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BEFORE THE DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES OF THE STATE OF MONTANA

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In the matter of the amendment of ARM 37.86.801, 37.86.802 and 37.86.805 pertaining to hearing aid services NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Concerned Persons

1. On June 27, 2024, at 9:00 a.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed amendment of the above-stated rules. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at: https://mtgov.zoom.us/j/82409300487?pwd=SXh1WFUrZ0FhdisvdWptUEJUd3FVdz09, meeting ID: 824 0930 0487, and password: 048132; or

(b) Dial by telephone: +1 646 558 8656, meeting ID: 824 0930 0487, and password: 048132. Find your local number: https://mt-gov.zoom.us/u/k8wQLEh8.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on June 13, 2024, to advise us of the nature of the accommodation that you need. Please contact Bailey Yuhas, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

<u>37.86.801 HEARING AID SERVICES, DEFINITIONS</u> (1) "Hearing aid" means an instrument or device designed for or represented as aiding or improving defective human hearing and includes the parts, attachments, or accessories of the instrument or device. "Audiologist" means a person holding a current audiology license issued by the Montana Board of Speech-Language Pathologists and Audiologists under Title 37, chapter 15, MCA, to engage in selling, dispensing, or fitting hearing aids.

(2) "Hearing aid dispenser" or "dispenser" means a person holding a current license issued by the Montana Board of Hearing Aid Dispensers under Title 37, chapter 16, MCA to engage in selling, dispensing, or fitting hearing aids. The term does not include any person to the extent that the person acts beyond the scope of the person's hearing aid dispenser license. "Licensed hearing aid dispenser" has the meaning as defined in 37-16-102, MCA.

(3) "Dispenser" also means a person holding a current audiology license issued by the Montana Board of Speech-Language Pathologists and Audiologists under Title 37, chapter 15, MCA to engage in selling, dispensing, or fitting hearing aids. The department adopts and incorporates into this rule the definition of "overthe-counter hearing aid" in 21 C.F.R. § 800.30 (April 1, 2024).

(4) The department adopts and incorporates into this rule the definition of "prescription hearing aid" in 21 C.F.R. § 801.422 (April 1, 2024).

AUTH: 53-6-113, MCA IMP: 53-6-101, 53-6-141, MCA

<u>37.86.802 HEARING AID SERVICES, REQUIREMENTS, AND</u> <u>LIMITATIONS</u> (1) remains the same.

(2) Medicaid payment for purchase of hearing aids will be made only to a licensed hearing aid dispenser or audiologist for Medicaid covered services provided in accordance with all applicable Medicaid requirements and within the scope of practice permitted under the dispenser's license. Over-the-counter hearing aids are not a covered benefit.

(3) A <u>prescription</u> hearing aid may be covered under the Medicaid program if <u>all of the following conditions are satisfied</u>:

(a) the recipient <u>member's</u> has been referred by a physician or mid-level practitioner <u>has referred the member to an audiologist</u> for an audiological <u>evaluation</u> examination and the physician or mid-level practitioner has determined that there is no medical reason for which a hearing aid would not be effective in correcting the recipient's hearing loss;

(b) the examination by a licensed audiologist results in a determination that a hearing aid or aids are needed; and the licensed audiologist has determined a prescription hearing aid would be effective in improving the member's hearing;

(c) the licensed audiologist's evaluation has concluded that the member requires a prescription hearing aid or aids;

(c)(d) the following criteria are met: prior authorization for the prescription hearing aid has been granted by the department or its designated review organization; and

(i) for persons over 21 years of age, the audiological examination results show that there is an average pure tone loss of at least 40 decibels for each of the frequencies of 500, 1000, 2000, and 3000 Hertz in the better ear and word recognition or speech discrimination scores obtained at a level to ensure pb max. The following criteria shall apply to adults aged 21 years or older for binaural hearing aids:

(A) the two frequency average at 1khz and 2khz must be greater than 40db in both ears;

(B) the two frequency average at 1khz and 2khz must be less than 90db in both ears;

(C) the two frequency average at 1khz and 2khz must have an interaural difference of less than 15db;

(D) the interaural word recognition or speech discrimination score must have a difference of not greater than 20%;

(E) demonstrated success in using a monaural hearing aid for at least six months; and

(F) documented need to understand speech with a high level comprehension based on an educational or vocational need.

(ii) for persons under 21 years of age, the department or its designee determines after review of the audiology report that the hearing aid would be appropriate for the person. Persons under 21 years of age will be evaluated under the early periodic screening and testing program.

(d)(e) the original hearing aid no longer meets the needs of the individual, and a new hearing aid is determined to be medically necessary by a licensed audiologist. the prescription hearing aid is provided by a licensed hearing aid dispenser or an audiologist.

(4) The audiologist shall indicate in a written report whether in his or her professional opinion a hearing aid is required for the recipient. The report shall also indicate the type of hearing aid required by the recipient and whether monaural or binaural hearing aids are required. The audiologist's report will be prepared in accordance with the format described in the audiologists' provider manual.

(5) A claim for coverage of a hearing aid must be approved in writing by the department or its designee prior to the provision of the service. Copies of the physician's referral and audiologist's report must be submitted with the claim.

(6)(4) The date of service is defined as the date the <u>prescription</u> hearing aid(s) is ordered by the dispenser.

(7)(5) For individuals members age aged 21 or over, a replacement prescription hearing aid purchased by Medicaid requires prior authorization. will be replaced no more than once in a five year period and only if:

(a) the original hearing aid has been irreparably broken after the one year warranty period or has been lost;

(b) the provider's records document the loss or broken condition of the original hearing aid; and

(c) the hearing loss criteria specified in this rule continue to be met.

AUTH: 53-2-201, 53-6-113, MCA IMP: 53-2-201, 53-6-101, 53-6-111, 53-6-141, MCA

<u>37.86.805 HEARING AID SERVICES, REIMBURSEMENT</u> (1) and (1)(a) remain the same.

(b) the amount specified for the particular service or item in the department's fee schedule. The department adopts and incorporates by reference the department's Hearing Aid Fee Schedule as provided in ARM 37.85.105(3)(c); or

(c) through (2) remain the same.

(a) Establishing a fee for a service that has been billed at least 50 times by all providers in the aggregate during the previous 12-month period. The department will set each fee at the payment-to-charge ratio under ARM $\frac{37.85.105(2)(d)}{37.85.105(2)(e)}$.

(b) through (3) remain the same.

AUTH: 53-2-201, 53-6-113, MCA

MAR Notice No. 37-1062

IMP: 53-2-201, 53-6-101, 53-6-113, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) is proposing to amend ARM 37.86.801, 37.86.802, and 37.86.805.

ARM 37.86.801 Hearing Aid Services, Definitions

The department proposes to remove the definition of "hearing aid" and replace it with definitions of "prescription hearing aid" and "over-the-counter hearing aid." This change is necessary to clarify that over-the-counter hearing aids are not a covered benefit of Medicaid, nor have they ever been a covered benefit of the Medicaid program.

SB 456, adopted during the 68th legislative session, added a definition of licensed hearing aid dispenser under 37-16-102, MCA. To ensure consistent definitions, the department proposes to remove the definition of "hearing aid dispenser" and replace it with the MCA definition of "licensed hearing aid dispenser."

The department proposes to remove the definition of "dispenser" and replace it with the more precise term "licensed hearing aid dispenser." This provides clarity and consistency of terminology in the rules.

The department proposes to add the definition of "audiologist" to provide clarity and consistency throughout the rules within ARM Title 37, chapter 86, subchapter 8.

<u>ARM 37.86.802 Hearing Aid Services, Requirements, and Limitations</u> The department proposes to amend ARM 37.86.802 to do the following:

- 1. Clarify that over-the-counter hearing aids are not covered by Medicaid and have never been.
- 2. Update references to "hearing aid" to "prescription hearing aid."
- 3. Consolidate and clarify coverage criteria by:
 - Moving the requirement for prescription hearing aids to be provided by a licensed hearing aid dispenser or audiologist from its own subsection to a requirement of coverage under (3).
 - Simplifying the rule text by removing the coverage criteria from rule and replacing it with plain language that states prescription hearing aids must be prior authorized. The coverage criteria will continue to be available for public review as it is listed in the Audiology and Hearing Aid Services Manual.
- 4. Remove (5) stating that approval must be in writing. This requirement is redundant as a provider confirmed medical necessity through the prior authorization process.
- 5. Remove the prescription hearing aid replacement criteria language as all prescription hearing aids require prior authorization. The replacement criteria will continue to be available for public review as it is listed in the Audiology and Hearing Aid Services Manual.

37.86.805(2)(a) Hearing Aid Services, Reimbursement

The department proposes to correct an invalid reference by replacing the reference to ARM 37.85.105(2)(d) to 37.85.105(2)(e).

Fiscal Impact

The proposed rule amendments have no anticipated fiscal impact implications.

5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Bailey Yuhas, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov, and must be received no later than 5:00 p.m., July 5, 2024.

6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Written requests may be mailed or delivered to the contact person in 5 above.

8. An electronic copy of this notice is available on the department's web site at https://dphhs.mt.gov/LegalResources/administrativerules, or through the Secretary of State's web site at http://sosmt.gov/ARM/register.

9. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

10. With regard to the requirements of 2-4-111, MCA, the department has determined that the amendment of the above-referenced rules will not significantly and directly impact small businesses.

11. Section 53-6-196, MCA, requires that the department, when adopting by rule proposed changes in the delivery of services funded with Medicaid monies, make a determination of whether the principal reasons and rationale for the rule can be assessed by performance-based measures and, if the requirement is applicable, the method of such measurement. The statute provides that the requirement is not applicable if the rule is for the implementation of rate increases or of federal law.

The department has determined that the proposed program changes presented in this notice are not appropriate for performance-based measurement and therefore are not subject to the performance-based measures requirement of 53-6-196, MCA.

<u>/s/ Brenda K. Elias</u> Brenda K. Elias Rule Reviewer <u>/s/ Charles T. Brereton</u> Charles T. Brereton, Director Department of Public Health and Human Services

Certified to the Secretary of State May 28, 2024.