State of Nevada
Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board

NOTICE OF PUBLIC MEETING

Advisory Committee on Fitting and Dispensing Hearing Aids

Wednesday, January 12, 2022 ~ 4:30pm

Location: Board Office ~ 6170 Mae Anne Avenue, Suite 1, Reno, Nevada 89523

Supporting materials relating to this meeting will be physically available but in an effort to reduce costs and preserve resources, attendees are encouraged to access electronic copies on the Board's website at https://www.nvspeechhearing.org/about/Minutes.asp

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Meeting ID: 860 3113 0754 **Passcode:** 876321

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AGENDA

The **ADVISORY COMMITTEE ON FITTING AND DISPENSING HEARING AIDS** of the **NEVADA SPEECH-LANGUAGE PATHOLOGY, AUDIOLOGY AND HEARING AID DISPENSING BOARD** may: (a) address agenda items out of sequence (b) combine agenda items or (c) pull or remove items from the agenda at any time. The Board may convene in closed session to consider the character, alleged misconduct, professional competence or physical or mental health of a person. (NRS 241.020, NRS 241.030). Action by the Committee on any item may be to approve, deny, amend, or table.

1. **Call to Order, Confirmation of Quorum**

2. **Public Comment**
   No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020)

3. **Approval of the Minutes: Advisory Committee on Fitting and Dispensing Hearing Aids of August 11, 2021**
   (for possible action)

4. **Consideration for Recommendations to Board for Revisions to NRS 637B Related to NBC-HIS Certification for HAS License**
   (for possible action)

5. **Update and Consideration of Recommendations on FDA Rulemaking for Over-the-Counter Hearing Aids**
   (for possible action)

6. **Reports from Committee Chair and Members**
   a. Report from Committee Chair and Board Members
      (for possible action)

   b. Next Meeting: Proposed for August 2022 – pending new matters needing to be addressed sooner.
      (for possible action)

   c. Future Agenda Items
      (for possible action)

7. **Public Comment**

   No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020)

8. **Adjournment**
   (for possible action)

Public comment is welcomed by the Committee. Public comment will be limited to five minutes per person and comments based on viewpoint will not be restricted. A public comment time will be available prior to action items on the agenda and on any matter not specifically included on the agenda as the last item on the agenda. At the discretion of the President, additional public comment may be heard when that item is reached. The Board Chair may allow additional time to be given a speaker as time allows and in his/her sole discretion. (NRS 241.020, NRS 241.030)

Prior to the commencement and conclusion of a contested case or a quasi-judicial proceeding that may affect the due process rights of an individual, the Board may refuse to consider public comment. (NRS 233B.126)

Persons with disabilities who require special accommodations or assistance at the meeting should contact the Board office at (775) 787-3421 or email at board@nvspeechhearing.org no later than 48 hours prior to the meeting. Requests for special accommodations made after this time frame cannot be guaranteed.

THIS MEETING HAS BEEN PROPERLY NOTICED AND POSTED IN THE FOLLOWING LOCATIONS:

Nevada Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board Administrative Office 6170 Mae Anne Avenue, Suite 1 Reno, Nevada 89523	**Nevada Speech-Language Pathology, Audiology and Hearing Aid Dispensing Board Website** www.nvspeechhearing.org	**State of Nevada Public Notice Website** www.notice.nv.gov

This agenda has been sent to all members of the Committee and other interested persons who have requested an agenda from the Board. Persons who wish to continue to receive an agenda and notice must request so in writing on an annual basis.

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Anyone desiring additional information regarding the meeting is invited to call the Board office at (775) 787-3421.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 1

Call to Order, Confirmation of Quorum

Call to Order, Confirmation of Quorum.

ACTION: Meeting called to order.

ATTACHMENT(S): None.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 2

Public Comment

No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020).

ACTION: None – INFORMATIONAL ONLY

ATTACHMENT(S): None.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 3

Approval of the Minutes: Advisory Committee on Fitting and Dispensing Hearing Aids of August 11, 2021

The minutes of the meeting of August 11, 2021 meeting are presented for approval.

ACTION: Approve, table, or take no action on the matter.

ATTACHMENT(S):
1. *2021 8 11 Minutes ~ Not Yet Approved*

Minutes have not yet been approved and are subject to revision at the next meeting.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board

MINUTES OF PUBLIC MEETING
Advisory Committee on Fitting and Dispensing Hearing Aids

August 11, 2021

Members Present:	Michael Hodes; Nanci Campbell; Jennifer Joy-Cornejo; Melissa Maestas
Members Absent:	Vacant, BC-HIS
Staff Present:	Jennifer Pierce, Executive Director Stacey Whittaker, Licensing Coordinator Henna Rasul, Sr. Deputy Attorney General
Public Present:	None

Call to Order, Confirmation of Quorum
Michael Hodes called the meeting to order at 4:00pm. A roll call confirmed a quorum was present.

Public Comment
There were no public comments.

Approval of the Minutes
Michael Hodes called for a motion. Jennifer Joy-Cornejo made the motion, seconded by Nanci Campbell to approve the minutes of January 8, 2020. The motion passed.

Discussion of Cerumen Management (Earwax Removal) and Ear Lavage Regulations, and Practice Updates Following COVID-19

- **Ear Lavage**
  Mike Hodes summarized prior Board discussions around ear lavage in the midst of COVID-19 due to the potential for particulates in the air and asked whether the Committee members felt it was prudent for practitioners to not engage in these services as the pandemic is ongoing and in the presence of the Delta variant. Nanci Campbell responded that she has been performing these services and feels the practice is safe as she and the patient are wearing masks and there is no liquid discharge. The committee members agreed and there was no action taken.

- **Cerumen Management**
  Ms. Pierce summarized that neither our NRS or NAC specifically allow or prohibit cerumen management by Hearing Aid Specialists, nor is it included in the NRS definitions of a Hearing Aid

Specialist, but this issue has been raised somewhat frequently as the Board Office receives requests for guidance and reviews related complaints. Ms. Pierce suggested that a recommendation may be made to the Board to consider this as a potential NRS revisions in a future legislative session to clarify this practice. There has been recent, similar legislation proposed in Tennessee that would allow a Hearing Aid Specialist to engage in cerumen management in the course of fitting hearing aids provided they complete an approved cerumen management course.

Melissa Maestas shared that she believes this practice by Hearing Aid Specialists varies based on the experience level of the provider, and that she herself will conduct it with informed consent from the patient, and if she can do it safely based on where the cerumen is located in the ear. Mike Hodes asked whether she thinks it's a fairly common practice and she stated she believes it is.

There was consensus among the group that if a recommendation were made to the Board to specifically address this in NRS or NAC, that there be a requirement for specific training in order to conduct the procedure, as it was acknowledged that cerumen management can be a dangerous procedure.

It was agreed that this should be referred to the Board to consider as a legislative priority. Mike Hodes called for a motion. Melissa Maestas made a motion to recommend the Board consider revisions to NRS and/or NAC to address cerumen management performed by Hearing Aid Specialists with the inclusion of required training to do so. Jennifer Joy-Cornejo seconded the motion. The motion passed.

Discussion on Ear Scanning for Digital Earmold Impressions and Persons Authorized to Conduct These Procedures

Ms. Pierce shared that new technology now allows providers to produce ear molds by taking digital scans of a patient's ears rather than making an impression of the ear canal and outer ear with molding compound, and some companies marketing the technology are promoting that unlicensed persons may conduct these scans.

Our NRS definition of the Practice of Fitting and Dispensing Hearing Aids (NRS 637B.055(1)) includes "making impressions for earmolds" in the scope of practice for Fitting and Dispensing Hearing Aids and IHS's *Position Statement on the Practice of Hearing Aid Dispensing* includes "taking ear impressions and preparing, designing, and modifying ear molds" in its scope of practice for Hearing Aid Specialists. Both sets of language likely pre-date the technology to create digital ear scans and assumes ear molds are being made using traditional methods, raising the question of whether the current language is sufficient to cover all types of ear mold impression practices.

Jennifer Joy-Cornejo suggested that because the scan still involves contact with the patient, it should not be allowable for an unlicensed person. Board Counsel, Henna Rasul, Deputy AG was consulted, and stated that she believes the current NRS language is sufficient to include any means by which a provider takes an ear impression.

No action was taken.

Update and Discussion on FDA Approval of Over-the-Counter Hearing Aids

Ms. Pierce provided an update on the FDA Reauthorization Act of 2017 which directed the FDA to develop regulations that would make Over-the-Counter (OTC) hearing aids available to the public by 2020. This process was delayed due to the COVID-19 pandemic, but the FDA now plans to address the

issue during the current rulemaking session. It is expected that new regulations will be published in 2022, at which time OTC hearing aids are expected to become available to the public. Prior Board and Committee discussions have surmised that OTC hearing aids are a "non-issue" for Hearing Aid Dispensers, as they have effectively already been on the market for many years and would not significantly impact business, and in some cases could create a new line of business for those who choose to carry them.

Ms. Pierce also shared that President Biden signed an Executive Order on July 9, 2021, that included a directive to the Department of Health and Human Services to consider issuing proposed rules within 120 days for allowing hearing aids to be sold over the counter. The Committee was provided with related position statements issued by several prominent organizations.

Mike Hodes suggested that support at the federal level as evidenced by the Executive Order will likely ensure the regulations pass, despite objections and caution that patients should still seek care from qualified hearing professionals. There was discussion around the Committee recommending the Board issue a position statement on the matter, and consensus to recommend doing so with a reference to the *Joint Statement on Consumer-Administered Hearing Tests and Direct-to-Consumer Hearing Aid Sales* issued by ADA, AAA, AAOHNS, and ASHA.

Mike Hodes called for a motion. Nanci Campbell made a motion to recommend the Board issue a position statement on Over-the-Counter hearing aids that agrees with and refers to the ADA, AAA, AAOHNS, and ASHA Joint Statement. Jennifer Joy-Cornejo seconded the motion. The motion passed.

Review and Discussion of Recommendations for Potential Revisions to NAC 637B Related to Fitting and Dispensing Hearing Aids

- ***NAC 637B.0355(1)(b) Requiring NBC-HIS Certification for HAS Apprentice Applicants***
  This section was presented for the Committee's review as there have been a handful of recent HAS Apprentices whose licenses have expired and as a result, were unable to continue pursuit of a Standard HAS License per NRS 637B.238 which limits the apprenticeship to three years.
  NBC-HIS exam candidates must hold a current state license in addition to other requirements to be eligible to sit for the exam, and Nevada is reportedly one of only a few states that requires NBC-HIS Certification for HAS licensure. Once the Apprentice license expires, the candidate is no longer eligible to apply to sit for the exam, even if they have completed the apprenticeship and passed the written ILE exam.

  Mike Hodes asked how many states require NBC-HIS certification currently, and Stacey Whittaker shared that she has requested this information but has not yet received a response from NBC-HIS. There was discussion on the benefits of holding this certification and the Committee members did not feel there is significant benefit and acknowledged that it was not required in years past by the prior Hearing Aid Specialists Board.

  There was a suggestion to recommend the Board consider a legislative priority to removing this requirement in NRS, but the Committee would like to know more about national trends and requested that Board staff gather more information and bring this item back for additional discussion. No action was taken.

- ***NAC 637B.0396 Qualifications to act as sponsor of apprentice; limitation on number of apprentices or sponsors; and NAC 637B.0398 Duties of sponsor; review of work; direct supervision not required for certain duties; prohibition on operating office or satellite office without approval of Board.***
  This section was presented for the Committee to consider recommending whether a sponsor must be a Nevada resident, as at least one inquiry has been received with a Sponsor and Apprentice considering this situation, which is not specifically prohibited. This NAC was revised in June 2020 to add that the sponsor *"Be employed by the same employer as the apprentice during the term of the on-site training and work experience portion of the in-service training of the apprentice."* The NAC requires that the Sponsor be physically on-site at the same location as the Apprentice during the first year of in-service training, however also removes this requirement and allows for *"daily communication"* after the first year on the Sponsor's recommendation and approval by the Board.

  The Committee discussed the matter and agreed that while a Sponsor and Apprentice residing in different states might test the rule, it does not break it, and acknowledged that there could be many cases where an out-of-state Sponsor resides in closer proximity to the Apprentice than some cases where both reside in Nevada. There was consensus that no recommendation was needed for changes to this NAC.

- ***NAC 637B.0442 Delegation of duties by hearing aid specialist or dispensing audiologist to unlicensed office assistant, aide or technician.***
  This section was presented for the Committee to consider suggestions for the addition or deletion of allowed or prohibited duties that may be delegated to an unlicensed office assistant, aide, or technician. There were no recommended changes, and no action was taken.

Public Comment
There were no public comments.

Adjournment
The meeting adjourned at 4:58pm.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 4

Consideration for Recommendation to Board for Revisions to NRS 637B Related to NBC-HIS Certification Requirement for HAS License

This section was presented for the Committee's review in the August 11, 2021 meeting as there have been a handful of recent HAS Apprentices whose licenses have expired and as a result, were unable to continue pursuit of a Standard HAS License per NRS 637B.238, which limits the apprenticeship to three years. NBC-HIS exam candidates must hold a current state license in addition to other requirements to be eligible to sit for the exam. Once the Apprentice license expires, the candidate is no longer eligible to apply to sit for the exam, even if they have completed the apprenticeship and passed the written ILE exam.

This certification is a requirement in Nevada for both the HAS Standard and Temporary licenses. An applicant for a Provisional HAS license is not required to hold certification if they are 1) licensed in another state but not holding current NBC-HIS certification, AND 2) are completing the NBC-HIS certification requirements.

We were aware that Nevada was reportedly one of only a few states that requires NBC-HIS Certification for HAS licensure, and confirmed via email from Mary Stone, NBC-HIS Certification Coordinator, on September 9, 2021 that we are only *one of two* states with this requirement:

> *"Utah is the only state that requires Board Certification in Hearing Instrument Sciences (BC-HIS) for initial licensure, outside of the nuanced Nevada law. IHS does not support using Board Certification as the entry level examination/credential, as it is meant to be an optional pursuit for the advanced hearing aid dispensing professional. IHS would be happy to engage with the Nevada board about modifying their standard to bring it in line with national standards for licensure."*

The requirement for NBC-HIS certification for HAS licensure is located in NRS 637B.193(2): *"An applicant for a license to engage in the practice of fitting and dispensing hearing aids must: 2. Except as otherwise provided in NRS 637B.201, be certified by the National Board for Certification in Hearing Instrument Sciences."* As such, any change would have to be undertaken during a legislative session.

ACTION: Take action, table the matter, or take no action on the request.

ATTACHMENT(S): None.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 5

Update and Consideration of Recommendations on FDA Rulemaking for Over-the-Counter Hearing Aids

This matter was heard during the August 2021 Committee meeting and a vote was taken to recommend the Board issue a position statement on Over-the-Counter hearing aids that agrees with and refers to the ADA, AAA, AAOHNS, and ASHA Joint Statement. The matter was on the agenda but tabled at the Board's October 2021 meeting. It is again on the January 19, 2022 Board Meeting agenda.

On October 20, 2021, the FDA released Proposed rules for Over the Counter Hearing Aids and Draft Guidance "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.", with public comments due on each by January 18, 2022, 11:59pm ET.

IHS issued *Guidance for Comments on FDA Proposed Hearing Aid Rules*, attached, which provides a helpful summary of the proposed regulations and related concerns.

The matter is brought to the Committee as an update and to consider any revisions to the earlier recommendation regarding the joint statement for consideration by the Board at the January 19th meeting.

ACTION: Take action, table the matter, or take no action on the request.

ATTACHMENT(S):
1. *Joint Statement on OTC Hearing Aids*
2. *IHS Guidance for Comments on FDA Proposed Hearing Aid Rules*

Joint Statement on Consumer-Administered Hearing Tests and Direct-to-Consumer Hearing Aid Sales

The Academy of Doctors of Audiology (ADA), American Academy of Audiology (AAA), American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), the American Speech-Language-Hearing Association (ASHA), and International Hearing Society (IHS) stand together, committed to increasing awareness of the benefits of amplification, and to finding safe and effective solutions that help the 75% of consumers who could benefit from hearing aids but cannot afford to purchase them or have chosen not to use them.

While we appreciate the desire of persons, companies, and organizations to reach more individuals in need of hearing aids, our organizations believe that patients must have access to a comprehensive hearing evaluation performed by a hearing health professional, be appropriately fitted by an individual licensed/registered in the state to dispense hearing aids, and have access to auditory rehabilitation and counseling to ensure appropriate fit and use of the hearing aid device. We urge all persons, companies, and organizations who are interested in assisting patients to work with the hearing health community in ensuring that patients have access to the professional services of all qualified hearing health professionals.

Federal and state laws related to the dispensing of a hearing aid are currently in place to protect and ensure consumer safety. Regulations issued by the Food and Drug Administration require that patients under the age of 18 receive a medical evaluation by a licensed physician prior to the purchasing of a hearing aid from a dispenser. A medical evaluation by a licensed physician is also recommended for adults prior to a hearing aid purchase. Many state laws also recognize the importance of consumer protection and safety by placing restrictions on the dispensing of hearing aids by direct mail and/or the internet.

All of our organizations have both health and efficacy concerns about the use of consumer-administered hearing tests and the direct sale of hearing aids to the consumer without the involvement of a licensed hearing health professional – an audiologist, hearing aid specialist, or otolaryngologist. We encourage our respective members and other hearing health care providers to work collaboratively to ensure patient safety and enhance consumer protections related to the purchase of hearing aids and related devices.

Details and Guidance from International Hearing Society on the FDA Proposed Rules and Public Comments

This document contains a summary of the proposed addition and changes to the current FDA hearing aid rules. We encourage you to review each section of this document and the proposed rules themselves as you consider and develop comments for submission to the FDA.

Your involvement in this process is very important, and we appreciate you taking time to be part of this historic and critical moment in the hearing aid market, industry, and profession.

Note: In this document, we use the term "traditional Hearing Aids" to represent hearing aids as we presently know them today, as are commonly dispensed by licensed hearing aid professionals (audiologists and hearing aid specialists).

With questions on any of the information contained in this document, contact IHS at advocacy@ihsinfo.org.

Background

In 2017 Congress passed H.R. 3, the Food and Drug Reauthorization Act of 2017, which contained a directive in Section 709 to the U.S. Food and Drug Administration (FDA) to create a new classification of "over-the-counter hearing aids" to be available and sold directly to the public without the involvement of a licensed professional, and stipulated certain safety and effectiveness requirements be addressed in the new classification and supplemental regulations.

Prior to this action, in December 2016 the FDA released non-binding "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids Guidance for Industry and Food and Drug Administration Staff." This non-binding guidance stated the FDA no longer intended to enforce the physician clearance requirement for adults, and the waiver and paperwork requirements for (traditional) hearing aids.

On October 20, 2021, the FDA released its proposed over-the-counter hearing aid rules, which also contained substantive changes to the approach for regulating traditional hearing aids, currently captured in 21 CFR 801.420 and 21 CFR 801.421, which also align with their 2016 Guidance.

View the Proposed Rules

The proposed rules and the FDA's explanation can be viewed through the Docket page under the "Content" section found in the main body of the page: https://www.regulations.gov/document/FDA-2021-N-0555-0001, or downloaded: https://downloads.regulations.gov/FDA-2021-N-0555-0001/content.pdf. The proposed rules begin on Federal Register page 58177.

Summary of the Proposed Rules

As stated in the background, the FDA's proposal modifies the current regulatory structure and requirements for traditional Hearing Aids and contains the addition of Over-the-Counter Hearing Aids.

Proposed Changes to (Traditional) Hearing Aid Regulation

The FDA is proposing to:

- Rename (traditional) hearing aids as "Prescription Hearing Aids" and modify their definition to newly be: "a hearing aid that is not an over-the-counter (OTC) hearing aid…or one that satisfies the requirements [for OTC hearing aids]."
- Repeal 21 CFR 801.420 and 21 CFR 801.421 (commonly referred to as the "hearing aid rule"), and capture regulation for Prescription Hearing Aids under new section 21 CFR 801.422.
- Repeal the Conditions for Sale for hearing aids, including the requirement for physician clearance (for all ages) and any need for a waiver and associated recordkeeping. This means Prescription Hearing Aids would no longer be "restricted devices."
- Recognize State and local jurisdictions' abilities to set forth requirements for obtaining written or oral authorization of a practitioner licensed by State law to administer the use of the devices.
- Modify labeling requirements by retaining (but moving) some current labeling, incorporating some labeling also used for OTC hearing aids, and revising some language directed at users to improve understandability. This includes enacting new and updated labeling requirements to inform consumers and dispensers of intended uses and warnings. The labeling captures "red flag conditions" in order to advise consumers and dispensers when a physician referral is warranted.
- Repeal past FDA rulings provided to individual states on whether their laws may continue to be enforced by the state if they are different from or in addition to (preempt) the federal requirements. For example, the FDA in the past may have authorized a state to require a licensed dispenser to provide certain information in a receipt to a hearing aid purchaser; whereas FDA may have rendered void a law that required a physician examination but permitted no waiver.

What would this mean?

For the provision of Prescription Hearing Aids, the FDA has struck special controls requiring a physician referral for consumers of any age, and use of the waiver for an informed adult. Instead, FDA is granting greater oversight authority to the states to determine who may provide written or oral authorization for a Prescription Hearing Aid, coupling that authorization with reliance on the licensed professional's clinical decision-making to determine whether referral is necessary and/or whether a hearing aid is the appropriate treatment for an individual presenting with hearing loss. The FDA rule, as proposed, would now focus solely on labeling requirements for the packaging and on the device, and federal enforcement activities would center around ensuring proper labeling of the device in accordance with the proposed rules.

This also means that – if hearing aid manufacturers choose not to apply and reclassify their hearing aids as OTC hearing aids – manufacturers and retailers could continue to market their devices as Prescription Hearing Aids with no meaningful federal controls. Instead oversight would fall to state attorneys generals and licensing agencies as they attempt to apply local rules governing distribution to non-licensed retailers, and those that may be located in other states.

Proposed New Category of Over-the-Counter Hearing Aids

The FDA is proposing the following requirements and controls for this new hearing aid category:

- Establish this new "Over the Counter Hearing Aid" classification and related controls under new section 21 CFR 800.30.
- Intended users are defined as adults with perceived mild to moderate hearing loss.

- Define which commercial activities related to an OTC device a state may not attempt to regulate, as "servicing, marketing, sale, dispensing, use, customer support, or distribution" of OTC hearing aids. States are also restricted from establishing and/or enforcing laws that would in any way impede the sale of an OTC device.
- Define persons who may not be subjected to state licensing laws as it relates to OTC hearing aids if advertising themselves as marketers, sellers, dispensers, distributors, or customer service representatives.
- Establish outside the box, inside the box, and on the device labeling requirements. These include but are not limited to: warnings about intended users, symptoms suggesting perceived mild to moderate loss, advice on seeking professional services, red flag warnings, return policies, warning about excessive sound output, user expectations, and adverse reporting, specifications, and maintenance details.
- Specifies output limits as 115dB SPL at any frequency; and 120 dB SPL at any frequency for devices with input-controlled compression and user-adjustable volume control. The proposal does not address gain limitations.
- Sets forth electroacoustic performance limits and other specifications, as well as design requirements; and relies on ANSI/CTA 2051 (PSAP) standard for measuring performance.

What would this mean?

The FDA is relying on labeling to convey controls and usage information to the consumer, and has defined a narrow window for states to play a role in regulating businesses and individuals who distribute OTC hearing aids based on their marketing and associated services. This will likely cause confusion for the states in developing and applying laws appropriately.

Further, the performance measurements of OTC hearing aids would rely on a different standard set than prescription hearing aids, which could impede a consumer's ability to provide a side-by-side comparison of an OTC hearing aid and a prescription hearing aid.

IHS Priorities for Public Comment

IHS encourages individual providers, state associations, licensing agencies, and other stakeholders to submit comments to the FDA on its proposed rules on OTC hearing aids and changes to the existing hearing aid rule.

How to Maximize Your Comment's Effectiveness

To maximize their effectiveness, your comments should be original (not based on a form letter), and be clear about which sections of the proposed rules that you agree with and those you disagree with. Your positions should be explained. The FDA bases its decisions largely on "law and science" and FDA staff look for "reasoning, logic, and good science" in submitted comments. If you have articles or other references that support your arguments, those should be included.

As active hearing care professionals, both your experience and knowledge are critically important to share as well. If your comments would be well explained or supported by highlighting professional or client experiences, be sure to maintain all necessary confidentialities in accordance with HIPAA and professional ethics to include removing and/or redacting any patient identifying information.

Note: Anything sent to the FDA is considered public and may be posted online.

IHS Suggested Areas of Focus for Comments

We recommend submitting comments on as many of the below points as desired. You may also have other areas of concern based on your read of the proposal, or want to highlight areas of the regulations you agree with. For each of the areas of concern below, we included the section reference where applicable, which should be noted in your comments.

As a reminder, your comments should not be simply copied and pasted from the below listing. As stated in the previous section, the FDA prefers unique comments rather than form letters.

Please note, the below is not an exhaustive of all IHS' concerns with the proposed rules. IHS will include additional concerns in its comments to the FDA, which will be shared with stakeholders upon completion.

Hearing Aid Regulation in General

1. Problem: FDA proposed to use the terms "dispensing" and "dispenser" in the OTC rules to represent OTC retailers and commercial activities that would not trigger a licensing requirement. Misuse of these terms in the OTC Hearing Aid regulations, however, will cause confusion, disregard the common use of these terms associated with professionally-fit prescription hearing aids, and create major difficulties for states in applying laws related to the professional services delivered alongside the sale of an OTC hearing aid.

   Solution: Use of the terms "dispenser" and "dispensing" should be used solely in relation to individuals and activities associated with Prescription Hearing Aids. The proposed rules for OTC Hearing Aids (Section 800.30 (a) and (h)) incorporate "dispensing" into its list of commercial activities for which a state may not require a license or impose specialized obligations. However, the act of dispensing does not purely reflect the conveyance of a device; it is a term that has been used for decades in federal and state law and rules, and by professional associations, to reference the package of professional services associated with attaining a hearing aid, including conducting and interpreting hearing assessment procedures to determine the type and extent of hearing loss, and selecting, fitting, adapting, and maintaining hearing aids. We recommend the "dispenser" and "dispensing" terms be struck from proposed 800.30, or be replaced with more appropriate terms that are not already in use in the hearing aid field, such as conveyance, conveyor, or seller.

2. Problem: Labeling in the proposed rule that directs consumers to seek professional care in certain circumstances, references both doctors and physicians. This could confuse the consumer and result in their seeking care from an unintended type of provider.

   Solution: References to "doctor" in OTC Hearing Aid and Prescription Hearing Aid Labeling (Sections 800.30 (c) and 801.422 (2)) should be replaced with "physician." The term doctor is used by both non-physicians (including audiologists and chiropractors) and medical physicians, and its use in labeling directed at consumers under the age of 18 is likely to cause confusion. "Physician" is a commonly understood term to identify a medical doctor. Consistent use of the term "physician," which is incorporated into other portions of the labeling, including in these warning sections, would alleviate any ambiguity about the type of healthcare professional a child should see for medical evaluation.

3. Problem: Hearing aid electroacoustic performance measurement standard sets are not consistent as proposed. Over-the-Counter Hearing Aid section 801.430 (e)(4) and (e)(5) direct manufacturers to measure frequency response bandwidth and smoothness against the ANSI/CTA-2051 PSAP standard. Prescription Hearing Aid measurements would (continue to) rely on the ANSI/ASA S3.22 2014 standard. These inconsistencies will limit consumers' ability to compare features between hearing aid

product offerings and treats these two types of hearing aids differently. Further, the ANSI/CTA standard set is designed for a non-medical consumer electronics product, not a medical device.

Solution: OTC Hearing Aids and Prescription Hearing Aids electroacoustic performance should be measured against the "current ANSI/ASA S3.22 hearing aid standard." Both devices are medical devices and should be measured against the same standard, and one that is designed for a medical device.

Prescription Hearing Aids

4. Problem: We are concerned that removing the Special Controls for Prescription Hearing Aids without replacing them with an appropriate alternative would enable the direct-to-consumer (DTC) hearing aid market to continue to exist and grow. This means that consumers will be choosing between OTC, DTC, and professional-involved hearing aid delivery models, leading to more confusion than they currently face. DTC Prescription Hearing Aids will fall outside the regulatory controls for OTC hearing aids, which include important protections for do-it-yourself consumers. Prescription Hearing Aid manufacturers may opt to remain as such but could easily bypass the state laws since states will have little to no control over unlicensed retailers and those operating across state lines.

   Solution: Prescription hearing aids (the requirements for which are set forth in Section 801.422 of the proposed rules) should continue to be regulated as restricted devices. Special controls should require Prescription Hearing Aids to be sold only pursuant to the written or oral authorization of a licensed hearing healthcare professional (a physician, hearing aid specialist, or audiologist). This approach aligns with the FDA's support for states to enact and enforce requirements for obtaining written or oral authorization of a licensed practitioner to administer use of the devices, outlined in its rationale. Because the proposed approach would create an overly burdensome process to modify 50 sets of state laws and rules that have been in place for decades and reflect the current federal standards, a new special control contained in the federal Prescription Hearing Aid rule would be the quickest, easiest, and most efficient means to this goal.

5. Problem: States have built their regulatory structure around the application of federal rule sections 21 CFR 801.420 and 801.421. The FDA is proposing to strike these sections and move regulatory controls related to Prescription Hearing Aids to a new section, 21 CFR 801.422. This will create inconsistencies in state laws and rules that contain specific references, and would create an undue burden on states to update these references, which can take extensive time and money to facilitate.

   Solution: Retain the use of 21 CFR 801.420 and/or 801.421 for Prescription Hearing Aid-specific regulations.

6. Problem: The proposed labeling for Prescription Hearing Aids (801.422 Section (c)(2)(i)(D)) instructs users to report minor adverse events (i.e. cuts, scratches) to the FDA rather than instructing consumers to seek care by their hearing aid provider or a medical professional, and does not suggest the reporting of serious events. While the approach of reporting minor events may make sense for OTC hearing aids, prescription hearing aids come with less risk due to professional intervention. Reporting should focus on more serious device events.

   Solution: Adverse event reporting for Prescription Hearing Aids should be restricted to reporting incidences of significant injury and/or death. This approach aligns with adverse event reporting for other medical devices, which capture serious events, and would ensure that the database captures the most important events rather than myriad minor injuries that will diminish the value of the database for resolving major problems that can result in serious harm.

Over the Counter Hearing Aids

7. Problem: Definitions and labeling indicate OTC hearing aids are intended for individuals with "perceived mild to moderate hearing loss," which will cause consumer confusion and suggests to manufacturers and retailers that these devices may be designed for more significant hearing losses. For example, outside the box labeling requires a listing of symptoms that suggest "perceived mild to moderate hearing loss."

   Solution: Recommend striking all uses of the term "perceived" in Section 800.30, Over-The-Counter Hearing Aid Controls. While the Federal legislation authorizing this new category sought to allow consumers to self-identify their loss and self-select OTC hearing aids as a potential solution, this literal application in the rules could create major consumer confusion about the effectiveness of this device. Striking this term would still permit consumer choice and would also minimize confusion about the maximum effectiveness of the device for hearing losses beyond those classified as mild or moderate. For example, an individual might perceive their severe hearing loss as being moderate, and may believe the device would still be effective because he/she has *perceived* his or her loss as moderate. Labeling should instead inform the consumer of symptoms suggesting "mild to moderate hearing loss."

8. Problem: From a safety standpoint, excessive output limits, and lack of gain limits and volume control place consumers at risk of overamplification and permanent hearing damage. Also, the rules suggest a non-standardized approach to insertion depth of the device (no deeper than to the bony-cartilaginous junction of the external canal).

   Solution: Specifications and limitations for OTC hearing aids should include/reflect the following:
   - The 2 cc coupler HFA full on gain, as measured at an input level of 50 dB SPL per ANSI S3.22-2014, is 25 dB or lower.
   - The peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, is not greater than 110 dB SPL, in combination with input compression and volume control.
   - All devices should have a volume control feature on the device.
   - Insertion depth should be limited to 15-17 mm.

9. Problem: The proposal lacks the necessary clarity to ensure that licensed professionals are not held to higher standard than OTC retailers when engaged in non-professional activities related to OTC hearing aid sales. Conversely, state licensing agencies need clarity on services provided in accompaniment to the sale of an OTC hearing aid for which they may require a license. For example, under the current proposal, states are not permitted to require licensure for services that would impede the sale of an OTC hearing aid; however, if an OTC seller performs a hearing evaluation on a consumer before the sale of an OTC hearing aid, it is unclear whether a state could require the seller to maintain a license for such an activity.

   Solution: The rule should send a clear message to state regulating agencies about which activities require a license, and which are exempted from licensing oversight based on the nature of the activity. Professional services, including the performance of hearing evaluations, hearing aid fittings, counseling, and other services that rely on the engagement of a licensed professional, should be activities subject to licensure, regardless of whether the consumer is purchasing an OTC hearing aid or prescription hearing aid.

10. Problem: OTC hearing aids lack a mandatory minimum return period, which places consumers at risk of financial harm if they purchase a device that does not work for them. State laws generally have

mandated varying minimum return periods. Consumers should be provided the same protections regardless of hearing aid device type.

Solution: Require OTC manufacturers to maintain a minimum return period, established by FDA. This return period should be no less than 30 days to allow for the individual to attain the device, try the device, and ship it back if needed. We agree with the FDA's approach of requiring the manufacturer to identify the return policy on the outside of the OTC hearing aid box.

Additional Questions

IHS encourages stakeholders who have reviewed the proposed rules to also ask questions or pose scenarios needing clarity from the FDA in their comments. A few examples:

- If a state requires the purchaser of a hearing aid to sign a bill of sale, should this requirement be applied to the sale of an OTC hearing aid as well?
- If a state requires a mandatory return period of 60 days for hearing aids, would that requirement apply to OTC hearing aids?
- Under the current proposal, could a state still apply a law requiring all consumers to attain medical clearance or use of a waiver, or refer if a "red flag" is present, for the purchase of a prescription hearing aid, or would that requirement be preempted?

Instructions on Submitting Comments to the FDA

Key Dates/Deadlines

FDA released proposed rules on October 20, 2021.
Comments are due by 11:59pm ET, January 18, 2022.

Accessing the Proposed Rules and Submitting Comments

The proposed rules and explanation can be found in the public docket, FDA-2021-N-0555 for "Establishing Over-the-Counter Hearing Aids, accessible online at https://www.regulations.gov/document/FDA-2021-N-0555-0001. The public can submit comments through the same Docket page by clicking on the "Comment" button found under the proposal title and following the instructions (see Image 1).

Electronic Submissions

Comments submitted electronically, including attachments, to https://www.regulations.gov (or via the Docket page) will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

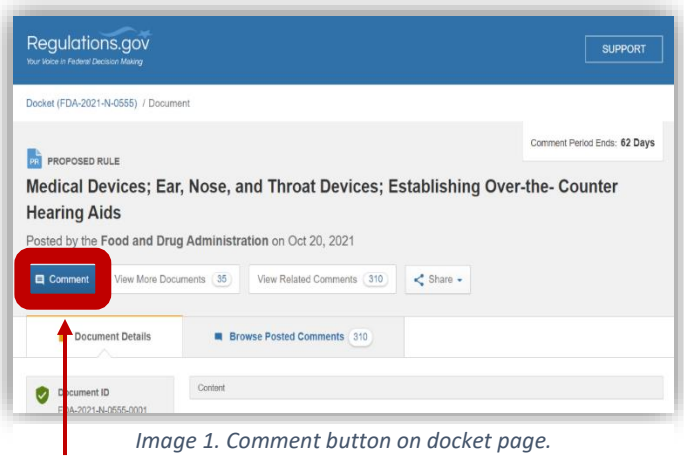

Image 1. Comment button on docket page.

*If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

For Mail/Hand Delivery/Courier (for written/paper submissions) address to: Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

All submissions received must include the Docket No. FDA-2021-N-0555 for “Establishing Over-the-Counter Hearing Aids.” Received comments, those filed in a timely manner, will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable.

Confidential Submissions: To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

With questions about commenting, visit the Regulations.gov FAQs page: https://www.regulations.gov/faq.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 6

Reports from Committee Chair and Members

a. Report from Committee Chair and Board Members

b. Next Meeting: Proposed for August 2022 – pending new matters needing to be addressed sooner.

c. Future Agenda Items

ACTION: Take action, table the matter, or take no action on the request.

ATTACHMENT(S): None.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 7

Public Comment

No vote may be taken upon a matter raised during a period devoted to public comment until the matter itself has been specifically included on an agenda as an item upon which action may be taken. (NRS 241.020)

ACTION: None – INFORMATIONAL ONLY.

ATTACHMENT(S): None.

State of Nevada
Speech-Language Pathology, Audiology & Hearing Aid Dispensing Board
Advisory Committee on Fitting and Dispensing Hearing Aids

AGENDA ITEM 8

Adjournment

ACTION: Meeting adjourned.

ATTACHMENT(S): None.