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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
HEARING AND SPEECH EXAMINING BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
October 30, 2024

The following agenda describes the issues that the Board, Committee, Council, Section plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board, Committee, Council, Section.

AGENDA

8:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1-4)

B. Approval of Minutes of June 26, 2024 (5-9)

C. Reminders: Conflicts of Interest, Scheduling Concerns

D. 8:30 A.M. PUBLIC HEARING: Clearinghouse Rule 24-062 on HAS 6 to 8, Relating to Implementation of the Audiology and Speech-Language Pathology Licensure Compact (10-21)
1) Review Public Hearing Comments and Respond to Clearinghouse Report

E. Audiology and Speech-Language Pathology Compact Matters – Discussion and Consideration

F. Introduction, Announcements, and Recognition
1) Introduction: Amy K. Kroll – Audiologist Member (Succeeds: Broeckert)

G. Administrative Matters – Discussion and Consideration
1) Department, Staff and Board Updates
2) Appointment of Liaisons and Alternates, Delegations of Authorities **(22-35)**
3) Board Members – Term Expiration Dates
   a. Beyer, Todd M. – 7/1/2027
   b. Harris, Michael S. – 7/1/2027
   c. Kanter, Catherine D. – 7/1/2028
   d. Kroll, Amy K. – 7/1/2027
   e. Lapidakis, Jerry A. – 7/1/2024
   f. Meyer, Jason J. – 7/1/2025
   g. Pazak, Kathleen A. – 7/1/2027
   h. Seligman, David H. – 7/1/2023
   i. Sikorski, Samantha – 7/1/2025

j. Willemon, Justen J. – 7/1/2025

H. Administrative Rule Matters – Discussion and Consideration (36-85)

1) 2023 Wisconsin Act 82: HAS 1, 4, 5, and 9, Relating to Cerumen Management
   a. Preliminary Rule Draft **(37-50)**
   b. Wisconsin Academy of Audiology Letter **(51-59)**
   c. Clinical Practice Guideline **(60-75)**
2) 2023 Wisconsin Act 179: HAS 1 and 4 to 6, Relating to Hearing Aids
   a. Preliminary Rule Draft **(76-79)**
   b. 2023 WI Act 179 **(80-82)**
   c. 21 USC 360j (q) **(83-84)**
3) Pending or Possible Rulemaking Projects **(85)**

I. Late Renewal of License – Board Discussion (86)

J. Legislative and Policy Matters – Discussion and Consideration

K. Discussion and Consideration of Items Added After Preparation of Agenda:

1) Introductions, Announcements and Recognition
2) Nominations, Elections, and Appointments
3) Administrative Matters
4) Election of Officers
5) Appointment of Liaisons and Alternates
6) Delegation of Authorities
7) Education and Examination Matters
8) Credentialing Matters
9) Practice Matters
10) Legislative and Policy Matters
11) Administrative Rule Matters
12) Liaison Reports
13) Board Liaison Training and Appointment of Mentors
14) Public Health Emergencies
15) Informational Items
16) Division of Legal Services and Compliance (DLSC) Matters
17) Presentations of Petitions for Summary Suspension
18) Petitions for Designation of Hearing Examiner
19) Presentation of Stipulations, Final Decisions and Orders
20) Presentation of Proposed Final Decisions and Orders
21) Presentation of Interim Orders
22) Petitions for Re-Hearing
23) Petitions for Assessments
24) Petitions to Vacate Orders
25) Requests for Disciplinary Proceeding Presentations
26) Motions
27) Petitions
28) Appearances from Requests Received or Renewed
29) Speaking Engagements, Travel, or Public Relation Requests, and Reports

L. Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to

consider closing disciplinary investigations with administrative warnings (ss. 19.85 (1)(b), and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.)

M. Credentialing Matters

1) **Application Review**
   a. P.C. – Audiology (IA 383033) **(87-113)**

N. Deliberation of Items Added After Preparation of the Agenda:

1) Education and Examination Matters
2) Credentialing Matters
3) DLSC Matters
4) Monitoring Matters
5) Professional Assistance Procedure (PAP) Matters
6) Petitions for Summary Suspensions
7) Petitions for Designation of Hearing Examiner
8) Proposed Stipulations, Final Decisions and Orders
9) Proposed Interim Orders
10) Administrative Warnings
11) Review of Administrative Warnings
12) Proposed Final Decisions and Orders
13) Matters Relating to Costs/Orders Fixing Costs
14) Case Closings
15) Board Liaison Training
16) Petitions for Assessments and Evaluations
17) Petitions to Vacate Orders
18) Remedial Education Cases
19) Motions
20) Petitions for Re-Hearing
21) Appearances from Requests Received or Renewed

O. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

P. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

Q. Open Session Items Noticed Above Not Completed in the Initial Open Session

R. Examination Ratification – Discussion and Consideration

ADJOURNMENT

NEXT MEETING: JANUARY 22, 2025

Board Member Training: November 15, 2024

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of any agenda item may be changed by the board for the convenience of the parties. The person credentialed by the board has the right to demand that the meeting at which final action may be taken against the credential be held in open session. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer or reach the Meeting Staff by calling 608-267-7213.

VIRTUAL/TELECONFERENCE
HEARING AND SPEECH EXAMINING BOARD
MEETING MINUTES
JUNE 26, 2024

PRESENT: Todd Beyer, Robert Broeckert, Catherine Kanter *(Catherine Kanter excused at 10:30 a.m.)*, Jerry Lapidakis, Jason Meyer, Kathleen Pazak, Samantha Sikorski, Justen Willemon

EXCUSED: Michael Harris, David Seligman

STAFF: Tom Ryan, Executive Director; Jameson Whitney, Legal Counsel; Nilajah Hardin, Administrative Rule Coordinator; Tracy Drinkwater, Board Administration Specialist; and other Department Staff

CALL TO ORDER

Justen Willemon, Chairperson, called the meeting to order at 8:30 a.m. A quorum was confirmed with eight (8) members present.

ADOPTION OF AGENDA

MOTION: Robert Broeckert moved, seconded by Catherine Kanter, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF APRIL 10, 2024

MOTION: Robert Broeckert moved, seconded by Jason Meyer, to approve the Minutes of April 10, 2024, as published. Motion carried unanimously.

INTRODUCTIONS, ANNOUNCEMENTS, AND RECOGNITION

Recognition: Robert Broeckert, Audiologist Member (Resigned: 7/01/2024, Member since 8/ 2016)

MOTION: Jerry Lapidakis moved, seconded by Justen Willemon, to recognize and thank Robert Broeckert for their years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

Recognition: Thomas Krier, Hearing Instrument Specialist Member (Resigned: 6/17/2024, Member since 9/2013)

MOTION: Todd Beyer moved, seconded by Robert Broeckert, to recognize and thank Thomas Krier for their years of dedicated service to the Board and State of Wisconsin. Motion carried unanimously.

ADMINISTRATIVE MATTERS

Appointment of Liaisons and Alternates

LIAISON APPOINTMENTS	
Credentialing Liaison(s)	Jason Meyer (AUD), Justen Willemon (HIS), Kathleen Pazak (SLP) *Alternate:* Todd Beyer (HIS), Catherine Kanter (SLP)
Examination Liaison(s)	Jason Meyer (AUD), Justen Willemon (HIS), Kathleen Pazak (SLP) *Alternate:* Catherine Kanter (SLP)
Continuing Education (CE) Liaison(s)	Jason Meyer (AUD), Kathleen Pazak (SLP) Samantha Sikorski (HIS) *Alternate:* Catherine Kanter (SLP)
Monitoring Liaison(s)	Jason Meyer (AUD), Catherine Kanter (SLP), David Seligman (HAU), Samantha Sikorski (HIS) *Alternate:*
Professional Assistance Procedure (PAP)	Jason Meyer (AUD), David Seligman (HAU) *Alternate:* Justen Willemon (HIS)
Legislative Liaison(s)	Kathleen Pazak (SLP), Michael Harris (OTO) *Alternate:* Justen Willemon (HIS)
Travel Authorization Liaison(s)	Jason Meyer (AUD), Kathleen Pazak (SLP) *Alternate:* David Seligman (HAU)
Website Liaison(s)	Todd Beyer (HIS), Jason Meyer (AUD), Kathleen Pazak (SLP) *Alternate:*
Practice Questions Liaison(s)	Catherine Kanter (SLP), Jason Meyer (AUD)

DRAFT

	Alternate: Kathleen Pazak (SLP)
Screening Panel	**Team A:** Michael Harris (OTO), Catherine Kanter (SLP), Jason Meyer (AUD), David Seligman (HAU), Justen Willemon (HIS) **Team B:** Jason Meyer (AUD) Kathleen Pazak (SLP), ***Alternates:*** Todd Beyer (HIS), Justen Willemon (HIS)
Audiology and Speech-Language Pathology Licensure Compact Commission	Jason Meyer (AUD) Catherine Kanter (SLP) *Alternate:* Kathleen Pazak (SLP)

ADMINISTRATIVE RULE MATTERS

2023 Wisconsin Act 56: HAS 6 to 8, Relating to Implementation of the Audiology and Speech-Language Pathology Interstate Compact – Permanent Rule Draft

MOTION: Catherine Kanter moved, seconded by Robert Broeckert, to approve the preliminary rule draft of HAS 6 to 8, Relating to Implementation of the Audiology and Speech-language Pathology Interstate Compact, for posting for economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

CLOSED SESSION

MOTION: Kathleen Pazak moved, seconded by Catherine Kanter, to convene to closed session to deliberate on cases following hearing (s. 19.85(1)(a), Stats.; consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider closing disciplinary investigation with administrative warning (s. 19.85(1)(b), Stats. and 440.205, Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and, to confer with legal counsel (s. 19.85(1)(g), Stats.). Justen Willemon, Chairperson, read the motion. The vote of each member was ascertained by voice vote. Roll Call Vote: Todd Beyer-yes; Robert Broeckert-yes; Catherine Kanter-yes; Jerry Lapidakis -yes; Jason Meyer-yes; Kathleen Pazak-yes; Samantha Sikorski-yes; and Justen Willemon-yes. Motion carried unanimously.

The Board convened to Closed Session at 10:11 a.m.

(Catherine Kanter excused at 10:30 a.m.)

CREDENTIALING MATTERS

Danalee Gray – Hearing Instrument Specialist

REVIEW OF APPLICATION

MOTION: Robert Broeckert moved, seconded by Samantha Sikorski, to issue an intent to deny the Hearing Instrument Specialist application of Danalee Gray, and offer a limited license with the following conditions: applicant shall follow the recommendations made in the April 6, 2024 Fitness For Duty evaluation, specifically participation in psychiatric consultation within 30 days of the date of the order and treatment (including appropriate medication) to manage trauma-related and mood symptoms; participation in therapy with a licensed treatment provider at a frequency to be determined by the treater to resolve trauma symptoms stemming from her burglary and assault with quarterly reports to the Department from the treater; applicant shall also present her order to her employer within 14 days of the date of this order and prior to starting any new employment and arrange for the submission of quarterly work reports to the Department; shall not work in a self-employed situation without prior approval from the Board or Board designee; comply with the terms of probation and have no new convictions or disciplinary orders; applicant may petition for modification of this order after one year and restoration of full and unencumbered licensure after two consecutive years of successful compliance. **Reasons for denial**: Wis. Stats. §§ 459.10(1)(f), practice while ability to practice was impaired by alcohol, drugs, or physical or mental disability or disease; & 440.08(4), denial of renewal necessary to protect public health, safety, and welfare. Motion carried unanimously.

(Justen Willemon recused himself and left the room for deliberation and voting in the matter concerning Danalee Gray, Hearing Instrument Specialist Application Review.)

RECONVENE TO OPEN SESSION

MOTION: Robert Broeckert moved, seconded by Todd Beyer, to reconvene to open session. Motion carried unanimously.

The Board reconvened into Open Session at 10:48 p.m.

VOTING ON ITEMS CONSIDERED OR DELIBERATED ON IN CLOSED SESSION

MOTION: Samantha Sikorski moved, seconded by Robert Broeckert, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

(Be advised that any recusals or abstentions reflected in the Closed Session motions stand for the purposes of the affirmation vote.)

DELEGATION AND RATIFICATION OF EXAMINATIONS, LICENSES AND CERTIFICATES

MOTION: Kathleen Pazak moved, seconded by Robert Broeckert, to delegate ratification of examination results to DSPS staff and to delegate and ratify all licenses and certificates as issued. Motion carried unanimously.

ADJOURNMENT

MOTION: Jerry Lapidakis moved, seconded by Robert Broeckert, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:50 a.m.

DRAFT

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**10/17/24** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Hearing and Speech Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/30/24	☒ Yes ☐ No	**8:30 A.M. Public Hearing for Clearinghouse Rule 24-062 on HAS 6 to 8, Relating to Implementation of the Audiology and Speech-Language Pathology Licensure Compact** **1. Review Public Hearing Comments and Respond to Clearinghouse Report**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

The Board will hold a public hearing on this rule as required by the rulemaking process.

11) Authorization

Nilajah D. Hardin — 10/17/24

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

STATE OF WISCONSIN
HEARING AND SPEECH EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE HEARING AND SPEECH EXAMINING BOARD	:	PROPOSED ORDER OF THE HEARING AND SPEECH EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Hearing and Speech Examining Board to amend HAS 6.01, 6.10 (1) (a) (intro.), 6.16, 6.18 (1) (intro.) and (a), (2) (b), (c), (e), (f), (o), (p)1., (s), (t) and (u), and (3) (intro), and create HAS 6.02 (4m), (4v), and 6.05, relating to implementation of the audiology and speech-language pathology interstate compact.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: subch. III ch. 459, Stats.

Statutory authority: ss. 15.08 (5) (b), 459.12 (1), 459.26 (2) (am) , and 459.28 (2), Stats.

Explanation of agency authority:
Section 15.08 (5) (b), Stats. states that "[t]he 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 459.26 (2) (am), Stats.: "The examining board shall by rule select and approve examinations for audiology."

Section 459.28 (2), Stats.: "The examining board may enter into reciprocal agreements with officials of other states or territories of the United States for licensing speech-language pathologists and audiologists and grant licenses to applicants who are licensed in those states or territories according to the terms of the reciprocal agreements."

Related statute or rule: 2023 Wisconsin Act 56

Plain language analysis: The Hearing and Speech Examining Board conducted a review of HAS 6 to 8 to implement the audiology and speech-language pathology interstate compact to ensure clarity and consistency with Wisconsin Statutes. The following updates were made as a result of this review:

- Section HAS 6.01 was updated to include compact privilege holders
- A definition for "compact privilege" was added to HAS 6.02
- A definition for "home state" was added to HAS 6.02
- Section HAS 6.05 was created to address the requirements for applying for compact privileges
- Section HAS 6.10 (1) (a) was revised to include a supervisor with compact privileges
- Section HAS 6.16 was updated to include compact privilege holders
- Various subsections of HAS 6.18 were updated to include compact privilege holders

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

Comparison with rules in adjacent states:

Illinois: Illinois has pending legislation regarding the Audiology and Speech-language Pathology Interstate Compact [2023 Illinois House Bill 3264].

Iowa: Iowa is a member state of the Audiology and Speech-language Pathology interstate compact [Iowa Code Title IV Chapter 147F].

Michigan: Michigan has not enacted the Audiology and Speech-language Pathology Interstate Compact [Michigan Compiled Laws Act 368 Part 176 Section 333.17601-333.17613].

Minnesota: Minnesota has pending legislation regarding the Audiology and Speech-language Pathology Interstate Compact [2023 House Bill HF2378 and Senate Bill SF2656].

Summary of factual data and analytical methodologies:
The proposed rules were developed by reviewing 2023 Wisconsin Act 56, which ratifies the Audiology and Speech-language Pathology Interstate Compact, and conducting a comprehensive evaluation and update of the Hearing and Speech Examining Board's rules to implement the Compact.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The proposed rules were 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. No comments were received.

Fiscal Estimate and Economic Impact Analysis:
The Fiscal Estimate and Economic Impact Analysis is attached.

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 October 30, 2024, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. HAS 6.01 is amended to read:

HAS 6.01 Authority and purpose. The rules in this chapter are adopted by the hearing and speech examining board under the authority of ss. 227.11 (2) and 459.24 to 459.34, Stats., to govern the licensure of speech-language pathologists, audiologists and temporary licensees, and the granting of compact privileges for speech-language pathologists and audiologists.

SECTION 2. HAS 6.02 (4m) and (4v) are created to read:

(4m) "Compact privilege" has the meaning given in s. 459.70 (2) (h), Stats.

(4v) "Home state" has the meaning given in s. 459.70 (2) (m), Stats.

SECTION 3. HAS 6.05 is created to read:

HAS 6.05 Applications for compact privilege. Every applicant for compact privilege as a speech-language pathologist or audiologist shall submit to the board all of the following:

(1) Evidence of an unencumbered home state license in another state that is party to the compact and satisfies the requirements under s. 459.70 (4), Stats.

(2) A completed application form provided by the board.

(3) The fee specified in s. 459.71 (2), Stats.

Note: Application instructions for compact privilege may be obtained from the Department of Safety and Professional Services' website at http://dsps.wi.gov.

SECTION 4. HAS 6.10 (1) (a) (intro.) is amended to read:

HAS 6.10 (1) (a) (intro.) Before commencing a postgraduate clinical fellowship in speech-language pathology an applicant shall obtain a temporary license to practice under the supervision of a licensed or compact privilege holding speech-language pathologist by submitting all the following:

SECTION 5. HAS 6.16 is amended to read:

HAS 6.16 Prohibited practice and use of titles. No person may engage in the practice of speech-language pathology or use the title "speech-language pathologist" or any similar title or engage in the practice of audiology or use the title "audiologist", "clinical audiologist" or any similar title, unless the person holds a current speech-language pathologist or audiologist license or compact privilege, as appropriate, granted by the board.

SECTION 6. HAS 6.18 (1) (intro.) and (a) are amended to read:

HAS 6.18 (1) (intro.) The board may reprimand a speech-language pathologist, audiologist, temporary licensee or a permittee, or deny, limit, suspend or revoke a license, compact privilege, or permit, if it finds that the applicant, licensee, compact privilege holder, or permittee has done any of the following:

(a) Made a material misstatement in an application for a license, compact privilege, or permit or for renewal of a license.

SECTION 7. HAS 6.18 (2) (b), (c), (e), (f), (o), (p)1., (s), (t) and (u) are amended to read:

HAS 6.18 (2) (b) Using the title "speech-language pathologist," "audiologist" or any similar title unless the individual holds a current speech-language pathologist or audiologist license or compact privilege granted under s. 459.24 (2), ~~or~~ (3), or (3e), Stats.

(c) Violating the conditions or limitations placed upon a license, compact privilege, or permit by the board.

(e) Having a license, compact privilege, certificate, permit or registration issued by another jurisdiction to practice as a speech-language pathologist or audiologist limited, suspended or revoked.

(f) Aiding or abetting an unlicensed person, knowingly conspiring with an unlicensed person, or allowing one's license or compact privilege to be used by an unlicensed person to evade the use of a title prohibited under s. 459.24 (1) or (1m), Stats.

(o) Failing to provide access to records of professional services rendered and products dispensed when requested by the board or its representative in connection with an investigation of a complaint filed against the applicant, licensee, compact privilege holder, or permittee.

(p) 1. The name of the licensee or compact privilege holder.

(s) Failing to practice speech-language pathology or audiology within the scope of the licensee's or compact privilege holder's competence, education, training and experience.

(t) Delegating the provision of clinical services to an unlicensed individual for whom the licensee or compact privilege holder does not provide direct supervision.

(u) Delegating the provision of clinical services to a temporary licensee for whom the licensee or compact privilege holder does not provide supervision.

SECTION 8. HAS 6.18 (3) (intro.) is amended to read:

HAS 6.18 (3) (intro.) In addition to the bases for unprofessional conduct set forth under sub. (2), the board may reprimand an audiologist, or deny, limit, suspend or revoke a license, compact privilege, or permit, if it finds that the applicant, licensee, compact privilege holder, or permittee has engaged in the following unprofessional conduct:

SECTION 9. 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)

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
07/26/24

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
HAS 6 to 8 (Permanent Rule)

4. Subject
Implementation of the Audiology and Speech-Language Pathology Licensure Compact

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
20.165 (1) (g)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☐ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy ☐ Specific Businesses/Sectors
☐ Local Government Units ☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
The Hearing and Speech Examining Board conducted a review of HAS 6 to 8 to implement the audiology and speech-language pathology interstate compact to ensure clarity and consistency with Wisconsin Statutes. The following updates were made as a result of this review:

- Section HAS 6.01 was updated to include compact privilege holders
- A definition for "compact privilege" was added to HAS 6.02
- A definition for "home state" was added to HAS 6.02
- Section HAS 6.05 was created to address the requirements for applying for compact privileges
- Section HAS 6.10 (1) (a) was revised to include a supervisor with compact privileges
- Section HAS 6.16 was updated to include compact privilege holders
- Various subsections of HAS 6.18 were updated to include compact privilege holders

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
DSPS estimates a total of $35,800 in one-time and $28,900 in annual ongoing costs for staffing and an indeterminate one-time IT impact to implement the bill. The one-time staff cost supports 0.9 limited term employee to undertake such tasks as amending and/or creating new application forms, working with Division of Enterprise Technology (DET) to create new methods and requirements in LicensE and the compact databases, updating information on website, facilitating staff training, creating checklists, and participating in systems testing. The estimated annual cost supports 0.5

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

full-time equivalent position for reviewing renewal applications, completing background checks, updating compact database with applicant and license holder information, updating privilege statuses, and responding to inquiries. An indeterminate amount of Division of Enterprise Technology (DET) hours at $85 per hour and/ or contractor hours will be required to provide LicensE integration and to align with software and payment systems of other states included in compact. The one-time and ongoing estimated costs cannot be absorbed in the currently appropriated agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The benefits of implementing this rule are that the Hearing and Speech Examining Board's section of the Administrative Code will be aligned with Wisconsin State Statutes.

16. Long Range Implications of Implementing the Rule

The long range implications of implementing this rule is clear requirements for practcing Audiology and Speech-Language Pathology in Wisconsin under compact privileges.

17. Compare With Approaches Being Used by Federal Government

None.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: Illinois has pending legislation regarding the Audiology and Speech-language Pathology Interstate Compact [2023 Illinois House Bill 3264].

Iowa: Iowa is a member state of the Audiology and Speech-language Pathology interstate compact [Iowa Code Title IV Chapter 147F].

Michigan: Michigan has not enacted the Audiology and Speech-language Pathology Interstate Compact [Michigan Compiled Laws Act 368 Part 176 Section 333.17601-333.17613].

Minnesota: Minnesota has pending legislation regarding the Audiology and Speech-language Pathology Interstate Compact [2023 House Bill HF2378 and Senate Bill SF2656].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	(608) 267-7139

This document can be made available in alternate formats to individuals with disabilities upon request.

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

LCRC
FORM 2

Wisconsin Legislative Council

RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Anne Sappenfield
Legislative Council Director

Margit Kelley
Clearinghouse Assistant Director

CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

CLEARINGHOUSE RULE **24-062**

AN ORDER to amend HAS 6.01, 6.10 (1) (a) (intro.), 6.16, and 6.18 (1) (intro.) and (a), (2) (b), (c), (e), (f), (o), (p) 1., (s), (t), and (u), and (3) (intro); and to create HAS 6.02 (4m) and (4v) and 6.05, relating to implementation of the audiology and speech-language pathology interstate compact.

Submitted by **HEARING AND SPEECH EXAMINING BOARD**

08-15-2024 RECEIVED BY LEGISLATIVE COUNCIL.
08-27-2024 REPORT SENT TO AGENCY.

MSK:AG

LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

   Comment Attached YES ☐ NO ☑

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

   Comment Attached YES ☑ NO ☐

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

   Comment Attached YES ☑ NO ☐

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS [s. 227.15 (2) (e)]

   Comment Attached YES ☐ NO ☑

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

   Comment Attached YES ☑ NO ☐

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL REGULATIONS [s. 227.15 (2) (g)]

   Comment Attached YES ☐ NO ☑

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

   Comment Attached YES ☐ NO ☑

Wisconsin Legislative Council
RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

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Clearinghouse Assistant Director

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Legislative Council Director

CLEARINGHOUSE RULE 24-062

Comments

[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Council Staff and the Legislative Reference Bureau, dated November 2020.]

2. Form, Style and Placement in Administrative Code

a. In SECTION 3 of the proposed rule, creating s. HAS 6.05, the second sentence after the section number appears to be an introductory clause, not a continuation of the section title. Only the title should be shown in bold typeface, and the second sentence should be shown in normal typeface if it is not part of the title. Titles are not considered part of the substance of the rule itself, and the second sentence does appear to be substantive. [See s. 1.10 (2), Manual.]

b. In SECTIONS 4 and 6, the subunit designation "(intro.)" could be removed from the text of the rule. Though it is proper to include the subunit designation "(intro.)" in the treatment clause, it is not necessary to be included in the text of the rule. [See s. 1.11 (1) and (3) (Example), Manual.]

c. SECTIONS 6, 7, and 8 could be combined into one rulemaking SECTION. When two or more subunits of the same rule section are affected by the same treatment, they may be included in the same SECTION of the rulemaking, as long as the intervening subunits are unaffected by other treatment. [See s. 1.03 (2) (c) 2., Manual.] Therefore, these three SECTIONS, which all amend various subunits of s. HAS 6.18, could be in the same SECTION of the rulemaking order.

3. Conflict With or Duplication of Existing Rules

In the current text of s. HAS 6.10 (a) (d), the Board should consider adding a reference to the compact privilege so that every reference to a licensed speech-language pathologist in ch. HAS 6 also includes reference to a compact privileged speech-language pathologist.

5. Clarity, Grammar, Punctuation and Use of Plain Language

In the agency's plain language analysis for the proposed rule, readability would be improved if the description included a period at the end of every listed item. [s. 1.01 (2) (b), Manual.]

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Paralegal Richanda Turner, on behalf of Attorney Jameson Whitney		2) Date when request submitted: 09/25/2024 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Hearing and Speech Examining Board			
4) Meeting Date: 10/30/2024	5) Attachments: ☒ Yes ☐ No	6) How should the item be titled on the agenda page? Delegation of Authorities	
7) Place Item in: ☒ Open Session ☐ Closed Session	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes <Appearance Name(s)> ☒ No	9) Name of Case Advisor(s), if applicable: N/A	
10) Describe the issue and action that should be addressed: The Board members need to review and consider the delegation of authorities as it relates to the Board Monitoring Liaison.			
11) Authorization *Richanda Turner* — Signature of person making this request		*09.25.24* — Date	
Supervisor (Only required for post agenda deadline items)		Date	
Executive Director signature (Indicates approval for post agenda deadline items)		Date	

Directions for including supporting documents:
1. This form should be saved with any other documents submitted to the Agenda Items folders.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

State of Wisconsin

DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

CORRESPONDENCE / MEMORANDUM

DATE: January 9, 2024

TO: Board, Council, and Committee Members

FROM: Legal Counsel

SUBJECT: Liaison Definitions and Delegations Explanations

Overall Purpose of Liaison Appointments

Each Board/Section (Board) has inherent authority that is established in our Wisconsin Statutes. This authority may change from Board to Board. For further information on your Board's authority review Wis. Stat. ch. 15. Generally, each Board has authority to grant credentials, discipline credential holders, and set standards for education and examinations. Additionally, Liaisons assist with the operations of the Boards purpose by weighing in on legislative matters, traveling to national conferences, or communicating with stakeholders.

The Department asks that each year the Boards make liaison appointments to assist the Board and Department to accomplish these tasks in an efficient manner. Your practical knowledge and experience, as an appointed member of a professional board, are essential in making determinations regularly. The Liaison positions below assist the Department to complete operations between Board meetings. In most cases, Liaisons can make decisions for the full Board in their designated area. These are determined through the delegation process. However, a Liaison may also decide to send the delegated issue to the full Board for consideration as appropriate. Delegations assist the Board in defining the roles and authorities of each Liaison.

Liaison Definitions

Credentialing Liaison: The Credentialing Liaison is empowered by the Board to review and make determinations regarding certain applications for credentials. The Credentialing Liaison may be called on by Department staff to answer questions that pertain to qualifications for licensure, which may include whether a particular degree is suitable for the application requirements, whether an applicant's specific work experience satisfies the requirements in statute or rule for licensure, or whether an applicant's criminal or disciplinary history is substantially related to the practice of the profession in such a way that granting the applicant a credential would create a risk of harm to the public. Questions will likely be sent by Department

staff to the Credentialing Liaison via email and may include application materials. The Credentialing Liaison serves a very important role in the credentialing process.

Monitoring Liaison: The Monitoring Liaison is empowered by the Board to make decisions on any credential that is limited either through a disciplinary order or initial licensure. The Department Monitors will send requests from credential holders to the Monitoring Liaison. These requests vary wildly. A common request could be to remove a limitation that has been placed on a credential or to petition for full licensure. The Monitoring Liaison can review these requests and make decisions on behalf of the Board. The Board has the authority to grant decision making latitude to their liaison to any degree. The specific monitoring delegations are found in the Monitoring Document attached to the agenda. If the Monitoring Liaison has a question on a request, it is advisable for the Liaison to consult further with Department staff or bring the matter to the full Board for consideration.

Professional Assistance Procedure (PAP) Liaison: PAP is a voluntary program open to credential holders with substance abuse issues who wish to seek help by being held accountable through treatment and monitoring by the Department and Board. As part of PAP, the credential holder enters into an agreement with the Department to undergo testing, counseling, or other rehabilitation. The PAP Liaison's role includes responding to credential holders' requests for modifications and terminations of provisions of the agreement. Similar to the Monitoring Liaison, the Department Monitors will send requests from credential holders to the PAP Liaison for further review.

Education and Examination Liaison: Some Boards are required by statute or rule to approve qualifying education and examinations. The Education and Examination Liaison provides guidance to Department staff to exercise authority of the Board to approve or decline examinations and educational programs. This determination requires a level of professional expertise and should be performed by a professional member of the Board. For some Boards, the Education and Examination Liaison will also be tasked with approving continuing education programs and courses.

Legislative Liaison: The Legislative Liaison is permitted to act and speak on the Board's behalf regarding pending and enacted legislation or actions being considered by the legislature outside of Board meetings. The Legislative Liaison is not the Board's designated lobbyist and should exercise their delegated authority carefully.

Travel Authorization Liaison: The Travel Authorization Liaison is authorized to approve a Board member to travel to events and speak or act on the Board's behalf between Board meetings. The Travel Authorization Liaison is called upon to make decisions when sufficient notice was not received, and the full Board could not determine a representative to travel. The Travel Authorization Liaison is tasked with making determinations if the Board appointed representative is not able to attend or if the Board becomes authorized to send additional members. As scholarship and funding streams can be unpredictable.

Communication Liaison: The Communication Liaison responds on behalf of the Board when questions arise that require a response from the Board. The Communication Liaison works with

the Department to cultivate an appropriate response. The Communication Liaison can be responsible for all types of communication on behalf of the Board. However, the Board can appoint a separate **Website Liaison** to work with DSPS staff to make changes and ensure the Board webpage contains updated and accurate information. Additionally, for the Boards that are required by statute to produce a newsletter or digest. The Board can appoint a separate **Newsletter/Digest Liaison** to assemble and approve content for those communications.

Screening Panel Members: The duties of the Screening panel are to review incoming complaints against credential holders and determine which complaints should be opened for investigation and which complaints should be closed without further action. The complexity and amount of work in this role depends substantially on your particular Board. As a member of the Screening panel you are asked to apply your professional expertise to determine if a complaint alleges unprofessional conduct.

Delegations Explanations

Credentialing Delegations

The overall purpose of credentialing delegations is to allow the credentialing process to proceed as efficiently and effectively as possible.

Delegation of Authority to Credentialing Liaison (Generic)

MOTION EXAMPLE: to delegate authority to the Credentialing Liaison(s) to serve as a liaison between the Department and the Board and to act on behalf of the Board in regard to credentialing applications or questions presented to them, including the signing of documents related to applications.

PURPOSE: To permit one representative of the Board to assist Department staff with credentialing applications and eliminate the need for the entire Board to convene to consider credential application content or questions. Additionally, it is most efficient to have the designated liaison who has assisted with the credentialing process to be able to effectuate decisions which require a signature.

Delegation of Authority to DSPS When Credentialing Criteria is Met

MOTION EXAMPLE: to delegate credentialing authority to the Department to act upon applications that meet all credentialing statutory and regulatory requirements without Board or Board liaison review.

PURPOSE: To permit Department staff to efficiently issue credentials and eliminate the need for Board/Section/Liaison review when all credentialing legal requirements are met in an application.

Delegation of Authority for Predetermination Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to make decisions regarding predetermination applications pursuant to Wis. Stat. § 111.335(4)(f).

PURPOSE: In general, the Wisconsin Fair Employment Act (codified in Wis. Stat. Ch. 111) prohibits licensing agencies from discriminating against applicants because of their arrest and/or conviction record. However, there are exceptions which permit denial of a license in certain circumstances. Individuals who do not possess a license have a legal right to apply for a determination of whether they are disqualified from obtaining a license due to their conviction record. This process is called "Predetermination". Predeterminations must be completed within 30 days. This delegation allows Department Attorneys to conduct predetermination reviews and efficiently make these legal determinations without need for Board/Section/Liaison review.

Delegation of Authority for Conviction Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve applications with convictions which are not substantially related to the practice.

PURPOSE: As used here, "substantially related" is a legal standard that is used in the Wisconsin Fair Employment Act. The concept of what is "substantially related" is informed by case law. This delegation permits Department Attorneys to independently conduct conviction reviews and efficiently approve applications if convictions are not substantially related to the practice of the profession. Applications that contain conviction records that may be substantially related to the practice of a profession will still be submitted to the Credentialing Liaison for input.

Delegation to DSPS When Applicant's History Has Been Previously Reviewed

MOTION EXAMPLE: to delegate authority to Department staff to approve applications where Applicant's prior discipline has been approved for a previous credential and there is no new discipline.

PURPOSE: Some Boards offer progressive levels of credentials. This delegation eliminates the need for a re-review of discipline that has already been considered and approved by the Board/Section/Liaison for a lower-level credential.

Delegation to DSPS When Applicant's Conviction History Has Been Previously Reviewed

MOTION EXAMPLE: to delegate authority to Department staff to approve applications where criminal background checks have been approved for a previous credential and there is no new conviction record.

PURPOSE: Some Boards offer progressive levels of credentials. This delegation eliminates the need for a re-review of conviction history that has already been reviewed and approved for a lower-level credential.

Delegation of Authority for Reciprocity Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve reciprocity applications in which the out of state license requirements meet Wisconsin license requirements. (specific legal standards are referenced in the motion depending on credential/profession type).

PURPOSE: Applications via reciprocity or endorsement require comparison of Wisconsin licensing requirements to the licensing requirements of another jurisdiction. These reviews consider the legal standard for reciprocity, which varies by profession, as well as the specified legal requirements to obtain licensure in the profession. This delegation permits Department Attorneys to independently conduct reciprocity reviews and efficiently approve applications if legal standards and requirements are met for licensure. Applications for which reciprocity may not be available will still be submitted to the Credentialing Liaison for input.

Delegation of Authority for Military Reciprocity Reviews

MOTION EXAMPLE: to delegate authority to the Department Attorneys to review and approve military reciprocity applications in which the individual meets the requirements of Wis. Stat. § 440.09.

PURPOSE: The law permits service members, former service members, and their spouses to be licensed if they hold licensure in other jurisdictions that qualify them to perform acts authorized by the credential they are seeking in Wisconsin. This is a shortened path to licensure that does not require meeting the specific requirements/standards for licensure/reciprocity in a profession. By law, the Department/Board must expedite the issuance of a reciprocal license via military reciprocity. This delegation permits Department Attorneys to independently conduct military reciprocity reviews and efficiently approve applications if legal standards and requirements are met for licensure. Applications for which reciprocity may not be available will still be submitted to the Credentialing Liaison for input.

Delegation of Authority for Application Denial Reviews

MOTION EXAMPLE: to delegate authority to the Department's Attorney Supervisors to serve as the Board designee for purposes of reviewing and acting on requests for hearing as a result of a denial of a credential.

PURPOSE: When an application is denied, the applicant has a legal right to appeal the denial determination. Applicants must meet a specified legal standard in order to have an appeal granted. Additionally, Wisconsin law sets specific time frames for appeal decisions. This delegation permits Department Attorney Supervisors to independently review and efficiently act on requests for hearing as a result of a denial of a credential.

Delegation to Department Attorneys to Approve Duplicate Legal Issue

MOTION EXAMPLE: to delegate authority to Department Attorneys to approve a legal matter in connection with a renewal application when that same/similar matter was already addressed by the Board and there are no new legal issues for that credential holder. Motion carried unanimously.

PURPOSE: The intent of this delegation is to be able to approve prior discipline by the Board for the renewal applicant. This delegation eliminates the need for a re-review of discipline that has already been considered and approved by the Board/Section/Liaison.

Monitoring Delegations

The overall purpose of monitoring delegations is to be able to enforce the Boards orders and limited licenses as efficiently and effectively as possible. Monitoring delegations have two categories: delegations to the monitoring liaison and delegations to the Department Monitor.

Delegation of Authority to Department Monitor

MOTION EXAMPLE: to delegate authority to the Department Monitor

a. to grant full reinstatement of licensure if education is the only limitation and credential holder has submitted the required proof of course completion.
b. to suspend the credential if the credential holder has not completed Board ordered education, paid costs, paid forfeitures, within the time specified by the Board Order.
c. to lift a suspension when compliance with education and costs provisions have been met.

PURPOSE: These delegations allow for the Department Monitor to automatically act on requests when certain criteria are met or not met without needing to burden the Board Monitoring Liaison. The Board can set their own criteria for what actions they would like to be handled by the Department, the Monitoring Liaison and the full Board.

Delegation of Authority to Monitoring Liaison

MOTION EXAMPLE: to delegate authority to the Monitoring Liaison to approve or deny all requests received by the credential holder.

PURPOSE: These delegations allow the Board to set criteria for what decisions can be made by the Board member(s) serving as the Monitoring Liaison and what matters should be decided by the full Board. The Board has the authority to set specific criteria or to permit the liaison to make all determinations at their discretion.

Education and Exam Delegations

MOTION EXAMPLE: to delegate authority to the Education and Examination Liaison(s) to address all issues related to continuing education and examinations. Motion carried unanimously. (Differs by Board)

PURPOSE: Some Boards are responsible for approving qualifying educational programs or continuing education courses. A delegation is executed in order for a Board member to make these determinations on behalf of the Boards and with assistance of the Department. Additionally, some Boards review examinations and individual scores to qualify for a credential.

Miscellaneous Delegations

Document Signature

MOTION EXAMPLE: to delegate authority to the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) to sign documents on behalf of the Board in order to carry out its duties. Motion carried unanimously.

MOTION EXAMPLE: in order to carry out duties of the Board, the Chairperson (or in absence of the Chairperson, the highest-ranking officer or longest serving board member in that succession) has the ability to delegate signature authority for purposes of facilitating the completion of assignments during or between meetings. The members of the Board hereby delegate to the Executive Director, Board Counsel or DPD Division Administrator, the authority to sign on behalf of a Board member as necessary. Motion carried unanimously.

PURPOSE: In order to take the action approved at Board meetings, the Department may need to draft correspondence and/or Orders after the meetings have adjourned. These actions then need to be signed by a Board Member. This interaction usually takes place over email and a Board member can authorize the use of his/her signature that is kept on file.

Urgent Matters

MOTION EXAMPLE: in order to facilitate the completion of urgent matters between meetings, the Board delegates its authority to the Chairperson (or, in the absence of the Chairperson, the highest-ranking officer or longest serving Board member in that succession), to appoint liaisons to the Department to act in urgent matters. Motion carried unanimously.

PURPOSE: Allows for quick responses to urgent matters that may need Board approval or for which the Department requires guidance from the Board.

Delegation to Chief Legal Counsel

Due to Loss of Quorum

MOTION EXAMPLE**:** to delegate the review and authority to act on disciplinary cases to the Department's Chief Legal Counsel due to lack of/loss of quorum after two consecutive meetings. Motion carried unanimously.

PURPOSE: Sometimes Boards can struggle to meet quorum necessary to conduct business. This happens for a multitude of reasons but this delegation allows for the Boards to have disciplinary cases decided by Chief Legal Counsel if the Board fails to meet quorum for two consecutive meetings.

Stipulated Resolutions

MOTION EXAMPLE: to delegate to the Department's Chief Legal Counsel (CLC) the authority to act on behalf of the Board concerning stipulated resolutions providing for a surrender, suspension, or revocation of a credential, where the underlying merits involve serious and dangerous behavior, and where the signed stipulation is received between Board meetings. The Board further requests that CLC only act on such matters when the best interests of the Board, Department and the Public are best served by acting upon the stipulated resolution at the time the signed stipulation is received versus waiting for the next Board meeting. Motion carried unanimously.

PURPOSE: For matters of public safety, it may be necessary to take immediate action on a stipulated agreement rather than allowing a credential holder to continue practicing unencumbered until the next scheduled meeting. This delegation allows CLC to act on behalf of the Board when there is a stipulated agreement. A stipulated agreement is an agreement to which all relevant parties have consented to the terms.

Voluntary Surrenders

MOTION: to delegate authority to the assigned case advisor to accept or refuse a request for voluntary surrender pursuant to Wis. Stat. § 440.19 for a credential holder who has a pending complaint or disciplinary matter.

MOTION: to delegate authority to the Department to accept the voluntary surrender of a credential when there is no pending complaint or disciplinary matter with the Department pursuant to Wis. Stat. § 440.19.

PURPOSE: Credential holders can ask the Boards to surrender their credentials at any time. These delegations are in place for the different situations that arise from those requests. If a credential holder is seeking to surrender their credential because they wish to leave the profession that can be processed with this delegation by the Department if they have no pending disciplinary complaints. If the credential holder wishes to surrender while they have a pending disciplinary complaint that request is reviewed by the individual Board member assigned to the case.

DLSC Pre-screening

MOTION EXAMPLE: to delegate pre-screening decision making authority to the DSPS screening attorney for opening cases where the credential holder has failed to respond to allegations contained in the complaint when requested by intake (Case will be opened on failure to respond and the merits of the complaint).

PURPOSE: Pre-Screening delegations exist so the Board can define specific parameters where the Department can review disciplinary complaints and open those cases if they meet certain criteria. Boards also have the authority to set certain criteria that would allow the Department to review and close a case if the criteria is met.

Roles and Authorities Delegated for Monitoring

The Monitoring Liaison ("Liaison") is a Board/Section designee who works with department monitors ("Monitor") to enforce Board/Section orders as explained below.

Authorities Delegated to the Monitoring Liaison

The Liaison may take the following actions on behalf of the Board/Section:

1. Grant a temporary reduction in random drug screen frequency upon Respondent's request if he/she is unemployed and is otherwise compliant with Board/Section order. The temporary reduction will be in effect until Respondent secures employment in the profession. The Department Monitor ("Monitor") will draft an order and sign on behalf of the Liaison.

2. Grant a stay of suspension if Respondent is eligible per the Board/Section order. The Monitor will draft an order and sign on behalf of the Liaison.

3. Remove the stay of suspension if there are repeated violations or a substantial violation of the Board/Section order. In conjunction with removal of any stay of suspension, the Liaison may prohibit Respondent from seeking reinstatement of the stay for a specified period of time. The Monitor will draft an order and sign on behalf of the Liaison.

4. Grant or deny approval when Respondent proposes continuing/disciplinary/remedial education courses, treatment providers, mentors, supervisors, change of employment, etc. unless the order specifically requires full-Board/Section approval.

5. Grant full reinstatement of licensure if Respondent has fully complied with all terms of the order without deviation. The Monitor will draft an order and obtain written authorization from the Liaison to sign on their behalf.

6. Grant or deny a request to appear before the Board/Section in closed session.

7. The Liaison may determine whether Respondent's petition is eligible for consideration by the full Board/Section.

8. Accept Respondent's written request to surrender credential. If accepted by the Liaison, Monitor will consult with Board Counsel to determine if a stipulation is necessary. If a stipulation is not necessary, Monitor will draft an order and sign on behalf of the Liaison. If denied by the Liaison, the request to surrender credential will go to the full Board for review. (Except PHM, MED)

9. Grant Respondent's petition for a reduction in drug screens per the standard schedule, below. If approved, Monitor will draft an order and sign on behalf of the Liaison. Orders that do not start at 49 screens will still follow the same standard schedule.

a. Initial:	49 screens (including 1 hair test, if required by original order)
b. 1st Reduction:	36 screens (plus 1 hair test, if required by original order)
c. 2nd Reduction:	28 screens plus 1 hair test
d. 3rd Reduction:	14 screens plus 1 hair test

10. (*Dentistry only*) Ability to approve or deny all requests from a respondent.

11. The Liaison may approve or deny Respondent's request to be excused from drug and alcohol testing for work, travel, etc. (Applies only to these Boards: Dietitians, Massage/Bodywork Therapy Board, DEN, PAB, CHI, MED, RAD)

12. The Liaison may have full authority to approve or deny a request from a Respondent that otherwise would require the approval of the full Board if the request cannot be heard and voted on due to lack of/loss of quorum.

13. The Liaison may have full authority to terminate any treatment ONLY upon written request from Respondent and written recommendation from Respondents treater.

Authorities Delegated to the Department Monitor

The Monitor may take the following actions on behalf of the Board/Section, draft an order and sign:

1. Grant full reinstatement of licensure if education is the sole condition of the limitation and Respondent has submitted the required proof of completion for approved courses.

2. Suspend the license if Respondent has not completed Board/Section-ordered education and/or paid costs and forfeitures within the time specified by the Board/Section order. The Monitor may remove the suspension and issue an order when proof of completion and/or payment have been received.

3. Suspend the license (or remove stay of suspension) if Respondent fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if Respondent ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.

4. Grant or deny approval when Respondent proposes treatment providers [mentors, supervisors, etc.] unless the Order specifically requires full-Board/Section or Board designee approval. (Except for MED)

5. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete Board/Section-ordered continuing/disciplinary/remedial education.

6. Grant a maximum of one 90-day extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by Respondent.

7. Grant a maximum of one 90-day extension, if warranted and requested in writing by Respondent, to complete a Board/Section-ordered evaluation or exam.

Authorities Delegated to Board Legal Counsel

Board Legal Counsel may take the following actions on behalf of the Board/Section:

1. Sign Monitoring orders that result from Board/Section meetings on behalf of the Board/Section Chair.

Delegation to Monitoring Liaison

MOTION: [Board Member Name] moved, seconded by [Board Member Name], to delegate authority to the Monitoring Liaison(s) to make any determination on Orders under monitoring and to refer to the Full Board any matter the Monitoring Liaison deems appropriate. Motion carried [ ].

Delegation to Department Monitor

MOTION: [Board Member Name] moved, seconded by [Board Member Name], to delegate authority to the Department Monitor as outlined below:

1. to grant reinstatement of licensure if education and/or costs are the sole condition of the order and the credential holder has submitted the required proof of completion for approved courses and paid the costs.
2. to suspend the license if the credential holder has not completed Board ordered education and/or paid costs and forfeitures within the time specified by the Board order. The Department Monitor may remove the suspension and issue an order when proof of completion and/or payment has been received.
3. to suspend the license (or remove stay of suspension) if a credential holder fails to enroll and participate in an Approved Program for drug and alcohol testing within 30 days of the order, or if credential holder ceases participation in the Approved Program without Board approval. This delegated authority only pertains to respondents who must comply with drug and/or alcohol testing requirements.
4. to grant or deny approval when a credential holder proposes treatment providers, mentors, and supervisors unless the Order specifically requires full-Board or Board designee approval.
5. to grant a maximum of one 90-day extension, if warranted and requested in writing by a credential holder, to complete Board ordered continuing, disciplinary, or remedial education.
6. to grant a maximum of one 90-day extension or payment plan for proceeding costs and/or forfeitures if warranted and requested in writing by a credential holder.
7. to grant a maximum of one 90-day extension, if warranted and requested in writing by a credential holder, to complete a Board ordered evaluation or exam.

Motion carried [ ].

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**10/17/24** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Hearing and Speech Examining Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
10/30/24	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** **1. 2023 Wisconsin Act 82: HAS 1, 4, 5, and 9, Relating to Cerumen Management** **a. Preliminary Rule Draft** **b. Wisconsin Academy of Audiology Letter** **c. Clinical Practice Guideline** **2. 2023 Wisconsin Act 179: HAS 1 and 4 to 6, Relating to Hearing Aids** **a. Preliminary Rule Draft** **b. 2023 WI Act 179** **c. 21 USC 360j (q)** **3. Pending or Possible Rulemaking Projects**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

Act on a Preliminary Rule Draft and Drafting of a New Rule; Review Board's Current Rule Projects
Attachments:

- 2023 WI Act 82: Redlined Code Text, Preliminary Rule Draft, WAA Letter, Clinical Practice Guideline
- 2023 WI Act 179: Preliminary Rule Draft; 2023 WI Act 179, 21 USC 360j (q)
- Rule Projects Chart

Copies of current Board Rule Projects Can be Viewed Here: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx

11) Authorization

Nilajah D. Hardin — 10/14/24

Signature of person making this request **Date**

Supervisor (if required) **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Chapter HAS 1

LICENSURE OF HEARING INSTRUMENT SPECIALISTS

Note: Chapter Had 1 was renumbered Chapter HAS 1 under s. 13.93 (2m) (b) 1, Stats., Register, April, 1992, No. 436.

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

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

(1a) "Board" means the hearing and speech examining board.

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

(2) "Department" means the department of safety and professional services.

(2a) "Direct supervision" means being physically present at the time the trainee makes ear impressions or measurements of human hearing for the purpose of fitting or selling a hearing instrument or fits or sells a hearing instrument.

(2m) "Full terms of sale" means the conditions of a sale agreed to by a hearing instrument specialist and the purchaser of a hearing instrument.

(2n) "Hearing instrument" means a hearing aid, as defined in s. 459.01 (2), Stats.

(3) "License" means a license issued by the department under s. 459.05, Stats., to hearing instrument specialists.

(5) "Practice" means the practice of fitting and dealing in hearing instruments, as defined in s. 459.01 (5), Stats.

(5e) "Seller's guarantee" means a promise made by a hearing instrument specialist to a hearing instrument purchaser to provide the minimum product warranty offered by a manufacturer.

(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.

(5n) "Sufficient cause" means illness or other hardship.

(6) "Trainee" means the holder of a permit.

(7) "Trainee permit" has the meaning given in s. 459.01 (7), Stats.

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Chapter HAS 4

HEARING INSTRUMENT SPECIALISTS MEASUREMENT OF HUMAN HEARING

Note: Chapter Had 4 was renumbered Chapter HAS 4 under s. 13.93 (2m) (b) 1, Stats., Register, April, 1992, No. 436.

HAS 4.01 Appropriate procedures for measurement of human hearing. The procedures accepted by the board for the measurement of human hearing by licensees and trainees comprise:

(1) Pure tone audiometry, including air conduction testing and bone conduction testing.

(2) Speech audiometry by live voice, or recorded voice, including speech reception threshold, speech discrimination testing, and most comfortable loudness measurements and loudness discomfort levels.

(3) Appropriate masking when indicated.

(4) Recording and interpretation of audiograms and speech audiometry to determine proper selection and adaptation of hearing instruments.

HAS 4.02 Ear molds. Taking impressions for ear molds includes:

(1) Otoscopic observation, pre- and post- impression.

(2) Proper cotton or foam block placement.

(3) Impression material insertion.

(4) Removal of completed impression.

(5) Proper ear mold selection.

HAS 4.03 Equipment used to measure hearing. (1) Pure tone audiometry must be conducted with a pure tone audiometer which conforms to the American National Standards Institute, Standard ANSI S3.6 2018 approved September 20, 2018. Such audiometer shall be capable of generating a minimum of 9 discrete frequencies, ranging from 250 Hz through 8 KHz (250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz). Output levels over the frequency range shall conform to standard ANSI S3.6 specified above.

Note: A copy of Standard ANSI S3.6 may be obtained from the American National Standards Institute website at www.ANSI.org. A copy of the Standard is on file at the Legislative Reference Bureau.

(2) A masking source shall be either available within, or capable of being attached to, the audiometer. The masking source shall have one of the following:

(a) White noise capability.

(b) Speech noise capability.

(c) Narrow band noise and white noise or narrow band noise and speech noise capability.

(3) Audiometric equipment used in the evaluation of hearing sensitivity for the fitting and sale of hearing instruments shall be calibrated not less than once every 12 months.

HAS 4.04 Appropriate time frame for hearing tests prior to fitting hearing instruments. Appropriate procedures for the measurement of human hearing as described in s. HAS 4.01 shall be performed and documented within 6 months prior to the selling and fitting of a hearing instrument.

Chapter HAS 5

HEARING INSTRUMENT SPECIALISTS UNPROFESSIONAL CONDUCT

Note: Chapter Had 5 was renumbered Chapter HAS 5 under s. 13.93 (2m) (b) 1, Stats., Register, April, 1992, No. 436.

HAS 5.01 Authority. The rules in this chapter are adopted pursuant to the authority in ss. 15.08 (5) (b), 227.11, 459.10 (1) (k), 459.12 (1), and 459.34 (2) (h), Stats.

HAS 5.013 Scope. The standards of practice and professional conduct in this chapter apply to a licensee regardless of whether services are provided in person or by telehealth.

HAS 5.015 Definition. In this chapter, “telehealth” has the meaning given in s. 440.01 (1) (hm), Stats.

HAS 5.02 Unprofessional conduct. (1) In this section, “client records" include:

(a) The results of all tests required under ch. HAS 4.

(b) Copies of all contracts, receipts and guarantees involving the sale of hearing instruments.

(c) Documentation of all pertinent client contacts, except those relating to the sale of batteries or product accessories.

(d) Copies of all written statements waiving medical evaluations, as required under 21 CFR 801.421.

Note: Hearing instrument specialists must comply with the recordkeeping requirements adopted by the U.S. Food and Drug Administration (FDA), as set forth in 21 CFR 801.421.

(2) The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct under s. 459.10 (1) (k), Stats.:

(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 ,licensee, or certified individual. There is a rebuttable presumption that a licensee , applicant, 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.

(b) Knowingly providing false information to the board.

(c) Knowingly placing false information in a client’s records or making a client’s record false.

(d) Failing to maintain client records for a period of 5 years.

(dm) Failing to record all of the following information in each client record:

1. The date of entry of pertinent information.
2. The name of the licensee.
3. Information sufficiently legible to allow interpretation by other individuals for the benefit of the client.

(e) Practicing in a manner which substantially departs from the standard of care ordinarily exercised by a hearing instrument specialist.

(f) Failing to maintain proper calibration of audiometric equipment, as specified in s. HAS 4.03 (3).

(fm) Failing to maintain adequate records of certification of calibrations of audiometric equipment for a period of 5 years or failing to provide access to those records when requested by the board or its representative.

(g) Failing to clearly state the full terms of sale on a receipt, as required in s. 459.03, Stats., and failing to comply with those terms. The full terms of sale shall include all of the following:

1. The amount and method of payment.
2. The date and place of delivery.
3. The terms of any guarantee.
4. The nature and duration of the trial period and extension, if any.
5. The refund policy and amount, if any.
6. The product return and exchange policy, if any.
7. The product repair policy, if any.

(h) Soliciting from or knowingly disclosing to any person or entity the content of an examination conducted under ch. HAS 3.

(i) Failing to utilize equipment and technology to provide telehealth services which enable the hearing instrument specialist to meet or exceed the standard of minimally competent practice.

(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.

(3) A person engaging in the practice of selling or fitting hearing aids to a patient located in this state, whether in-person or via telehealth, shall be licensed under ch. 459, Stats., as a hearing instrument specialist or audiologist.

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, and hospitalizations.

(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 a postgraduate clinical fellowship with a supervising otolaryngologist or other physician in cerumen management that has been approved by the board.

Note: Requests for board approval of postgraduate clinical fellowships 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.

(l) 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.

(r) A tympanic membrane that the certified individual is unable to see.

(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 comply with all of the following infection control procedures:
(a) Universal health precautions.
(b) Decontamination.
(c) Cleaning, disinfection, and sterilization of multiple use equipment.
(d) 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.

STATE OF WISCONSIN
HEARING AND SPEECH EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE HEARING AND SPEECH EXAMINING BOARD	:	PROPOSED ORDER OF THE HEARING AND SPEECH EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

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 and 9 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 and 9, 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:

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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, 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, and hospitalizations.
- **(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 a postgraduate clinical fellowship with a supervising otolaryngologist or other physician in cerumen management that has been approved by the board.

Note: Requests for board approval of postgraduate clinical fellowships 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.

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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.
(l) 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.
(r) A tympanic membrane that the certified individual is unable to see.

(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 comply with all of the following infection control procedures:

(a) Universal health precautions.
(b) Decontamination.
(c) Cleaning, disinfection, and sterilization of multiple use equipment.
(d) 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.

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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)

DRAFT

WISCONSIN ACADEMY OF AUDIOLOGY

TO: Ms. Nilajah Hardin
Administrative Rules Coordinator at Wisconsin Department of Safety and Professional Services
4822 Madison Yards Way
P.O. Box 8366
Madison, Wisconsin 53708

From: Wisconsin Academy of Audiology

RE: Administrative Rules for Wisconsin Act 82

Date: June 26, 2024

The Wisconsin Academy of Audiology (WAA) is a membership organization of more than 60 audiologists from across Wisconsin. WAA was formed in the fall of 2023, to give audiologists a unified voice, to raise professional concerns, and to speak out on behalf of patient safety. We are the **only organization in Wisconsin that speaks solely for licensed audiologists.**

We wanted to provide a copy of the recommendations we have made to DSPS. We appreciate your service to the WI Hearing and Speech Examining Board and look forward to active involvement in all things audiology.

We write today to offer our insights and recommendations for rulemaking around the recently enacted Wisconsin Act 82. Under Act 82, Hearing Instrument Specialists (HIS) are allowed to engage in cerumen management and must be certified to do so. Absent a suitable course in cerumen management available to HIS, the HAS Board must find another suitable course or administer its own course and examination.

We urge the Board to consider the implications of insufficient training and the potential hazards it poses not only to consumer safety but also to the credibility of the licensing board certificate program for HIS. We recommend the establishment of a robust, board-administered cerumen management course that includes rigorous written and practical examinations and ongoing competency assessments to maintain the highest standards of practice.

Our comments and recommendations below highlight the essential areas that require meticulous attention to ensure that the safety and well-being of our patients are maintained at the highest standards in cerumen management practices. In developing any certification protocol or training, three key elements must be present.

1. **Hands-on Training:** Hands-on training is essential to gain proficiency and confidence in safely conducting cerumen removal. We propose a model akin to the rigorous practical requirements mandated for ear mold impressions. This model has proven effective in equipping HISs with the necessary skills through direct, supervised practice. Similarly, a structured, comprehensive training module for cerumen management must include both theoretical knowledge and practical, hands-on sessions to ensure HIS are well-prepared for all procedural eventualities.

2. **Understanding and Managing Contraindications:** The ability to identify and appropriately refer cases with contraindications is critical for patient safety. HISs should be trained to perform detailed assessments to recognize conditions such as tympanic membrane perforations, history of ear surgeries, or anatomical abnormalities that significantly heighten the risk of complications. Training must rigorously address these aspects to prevent adverse outcomes and ensure HIS are prepared to make judicious decisions about when to proceed with cerumen removal. This is why we strongly recommend only licensed Hearing Instrument Specialists (HIS) with at least 5 consecutive years of work experience as an HIS can perform cerumen management.

3. **Stringent Infection Control Measures:** Infection control is a non-negotiable aspect of any procedure involving bodily contact. The current practices in audiology and speech-language pathology, as referenced by Kemp et al., underscore the necessity of adhering to high standards of infection prevention. We advocate for the integration of similar, if not even more rigorous protocols in the training and certification of HIS for cerumen management. This includes comprehensive training on the use of personal protective equipment (PPE), proper sterilization techniques, and protocols to minimize the risk of transmitting infections.

Insufficient or inadequate training poses potential hazards to consumer safety and to the credibility of the licensing board certificate program for HIS. The guidelines below seek to ensure the safety and effectiveness of cerumen management.

Thank you for your attention to these vital matters.

Respectfully yours,

Veronica H. Heide, Au.D.
Doctor of Audiology
President, Wisconsin Academy of Audiology

cc: Gary Goyke, Lobbyist

Wisconsin Academy of Audiology Recommendations

The Wisconsin Academy of Audiology (WAA) respectfully submits the following recommendations for consideration as the WI Hearing and Speech Examining Board drafts its Administrative Rules regarding certification of hearing instrument specialists (HIS) in cerumen management, pursuant to 2023 Wisconsin Act 82.

Background

Current requirements for licensing as a HIS are minimal.

A hearing instrument specialist (HIS) who is currently licensed in Wisconsin, with or without obtaining a certificate for cerumen management:

- Has no credentialed academic education requirement other than a high school diploma or GED.
- Is not required to have any academic coursework in the anatomy and physiology of the ear and applied science.
- Is not required to have a vocational education such as is required for registered nurses (RN), licensed practical nurses (LPN), and medical assistants (MA). The HIS training might be occupational (on the job) but even this is not required for the HIS license in Wisconsin.
- Has no supervised practicum requirement
- Can immediately work independently upon being licensed.

Act 82 Creates Chapter 459.115 - Cerumen Management which reads:

(1) The Examining Board shall issue a certificate to engage in cerumen management to licensed individuals who complete an approved cerumen management course as defined in subsection (3).
(2) Engaging in cerumen management is restricted to those holding a valid certificate issued under subsection (1).
(3) The Board shall define and approve cerumen management courses. Courses must include at least 6 hours of instruction covering a variety of safe cerumen removal techniques and include a final examination.
(4) The Board will develop necessary rules to administer this section, including defining the scope of cerumen management and establishing contraindications for consumer referrals.
(5) Certificates are permanent unless revoked and do not require renewal.
(6) Certificate holders must annually provide proof of adequate malpractice liability insurance.

Proposed Guidelines for Implementing Act 82:

It is with consideration of this background information and our professional knowledge and experiences, as well as our service as members and examiners to the Hearing and Speech Examining Board that we respectfully submit the following proposed guidelines for developing the Administrative Rules to implement Act 82.

1. Licensing and Certification Requirements:

- Only licensed Hearing Instrument Specialists (HIS) with at least 5 consecutive years of work experience as an HIS can perform cerumen management.
- Certification requires passing both written and practical exams.

- The certificate issued under sub. (1) should be prominently displayed in the room in which the HIS does cerumen management.
- HIS must maintain liability insurance in the minimum amounts of $1,000,000 each claim and $3,000,000 aggregate.

2. Scope of Practice:

- Includes consumer assessment, otoscopic examination, and cerumen removal using appropriate tools such as aural irrigation, cerumen loop, or forceps. The procedure must be deemed low risk and appropriate for HIS intervention based on consumer assessment.
- HIS should also provide consumer education on cerumen management and self-care.
- Nothing in this statute or rule is to be construed as allowing a Hearing Instrument Specialist to evaluate a consumer's ear canal via telehealth parameters.

3. Training and Competency Requirements:

- HISs must complete a Board-approved training program in ear wax removal, which includes theoretical instruction and practical training.
- Mandatory completion of a minimum 6-hour DSPS-approved cerumen management course, plus practicum hours and including a practical exam.
- HISs must demonstrate competency through a practical examination and periodic competency reviews, as determined by their employer.
- HISs must complete a written examination on cerumen management.

4. Equipment and Techniques:

- Approved Methods for Ear Wax Removal:
  - Manual Removal: Utilize cerumen loops.
  - Irrigation: Employ gentle lavage of the ear canal with water or saline solution to remove ear wax.
  - Proceed with cerumen removal only if there are no contraindications.
- Contraindications:
  - Avoid treatment in cases of perforated tympanic membranes, history of middle ear surgery, abnormalities in the ear canal structure, unilateral hearing loss, or immunocompromised consumers.
- Equipment Standards:
  - All equipment, including cerumen loops, irrigation, syringes, and otoscopes must meet the hearing healthcare industry's sterilization and safety protocols (Kemp, et.al, 1996).
- Cerumenolytic Agents:
  - Use mineral oil or OTC cerumenolytics (e.g. Debrox or EarwaxMD) to soften debris in the ear canal, facilitating easier wax removal.

- Cerumenolytics or cerumen removal should not be used or attempted in consumers with sensitive or surgically altered ears or conditions referred to in item 6 of this document.

5. Consumer Assessment and Documentation:

HISs must conduct a thorough otoscopic examination and consumer history before attempting cerumen removal:

- History should include inquiries about a history of ear infections, tympanic membrane status, previous ear surgery, diabetes mellitus, autoimmune disease, unilateral hearing loss, and dizziness or balance problems.
- Documentation must include assessment findings, method of removal, consumer response to the procedure, and any follow-up care instructions.

6. Contraindications and Referrals:

Identifying Contraindications:

Cerumen removal should not be performed by an HIS, and the consumer referred to a medical practitioner, preferably an otolaryngologist if any of the following conditions are present:

Age Restrictions:

- Children under the age of eighteen (18) should be referred.

Anatomical and Surgical Considerations:

- Perforated Tympanic Membrane: Increases the risk of infection and complications, including but not limited to rupture of the inner ear with total loss of hearing during irrigation.
- Recent Ear Surgery: Consumers who have a history of ear surgery.
- Tympanostomy Tubes (see risks associated with perforated tympanic membrane).
- Congenital or Traumatic Deformities: Abnormal ear structures can complicate the removal process and increase the risk of injury.
- Stenosis or Bony Exostosis: Narrowing or bony growths in the ear canal can trap instruments or irrigation fluids, leading to pain and/or infection.

Medical Conditions:

- Unable to visualize the tympanic membrane: A tympanic membrane that the HIS is unable to visualize.
- Cerumen impaction that totally occludes the ear canal or cerumen located medial to the cartilaginous external auditory canal.
- Stenosis or bony exostosis of the ear canal.
- Bleeding Disorders: Consumers with conditions that predispose them to excessive bleeding, such as those on anticoagulant therapy, should be managed by a physician.

- Immunocompromised Status: Includes consumers with diabetes or other conditions that weaken the immune system, increasing the risk of severe infections following cerumen removal.
- Foreign Bodies: Suspected foreign objects in the ear require delicate removal to avoid damage to the ear canal or tympanic membrane.
- Unilateral Hearing Loss: Special caution is needed when managing cerumen in a consumer's only hearing ear to avoid damage and hearing loss.

7. Legal and Ethical Considerations:

HISs are required to obtain written informed consent from consumer or his/her guardians before performing cerumen removal. This information is detailed below in "Cerumen Management Course for HIS/Course Content/Assessment."

8. Quality Assurance and Oversight:

HISs must ensure ongoing quality assurance practices are in place, including consumer outcomes related to cerumen removal.

9. Continuing Education:

HISs are required to complete continuing education units (CEUs) on ear care and cerumen removal as part of their licensure renewal process.

Cerumen Management Course for Hearing Instrument Specialists (HIS)

Course Objectives

- Equip HISs with basic skills in cerumen management, ensuring they can safely and effectively manage cerumen removal in normal, healthy ears.
- Prepare HISs for safe practice by adhering to industry standards, ethical considerations, and legal requirements.
- Identify medical contraindications that involve both anatomical factors and comprehensive medical history.

Course Content

1. Anatomy and Physiology specific to Cerumen Management
    - Anatomy of the Ear Canal: Detailed study of the ear canal structure, from the outer ear to the tympanic membrane, including variations in anatomy.
    - Cerumen Types and Characteristics: Discussion on different types of cerumen (wet and dry), their physical and chemical properties, and how these affect cerumen accumulation and removal strategies.
2. Consumer Assessment
    - Comprehensive Consumer History: Techniques for obtaining a detailed medical history, focusing on ear-related symptoms and previous ear conditions.

- Otoscopic Examination: Hands-on training in the use of an otoscope to examine the ear canal and tympanic membrane, identifying normal and abnormal findings.
- Identifying Cerumen Characteristics: Training on assessing the consistency, quantity, and position of cerumen to decide the appropriate method of removal.

3. Procedural Techniques
    - Aural Irrigation Procedure: Step-by-step instruction on the safe setup and execution of ear irrigation, including temperature control, pressure techniques, and post-procedure care.
    - Manual Removal Using Cerumen Loops: Training on the correct use of cerumen loops, focusing on gentle and effective removal techniques to avoid damaging the ear canal.
4. Cerumenolytic Agents
    - Use of Mineral Oil and Other Agents: Overview of various cerumenolytic agents, their indications, and methods of application.
    - Contraindications for Use: Identification of situations where cerumenolytic agents are contraindicated, such as perforated eardrums or ears with surgical alterations.
5. Red Flags and Contraindications
    - Conditions Warranting Referral to a Physician: Clear guidelines on when to refer consumers, including but not limited to presence of pain, drainage, bleeding, suspicion of foreign bodies or severe impaction, bleeding disorders or blood-thinning medications, diabetes or other conditions that weaken the immune system, and unilateral hearing loss.
    - Specific Contraindications for Each Removal Technique: Detailed discussion on which consumer's conditions and ear characteristics make certain removal techniques risky or inappropriate.
6. Legal and Ethical Considerations
    - Informed Consent Process: Comprehensive training on obtaining informed consent, including explaining the procedure, potential risks, and alternatives.
    - Advanced Beneficiary Notice (ABN): Detailed instructions on when and how to use ABN forms, particularly in scenarios involving Medicare and Medicaid.
    - Financial Disclosure: Guidelines on informing consumers about procedure costs, possible insurance coverage if cerumen management is provided by a physician, or other healthcare provider, and payment responsibilities.
    - Liability Issues and Professional Insurance Requirements: Explanation of the importance of professional liability insurance and guidelines for what it should cover.
7. Infection Control and Safety Practices

    Cerumen is classified as a bodily fluid and therefore must be handled with universal health precautions. Below are some vital considerations regarding how to manage the risk of transmitting infections when dealing with cerumen removal:

- Universal Health Precautions: Training on universal precautions to prevent infection, including proper hand hygiene and use of personal protective equipment (PPE).
- Decontamination and Sterilization of Equipment: Procedures for the proper cleaning, disinfection, and sterilization of reusable equipment.
- Prevention of Transmission of Pathogens: Detailed education on preventing the spread of HIV, hepatitis B, and other blood-borne pathogens in compliance with occupational safety and health standards.

Practical Training Requirements

- Hands-On Practicum: Structured, in-person sessions where participants practice removing cerumen using both irrigation cerumen loops and forceps on ear canal models, supervised by medical professionals.
- Skill Evaluation: Practical assessments to evaluate the ability to safely and effectively manage cerumen removal, considering consumer variability and infection control practices.

Referral Protocols

- Documentation and Procedural Protocol for Referrals: Training on-documenting the need for referral and on effective communication with otolaryngologists or other healthcare providers for seamless consumer care.

Certification and Compliance

- Examinations: Participants must pass both written and practical exams that test their knowledge of course material and their proficiency in cerumen management techniques.
- Certification: Details on the certification process, including the criteria for passing and the validity period of the certification.

Disciplinary grounds

- Subject to subch. II of ch. 111 and the rules adopted under s. 440.03 (1), the examining board may reprimand the licensee or permit holder or revoke, suspend, limit or deny the trainee permit, license, or certificate to engage in cerumen management under s. 459.115, or any combination thereof, of any person who has done any of the infractions listed in 459.10 (1) and (2).
- Administrative Rule HAS 2.01 Trainees should be modified to exclude cerumen management with a trainee permit.

Continuing Education

- WI Administrative Rule HAS 8.03 Continuing education should be modified to read:
    - (1) Except as provided in sub. (6), hearing instrument specialists, audiologists and speech-language pathologists shall complete at least 20 hours of board-approved continuing education programs or courses of study which pertain to the practice of fitting and dealing in hearing instruments, audiology or speech-language pathology, as

appropriate, in each biennial renewal period. Of the 20 required hours, at least 2 hours shall relate to ethics.

- (2) For an HIS with a certificate in cerumen management, an additional 2 hours of continuing education shall relate to cerumen management.

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AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Invited Article

Otolaryngology–Head and Neck Surgery
2017, Vol. 156(1) 14–29
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DOI: 10.1177/0194599816678832
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Clinical Practice Guideline (Update): Earwax (Cerumen Impaction) Executive Summary

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

The American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) has published a supplement to this issue of *Otolaryngology–Head and Neck Surgery* featuring the updated Clinical Practice Guideline: Earwax (Cerumen Impaction). To assist in implementing the guideline recommendations, this article summarizes the rationale, purpose, and key action statements. The 11 recommendations emphasize proper ear hygiene, diagnosis of cerumen impaction, factors that modify management, evaluating the need for intervention, and proper treatment. An updated guideline is needed due to new evidence (3 guidelines, 5 systematic reviews, and 6 randomized controlled trials) and the need to add statements on managing cerumen impaction that focus on primary prevention, contraindicated intervention, and referral and coordination of care.

Keywords

cerumen, earwax, impaction, ear candling, ear coning, clinical practice guideline

Received October 14, 2016; accepted October 22, 2016.

Differences from Prior Guideline

This clinical practice guideline is as an update, and replacement, for an earlier guideline published in 2008 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF).[1] An update was planned for 5 years after the initial publication date and was further necessitated by new primary studies and systematic reviews that might suggest a need for modifying clinically important recommendations.[2] Changes in content and methodology from the prior guideline include the following:

- addition of a consumer advocate to the guideline update group (GUG);
- 3 guidelines, 5 systematic reviews, and 6 randomized controlled trials (RCTs);
- emphasis on patient education and counseling with new explanatory tables;
- expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion;
- enhanced external review process to include public comment and journal peer review;
- new algorithm to clarify decision making and action statement relationships; and
- 3 new key action statements on managing cerumen impaction that focus on primary prevention, contraindicated intervention, and referral and coordination of care.

Introduction

Cerumen or ''earwax'' is a naturally occurring substance that cleans, protects, and lubricates the external auditory canal. It is also the primary reason why the ear canal can become obstructed. While often harmless, blockage of the ear canal from cerumen can lead to a host of symptoms, including hearing loss, tinnitus, fullness, itching, otalgia, discharge, odor, or cough.[3] In addition, cerumen impaction can prevent diagnostic assessment by preventing complete examination of the external auditory canal and/or eardrum (tympanic membrane) or by interfering with diagnostic assessment (ie, audiometry, tympanometry).[4]

Cerumen forms when glandular secretions from the outer two-thirds of the ear canal mix with exfoliated squamous epithelium.[5] Normally, cerumen is eliminated or expelled by a self-cleaning mechanism, which causes it to migrate out of the ear canal assisted by jaw movement.[6] **Figure 1** provides an illustration of where cerumen occurs,[7] and **Figure 2** is a photograph of impacted cerumen.

Accumulation of cerumen, caused by failure of the self-cleaning mechanism, is one of the most common reasons that patients seek medical care for ear-related problems.[4,8] Excessive or impacted cerumen is present in 1 in 10 children, 1 in 20 adults, and more than one-third of the geriatric and developmentally delayed populations. [3,9,10] About 12 million people seek medical care annually for problematic cerumen in the United States, resulting in nearly 8 million cerumen removal procedures.[11,12] Nearly $50 million was spent by Medicare in 2012 for cerumen-related procedures, and cerumen impaction was a diagnosis in up to 5% of Medicare patients.[13] Moreover, excessive or impacted cerumen in high-risk populations, such as the elderly and developmentally delayed, is underdiagnosed and likely undertreated.[10,14,15]

The target patient for this guideline is over 6 months of age with a clinical diagnosis of cerumen impaction.

- *Cerumen* is defined as a mixture of secretions (sebum together with secretions from modified apocrine sweat glands) and sloughed epithelial cells and is a normal substance present in the external auditory canal. As cerumen migrates laterally, it may mix with hair and other particulate matter.
- *Cerumen impaction* as defined for this guideline is an accumulation of cerumen that causes symptoms and prevents a needed assessment of the ear canal/tympanic membrane, audiovestibular system, or both.
- *Impaction vs obstruction.* Although ''impaction'' usually implies that cerumen is lodged, wedged, or firmly packed in the ear canal (**Figure 2**), our definition of cerumen impaction does not require a complete obstruction. This definition implies that the cerumen is associated with symptoms that may be attributable to it or that the cerumen prevents a necessary ear examination.

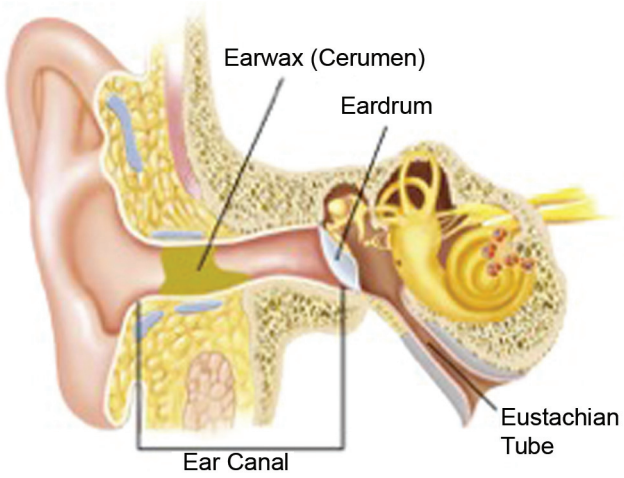

Figure 1. Cerumen is formed in the outer two-thirds (cartilaginous portion) of the ear canal and not the inner third (bony portion) that ends at the eardrum. Impacted cerumen (green-like collection) can completely obstruct the ear canal. Adapted and reproduced with permission.[7]

Figure 2. Otoscopic view of impacted cerumen that completely fills the ear canal. Image courtesy of the Yanagisawa image library©. AAO-HNSF 2015.

We have defined this term pragmatically to designate cerumen that requires management.[3-5] Some patients will present with nonimpacted cerumen that does not cause symptoms and does not prevent assessment of the ear and is

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''asymptomatic.'' Asymptomatic cerumen does not require active management. This guideline will discuss considerations relevant to watchful waiting and surveillance.

Purpose

The primary purpose of this guideline is to help clinicians identify patients with cerumen impaction who may benefit from intervention and to promote evidence-based management. Another purpose of the guideline is to highlight needs and management options in special populations or in patients who have modifying factors. A guideline is necessary given evidence of practice variation in medicine and the literature. The secondary goal includes creating a guideline suitable for deriving a performance measure on cerumen impaction. This update is needed due to the time since the original publication and the presence of new evidence.

The guideline is intended for all clinicians who are likely to diagnose and manage patients with cerumen impaction and applies to any setting in which cerumen impaction would be identified, monitored, or managed.

The guideline does *not* apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal, recurrent otitis externa, keratosis obturans, prior radiation therapy affecting the ear, exostoses or osteoma, neoplasms of the ear canal, previous tympanoplasty/myringoplasty or canal wall-down mastoidectomy, or other surgery affecting the ear canal. However, the guideline will discuss the relevance of these conditions in cerumen management. The following modifying factors are not the primary focus of the guideline but will be discussed relative to their impact on management: nonintact tympanic membrane (perforation or tympanostomy tube), ear canal stenosis, exostoses, diabetes mellitus, immunocompromised state, anticoagulant therapy, or bleeding disorder.

The goal of this document is to update the original multidisciplinary guideline looking at previously and newly identified quality improvement opportunities in the management of impacted cerumen. The GUG sought to achieve this with a limited set of focused recommendations based on a transparent and explicit process that considers levels of evidence, harm-benefit balance, consumer input, and expert consensus to fill evidence gaps.

Methods

General Methods and Literature Search

This guideline update was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm, as outlined in the third edition of *Clinical Practice Guideline Development Manual: A Quality-Driven Approach for Translating Evidence into Action*.[16]

The original cerumen impaction guideline[1] was first sent to a panel of expert reviewers who were asked to assess the key action statements and decide if they should be revised, be kept unaltered, or removed based on relevancy, omissions, or controversies that the guideline spurred and to identify any new literature or treatments that might affect the guideline recommendations. The reviewers concluded that the original guideline action statements remained valid but should be updated with minor modifications. A suggestion was also made for a new key action statement on the role of alternative therapies in management.

A literature search was performed by an information specialist to identify systematic reviews, clinical practice guidelines, and RCTs published since the prior guideline cutoff (September 2007). The following databases were searched from October 2007 to April 2015: MEDLINE (OvidSP), Embase (OvidSP), AMED (OvidSP), Cumulative Index to Nursing and Allied Health (CINAHL), PubMed, National Guidelines Clearinghouse, and Cochrane Controlled Trials Register (CCTR). The databases were searched for the topic of interest using both controlled vocabulary words and synonymous free text words (cerumen, earwax, and impaction). The search strategies were adjusted for the syntax appropriate for each database/platform.

The initial English-language search identified 1 potential clinical practice guideline, 6 systematic reviews, 5 RCTs, and 6 other studies. All searches were conducted on April 3, 2015. Systematic reviews were included if they met quality criteria of (a) clear objective and methods, (b) an explicit search strategy, and (c) valid data extraction. Additional evidence was identified, as needed, with targeted searches to support needs of the guideline development group in updating sections of the guideline text. Specifically, ear candling/coning was identified as an area of concern by the reviewers. The databases were also searched using both controlled vocabulary words and synonymous free text words for the topic of interest (ear candling and ear coning) in this population. The search strategies were adjusted for the syntax appropriate for each database/platform. The search was not limited by date range or study design but was limited to English language. After assessing the quality and relevance of all of the new search results, we retained 3 guidelines, 5 systematic reviews, and 6 RCTs.

The AAO-HNSF assembled a GUG representing the disciplines of otolaryngology–head and neck surgery, otology/neurotology, family medicine, audiology, advanced practice nursing, pediatrics, geriatrics, a resident physician (otolaryngology), and a consumer advocate. The GUG also included a staff liaison from AAO-HNSF, but this individual was not a voting member of the GUG and served only in an editorial capacity in writing the guideline. Several group members had significant prior experience in developing clinical practice guidelines.

The GUG had several conference calls and 1 in-person meeting, during which comments from the expert panel review and the literature search were reviewed for each key action statement. The GUG then decided to leave the statements unaltered, change slightly, or rewrite the statement based on the impact of the literature search, the reviewer comments, and the benefit-harm balance. The supporting text was then edited to explain any changes from the

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Table 1. Strength of Action Terms in Guideline Statements and Implied Levels of Obligation.

Strength	Definition	Implied Obligation
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (Grade A or B).[a] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of evidence is not as high (Grade B or C).[a] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence is suspect (Grade D)[a] or that well-done studies (Grade A, B, or C)[a] show little clear advantage to one approach vs another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

[a]See **Table 2** for definitions of evidence grades.

original key action statement, and the recommendation level was modified accordingly.

The evidence profile for each statement was then converted into an action statement profile, which was moved up in the text to immediately follow the action statement. Statements about the quality improvement opportunity, level of confidence in the evidence, differences of opinion, intentional vagueness, and any exclusion to which the action statement does not apply were added to the action statement profiles. These additions reflect the current methodology for guideline development by the AAO-HNSF and conform to the Institute of Medicine's standards for developing trustworthy guidelines.[2,16] The updated guideline then underwent Guideline Implementability Appraisal (GLIA) to appraise adherence to methodologic standards, to improve clarity of recommendations, and to predict potential obstacles to implementation.[17] The GUG received summary appraisals in October 2015 and modified an advanced draft of the guideline based on the appraisal.

The final draft of the updated clinical practice guideline was revised based on comments received during multidisciplinary peer review, open public comment, and journal editorial peer review. A scheduled review process will occur at 5 years from publication or sooner if new, compelling evidence warrants earlier consideration.

Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, to produce optimal health outcomes for patients, and to minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the *quality of evidence* and the *balance of benefit and harm* that is anticipated when the statement is followed. The definitions for evidence-based statements[18] are listed in **Tables 1** and **2**.

Guidelines are never intended to supersede professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability.[19] Clinicians should always act and decide in a way that they believe will best serve their individual patients' interests and needs, regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.[18]

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Values applied by the GUG sought to minimize harm and diminish unnecessary and inappropriate therapy. A major goal of the GUG was to be transparent and explicit about how values were applied and to document the process.

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Table 2. Aggregate Grades of Evidence by Question Type.[a]

Grade	Treatment	Diagnosis	Prognosis
A	Systematic review[b] of randomized trials	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	Randomized trials, or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]
C	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor-quality prognostic cohort study
D	Case reports, mechanism-based reasoning, or reasoning from first principles		
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm		

[a]American Academy of Otolaryngology—Head and Neck Surgery Foundation guideline development manual.[16]
[b]A systematic review may be downgraded to grade B because of study limitations, heterogeneity, or imprecision.
[c]A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the AAO-HNSF. Potential conflicts of interest for all panel members in the past 5 years were compiled and distributed before the first conference call. After review and discussion of these disclosures,[20] the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Last, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established ''stake'' in an issue.[21]

Guideline Action Statements

Each evidence-based statement is organized in a similar fashion: a key action statement in bold, followed by the strength of the recommendation in italics, and an ''action statement profile'' that explicitly states the quality improvement opportunity (and corresponding National Quality Strategy domain based on the original priorities),[22] aggregate evidence quality, level of confidence in evidence (high, medium, low), benefit, harms, risks, costs, and a benefits-harm assessment. In addition, there are statements of any value judgments, the role of patient (caregiver) preferences, clarification of any intentional vagueness by the panel, exceptions to the statement, any differences of opinion, and a repeat statement of the strength of the recommendation. Several paragraphs subsequently discuss the evidence base supporting the statement. An overview of each evidence-based statement in this guideline can be found in **Table 3**, and the relationship between statements is illustrated in **Figure 3**.

The role of patient preference in decision making deserves further clarification. For some statements, where the evidence base demonstrates clear benefit, although the role of patient preference for a range of treatments may not be relevant, clinicians should provide patients with clear and comprehensible information on the benefits and harms to facilitate patient understanding and shared decision making, which leads to better patient adherence and outcomes. In cases where evidence is weak or benefits are unclear, the practice of shared decision making, again where the management decision is made by a collaborative effort between the clinician and an informed patient, is extremely useful. Factors related to patient preference include (but are not limited to) absolute benefits (numbers needed to treat), adverse effects (number needed to harm), cost of drugs or procedures, and frequency and duration of treatment.

Key Action Statements

STATEMENT 1. PRIMARY PREVENTION: Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen. *Recommendation based on observational studies and a preponderance of benefit over harm.*

Action Statement Profile for Statement 1

- Quality improvement opportunity: Communicating safe preventive measures to patients (**Tables 4** and **5**) (National Quality Strategy domain: Patient and Family Engagement)
- Aggregate evidence quality: Grade C, based on preponderance of survey studies and 1 prospective pilot study
- Level of confidence in evidence: Medium

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Table 3. Summary of Guideline Action Statements.

Statement	Action	Strength
1. Primary prevention	Clinicians should explain proper ear hygiene to prevent cerumen impaction when patients have an accumulation of cerumen.	Recommendation
2A. Diagnosis of cerumen impaction	Clinicians should diagnose cerumen impaction when an accumulation of cerumen seen on otoscopy (1) is associated with symptoms, (2) prevents needed assessment of the ear, or (3) both.	Recommendation
2B. Modifying factors	Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management such as 1 or more of the following: anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, and nonintact tympanic membrane.	Recommendation
3A. Need for intervention if impacted	Clinicians should treat, or refer to another clinician who can treat, cerumen impaction, when identified.	Strong recommendation
3B. Nonintervention if asymptomatic	Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined.	Recommendation
3C. Need for intervention in special populations	Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults) and promptly evaluate the need for intervention.	Recommendation
4. Intervention in hearing aid users	Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter.	Recommendation
5A. Recommended interventions	Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include 1 or more of the following: cerumenolytic agents, irrigation, or manual removal requiring instrumentation.	Recommendation
5B. Contraindicated intervention (ear candling/coning)	Clinicians should recommend against ear candling/coning for treating or preventing cerumen impaction.	Recommendation
6. Cerumenolytic agents	Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction	Option
7. Irrigation	Clinicians may use irrigation in the management of cerumen impaction	Option
8. Manual removal	Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction.	Option
9. Outcomes assessment	Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, the clinician should evaluate the patient for alternative diagnoses.	Recommendation
10. Referral and coordination of care	Clinicians should refer patients with persistent cerumen impaction after unsuccessful management by the initial clinician to a clinician with specialized equipment and training for cleaning and evaluating the ear canal and tympanic membrane.	Recommendation
11. Secondary prevention	Clinicians may educate/counsel patients with cerumen impaction/excessive cerumen regarding control measures.	Option

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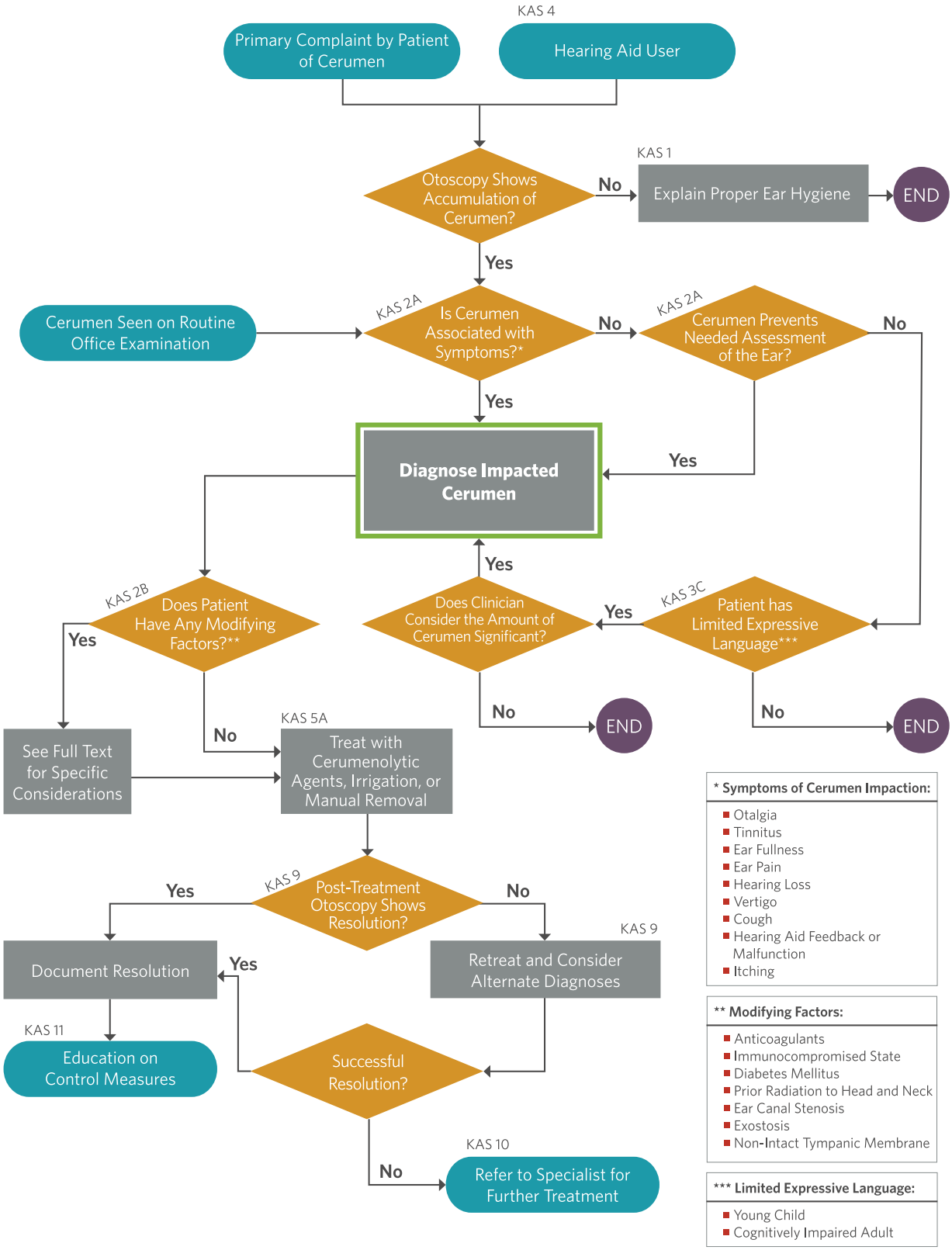

Figure 3. Algorithm showing the interrelationship of guideline key action statements (KAS, key action statement). The guideline does not apply to patients with cerumen impaction associated with the following conditions: dermatologic diseases of the ear canal, recurrent otitis externa, keratosis obturans, prior radiation therapy affecting the ear, previous tympanoplasty/myringoplasty or canal-wall down mastoidectomy, or other surgery affecting the ear canal.

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Table 4. Frequently Asked Questions: Earwax Primary Prevention.

Frequently Asked Questions	
1. Is it necessary to treat your ears to prevent accumulation of earwax?	Prevention is best for certain groups of people, yet not everyone needs it. Among these who may be helped are the elderly, people with hearing aids, and those with a history of excessive earwax. Discussion with your doctor will help determine whether or not anything should be done for you.
2. What will happen if I just leave my ears alone and do not clean them?	Most people do not need a regular schedule for prevention of earwax accumulation. Some may find it necessary to have a cleaning procedure performed occasionally. Earwax is formed naturally by your body and helps protect your ear canal skin and kill germs. A doctor may find an excess of earwax at a regularly scheduled general checkup and perform a cleaning procedure.
3. What symptoms could be caused by excessive earwax?	Common complaints include itching, hearing problems, or a sense of fullness in the ear canal. Other problems that might occur include discharge, odor, cough, or ear pain.
4. Does it hurt to remove earwax?	The procedures used to remove earwax should not cause any pain. If you are putting a type of liquid into the ear, it may feel funny, but should not hurt.
5. If earwax is removed, will my hearing get better?	The type of treatment used to prevent the buildup of wax in your ear should usually not affect your hearing. If your ear canal is completely, or almost completely, blocked by excess earwax, then removing the wax will allow your hearing to return to preimpaction levels.
6. How often should I remove wax from my ears?	There is no standard procedure for preventing earwax buildup, and for most people, nothing needs to be done unless excess wax develops. Ask your health care provider if there is anything special you should do to prevent or reduce accumulation of earwax. There are several procedures with different time periods for the treatment.
7. Is removing earwax expensive?	Most procedures use over-the-counter materials and are not expensive. Your health care provider can help with the choices.
8. Do cotton-tipped swabs remove wax from the ear?	Cotton-tipped swabs can remove some wax, but they often simply push the wax deeper into the ear and may worsen an impaction or traumatize the ear canal.
9. Who can I see to clean my ears?	Many primary care clinicians have the ability to irrigate cerumen in their clinics. Alternatively, an otolaryngologist can remove obstructed cerumen.

- Benefit: Promote safe and effective self-care behaviors in ear hygiene; prevent self-inflicted harms such as abrasions, cuts, and impaction; reduction in health care utilization
- Risks, harms, costs: Induced patient anxiety regarding an asymptomatic condition; time spent in counseling; potential for increased use of health care resources if self-cleaning with cotton-tipped applicators is abandoned
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Perception by the group that patients overmanipulate the ears (ie, cotton swabs use) and that there is benefit in educating patients about proper ear hygiene
- Intentional vagueness: The term *proper ear hygiene* is used and discussed in detail in the text. The term *accumulation* is used but is not precisely defined as it is up to the clinician to determine. This statement applies to patients with impacted cerumen and those who are at risk.
- Role of patient preferences: Small; patient can decline education
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 2A. DIAGNOSIS OF CERUMEN IMPACTION: Clinicians should diagnose cerumen impaction when an accumulation of cerumen seen with otoscopy (1) is associated with symptoms, (2) prevents needed assessment of the ear, or (3) both. *Recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.*

Action Statement Profile for Statement 2A

- Quality improvement opportunity: Allow for accurate diagnosis and properly identify patients in need of treatment. (National Quality Strategy domain: Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade B, diagnostic studies with minor limitations regarding impact of cerumen on hearing and visualizations and Grade C with respect to signs and symptoms associated with cerumen impaction
- Level of confidence in evidence: High

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Table 5. Patient Education: Dos and Don'ts of Cerumen (Earwax).

Do
1. Understand cerumen (earwax) is normal. Earwax not causing symptoms or blocking the ear canal should be left alone.
2. Understand symptoms of cerumen impaction (wax blocking the ear): decreased hearing, fullness, tinnitus, and distortion/changes to hearing aid function.
3. Seek medical evaluation if you have symptoms of hearing loss, ear fullness, or ear pain if you are not certain they are from cerumen. Otitis media (fluid behind the ear drum), otitis externa (ear canal infection), and sudden inner ear hearing loss can all masquerade as cerumen impaction.
4. Ask your provider about ways you can treat your cerumen impaction at home. You may have certain medical or ear conditions that may make some options unsafe.
5. Seek medical attention with ear pain, drainage, or bleeding. These are not symptoms of cerumen impaction and need further evaluation.
Don't
1. Overclean your ears. Excessive cleaning may irritate the ear canal, cause infection, and may even increase the chances of cerumen impaction.
2. Put anything smaller than your elbow in your ear. Your mother was right! Cotton swabs, hairpins, car keys, toothpicks, et cetera. . . . These can all injure your ear and may cause a laceration (cut) in the ear canal, perforation (hole) in the eardrum, and/or dislocation of the hearing bones, leading to hearing loss, dizziness, ringing, and other symptoms of ear injury.
3. Use ear candles. There is no evidence that they remove impacted cerumen, and candling can cause serious damage to the ear canal and drum.
4. Ignore your symptoms if home remedies are unsuccessful. Seek medical attention if attempts at home have not resolved the problem.
5. Irrigate or try cerumen-removing/softening drops if you've had previous ear surgery or a perforated eardrum unless specifically cleared to do so by your otolaryngologist (ear, nose, and throat surgeon).
6. Forget to clean your hearing aids as the manufacturer and your hearing health professional recommend.

- Benefit: Identify individuals with cerumen impaction who require intervention, including those with otologic symptoms and those who require diagnostic assessment (raise awareness of the consequences of cerumen impaction; eg, cerumen impaction may prevent caloric stimulation during electronystagmography)
- Risks, harms, costs: Overdiagnosis of cerumen impaction based on symptoms as a criterion resulting in failure to identify another cause of the symptoms. No additional cost
- Benefit-harm assessment: Preponderance of benefit over harms
- Value judgments: Emphasis on clinical symptoms and signs for initial diagnosis; importance of avoiding unnecessary diagnostic tests; consensus on using the term *cerumen impaction* to imply cerumen that requires treatment
- Intentional vagueness: Symptoms are defined in the supporting text. Prevention of needed assessments is defined by the clinician.
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 2B. MODIFYING FACTORS: Clinicians should assess the patient with cerumen impaction by history and/or physical examination for factors that modify management such as 1 or more of the following: anticoagulant therapy, immunocompromised state, diabetes mellitus, prior radiation therapy to the head and neck, ear canal stenosis, exostoses, and non-intact tympanic membrane. *Recommendation based on observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 2B

- Quality improvement opportunity: Avoiding harms from intervention in people at increased risk based on patient characteristics. (National Quality Strategy domain: Patient Safety)
- Aggregate evidence quality: Grade C, recommendations regarding diabetes mellitus and prior radiation therapy; Grade D, recommendations regarding immunocompromised state, anticoagulation, and anatomic abnormalities of the ear canal and tympanic membrane
- Level of confidence in evidence: Medium
- Benefits: Reduce complications
- Risks, harms, costs: Time of the assessment
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Consensus that identifying modifying factors and modifying management will improve outcomes

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- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 3A. NEED FOR INTERVENTION IF IMPACTED: Clinicians should treat, or refer to another clinician who can treat, cerumen impaction, when identified. *Strong recommendation based on randomized controlled trials with heterogeneity with a preponderance of benefit over harm.*

Action Statement Profile for Statement 3A

- Quality improvement opportunity: Prioritize patients for intervention (National Quality Strategy domain: Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade B, randomized controlled trials with heterogeneity
- Level of confidence in the evidence: High
- Benefits: Improved hearing and symptom relief compared with no treatment
- Risks, harms, costs: Potential complications related to treatment. Direct cost of managing the impaction
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: None
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

STATEMENT 3B: NONINTERVENTION IF ASYMPTOMATIC: Clinicians should not routinely treat cerumen in patients who are asymptomatic and whose ears can be adequately examined. *Recommendation against based on control groups in randomized trials and observational studies and a preponderance of benefit over harms.*

Action Statement Profile for Statement 3B

- Quality improvement opportunity: Avoidance of harm, efficient use of health care resources (National Quality Strategy domains: Patient Safety and Efficient Use of Health Care Resources)
- Aggregate evidence quality: Grade C, control groups in randomized trials and observational studies
- Level of confidence in the evidence: Medium
- Benefits: Avoid unnecessary treatment with potential adverse events and costs
- Risks, harms, costs: Potential progression to impaction
- Benefits-harm assessment: Preponderance of benefit over harms
- Value judgments: Presence of cerumen is not in itself harmful and may not progress to impaction and in fact may resolve spontaneously. If it progresses, it can be managed at that time.
- Intentional vagueness: The word *routinely* was added to this statement to acknowledge that there may be circumstances where cerumen removal may be offered anyway, such as in a patient with hearing aids.
- Role of patient preferences: Substantial role for shared decision making. The patient may still opt for removal of the cerumen.
- Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, history of recurrent cerumen impaction.
- Policy level: Recommendation against
- Differences of opinion: None

STATEMENT 3C. NEED FOR INTERVENTION IN SPECIAL POPULATIONS: Clinicians should identify patients with obstructing cerumen in the ear canal who may not be able to express symptoms (young children and cognitively impaired children and adults) and promptly evaluate the need for intervention. *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 3C

- Quality improvement opportunity: Efficient use of health care resources/coordination of care (National Quality Strategy domains: Care Coordination and Efficient Use of Health Care Resources)
- Aggregate evidence quality: Grade C, cohort and observational studies
- Level of confidence in the evidence: High
- Benefits: Improved hearing and functional health status, improved evaluation of external auditory canal, tympanic membrane, and middle ear
- Risks, harms, costs: Potential overtreatment of cerumen that is asymptomatic; evaluation and treatment costs; substantial administrative burden in settings with a high prevalence of cognitively impaired individuals, such as nursing homes and institutional facilities
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of identifying and treating cerumen impaction in special populations
- Intentional vagueness: The term *young children* does not specify age but rather indicates children who are unable or too immature to express symptoms or who fail to disclose real symptoms out of

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fear of treatment. Additionally, the term *promptly* does not specify a time frame but allows for clinical judgment as to how expedient the evaluation should be.
- Role of patient preferences: None for the patient, but moderate for patient advocates
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 4. INTERVENTION IN HEARING AID USERS: Clinicians should perform otoscopy to detect the presence of cerumen in patients with hearing aids during a health care encounter. *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 4

- Quality improvement opportunity: Effective use of health care resources and prevent problems with hearing aid use in high-risk populations. (National Quality Strategy domains: Efficient Use of Health Care Resources and Clinical Processes/ Effectiveness)
- Aggregate evidence quality: Grade C, observational studies
- Level of confidence in the evidence: High
- Benefits: Prevent hearing aid dysfunction and associated repair costs
- Risks, harms, costs: Overtreatment of asymptomatic cerumen
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Cerumen can have a disproportionate effect on patients with hearing aids due to their underlying hearing loss and the impact of the cerumen on the hearing aid even if there is not an actual impaction.
- Intentional vagueness: The term *health care encounter* is somewhat vague but is intended to indicate any time that a patient with a hearing aid is assessed by a health care worker.
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 5A. RECOMMENDED INTERVENTIONS: Clinicians should treat, or refer to a clinician who can treat, the patient with cerumen impaction with an appropriate intervention, which may include 1 or more of the following: cerumenolytic agents, irrigation, or manual removal requiring instrumentation. *Recommendation based on randomized controlled trials and observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 5A

- Quality improvement opportunity: Patient and family engagement. Promote the use of effective therapy (National Quality Strategy domains: Patient and Family Engagement and Clinical Processes/ Effectiveness)
- Aggregate evidence quality: Grade B, randomized controlled trials with limitations and cohort studies
- Level of confidence in the evidence: High
- Benefits: Improved cerumen removal by using effective therapies and avoiding harm from ineffective or untested therapies
- Risks, harms, costs: Specific adverse effects related to treatments used; no cost associated with the decision to use appropriate therapy
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Therapy should be effective and minimize harm
- Intentional vagueness: This does not specify one method as superior as studies have not compared them head to head, and all may be effective.
- Role of patient preferences: Large (**Table 6** is a shared decision grid for patients and caregivers[22])
- Exceptions: Irrigation and cerumenolytics should not be used in the setting of a nonintact tympanic membrane.
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 5B: CONTRAINDICATED INTERVENTION (EAR CANDLING/CONING): Clinicians should recommend against ear candling/coning for treating or preventing cerumen impaction. *Recommendation against based on randomized controlled trials and observational studies with a preponderance of benefit over harm.*

Action Statement Profile for Statement 5B

- Quality improvement opportunity: Reducing harm and avoiding ineffective treatments (National Quality Strategy domain: Patient Safety and Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade C
- Level of confidence in evidence: Medium
- Benefits: Avoid ineffective therapy; avoid harms; cost savings; prevent delay of effective therapy
- Risk, harm, cost: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Strong consensus among the group to avoid potentially harmful and costly therapies with no proven benefit

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Table 6. Shared Decision Grid for Patients and Caregivers for Cerumen Management.

Frequently Asked Questions	Observation (KAS 3b)	Cerumenolytic Agents (KAS 6)	Irrigation (KAS 7)	Manual Removal (KAS 8)
Are there any age restrictions?	No	Yes. Not recommended for ages below 3 years and in patients with nonintact eardrums	No, but small children may be noncooperative	No, but small children may be noncooperative
What does it involve?	See provider periodically to examine the ear canal	Instill several drops of earwax-softening products once or twice daily for 3 to 5 days	Cleaning the ear canal with water to flush the earwax out of the ear canal	Earwax is removed by the clinician inserting a curette, forceps, or suction tip into the ear, dislodging the wax and retracting it
How long does the treatment take?	Time to examine the ear canal	Less than 5 minutes to instill drops	Should not take more than 30 minutes (includes preparation time)	The procedure takes a few minutes and does not need anesthesia
What are the benefits?	Reduce unneeded treatment	Noninvasive. Done at home, avoid clinician visits	Immediate resolution of symptoms caused by the cerumen impaction Self-irrigation can also be done at home	Immediate resolution of symptoms caused by the cerumen impaction
What are the potential risks and side effects?	Small amount of cerumen could progress to impaction	None reported	Temporary dizziness, pain, and/or eardrum rupture	Trauma to the ear canal skin, leading to bleeding or infection, discomfort from the instruments or noise of the suction, and/or rare tinnitus or hearing loss from the noise of the suction
What usually happens in the long term?	Nothing	Cerumen may reaccumulate and require additional treatment	Cerumen may reaccumulate and require additional treatment	Cerumen may reaccumulate and require additional treatment
Are there any special precautions?	None at this time	Should seek medical attention if excessive pain or discomfort or loss of hearing is noticed	Not recommended for patients with PE tubes, nonintact eardrum, and susceptible to ear infection. (See KAS 2B)	Cautious when treating patients who are taking blood thinners and susceptible to bleeding easily

Abbreviations: KAS, key action statement; PE, pressure equalization.

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- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: None
- Policy level: Recommendation against
- Differences of opinion: None

STATEMENT 6. CERUMENOLYTIC AGENTS: Clinicians may use cerumenolytic agents (including water or saline solution) in the management of cerumen impaction. *Option based on limited randomized trials with a balance of benefit and harm.*

Action Statement Profile for Statement 6

- Quality improvement opportunity: Encourage use of effective care; promote effective therapy (National Quality Strategy domain: Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade C, individual treatment arms of randomized trials showing beneficial outcomes, 1 RCT suggesting better outcomes over no treatment
- Level of confidence in the evidence: High
- Benefits: Safe and effective removal of impacted cerumen
- Risks, harms, costs: Potential external otitis, allergic reactions, and otalgia; cost of cerumenolytic agents other than water or saline solution, cost of procedure if performed in an office setting
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: The panel values cost control and safety in view of limited data on absolute and comparative efficacy.
- Intentional vagueness: None
- Role of patient preferences: Large role for shared decision making
- Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, persons with a history of allergic reactions to any component, persons with infection of the ear canal or active dermatitis, and persons with a nonintact tympanic membrane.
- Policy level: Option
- Differences of opinion: None

STATEMENT 7. IRRIGATION: Clinicians may use irrigation in the management of cerumen impaction. *Option based on randomized controlled trials with heterogeneity and with a balance of benefit and harm.*

Action Statement Profile for Statement 7

- Quality improvement opportunity: Promote effective therapy (National Quality Strategy domain: Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade B, with 1 RCT verifying absolute efficacy but multiple treatment arms of comparative studies verifying benefit over cerumenolytic alone
- Level of confidence in the evidence: High
- Benefits: Resolve cerumen impaction
- Risks, harms, costs: External otitis, vertigo, tympanic membrane perforation, otalgia, temporal bone osteomyelitis; cost of supplies and procedure
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: Panel enthusiasm was tempered by the lack of appropriate head-to-head trials comparing irrigation to manual removal or cerumenolytics.
- Intentional vagueness: None
- Role of patient preferences: Large
- Exceptions: Medical reasons for exceptions to this statement include, but are not limited to, patients with nonintact tympanic membrane, active dermatitis or infection of the ear canal and surrounding tissue, previous intolerance or adverse reaction to this technique, anatomic abnormalities of the ear canal, or history of surgery of the ear or ear canal, including ear tubes.
- Policy level: Option
- Differences of opinion: None

STATEMENT 8. MANUAL REMOVAL: Clinicians may use manual removal requiring instrumentation in the management of cerumen impaction. *Option based on case series and expert opinion with a balance of benefit and harm.*

Action Statement Profile for Statement 8

- Quality improvement opportunity: Promote effective therapy (National Quality Strategy domain: Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade C, observational case series and expert opinion
- Level of confidence in the evidence: High
- Benefits: Removal of cerumen impaction under direct visualization
- Risks, harms, costs: Bleeding, laceration, tympanic membrane perforation, otalgia; procedural cost; equipment cost
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: Recommendation acknowledges widespread practice of manual removal, but this is tempered by the relative absence of evidence.
- Intentional vagueness: None
- Role of patient preferences: Large
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

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STATEMENT 9. OUTCOMES ASSESSMENT: Clinicians should assess patients at the conclusion of in-office treatment of cerumen impaction and document the resolution of impaction. If the impaction is not resolved, the clinician should use additional treatment. If full or partial symptoms persist despite resolution of impaction, the clinician should evaluate the patient for alternative diagnoses. *Recommendation based on randomized controlled trials with limitations supporting a failure of clearance of cerumen in some cases and randomized controlled trials with limitations and a preponderance of benefit over harm.*

Action Statement Profile for Statement 9

- Quality improvement opportunity: Ensuring effectiveness of treatment to optimize patient outcomes and ensuring accurate diagnosis of cause of symptoms. (National Quality Strategy domain: Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade C. Observation in treatment arms of several randomized trials shows that retreatment is sometimes necessary and can be effective; first principles support evaluation for efficacy after treatment.
- Level of confidence in the evidence: High
- Benefits: Detect complications, encourage proper diagnosis, ensure effective therapy
- Risks, harms, costs: See sections on individual treatments; cost of additional treatment or evaluation
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of clinician assessment after treatment; avoid misdiagnosis
- Intentional vagueness: The term *additional treatment* does not specify what type of treatment. Additional treatment can be repeating the same treatment or trying an alternative method (ie, manual removal if irrigation was tried first or use of softening agents if not used initially).
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 10. REFERRAL AND COORDINATION OF CARE: Clinicians should refer patients with persistent cerumen impaction after unsuccessful management by the initial clinician to a clinician with specialized equipment and training for cleaning and evaluating the ear canal and tympanic membrane. *Recommendation based on individual arms of randomized trials and preponderance of benefit over harm.*

Action Statement Profile for Statement 10

- Quality improvement opportunity: Coordination of care and treating effectively (National Quality Strategy domains: Care Coordination and Clinical Processes/Effectiveness)
- Aggregate evidence quality: Grade C, individual arms of randomized trials
- Level of confidence in evidence: High
- Benefits: Promote successful removal of cerumen impaction; timely coordination of care; avoidance of harm from repeated unsuccessful interventions; avoiding patient and clinician frustration; avoiding misdiagnosis
- Risk, harm, cost: Cost of additional care; limited access to specialty care
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Skill and instruments will promote a better outcome. The level of care that can be rendered can be limited by the available equipment and training.
- Intentional vagueness: The specialized equipment and training is vague but may include access to binocular microscopy, suction, microinstruments, or access to the operating room. Type of training is not specified, but this refers to someone with advanced capabilities of removing cerumen. Unsuccessful treatment may entail a repeat visit or multiple treatments by the initial clinician to allow for use of softening agents or spontaneous improvement of impacted cerumen.
- Role of patient preferences: Small
- Exclusions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 11. SECONDARY PREVENTION: Clinicians may educate/counsel patients with cerumen impaction/excessive cerumen regarding control measures. *Option based on survey and comparative studies with unclear balance of benefit vs harm*.

Action Statement Profile for Statement 11

- Quality improvement opportunity: Patient and family engagement (National Quality Strategy domain: Patient and Family Engagement)
- Aggregate evidence quality: Grade C; observational studies, experimental pilot studies, and expert opinion
- Level of confidence in the evidence: High
- Benefits: Prevent development of cerumen impaction or recurrent cerumen impaction
- Risks, harms, costs: Time for counseling and potential risk of preventive measures if used

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- Benefits-harm assessment: Balance benefit over harm
- Value judgments: Importance of prevention in managing patients with cerumen impaction
- Intentional vagueness: The term *excessive cerumen* is used to indicate when cerumen is present but not actively causing symptoms to allow the clinician freedom to counsel patients who appear to be at risk for cerumen impaction even when the ear is not actually impacted
- Role of patient preferences: Large, opportunities for shared decision making
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

Acknowledgments

We gratefully acknowledge the support of Janene Batten, MLS, for her assistance with the literature searches. In addition, we acknowledge the work of the original guideline development group that includes Peter S. Roland, MD; Timothy L. Smith, MD, MPH; Seth R. Schwartz, MD, MPH; Richard M. Rosenfeld, MD, MPH; Bopanna Ballachanda, PhD; Jerry M. Earll, MD; Jose Fayad, MD; Allen D. Harlor Jr., MD; Barry E. Hirsch, MD; Stacie S. Jones, MPH; Helene J. Krouse, PhD, RN; Anthony Magit, MD, MPH; Carrie Nelson, MD, MS; David R. Stutz, MD; and Stephen Wetmore, MD, MBA.

Disclaimer

The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing cerumen impaction. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNS, Inc emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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Seth R. Schwartz, writer, chair; **Anthony E. Magit**, writer, assistant chair; **Richard M. Rosenfeld**, writer, methodologist; **Bopanna B. Ballachanda**, writer, panel member; **Jesse M. Hackell**, writer, panel member; **Helene J. Krouse**, writer, panel member; **Claire M. Lawlor**, writer, panel member; **Kenneth Lin**, writer, panel member; **Kourosh Parham**, writer, panel member; **David R. Stutz**, writer, panel member; **Sandy Walsh**, writer, panel member; **Erika A. Woodson**, writer, panel member; **Ken Yanagisawa**, writer, panel member; **Eugene R. Cunningham Jr.**, writer, AAO-HNSF staff liaison.

Disclosures

Competing interests: Bopanna B. Ballachanda, chief of audiology and consultant for Audiology Management Group; Jesse M. Hackell, shareholder of Pfizer and GSK, expert witness, medical malpractice consultant; Helene J. Krouse, AAO-HNS journal editor, spouse on AAO-HNS Board of Directors, SOHN Research Funding; Erika A. Woodson, consultant for Oticon Medical, speaker honoraria for CitiGroup; Eugene R. Cunningham Jr., salaried employee of AAO-HNSF.

Sponsorships: American Academy of Otolaryngology—Head and Neck Surgery Foundation.

Funding source: American Academy of Otolaryngology—Head and Neck Surgery Foundation.

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STATE OF WISCONSIN
HEARING AND SPEECH EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE HEARING AND SPEECH EXAMINING BOARD	:	PROPOSED ORDER OF THE HEARING AND SPEECH EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Hearing and Speech Examining Board to amend HAS 1.01 (2a) and (5). 5.02 (3), and 6.02 (6a) and create HAS 5.02 (2) (g) (Note), relating to hearing aids.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: Section 459.02, Stats.

Statutory authority: Sections 15.08 (5) (b) and 459.12 (1), 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."

Related statute or rule: 2023 Wisconsin Act 179

Plain language analysis:
The objective of the rule is to implement 2023 Wisconsin Act 82 by updating Wisconsin Administrative Code Chapters HAS 1, 5, and 6. These changes include:

- Updating the definition of "direct supervision" in HAS 1.01 (2a).
- Updating the definition of "practice" in HAS 1.01 (5).
- Adding a Note to HAS 5.02 (2) (g) regarding receipts for over the counter hearing aids.
- Updates to HAS 5.02 (3) regarding the ordering, fitting, and dealing of hearing aids.
- Updating the definition of "practice" in HAS 6.02 (6a).

Summary of, and comparison with, existing or proposed federal regulation:
Listed in the Federal, Food, Drug, and Cosmetic Act Subchapter V Part A under Section 360j (q) are regulations for over-the-counter hearing aids. According to these regulations, over-the-counter hearing aids are those devices used by those with hearing impairment that are available without the supervision of or prescription from a licensed individual.

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 [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 [645 Iowa Administrative Code Chapter 123].

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 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. Hearing aid dispensing does not include the sale of over-the counter hearing aids in Minnesota [Michigan Compiled Laws 333.1301 to 1309].

Summary of factual data and analytical methodologies:
While promulgating this rule, the Board reviewed 2023 Wisconsin Act 179 and made changes to the Wisconsin Administrative Code accordingly.

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 1.01 (2a) and (5) are amended to read:

HAS 1.01 (2a) "Direct supervision" means being physically present at the time the trainee makes ear impressions or measurements of human hearing for the purpose of ordering, fitting, and dealing in ~~or selling a~~ hearing ~~instrument~~ instruments.

(5) "Practice" means the practice of ordering, fitting, and dealing in hearing instruments, as defined in s. 459.01 (5) , Stats.

SECTION 2. HAS 5.02 (2) (g) (Note) is created to read:

HAS 5.02 (2) (g) (Note): Pursuant to s. 459.03 (1m), a receipt is not required if the hearing aid is an over the counter hearing aid as defined in 21 USC 360j (q).

SECTION 3. HAS 5.02 (3) is amended to read:

HAS 5.02 (3) A person engaging in the practice of ordering, ~~selling or~~ fitting, and dealing in hearing aids to a patient located in this state, whether in-person or via telehealth, shall be licensed under ch. 459, Stats., as a hearing instrument specialist or audiologist.

SECTION 4. HAS 6.02 (6a) is amended to read:

HAS 6.02 (6a) "Practice of ordering, fitting, and dealing in hearing aids" has the meaning given in s. 459.20 (3p), Stats.

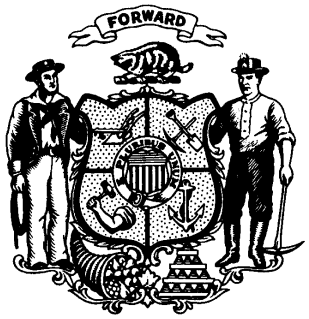
DRAFT

SECTION 5. 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)

DRAFT

State of Wisconsin



Date of enactment: **March 22, 2024**
2023 Senate Bill 373 Date of publication*: **March 23, 2024**

2023 WISCONSIN ACT 179

AN ACT ***to amend*** 459.01 (3), 459.01 (5), 459.02 (1), 459.02 (2), 459.03 (1), 459.05 (1m), 459.06 (3), 459.07 (2), 459.08 (1), 459.095 (3), 459.10 (1) (d), 459.10 (1) (e), 459.10 (1) (j), 459.10 (1) (k), 459.20 (2) (b), 459.20 (3p), 459.22 (2) (f), 459.30 (2) (intro.), 459.30 (2) (a) and 459.34 (2) (ce); and ***to create*** 459.02 (3), 459.03 (1m) and 459.24 (3r) of the statutes; **relating to:** practice of ordering, fitting, and dealing in hearing aids and selling and fitting over−the−counter hearing aids.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 459.01 (3) of the statutes is amended to read:

459.01 **(3)** "Hearing instrument specialist" means any person who is or is required to be licensed under s. 459.05 to engage in the practice of ordering, fitting, and dealing in ~~or fitting~~ hearing aids.

SECTION 2. 459.01 (5) of the statutes, as affected by 2023 Wisconsin Act 82, is amended to read:

459.01 **(5)** "Practice of ordering, fitting, and dealing in hearing aids" means the measurement of human hearing by means of an audiometer or by any other means accepted by the examining board solely for the purpose of ordering the use of hearing aids or making selections, adaptations, or sales of prescription hearing aids intended to compensate for impaired hearing. This term also includes making impressions for ear molds and includes cerumen management in the course of examining ears, taking ear impressions, or fitting prescription hearing aids by an individual who holds a certificate to engage in cerumen management under s. 459.115.

SECTION 3. 459.02 (1) of the statutes is amended to read:

459.02 **(1)** No person may engage in the practice of ~~selling or~~ ordering, fitting, and dealing in hearing aids or display a sign or in any other way advertise or represent himself or herself as a person who ~~practices the~~ engages in the practice of ordering, fitting ~~or sale of~~, and dealing in hearing aids unless he or she holds a valid license issued under this subchapter or a valid license or permit to practice audiology issued under subch. II. The license required by s. 459.05 shall be conspicuously posted in his or her office or place of business as registered with the department at all times. Duplicate licenses shall be issued by the department under this subchapter to valid license holders operating more than one office without additional payment.

SECTION 4. 459.02 (2) of the statutes is amended to read:

459.02 **(2)** Nothing in this subchapter or subch. II shall prohibit any corporation or mercantile establishment which maintains an established business address from engaging in the business of selling or offering for sale hearing aids at retail without a license, provided that for the purpose of ~~selling~~ ordering and fitting hearing aids it employs persons licensed under this subchapter or per-

* Section 991.11, WISCONSIN STATUTES: Effective date of acts. "Every act and every portion of an act enacted by the legislature over the governor's partial veto which does not expressly prescribe the time when it takes effect shall take effect on the day after its date of publication."

sons issued licenses or permits to practice audiology under subch. II.

SECTION 5. 459.02 (3) of the statutes is created to read:

459.02 **(3)** No license is required under this subchapter or subch. II to sell or fit an over−the−counter hearing aid, as defined in 21 USC 360j (q).

SECTION 6. 459.03 (1) of the statutes is amended to read:

459.03 **(1)** ~~A~~ Except as provided in sub. (1m), a hearing instrument specialist who engages in the practice of ordering, fitting, and dealing in hearing aids shall deliver to each person supplied with a hearing aid a receipt. The receipt shall contain the signature and show the business address and license title and number of the hearing instrument specialist, together with specifications as to the make and model of the hearing aid furnished and full terms of sale clearly stated. If a hearing aid which is not new is sold, the receipt and the container thereof must be clearly marked as "used" or "reconditioned" whichever is applicable.

SECTION 7. 459.03 (1m) of the statutes is created to read:

459.03 **(1m)** A hearing instrument specialist is not required to deliver a receipt to a person supplied with a hearing aid if the supplied hearing aid is an over−the−counter hearing aid, as defined in 21 USC 360j (q).

SECTION 8. 459.05 (1m) of the statutes is amended to read:

459.05 **(1m)** Whenever the examining board determines that another state or jurisdiction has requirements equivalent to or higher than those in effect in the state for the practice of ordering, fitting, and ~~selling~~ dealing in hearing aids, and that such state or jurisdiction has a program equivalent to or stricter than the program for determining whether applicants in this state are qualified to ~~fit and sell~~ engage in the practice of ordering, fitting, and dealing in hearing aids, the department may issue a license by reciprocity to applicants who hold valid licenses to order, deal in, or fit hearing aids in such other state or jurisdiction, who pay the fee specified in s. 440.05 (2), and who are otherwise qualified for licensure. No applicant for a license by reciprocity under this subsection shall be required to submit to or undergo a qualifying examination, if the applicant personally appears at the next meeting of the examining board after filing the application to answer any questions the examining board has.

SECTION 9. 459.06 (3) of the statutes is amended to read:

459.06 **(3)** The applicant for license by examination shall appear at a time and place as the examining board designates, to be examined by means of written and practical tests in order to demonstrate that he or she is qualified to engage in the practice ~~the~~ of ordering, fitting ~~of~~, and dealing in hearing aids. Such examinations shall be conducted at least twice a year and at such other times and places designated by the examining board.

SECTION 10. 459.07 (2) of the statutes is amended to read:

459.07 **(2)** Upon receiving an application under this section, accompanied by the fee under s. 440.05 (6), the examining board may grant a trainee permit which may entitle the applicant to engage in the practice of ordering, fitting ~~of~~, and dealing in hearing aids for a period of one year. A person holding a valid hearing instrument specialist license issued under this subchapter or a valid license to practice audiology issued under s. 459.24 (3) shall be responsible for the direct supervision and training of the applicant and shall be liable for all negligent acts and omissions of the trainee in the practice of ordering, fitting ~~of~~, and dealing in hearing aids.

SECTION 11. 459.08 (1) of the statutes is amended to read:

459.08 **(1)** A person who holds a license shall notify the department in writing or in accordance with other notification procedures approved by the department of the regular address of the places where he or she engages or intends to engage in the practice of ordering, fitting ~~or selling~~, and dealing in hearing aids. The licensee shall inform the board of any changes in these addresses within 30 days of the change.

SECTION 12. 459.095 (3) of the statutes is amended to read:

459.095 **(3)** In consultation with the department, promulgate rules that require each person issued a license under this subchapter to whom s. 459.09 (1) (b) applies to complete a specified continuing education program or course of study to ensure competence with respect to a matter related to the practice of ordering, fitting, and dealing in hearing aids if the examining board has received a significant number of consumer complaints about the matter or if the examining board otherwise determines that there is a need for such a requirement. Rules promulgated under this subsection shall establish criteria for the examining board's approval of the continuing education program or course of study and of sponsors and cosponsors of the continuing education program or course of study. The rules shall also require the examining board to administer, prior to the continuing education program or course of study, an examination on the matter that is the subject of the continuing education program or course of study and to waive a requirement to complete the continuing education program or course of study if a person granted a license under this subchapter passes the examination. A person who takes an examination specified in this subsection shall pay the fee specified in s. 440.05 (1) (b).

SECTION 13. 459.10 (1) (d) of the statutes is amended to read:

459.10 **(1)** (d) Been found guilty of an offense the circumstances of which substantially relate to the practice of ordering, fitting, and dealing in hearing aids.

Section 14. 459.10 (1) (e) of the statutes is amended to read:

459.10 **(1)** (e) Violated this subchapter or ch. 440 or any federal or state statute or rule which relates to the practice of ordering, fitting, and dealing in hearing aids.

Section 15. 459.10 (1) (j) of the statutes is amended to read:

459.10 **(1)** (j) Engaged in conduct which evidenced a lack of knowledge or ability to apply principles or skills of the practice of ordering, fitting, and dealing in hearing aids.

Section 16. 459.10 (1) (k) of the statutes is amended to read:

459.10 **(1)** (k) Engaged in unprofessional conduct. In this subsection, "unprofessional conduct" means the violation of any standard of professional behavior which through experience, state statute, or administrative rule has become established in the practice of ordering, fitting, and dealing in hearing aids.

Section 17. 459.20 (2) (b) of the statutes is amended to read:

459.20 **(2)** (b) Engaging in the practice of ordering, fitting, and dealing in hearing aids.

Section 18. 459.20 (3p) of the statutes is amended to read:

459.20 **(3p)** "Practice of ordering, fitting, and dealing in hearing aids" means the measurement of human hearing by means of an audiometer or by any other means accepted by the examining board for the purpose of ordering the use of hearing aids or making selections, adaptations, or sales of hearing aids intended to compensate for impaired hearing~~, and~~. This term also includes making impressions for ear molds.

Section 19. 459.22 (2) (f) of the statutes is amended to read:

459.22 **(2)** (f) Require an individual to be licensed under this subchapter to engage in the practice of speech–language pathology or audiology, other than engaging in the practice of ordering, fitting, and dealing in hearing aids, in a position for which the department of public instruction requires licensure as a speech and language pathologist or audiologist, if the individual's entire practice of speech–language pathology or audiology, other than engaging in the practice of ordering, fitting, and dealing in hearing aids, is limited to the duties of that position.

Section 20. 459.24 (3r) of the statutes is created to read:

459.24 **(3r)** Delivery of receipt. An audiologist is not required to deliver a receipt to a person supplied with a hearing aid if the supplied hearing aid is an over–the–counter hearing aid, as defined in 21 USC 360j (q).

Section 21. 459.30 (2) (intro.) of the statutes, as affected by 2023 Wisconsin Act 56, is amended to read:

459.30 **(2)** Fitting and sale of hearing aids. (intro.) An audiologist licensed under this subchapter, an audiologist who holds a valid compact privilege, or an individual granted a permit to practice audiology under this subchapter who engages in the practice of ordering, fitting, and dealing in hearing aids shall do all of the following:

Section 22. 459.30 (2) (a) of the statutes, as affected by 2023 Wisconsin Act 56, is amended to read:

459.30 **(2)** (a) ~~Deliver~~ Except as provided in sub. (3r), deliver to each person supplied with a hearing aid a receipt. The receipt shall contain the signature and show the business address, license or permit title, and number of the licensee, compact privilege holder, or permittee, together with specifications as to the make and model of the hearing aid and full terms of sale clearly stated. If a hearing aid that is not new is sold, the receipt and the container must be clearly marked as "used" or "reconditioned", whichever is applicable. The terms of the guarantee, if there is any given, shall be set out in not less than 8–point type.

Section 23. 459.34 (2) (ce) of the statutes is amended to read:

459.34 **(2)** (ce) Violated any federal or state statute, rule or regulation that relates to the practice of ordering, fitting, and dealing in hearing aids. This paragraph does not apply to speech–language pathologists.

(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to-

(A) exercise enforcement discretion as to any device subject to regulation under this chapter;

(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

(C) regulate software as a device under this chapter if such software meets the criteria under section 360c(a)(1)(C) of this title.

(p) Diagnostic imaging devices intended for use with contrast agents

(1) In general

The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a supplement to such an application) submitted under section 360e of this title with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 360(k) of this title, may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 360c(f)(2) of this title for an applicable medical imaging device, if such application, notification, or request involves the use of a contrast agent that is not-

(A) in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in concentration, rate of administration, or route of administration exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in region, organ, or system of the body exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

(C) in a patient population that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines such differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

(D) in an imaging modality that is different from those described in the approved labeling of the contrast agent.

(2) Premarket review

The agency center charged with premarket review of devices shall have primary jurisdiction with respect to the review of an application, notification, or request described in paragraph (1). In conducting such review, such agency center may-

(A) consult with the agency center charged with the premarket review of drugs or biological products; and

(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under section 355 of this title or section 262 of title 42, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging device that is the subject of such review a right of reference and the application is submitted in accordance with this subsection.

(3) Applicable requirements

An application submitted under section 360e of this title, a notification submitted under section 360(k) of this title, or a request submitted under section 360c(f)(2) of this title, as described in paragraph (1), with respect to an applicable medical imaging device shall be subject to the requirements of such respective section. Such application, notification, or request shall only be subject to the requirements of this chapter applicable to devices.

(4) Definitions

For purposes of this subsection-

(A) the term "applicable medical imaging device" means a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for an imaging use that is not described in the approved labeling of such contrast agent (or the approved labeling of any contrast agent in the same class as such contrast agent); and

(B) the term "contrast agent" means a drug that is approved under section 355 of this title or licensed under section 262 of title 42, is intended for use in conjunction with an applicable medical imaging device, and-

(i) is a diagnostic radiopharmaceutical, as defined in section 3 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.

(q) Regulation of over-the-counter hearing aids

(1) Definition

(A) In general

In this subsection, the term "over-the-counter hearing aid" means a device that-

(i) uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

(ii) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment;

(iii) through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

(iv) may-

(I) use wireless technology; or

(II) include tests for self-assessment of hearing loss; and

(v) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(B) Exception

Such term does not include a personal sound amplification product intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird-watching.

(2) Regulation

An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 709(b) of the FDA Reauthorization Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).

(June 25, 1938, ch. 675, §520, as added Pub. L. 94–295, §2, May 28, 1976, 90 Stat. 565 ; amended Pub. L. 101–629, §§3(b)(2), 4(b)(2), 5(c)(2), 6(b)(2), 11, 14(a), 18(e), (f), Nov. 28, 1990, 104 Stat. 4514 , 4516, 4518, 4519, 4522, 4524, 4529; Pub. L. 102–571, title I, §107(10), Oct. 29, 1992, 106 Stat. 4499 ; Pub. L. 105–115, title I, §125(b)(2)(E), title II, §§201(a), 203, 216(a)(1), title IV, §410(a), Nov. 21, 1997, 111 Stat. 2325 , 2332, 2334, 2349, 2372; Pub. L. 109–96, §1, Nov. 9, 2005, 119 Stat. 2119 ; Pub. L. 110–85, title III, §303(a), title VIII, §801(b)(3)(E), Sept. 27, 2007, 121 Stat. 860 , 921; Pub. L. 112–144, title V, §507(c), title VI, §§601, 606, 613(a), 617, July 9, 2012, 126 Stat. 1045 , 1051, 1054, 1060, 1062; Pub. L. 114–255, div. A, title III, §§3024(a), 3038(b), 3052(a), 3056, 3060(a), Dec. 13, 2016, 130 Stat. 1099 , 1110, 1124, 1128, 1130; Pub. L. 115–52, title V, §502(b), title VII, §§706(a), 709(a), Aug. 18, 2017, 131 Stat. 1037 , 1058, 1065; Pub. L. 117–180, div. F, title V, §5002, Sept. 30, 2022, 136 Stat. 2167 ; Pub. L. 117–229, div. C, title III, §303, Dec. 16, 2022, 136 Stat. 2312 ; Pub. L. 117–286, §4(a)(156), Dec. 27, 2022, 136 Stat. 4323 ; Pub. L. 117–328, div. FF, title III, §§3103, 3601(b), Dec. 29, 2022, 136 Stat. 5807 , 5861.)

Delayed Applicability of Amendment

For provisions related to delayed applicability of subsection (g)(9) of this section as added by section 3601(b) of Pub. L. 117–328, see Effective Date of 2022 Amendment note set out under section 355 of this title.

Editorial Notes

References in Text

July 9, 2012, referred to in subsec. (b)(3), was in the original "the date of enactment of this section", which was translated as meaning the date of enactment of Pub. L. 112–144, which amended subsec. (b) generally, to reflect the probable intent of Congress.

Section 709(b) of the FDA Reauthorization Act of 2017, referred to in subsec. (q)(2), is section 709(b) of Pub. L. 115–52, which is set out as a note below.

Codification

In subsec. (k), "section 3324(a) and (b) of title 31 and section 6101 of title 41" substituted for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067 , which Act enacted Title 31, Money and Finance, and Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854 , which Act enacted Title 41, Public Contracts.

Amendments

2022-Subsec. (f)(3). Pub. L. 117–286 substituted "Section 1013 of title 5" for "Section 14 of the Federal Advisory Committee Act" in concluding provisions.

Subsec. (g)(9). Pub. L. 117–328, §3601(b), added par. (9).

Subsec. (m)(6)(A)(iv). Pub. L. 117–328, §3103, substituted "October 1, 2027" for "December 24, 2022".

Hearing and Speech Examining Board
Rule Projects (updated 10/17/24)

Clearinghouse Rule Number	Scope #	Scope Expiration	Code Chapter Affected	Relating clause	Current Stage	Next Step
Not Assigned Yet	021-24	08/12/2026	HAS 1, 4, 5, and 9	Cerumen Management	Drafting	Board Approval of Preliminary Rule Draft for EIA Comment Posting and Clearinghouse Review
Not Assigned Yet	078-24	1/22/2027	HAS 1 and 4 to 6	Hearing Aids	Drafting	Board Approval of Preliminary Rule Draft for EIA Comment Posting and Clearinghouse Review
Not Assigned Yet	020-24	08/12/2026	HAS 6 to 8	Implementation of the Audiology and Speech-Language Pathology Licensure Compact	Emergency Rule Draft: Paused Permanent Rule Draft: Public Hearing Held at 10/30/24 Meeting	Emergency Rule: N/A Permanent Rule: Draft Final Rule and Legislative Report

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Kathy Pazak, Secretary of the Board		**2) Date when request submitted:** 10/9/2024 **Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting**	
3) Name of Board, Committee, Council, Sections: Hearing and Speech Examining Board			
4) Meeting Date: 10/30/2024	**5) Attachments:** ☐ Yes ☒ No	**6) How should the item be titled on the agenda page?** Late Renewal of License – Board Discussion	
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes ☒ No	**9) Name of Case Advisor(s), if applicable:** N/A	
10) Describe the issue and action that should be addressed: Ms. Pazak will discuss SLP renewal requirements under Wis. Stat. s. 440.08 (3) and Wis. Admin. Code HAS 7.03.			
11) Authorization			
Signature of person making this request		**Date**	
Supervisor (Only required for post agenda deadline items)		**Date**	
Executive Director signature (Indicates approval for post agenda deadline items)		**Date**	

Directions for including supporting documents:

1. **This form should be saved with any other documents submitted to the Agenda Items folders.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**