BEFORE THE DEPARTMENT OF LABOR AND INDUSTRY STATE OF MONTANA

In the matter of the adoption of NEW)	NOTICE OF PUBLIC HEARING ON
RULES I through VII and the repeal of)	PROPOSED ADOPTION, AND
ARM 24.150.101, 24.150.201,)	REPEAL
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 October 3, 2023, at 10:00 a.m., a public hearing will be held via remote conferencing to consider the proposed changes to the above-stated rules. There will be no in-person hearing. Interested parties may access the remote conferencing platform in the following ways:
 - a. Join Zoom Meeting, https://mt-gov.zoom.us/j/83434695647Meeting ID: 834 3469 5647, Passcode: 052816-OR-
 - b. Dial by telephone, +1 406 444 9999 or +1 646 558 8656
 Meeting ID: 834 3469 5647, Passcode: 052816
- 2. The Department of Labor and Industry (department) will make reasonable accommodations for persons with disabilities who wish to participate in this public hearing or need an alternative accessible format of this notice. If you require an accommodation, contact the department no later than 5:00 p.m., on September 26, 2023, to advise us of the nature of the accommodation that you need. Please contact the department at P.O. Box 1728, Helena, Montana 59624-1728; telephone (406) 444-5466; Montana Relay 711; or e-mail laborlegal@mt.gov.
- 3. <u>GENERAL REASONABLE NECESSITY</u>: In support of the Governor's Red Tape Relief Initiative, the Department of Labor and Industry (department) is conducting comprehensive reviews of the administrative rules of the professional licensing boards and programs administratively attached to the department. This review focuses on updating rules to current standards and procedures, and eliminating unnecessary, redundant, and overburdensome regulations and those duplicated in statute. Other changes replace out-of-date terminology for current language and processes, and amend rules and catchphrases for accuracy, consistency, simplicity, better organization, and ease of use for customers and staff. The streamlined rules will increase department efficiencies by further standardizing procedures used among all licensing boards and programs.

The 2023 Montana Legislature enacted Chapter 483, Laws of 2023 (Senate Bill (SB) 456), an act generally revising laws related to hearing aid dispensers and

transferring regulatory oversight from a board (Board of Hearing Aid Dispensers) to a department program (Licensed Hearing Aid Dispenser program). The bill was signed by the Governor on May 8, 2023, and will be effective October 1, 2023. It is reasonably necessary to repeal the board's rules and adopt new, updated program rules to implement the bill.

The department determined it is reasonably necessary to repeal 17 rules and adopt seven new rules to align with the Red Tape Relief Initiative and implement the 2023 legislative changes. The new program rules will be placed in a new ARM chapter. Where additional specific basis for a proposed action exist, the department will identify those reasons immediately following the specific rule.

4. The proposed new rules are as follows:

NEW RULE I FEE SCHEDULE

- (1) Application
- (a) Hearing aid dispenser

\$300

(b) Trainee

600

(2) Active renewal - Hearing aid dispenser

- 550
- (3) Additional standardized fees are in ARM 24.101.403.(4) All fees are nonrefundable.
- (5) Examination fees are set by the examination administrator and paid by the applicant directly to the examination administrator.

AUTH: 37-16-202, MCA IMP: 37-16-402, MCA

<u>REASON</u>: The department is repealing ARM 24.150.401 and replacing it with this more streamlined new rule. Fees for the practical and jurisprudence examinations are stricken to align with adoption of NEW RULE II. Because current processing costs for initial hearing aid dispenser licenses and out-of-state applicants are very similar, the department will charge the same fee no matter the type of applicant.

The department is eliminating inactive status for hearing aid dispensers and repealing ARM 24.150.505. The historically consistent small number of inactive HAD licensees does not justify the staffing and costs associated with monitoring and renewing them.

Trainee licenses are valid for a full year and may be renewed once without department permission. Because trainees generally complete their supervised experience within the first year and rarely renew even once, the department concluded that it is not necessary to set a fee for trainee renewals. The remaining fees for hearing aid dispenser and trainee licensure and dispenser renewals are staying the same.

There have only been three out-of-state HAD applicants in the past year and the department collected no fees for any reexamination or inactive renewal in the same period. The department estimates the cumulative fee changes will affect approximately three applicants and result in a \$600 reduction in annual revenue.

<u>NEW RULE II EXAMINATION</u> (1) Hearing aid dispenser applicants must pass the International Hearing Society (IHS) written examination or its equivalent.

AUTH: 37-16-202, MCA IMP: 37-16-402, MCA

<u>REASON</u>: It is reasonably necessary to repeal ARM 24.150.501 and replace it with this new rule to align with statutory changes in SB 456. The bill repealed 37-16-405, MCA, the former trainee license statute, and simplified the examination process with amendments to 37-16-402, MCA.

All licensees are required to know and adhere to all applicable statutes and administrative rules. Requiring an exam that only calls out certain regulations does not lead to greater compliance with the regulations or add to public protection. The department concluded that striking the jurisprudence exam will also eliminate unnecessary delays in the application process.

NEW RULE III BILLS OF SALE/RECEIPTS (1) In addition to provisions of 37-16-303, MCA, each bill of sale and receipt must contain a plain and simple notice of those hearing aids that must be programmed or adjusted only by authorized dealers or dispensers and must be signed by the licensee and purchaser.

- (2) For trainee-provided services, all bills of sale and receipts must clearly show:
 - (a) trainee's designation, name, and license number; and
 - (b) supervisor's name and license number.

AUTH: 37-16-202, MCA

IMP: 37-16-202, 37-16-303, MCA

<u>REASON</u>: It is reasonably necessary to adopt this rule to align with the provisions of SB 456 and replace ARM 24.150.602 which is being repealed. This new rule streamlines and reorganizes the transactional document provisions for ease of use, simplicity, and to implement the statutory changes. The department believes that licensed dispensers and trainees will provide clients clear, readable documents as per acceptable practice standards.

NEW RULE IV TRAINEE LICENSURE – SUPERVISED TRAINING

- (1) Hearing aid dispenser applicants must complete 1,000 hours of supervised training while licensed as hearing aid dispenser trainees.
- (2) Trainee licenses are valid for one year unless renewed and may be renewed only once without prior department approval.
- (3) Trainees must be supervised by qualified licensed hearing aid dispensers who are available for regular and prompt observation, instruction, consultation, and treatment.
 - (4) To supervise, hearing aid dispensers must:
- (a) be currently licensed and actively practicing in Montana for at least one year; and

- (b) have no final discipline in any state against the dispenser's license or a related license such as audiologist, in the two years preceding the request to supervise.
- (5) The supervisor and trainee shall immediately notify the department and provide the reasoning for any pause in or termination of the training.
- (6) Unsupervised trainees may not practice and must receive department approval before continuing in trainee status.
- (7) Credit toward the training is only given when trainees have documented supervision.
- (8) Trainees must maintain and submit to the department every 90 days, a dated log documenting their daily tasks and duties that is signed by the trainee and supervisor.
- (9) Trainees must submit the final log upon conclusion of the supervised training to obtain approval to sit for the examination per [NEW RULE II].

AUTH: 37-16-402, MCA IMP: 37-16-402, MCA

<u>REASON</u>: It is reasonably necessary to repeal ARM 24.150.503 and replace it with this new rule to align with statutory changes in SB 456. The bill repealed 37-16-405, MCA, the former trainee license statute, and amended 37-16-402, MCA, to provide for training and examination requirements in department rule. Supervision requirements are being broadened to allow for supervisor discretion as well as multiple business locations.

<u>NEW RULE V RECORD RETENTION</u> (1) As applicable, patient records must include:

- (a) dates, locations, and methods for all patient contacts;
- (b) description of services;
- (c) a record of and receipt for any hearing aids returned; and
- (d) a copy of all final bills of sale.
- (2) Dispensers shall maintain patient records for a minimum of seven years from the last recorded date of service. Deceased patient records may be discarded one year after the date of death.

AUTH: 37-16-202, MCA

IMP: 37-16-301, 37-16-303, MCA

<u>REASON</u>: The department is repealing ARM 24.150.402 and adopting this new rule to update in favor of more general and reasonable requirements for record retention. It is reasonable to no longer require that patients receive original documents as licensees will provide originals or quality copies as per generally accepted standards of practice.

The department is removing provisions for record of medical recommendations, mandatory refunds, and delivery verification forms to align with SB 456. The bill struck medical recommendations from 37-16-303, MCA, and repealed 37-16-304, MCA, which contained all refund provisions.

It is reasonably necessary to remove the hearing test requirements and reference to ARM 24.150.601 to align with federal regulations. Effective October 17, 2022, the federal Food and Drug Administration (FDA) finalized a rule establishing a regulatory category for over-the-counter hearing aids at 87 FR 50755. The rule also made related amendments to update the regulatory framework for prescription hearing aids, including the repeal of conditions for sale of hearing aids formerly at 21 CFR 801.421.

It is unnecessary to retain the requirement for dispensers to keep advertisement records. Anyone complaining about a dispenser's advertisements would have the burden of producing a copy of the advertisement to proceed.

<u>NEW RULE VI UNPROFESSIONAL CONDUCT</u> (1) It is unprofessional conduct for licensed hearing aid dispensers to:

- (a) violate a federal, state, or local law or rule relating to the conduct of the profession;
- (b) initiate telephone contact without first identifying the dispenser's name and company, or making more than one contact, unless the person specifically requests further contact;
- (c) contact a person more than once who has a hearing aid still under warranty, unless:
 - (i) contact is made by the original dispenser; or
 - (ii) the person specifically requests the additional contact;
- (d) perform services outside the licensee's area of training, expertise, competence, or scope of practice or licensure;
- (e) fail to adequately supervise, manage, train, or control auxiliary staff or supervisees;
 - (f) discontinue professional services, unless:
 - (i) services are completed;
 - (ii) the person requests the discontinuation;
 - (iii) alternative or replacement services are arranged; or
- (iv) the person is given reasonable opportunity to arrange alternative or replacement services;
 - (g) delegate a professional task to an unqualified person;
 - (h) fail to obtain informed consent when warranted;
 - (i) physically or verbally abuse a patient; and
- (j) fail to account for funds received in connection with any services rendered or to be rendered.

AUTH: 37-16-202, MCA IMP: 37-16-411, MCA

<u>REASON</u>: The department is repealing ARM 24.150.2301 and replacing it with this rule to update, reorganize, and streamline the unprofessional conduct for licensed hearing aid dispensers. This new rule also eliminates any unnecessary duplication between statute and rule. Instead of stating specific state or federal regulations to follow, the department is including (1)(a) to require licensees comply with all applicable laws and regulations.

NEW RULE VII AUDIOMETER CALIBRATION (1) The department may randomly audit renewed licensed hearing aid dispensers for calibration compliance with American National Standards Institute (ANSI) standards.

AUTH: 37-16-202, MCA IMP: 37-16-202, MCA

<u>REASON</u>: It is reasonably necessary to adopt this new rule to implement 37-16-202, MCA, which permits the periodic inspection and calibration of licensed hearing aid dispensers' audiometric equipment. This rule will provide notice that department auditors will utilize current ANSI standards in their calibration audits.

5. The rules proposed to be repealed are as follows:

24.150.101 BOARD ORGANIZATION

AUTH: 2-4-201, MCA IMP: 2-4-201, MCA

<u>REASON</u>: It is reasonably necessary to repeal this rule and ARM 24.150.201, 24.150.202, and 24.150.404 to implement SB 456 which eliminated the board and transferred regulation of hearing aid dispensers to the department. There is no need to incorporate the department's own rules.

24.150.201 PROCEDURAL RULES

AUTH: 2-4-201, MCA IMP: 2-4-201, MCA

24.150.202 PUBLIC PARTICIPATION

AUTH: 2-3-103, MCA IMP: 2-3-103, MCA

24.<u>150.301 DEFINITIONS</u>

AUTH: 37-1-131, 37-16-202, MCA

IMP: 37-1-131, 37-1-304, 37-16-301, 37-16-303, 37-16-304, MCA

<u>REASON</u>: The department is repealing this definitions rule as no longer necessary. SB 456 repealed 37-16-304, MCA, the authorizing statute for a "dispensing fee," as well as the right to cancel provisions that necessitated cancellation notice being "prominently displayed."

The department is removing the "related devices" definition as any device utilized in a licensee's practice is to be used within the generally accepted standards of practice. It is not necessary to define the specific devices.

It is reasonably necessary to strike the definition of "substantially equivalent" as SB 456 greatly simplified licensure requirements for licensed hearing aid dispensers and trainees in 37-16-402, MCA.

24.150.401 FEES

AUTH: 37-1-131, 37-1-134, 37-16-202, MCA

IMP: 37-1-131, 37-1-134, 37-1-141, 37-16-402, 37-16-405, 37-16-406,

MCA

<u>REASON</u>: The department is repealing this rule and replacing it with NEW RULE I. See the REASON for NEW RULE I.

24.150.402 RECORD RETENTION

AUTH: 37-1-131, 37-16-202, MCA

IMP: 37-1-131, 37-16-301, 37-16-303, 37-16-304, 37-16-411, MCA

<u>REASON</u>: The department is repealing this rule and replacing it with NEW RULE V. See the REASON for NEW RULE V.

24.150.404 FEE ABATEMENT

AUTH: 37-1-131, MCA

IMP: 17-2-302, 17-2-303, 37-1-134, MCA

See the REASON for ARM 24.150.101.

24.150.501 EXAMINATION - PASS/FAIL POINT

AUTH: 37-1-131, 37-16-202, MCA IMP: 37-16-405, 37-16-406, MCA

<u>REASON</u>: The department is repealing this rule and replacing it with NEW RULE II. See the REASON for NEW RULE II.

24.150.503 TRAINEESHIP REQUIREMENTS AND STANDARDS

AUTH: 37-1-131, 37-16-202, MCA

IMP: 37-1-131, 37-16-301, 37-16-405, MCA

<u>REASON</u>: The department is repealing this rule and replacing it with NEW RULE IV. See the REASON for NEW RULE IV.

24.150.505 INACTIVE STATUS

AUTH: 37-1-319, MCA

IMP: 37-1-131, 37-1-306, 37-1-319, MCA

<u>REASON</u>: It is reasonably necessary to repeal this rule and eliminate inactive status for hearing aid dispensers. The historically consistent small number of inactive HAD licensees does not justify the staffing and costs associated with monitoring and renewing them.

24.150.507 MILITARY TRAINING OR EXPERIENCE

AUTH: 37-1-145, MCA IMP: 37-1-145, MCA

<u>REASON</u>: The 2023 Montana Legislature enacted Chapter 390, Laws of 2023 (House Bill 583), an act generally revising licensing and certification laws for military members, military spouses, and veterans. The bill was signed by the Governor on May 3, 2023, and will be effective July 1, 2024.

It is reasonably necessary to repeal this rule to align with the bill's amendments to 37-1-145, MCA. The amended statute provides for all boards and programs to accept relevant military education, training, or service toward license qualifications. Specific board or program rules are no longer needed.

24.150.512 NONROUTINE APPLICATIONS

AUTH: 37-1-131, MCA

IMP: 37-1-101, 37-1-131, MCA

<u>REASON</u>: It is reasonably necessary to repeal this rule and ARM 24.150.513 to implement SB 456 which eliminated the board and transferred regulation of hearing aid dispensers to the department. There is no need to incorporate the department's own rules.

24.150.513 APPLICANTS WITH CRIMINAL CONVICTIONS

AUTH: 37-1-131, MCA

IMP: 37-1-101, 37-1-131, MCA

24.150.601 MINIMUM TESTING

AUTH: 37-16-202, MCA IMP: 37-16-202, MCA

<u>REASON</u>: Effective October 17, 2022, the FDA finalized a rule establishing a regulatory category for over-the-counter hearing aids at 87 FR 50755. The rule also made related amendments to update the regulatory framework for hearing aids, including the repeal of conditions for sale of hearing aids formerly at 21 CFR 801.421. It is reasonably necessary to repeal this rule to align with and remove provisions that conflict with the federal regulations.

24.150.602 TRANSACTIONAL DOCUMENT REQUIREMENTS - FORM AND CONTENT

AUTH: 37-16-202, MCA

IMP: 37-16-202, 37-16-303, 37-16-304, MCA

<u>REASON</u>: The department is repealing this rule and replacing it with NEW RULE III. See the REASON for NEW RULE III.

24.150.2201 CONTINUING EDUCATION REQUIREMENTS

AUTH: 37-1-131, 37-1-319, MCA

IMP: 37-1-131, 37-1-306, 37-1-319, MCA

<u>REASON</u>: The department is repealing this rule and eliminating continuing education (CE) requirements for licensed hearing aid dispensers. There is no conclusive proof that requiring CE results in safer hearing aid dispensers. The department believes that licensees will continue to obtain the education necessary to maintain high standards of practice.

24.150.2301 UNPROFESSIONAL CONDUCT

AUTH: 37-1-131, 37-1-319, 37-16-202, MCA

IMP: 37-1-131, 37-1-316, 37-1-319, 37-16-411, MCA

<u>REASON</u>: The department is repealing this rule and replacing it with NEW RULE VI. See the REASON for NEW RULE VI.

- 6. Concerned persons may present their data, views, or arguments at the hearing. Written data, views, or arguments may also be submitted at dli.mt.gov/rules or P.O. Box 1728; Helena, Montana 59624. Comments must be received no later than 5:00 p.m., October 6, 2023.
- 7. An electronic copy of this notice of public hearing is available at dli.mt.gov/rules and sosmt.gov/ARM/register.
- 8. The agency maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by the agency. Persons wishing to have their name added to the list may sign up at dli.mt.gov/rules or by sending a letter to P.O. Box 1728; Helena, Montana 59624 and indicating the program or programs about which they wish to receive notices.
- 9. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was contacted on May 26, 2023, by electronic mail.

- 10. Pursuant to 2-4-111, MCA, the agency has determined that the rule changes proposed in this notice will not have a significant and direct impact upon small businesses.
- 11. Department staff has been designated to preside over and conduct this hearing.

/s/ DARCEE L. MOE/s/ SARAH SWANSONDarcee L. MoeSarah Swanson, CommissionerRule ReviewerDEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State August 29, 2023.