

BEFORE THE DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the adoption of NEW) NOTICE OF ADOPTION AND
RULES I through VII and the repeal of) REPEAL
ARM 24.150.101, 24.150.201,)
24.150.202, 24.150.301, 24.150.401,)
24.150.402, 24.150.404, 24.150.501,)
24.150.503, 24.150.505, 24.150.507,)
24.150.512, 24.150.513, 24.150.601,)
24.150.602, 24.150.2201, and)
24.150.2301 regarding the Licensed)
Hearing Aid Dispenser Program)

TO: All Concerned Persons

1. On September 8, 2023, the Department of Labor and Industry published MAR Notice No. 24-150-42 regarding the public hearing on the proposed changes to the above-stated rules, at page 984 of the 2023 Montana Administrative Register, Issue No. 17.

2. On October 3, 2023, a public hearing was held on the proposed changes to the above-stated rules via the videoconference and telephonic platform. Comments were received by the deadline.

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

COMMENT 1: Several commenters suggested specifying in NEW RULE I(1)(a) that the application fee for hearing aid dispensers is for both in-state and out-of-state applicants.

RESPONSE 1: The department determined that separating the types of HAD applicants is unnecessary as the process and fees are the same. The department is adopting the new rule as proposed.

COMMENT 2: Several commenters requested the department require both a practical and written licensure exam in NEW RULE II.

RESPONSE 2: The department determined that the practical examination presented concerns for legal defensibility and barriers to exam delivery and did not have a demonstrated risk it mitigated through an evidence basis. The department's evaluation of the exam requirements of all 50 states demonstrated that several states have either no exam requirement or the written exam only. The written exam does evaluate both knowledge and ability, has greater legal defensibility, and can be delivered in a monitored and accessible manner.

COMMENT 3: Several commenters requested adding guidance to NEW RULE III regarding an appropriate time limit for a return policy.

RESPONSE 3: As simplified by Senate Bill 456, 37-16-303, MCA, now sets forth the mandatory provisions in bills of sale that licensees must provide to hearing aid customers. The statute requires bills of sale to contain any warranty or return policy provided, or the lack of either. There are no further statutory requirements on warranties or return policies. Because the department believes that licensed dispensers and trainees will provide clients clear, complete bills of sale that comply with the statutory minimum requirements, the department is adopting NEW RULE III exactly as proposed.

COMMENT 4: Several commenters recommended the department specify direct or indirect supervision of trainees based on supervisor location in NEW RULE IV.

RESPONSE 4: The department believes supervisors will provide the appropriate supervision in every training environment. Supervision requirements are being broadened in this new rule to allow for supervisor discretion as well as multiple business locations.

COMMENT 5: Several commenters asked the department to amend NEW RULE V(2) to use "licensed hearing aid dispensers" in place of "dispensers."

RESPONSE 5: Several terms are used throughout the new rules to mean licensed hearing aid dispensers. The department has jurisdiction over licensed dispensers only and does not believe use of "dispensers" causes undue confusion.

COMMENT 6: Several commenters opposed the repeal of ARM 24.150.601 and recommended the department continue to require hearing tests before licensees dispense prescription hearing aids.

RESPONSE 6: The rule finalized by the Food and Drug Administration on October 17, 2022, established a regulatory category for over-the-counter hearing aids. Additionally, the rule made related amendments to the regulatory framework for prescription hearing aids. One of the changes was the repeal of conditions for sale for prescription hearing aids, formerly at 21 CFR 802.421. Because the rule eliminated the hearing test requirement for sale of prescription hearing aids, the department is not requiring mandatory hearing tests going forward to align with and not have stricter standards than the federal requirements. Licensees may still choose to require such tests in their practices.

COMMENT 7: Several commenters opposed the repeal of ARM 24.150.2201 and requested the department continue to require continuing education (CE) for hearing aid dispensers.

RESPONSE 7: The department believes that licensees will continue to obtain whatever education and training is necessary to maintain high standards of practice, even without the department requiring and monitoring mandatory CE.

4. The agency has adopted NEW RULES I (24.151.401), II (24.151.501), III (24.151.601), IV (24.151.504), V (24.151.404), VI (24.151.2301), and VII (24.151.604) as proposed.

5. The agency has repealed ARM 24.150.101, 24.150.201, 24.150.202, 24.150.301, 24.150.401, 24.150.402, 24.150.404, 24.150.501, 24.150.503, 24.150.505, 24.150.507, 24.150.512, 24.150.513, 24.150.601, 24.150.602, 24.150.2201, and 24.150.2301 as proposed.

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

/s/ SARAH SWANSON
Sarah Swanson, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State October 24, 2023.