ensuring that qualified and competent individuals perform clinical laboratory testing. Establishing qualifications for initial licensure, scope of practice, and continued licensure of clinical laboratory personnel is one aspect of the board's role. The board conducts on-site inspections to enforce the licensure and scope of practice requirements for clinical laboratory personnel to further safeguard patients. Additionally, the board's on-site inspections have found unlicensed individuals performing clinical laboratory tests. The board and department will continue to seek and implement ways to reduce costs associated with board functions.

4. The board has amended ARM 24.129.401, 24.129.402, 24.129.603, 24.129.605, 24.129.612, and 24.129.2301 exactly as proposed.

5. The board has adopted NEW RULE I (24.129.606) exactly as proposed.

BOARD OF CLINICAL LABORATORY
SCIENCE PRACTITIONERS
VICKI RICE, PRESIDING OFFICER

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

/s/ PAM BUCY
Pam Bucy, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State February 27, 2017.