STATE OF WISCONSIN HEARING AND SPEECH EXAMINING BOARD

IN THE MATTER OF RULEMAKING : NOTICE OF TIME PERIOD PROCEEDINGS BEFORE THE : FOR COMMENTS FOR THE HEARING AND SPEECH EXAMINING : ECONOMIC IMPACT ANALYSIS

BOARD :

NOTICE IS HEREBY GIVEN of the time period for public comment on the economic impact of this proposed rule of the Hearing and Speech Examining Board on HAS 1, 4, 5, and 9, relating to Cerumen Management, including how this proposed rule may affect businesses, local government units and individuals. The comments will be considered when the Department of Safety and Professional Services prepares the Economic Impact Analysis pursuant to § 227.137. Written comments may be submitted to:

Nilajah Hardin, Administrative Rules Coordinator
Division of Policy Development
Department of Safety and Professional Services
PO Box 8366
Madison, WI 53708-8935

DSPSAdminRules@wisconsin.gov

The deadline for submitting economic impact comments is May 7, 2025.

PROPOSED ORDER

An order of the Hearing and Speech Examining Board to amend HAS 1.005, 1.01 (intro.), and 5.02 (2) (a); to create HAS 1.01 (1m) and (5h), 5.02 (2) (j), and chapter HAS 9; and to renumber HAS 1.01 (5m), relating to cerumen management.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: Section 459.115, Stats.

Statutory authority: Sections 15.08 (5) (b), 459.12 (1), and 459.115 (4) Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats.: "Each examining board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession."

Section 459.12 (1), Stats.: "The examining board may make rules not inconsistent with the laws of this state which are necessary to carry out the intent of this chapter."

Section 459.115 (4), Stats: "The examining board shall promulgate rules necessary to administer this section, including rules for all of the following:

- (a) Defining the scope of cerumen management.
- (b) Establishing contraindications for which a person licensed under this subchapter shall refer a patient to an otolaryngologist or a physician for cerumen management.
- (c) Establishing proper infection control practices."

Related statute or rule: 2023 Wisconsin Act 82

Plain language analysis:

The objective of the rule is to implement 2023 Wisconsin Act 82 by creating a new chapter of the Wisconsin Administrative Code, HAS 9, to outline requirements for Cerumen Management Certification for Hearing Instrument Specialists. Definitions for "cerumen management" and "significant pain" were also added to chapter HAS 1, and chapter HAS 5 was updated to include unprofessional conduct for an individual certified to practice cerumen management.

Summary of, and comparison with, existing or proposed federal regulation: None.

Comparison with rules in adjacent states:

Illinois: In the Illinois Compiled Statutes Chapter 225, the Hearing Instrument Consumer Protection Act outlines the requirements for licensure, continuing education, renewal, and discipline of Hearing Instrument Dispensers or Professionals. The practice of a Hearing Instrument Dispenser in Illinois includes the selling, practice of testing, fitting, selecting, recommending, adapting, dispensing, or servicing hearing aids. The practice of a Hearing Instrument Dispenser in Illinois does not include cerumen management [225 Illinois Compiled Statutes 50].

Iowa: Chapter 154A of the Iowa Code outlines the requirements for the licensure of Hearing Aid Specialists. Hearing Aid Specialists may perform hearing aid fitting which includes the sale of hearing aids and making earmold impressions as part of the fitting process [Iowa Code Chapter 154A]. Chapters 121 through 124 further elaborate on the requirements for the practice of Hearing Aid Specialists including licensure, supervision, continuing education, and dispensing of hearing aids. If a Hearing Aid Specialist observes cerumen impaction in a patient prior to fitting a hearing aid, they are required to suggest to the patient in writing that they consult a physician, preferably one with a specialization in diseases of the ear[Iowa Administrative Code Chapter 123 Section 123.2 (3) (f)].

Michigan: The Michigan Compiled Laws, Chapter 339, Act 299 includes requirements for licensure and regulation of Hearing Aid Dealers and Salespersons, as well as the Board of hearing aid dealers. In Michigan, licensed Hearing Aid Dealers perform the practice of selling or fitting a hearing aid, which includes audiometric testing and making ear mold impressions. Michigan does not appear to address Cerumen Management by Hearing Aid Dealers in their laws [Michigan Compiled Laws 333.1301 to 1309].

Minnesota: The Minnesota Statutes chapter 148 includes requirements for audiology, as well as the practice of hearing aid dispensing. The practice of hearing aid dispensing includes making ear mold impressions, prescribing a hearing aid, testing human hearing and helping a customer select a prescription hearing aid. In Minnesota, prescription hearing aids may be dispensed by Audiologists or Certified Hearing Dispensers. Minnesota does not appear to address Cerumen Management by Certified Hearing Dispensers in their laws [Minnesota Statutes ss.148.511 to 148.5198].

Summary of factual data and analytical methodologies:

While promulgating this rule, the Board reviewed recommendations from the Wisconsin Audiology Association, a "Clinical Practice Guideline (Update) on Earwax (Cerumen Impaction) Executive Summary" from the American Academy of Otolaryngology – Head and Neck Surgery Foundation published in 2017, language on cerumen management from Tennessee regulations, and the definition of "pain" from the International Association for the Study of Pain, among other resources.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov or phone at 608-266-2112.

Agency contact person:

Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708-8306; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received on or before the public hearing, held on a date to be determined, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. HAS 1.005 is amended to read:

HAS 1.005 Authority. The rules in chs. HAS 1 to 5 <u>and 9</u> are adopted pursuant to ss. 15.08 (5) (b), 227.11 (2), and 459.12 (1), and 459.115 (4), Stats.

SECTION 2. HAS 1.01(intro.) is amended to read:

HAS 1.01 Definitions. As used in chs. HAS 1 to 5 <u>and 9</u>, unless the context otherwise requires:

SECTION 3. HAS 1.01 (1m) is created to read:

HAS 1.01 (1m) "Cerumen" has the meaning given in s. 459.01 (1b), Stats.

SECTION 4. HAS 1.01 (5m) is renumbered to (5e).

SECTION 5. HAS 1.01 (5h) is created to read:

HAS 1.01 (5h) "Significant pain" means an unpleasant sensory and emotional experience associated with, or resembling association with actual or potential tissue damage that is so bothersome that a patient cannot continue to verbalize consent, communicate symptoms with a health care practitioner, remain conscious and alert, or any combination of the above.

SECTION 6. HAS 5.02 (2) (a) is amended to read:

HAS 5.02 (2) (a) After a request by the board, failing to cooperate in a timely manner with the board's investigation of complaints filed against the applicant, or licensee, or certified individual. There is a rebuttable presumption that a licensee, or applicant, the applicant, or licensee, or certified individual who takes longer than 30 days to respond to a request of the board has not acted in a timely manner under this subsection.

SECTION 7. HAS 5.02 (2) (j) is created to read:

HAS 5.02 (2) (j) If the licensee maintains a cerumen management certificate under s.459.115, Stats, and ch. HAS 9, failure to do any of the following:

- 1. Safely engage in the practice of cerumen management.
- 2. Refer a patient for cerumen management under s. HAS 9.04 when appropriate.
- 3. Follow proper infection control procedures under s. HAS 9.05.
- 4. Maintain the required amount malpractice liability insurance under s. HAS 9.06.

SECTION 8. Chapter HAS 9 is created to read:

Chapter HAS 9

CERUMEN MANAGEMENT CERTIFICATION

- HAS 9.01 Applicability and Scope. (1) Pursuant to s. 459.115 (1) and (2), Stats., the standards of practice for cerumen management in this chapter apply to all licensees who maintain a certification in cerumen management. An audiologist licensed under s. 459.24 (3), Stats. is not required to maintain a cerumen management certification.
- (2) The practice of cerumen management may include any of the following services:
 - (a) Conducting Audiometric testing.
 - **(b)** Making ear impressions.
 - (c) Monitoring use of hearing aids.
 - (d) Fitting Hearing Protection or prosthetic devices.
 - (e) Conducting a thorough case history including medication list, surgical history, hospitalizations, and chronic health conditions.
 - (f) Other services approved by the board.
- (3) When performing cerumen management, the certified individual shall only remove cerumen within the lateral external auditory canal using the following instruments:
 - (a) Cerumen loop.
 - (b) Cerumenolytic fluid.
 - (c) Irrigation for patients with all of the following:
 - 1. Intact tympanic membranes.
 - 2. Closed mastoid cavity.
 - 3. No prior mastoid surgery.
 - 4. No tympanostomy tubes.
 - 5. No recent ear surgery.
 - 6. No recent dizziness.
 - (d) Suction used lateral to the bony canal limited to a suction tip in size 5 on the French scale for patients with all of the following:
 - 1. No recent ear surgery.
 - 2. Intact tympanic membranes.
 - 3. No clear otorrhea.
- (4) Cerumen management shall always be performed under otoscopy or micro-otoscopy.
- **HAS 9.02 Certification.** (1) An applicant for cerumen management certification shall complete the following:
 - (a) Submit a completed application form as specified by the Department. Note: Instructions for applications are available on the department of safety and professional services' website at http://dsps.wi.gov.
 - **(b)** Pay the fee as required by s. 440.05 (1), Stats.
 - (c) Submit proof of completion of the education requirements under s. HAS 9.03.
 - (d) Submit evidence satisfactory to the board that the licensee is in compliance with s. HAS 9.06.
- (2) Pursuant to s. 459.115 (5), Stats., once granted, a certification to practice cerumen management is permanent unless revoked and is not subject to periodic renewal.

HAS 9.03 Education Requirements. (1) The board accepts education courses for cerumen management that satisfy all of the following criteria:

- (a) The course provides at least 6 hours of instruction.
- (b) The subject matter of the course relates to removal of cerumen from the ear canal using safe techniques.
- (c) The course must include a final practical examination on proper cerumen management procedures.
- (d) The course is one of the following:
 - **1.** Sponsored or recognized by a local, state, regional, national, or international association of hearing instrument specialists or audiology.
 - **2.** A course preapproved by the Board or its designee as sufficient.
- (2) In place of a course that satisfies the requirements under sub (1), an applicant may submit evidence of completion of approved practical or occupational training, with a licensed supervising otolaryngologist or licensed audiologist, in cerumen management that has been approved by the board. Approved practical or occupational training in cerumen management shall be at least 6 hours in duration and include practical training in proper cerumen management procedures.

Note: Requests for board approval of practical or occupational training in cerumen management may be sent to the department of safety and professional services at dsps@wi.gov or 4822 Madison Yards Way Madison, WI 53705.

(3) For the duration of their cerumen management certification, an individual shall complete at least two of the 20 hours required under s. HAS 8.03 on the topic of diseases of the ear or a similar topic approved by the board.

HAS 9.04 Referrals. (1) An individual certified to perform cerumen management shall refer a patient to an otolaryngologist or licensed physician for cerumen management when the patient presents with any of the following:

- (a) Is less than 18 years of age.
- **(b)** A perforated tympanic membrane.
- (c) History of pain, active drainage, or bleeding from the ear.
- (d) Evidence of congenital or traumatic deformity of the ear.
- (e) On anticoagulant therapy.
- **(f)** Are immunocompromised.
- (g) Have Diabetes mellitus.
- (h) History of prior radiation therapy to the head and neck.
- (i) History of ear canal stenosis or exostoses.
- (j) A nonintact tympanic membrane.
- (k) Ear surgery within the last six months.
- (I) Tympanostomy tubes, such that irrigation should not be used.
- (m)A bleeding disorder.
- (n) Actual or suspected foreign body in the ear.
- (o) Stenosis or bony exostosis of the ear canal.
- (p) Cerumen impaction that totally occludes the ear canal.
- (q) Cerumen located medial to the cartilaginous external auditory canal or beyond the second bend.
- (r) A tympanic membrane that the certified individual is unable to see.
- (s) Vertigo.

- (2) The certified individual shall immediately stop the procedure and refer a patient to an otolaryngologist or a licensed physician if any of the following occur while performing cerumen management:
 - (a) Significant pain.
 - **(b)** Uncontrolled bleeding.
 - (c) Laceration of the external auditory canal.
 - (d) Acute onset of dizziness or vertigo.
 - (e) Sudden hearing loss.

HAS 9.05 Infection Control. An individual certified to perform cerumen management under this chapter shall establish a written protocol to comply with all of the following infection control procedures:

- (1) Standard precautions for all health care providers.
- (2) Cleaning, disinfection, and sterilization based on manufacturer instructions, where appropriate, of multiple use equipment.
- (3) Universal precautions for prevention of the transmission of human immunodeficiency virus, hepatitis B virus, and other blood borne pathogens as defined by the occupational safety and health standards in 29 CFR 1910.1030.

HAS 9.06 Malpractice Liability Coverage. An individual applying for cerumen management certification shall obtain and maintain malpractice liability insurance for the duration of their certification. The insurance policy shall provide professional liability coverage of at least \$1,000,000 for each incident or claim.

SECTION 8. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)