



## Board of Hearing Aid Dispensers and Audiologists

Mailing Address:  
810 North Main Street, Suite 298  
Spearfish, SD 57783

Phone: (605) 642-1600 E-Mail: [office@sdlicensing.com](mailto:office@sdlicensing.com)  
Home Page: [www.doh.sd.gov/boards/audiology](http://www.doh.sd.gov/boards/audiology)

### Draft-Teleconference BOARD MEETING AGENDA

TO: All Board Members  
FROM: Carol Tellinghuisen  
DATE: December 21, 2022  
MEETING DATE: January 9, 2023  
LOCATION: Teleconference

Persons interested in joining the meeting may do so by calling the teleconference number at 1-866-705-2554. Key in the Passcode: 263756

MEETING TIME: 12:00 PM CST / 11:00 AM MST

#### Agenda Item Number

1. Call to Order/Welcome and Introductions-Decker
2. Roll Call
3. Introduction – Mariah Pokorny, Director of Accreditation and Reporting, DOH
4. Corrections or additions to the agenda
5. Approval of the agenda
6. Public comment at 12:05 p.m. CST
7. Approval of the minutes from July 11, 2022
8. FY financial update
9. OTC Hearing Aids – FDA Letter and American Academy of Audiology Handout
10. Update on Audiology/HAD Bill
11. Discussion on committee for statute revisions
12. Discussion on practicum for licensed out-of-state applicants
13. Election of Officers
14. Schedule next meeting(s)
15. Executive Session pursuant to SDCL 1-25-2
  - a. Executive Secretary Contract Renewal
16. Any other business coming in between date of mailing and date of meeting
17. Adjourn



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## DRAFT-OFFICIAL BOARD MINUTES FOR JULY 11, 2022 Teleconference

**MEMBERS PRESENT:** Todd Decker, President  
Dan Smith, Secretary/Treasurer  
Clint Hinker, Member  
Norman Sorensen, Member  
Julie Paluch, Lay Member

**MEMBERS ABSENT:** None

**OTHERS PRESENT:** Carol Tellinghuisen, Executive Secretary  
Brooke Tellinghuisen Geddes, Executive Assistant  
Abby Rehorst, Executive Assistant  
Megan Borchert, Assistant Attorney General

President Decker called the meeting to order at 11:00 a.m. MDT.

**ROLL CALL:** Decker asked Tellinghuisen Geddes to call the roll. Decker, yes; Smith, yes; Hinker, yes; Sorensen, yes; Paluch, yes. A quorum was present.

**CORRECTIONS OR ADDITIONS TO THE AGENDA:** None.

**APPROVAL OF THE AGENDA:** Hinker made a motion to approve the agenda. Paluch seconded the motion. **MOTION PASSED** by unanimous voice vote.

**PUBLIC COMMENT:** Decker called for public comment. There were no public comments.

**APPROVAL OF MINUTES:** Sorensen made a motion to approve the minutes from January 10, 2022. Smith seconded the motion. **MOTION PASSED** by unanimous voice vote.

**FY FINANCIAL UPDATE:** Tellinghuisen Geddes reported year to date figures as of April 30, 2022; revenue of \$10,240.13; expenses of \$24,448.74 and cash balance of \$89,699.46. Tellinghuisen Geddes stated that the June report shows revenue of \$32,070.97 with a cash balance of \$108,664.73.

**UPDATE ON ONLINE RENEWAL SYSTEM:** Tellinghuisen Geddes reported the credit card processing is up and running and the system will be available for online renewals for the next

renewal period.

**LEGISLATIVE UPDATES (LEGAL COUNSEL):** No legislative updates were reported.

**VOTE ON REVISED SDCL 36-24:** The Board discussed the proposed clean-up Bill for the upcoming 2023 legislative session. Decker expressed the Board's gratitude to Susan Sporrer, Department of Health for all her work on the draft Bill as well as to the Board office. Decker motioned to approve the proposed bill with the caveat that SDCL 36-24-8 be revised to strike the term limit language for the Board President. Sorensen seconded the motion. **MOTION PASSED** by roll call vote. Decker, yes; Sorensen, yes; Smith, yes; Hinker, yes; Paluch, yes.

Sorensen questioned licensure for audiology assistants. Discussion was held. It was advised that the Bill needs to be in its final form by September 2022. Sorensen will research the topic and contact the Board office if he thinks it should go forward for this legislative session.

**ANY OTHER BUSINESS:** There was no other business.

**SCHEDULE NEXT MEETING:** The Board scheduled the next meeting for January 9, 2023 at 11:00 a.m. MST / 12:00 p.m. CST.

**EXECUTIVE SESSION PURSUANT TO SDCL 1-25-2:** Hinker motioned to enter Executive Session at 11:33 a.m. MDT. Paluch seconded the motion. **MOTION PASSED** by unanimous voice vote.

Decker adjourned the meeting at 11:38 a.m. MDT.

Respectfully submitted,

Carol Tellinghuisen  
Executive Secretary

1-27-1.17. Draft minutes of public meeting to be available--Exceptions--Violation as misdemeanor. The unapproved, draft minutes of any public meeting held pursuant to § 1-25-1 that are required to be kept by law shall be available for inspection by any person within ten business days after the meeting. However, this section does not apply if an audio or video recording of the meeting is available to the public on the governing body's website within five business days after the meeting. A violation of this section is a Class 2 misdemeanor. However, the provisions of this section do not apply to draft minutes of contested case proceedings held in accordance with the provisions of chapter 1-26.

STATE OF SOUTH DAKOTA  
 REVENUE SUMMARY BY BUDGET UNIT  
 FOR PERIOD ENDING: 11/30/2022

AGENCY	BUDGET UNIT	HEALTH	BOARD OF HEARING AID DISPENSERS - INFO	CURRENT MONTH	YEAR-TO-DATE
CENTER	COMP	ACCOUNT	DESCRIPTION		
092030061811	6503	4293954	HEARING AID DISPENSER	400.00	7,850.00
COMPANY NO 6503					
COMPANY NAME PROFESSIONAL & LICENSING BOARDS					
ACCT: 4293			BUSINESS & OCCUP LICENSING (NON-GOVERNMENTAL)	400.00	7,850.00
ACCT: 42			LICENSES, PERMITS & FEES	400.00	7,850.00
092030061811	6503	4920045	NONOPERATING REVENUES	.00	846.77
ACCT: 4920			NONOPERATING REVENUE	.00	846.77
ACCT: 49			OTHER REVENUE	.00	846.77
CNTR: 092030061811				400.00	8,696.77
CNTR: 092030061				400.00	8,696.77
CNTR: 0920300				400.00	8,696.77
COMP: 6503				400.00	8,696.77
B UNIT: 09203				400.00	8,696.77

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STATE OF SOUTH DAKOTA  
MONTHLY OBJECT/SUB-OBJECT REPORT BY BUDGET UNIT  
FOR PERIOD ENDING: 11/30/2022

AGENCY BUDGET CENTER	UNIT	09203	HEALTH BOARD OF HEARING AID DISPENSERS - INFO	COMP	ACCOUNT	DESCRIPTION	CURRENT MONTH	YEAR-TO-DATE	
COMPANY NO 6503 COMPANY NAME PROFESSIONAL & LICENSING BOARDS									
092030061811	6503	510103000000000000	BOARD & COMM MBR'S FEES				.00	360.00	
ACCT: 5101 EMPLOYEE SALARIES 092030061811 6503 510201000000000000 CASI-EMPLOYER'S SHARE									
ACCT: 5102 EMPLOYEE BENEFITS ACCT: 51 PERSONAL SERVICES									
092030061811	6503	520303000000000000	AUTO-PRIV (IN-ST.) H/RTE				.00	148.68	
092030061811	6503	520310000000000000	LODGING/IN-STAFFE				.00	125.00	
092030061811	6503	520314000000000000	TAXABLE MEALS/IN-STATE				.00	14.00	
092030061811	6503	520315000000000000	NON-TAXABLE MEALS/IN-ST				.00	14.00	
ACCT: 5203 TRAVEL 092030061811 6503 520405000000000000 COMPUTER CONSULTANT									
092030061811	6503	520408000000000000	LEGAL CONSULTANT				87.00	301.68	
092030061811	6503	520409000000000000	MANAGEMENT CONSULTANT				141.40	348.00	
092030061811	6503	520420000000000000	CENTRAL SERVICES				11,921.89	141.40	
092030061811	6503	520420700000000000	RECORDS MGMT SERVICES				302.18	474.21	
092030061811	6503	520420700000000000	HUMAN RESOURCES SERVICES				.00	104.00	
092030061811	6503	520496000000000000	OTHER CONTRACTUAL SERVICE				.00	170.34	
092030061811	6503	520496000000000000	OTHER CONTRACTUAL SERVICE				52.00	118.00	
ACCT: 5204 CONTRACTUAL SERVICES ACCT: 52 OPERATING EXPENSES									
COMP: 6503 PROFESSIONAL & LICENSING BOARDS CENTER: 092030061811 B UNIT: 09203									
							2,570.58	13,277.84	*
							2,570.58	13,579.52	**
							2,570.58	13,968.13	***
							2,570.58	13,968.13	****
							2,570.58	13,968.13	*****

AGENCY: 09 HEALTH  
BUDGET UNIT: 09203 BOARD OF HEARING AID DISPENSERS - INFO

COMPANY	CENTER	ACCOUNT	BALANCE	DR/CR	CENTER DESCRIPTION
6503	092000061811	1140000	103,393.37	DR	BOARD OF HEARING AID DISPENSERS
COMPANY/SOURCE TOTAL 6503 618			103,393.37	DR *	
COMP/BUDG UNIT TOTAL 6503 09203			103,393.37	DR **	
BUDGET UNIT TOTAL 09203			103,393.37	DR ***	

**OTC Hearing Aids and Implications for State  
Statutes and Regulations: Considerations and Recommendations**

November 2022

*Disclaimer: This document is intended for informational purposes and does not, and is not intended to, constitute legal advice. Please consult qualified professional counsel for any state-specific matter.*

**Overview**

The Over-the-Counter Hearing Aid Act of 2017 directed the FDA to create a new category of over-the-counter (OTC) hearing aids for *adults with mild to moderate hearing loss available for use by consumers without professional assistance*. The final rule implementing this law became effective October 17, 2022, and provides that "no State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids." This final rule has implications for existing State laws that were enacted to regulate certain aspects of traditional hearing aids.

States may necessarily need to evaluate certain state laws and regulations pertaining to hearing aids particularly as they relate to definitions, consumer protection provisions, State licensing provisions, and professional codes of ethics. In addition, OTC hearing aids may or may not qualify for a medical device exemption from State sales tax depending on the law of the individual State.

**Definition of Hearing Aid**

Under the final FDA Regulation; all hearing aids now fall into two categories: "Over-the-Counter" and "Prescription." Currently State statutes and regulations do not distinguish between these two categories and may simply include a general definition of a hearing aid. States will need to create separate definitions for "OTC" and "Prescription" hearing aids to take into account those types of regulatory actions that may be allowed for prescription hearing aids but may not be allowed for OTC devices per FDA regulation. The FDA has provided clarification that the designation of traditional hearing aids as "prescription" is not intended to make any changes to the current State licensure requirements necessary to order or provide these devices. (See Appendix A)

## Definitions for “OTC” and “Prescription”

1. The FDA defines OTC Hearing Aids as: *“devices 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.”*
2. The FDA defines “Prescription Hearing Aids” as those subject to the requirements in § 801.109 (21 CFR 801.109), including that “they be sold only to or on the prescription or other order of a practitioner licensed by law to use or order the use of or prescribe.”  
[**Note:** FDA has clarified that this final rule “does not change the necessary qualification of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting and dispensing of these devices.” See Appendix A.]

## Existing State Consumer Protection Provisions and Hearing Aids

The FDA Final Rule is clear that States may not “restrict or interfere with” commercial activity involving OTC hearing aids. Commercial activity involving OTC hearing aids refers to any or all of the following activities: servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online. Whether a State or local consumer protection requirement that specifically related to hearing products would “restrict or interfere with” commercial activity involving OTC hearing aids may depend on the specific facts.

For guidance on specific State provisions and whether they would be preempted by federal law regarding OTC hearing aids, States may contact:

[cdrombudsman@fda.hhs.gov](mailto:cdrombudsman@fda.hhs.gov)

[IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov)

## State Medical Clearance/Waiver

Under the final rule, the FDA is repealing 21 CFR 801.421—a federal regulation that required medical clearance before the provision of a prescription hearing aid and allowed the waiver of this requirement if the individual was over 18 years of age. Many States have similar requirements in statute or regulation. The FDA has stated that States that choose to continue to keep these requirements in place for prescription hearing aids only may not apply this to OTC hearing aids.

### Considerations:

- States may wish to remove an existing requirement for a medical clearance/waiver for prescription hearing aids altogether to align with the FDA stance on this issue.
- A State that wishes to retain this requirement would need to clarify that this would apply to non-OTC or prescription hearing aids only.



- States may wish to remove an existing requirement for adults and retain this requirement for individuals under the age of 18 for prescription hearing aids

#### Warranty/ Return/Receipt Requirements for Hearing Aids

Many States have warranty and return requirements in effect for prescription or non-OTC hearing aids. The FDA has expressed that “State or local requirements that provide for a reasonable warranty or return period for hearing aids would likely promote, rather than restrict or interfere with commercial activity involving OTC hearing aids.” Additionally, “State or local requirements that provide for reasonable disclosure of the terms of sale in a receipt or similar document would likely promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids.

- Thirty-two States with a minimum right to return provision for hearing aids: AK, CA, CO, CT, DC, FL, ID, IL, KY, LA, ME, MD, MA, MN, MT, NV, NH, NY, OH, OK, OR, PA, RI, SD, TN, TX, UT, VT, VA, WA, WV
- Forty-six States and the District of Columbia require a receipt or contract of sale that enumerates specific items that must be included on such document (State w/out such requirement—DE, IN, MI, NM)

#### Considerations:

- States may continue these requirements for prescription/non-OTC hearing aids
- States may also apply these requirements to OTC hearing aids; *however*, those States would have to amend statutes or regulations to do so.

#### State Licensed Individuals

The FDA final rule does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting and dispensing of these devices. However, under Federal law, a State or locality cannot require a seller or dispenser of OTC-only hearing aids to undertake special licensing or equivalent activities because that would in essence require the involvement of a licensed person.

#### Considerations:

- “Audiologist” is a protected title in all fifty states and still requires State licensure
- “Hearing aid dispenser” is not a protected title and does not require licensure
- “Licensed dispenser” or “licensed hearing aid dispenser” is a title that requires State licensure for use

- States may need to amend terminology/definitions related to “hearing aid dispenser” and “licensed hearing aids dispenser”

### State Hearing Aid Protocols and Codes of Conduct for Audiologists

Some States include in their regulations a set of required protocols or procedures that licensed audiologists must follow prior to dispensing a hearing aid. These provisions are typically found in the audiology “Code of Conduct” or in sections that pertain specifically to the dispensing of hearing aids.

Some examples include:

- Georgia Rule 609-4-.03 “Licensees shall use only reliable assessment data to select or recommend specific products to be dispensed”
- Nevada NAC 637B.0448: “A dispensing audiologist shall provide for the service and repair of each hearing aid he or she sells or fits
- Utah 58-41-17: “A person licensed under this chapter who offers to sell a hearing aid to a consumer must inform the consumer about hearing aids that work with assistive listening systems that are compliant with the ADA Standards for Accessible Design.”
- Oklahoma Administrative Code 690:15-1-3: “Products dispensed to the person must be evaluated to determine effectiveness.”

Considerations:

These existing State provisions were drafted and intended for traditional or “prescription” hearing aids. States will need to examine these types of provisions that currently exist in State regulations. Many of these, if applied to OTC hearing aids, may violate the FDA final rule that stipulates that States may not maintain any requirements that would “restrict or interfere” with OTC hearing aid sales—even though they may be considered “best practices.”

### **State Sales Tax and Hearing Aids (Prescription and OTC)**

States have wide variability in the sales tax treatment of medical devices in general—including hearing aids. Many States provide exemptions from sales tax for medical devices but may limit that exemption to those devices that are provided pursuant to an order provided by an individual who is required to hold, and actively holds, a valid State license. Some State provisions condition the exemption on whether the device is provided through the Medicare or Medicaid program. Still other States attempt to condition an exemption on whether the device is considered a prosthetic or durable medical equipment. Finally, in addition to State sales tax provisions, many counties or localities may have the ability to levy an additional tax on these devices. There are many nuances to State tax laws, which are frequently updated via advisory opinions.

Considerations:

- The following States *generally* exempt medical devices from tax when they are sold on a written order from a licensed professional: Arkansas, California, Colorado, District of Columbia, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, North Carolina, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia.
- The following States *generally* exempt medical devices from sales tax regardless of whether they are provided on the basis of an order of a medical/written order: Arizona, Connecticut, Missouri, Nevada, New Jersey, New York, North Dakota, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Wisconsin, Wyoming
- **Other States**
  - DE, MT, NH, OR: No State sales tax
  - AK: No State sales tax, but cities and towns may levy taxes
  - AL: Exempt if provided on a written order and covered by and billed to Medicare, Medicaid or health benefit plan
  - IL: Devices taxed at 1% reduced rate
  - MN: Exempt if sold for home use
  - MS: Exempt if ordered/prescribed and paid under Medicare/Medicaid
  - NE: Exempt if sold pursuant to order and must be of the same types of devices covered under state Medical Assistance Program
  - NM: Exempt if provided by licensed professional and device and service included in the cost
  - SC: Generally subject to tax unless provided under Medicare/Medicaid
  - WA: Generally subject to tax unless prosthetic devices that are prescribed, furnished, or fitted by a person licensed to do so.
- Audiologists will need to check State & local tax requirements to determine if they should collect sales tax should they choose to sell OTC and/or prescription hearing aids.

## Appendix A



**FDA** U.S. FOOD & DRUG  
ADMINISTRATION

October 13, 2022

Dear State Official:

It has come to our attention that there may be some confusion with FDA's final rule establishing a regulatory category for over-the-counter (OTC) hearing aids and amending certain FDA regulations. We published the final rule on August 17, 2022, and it goes into effect on October 17, 2022 (see 87 FR 50698). The final rule primarily establishes a category of OTC hearing aids that consumers aged 18 years and older with perceived mild to moderate hearing impairment can purchase without the involvement of a hearing healthcare professional. The final rule also makes several changes to Federal regulations that apply to hearing aids, including: repealing the conditions for sale for hearing aids under 21 CFR § 801.421; defining non-OTC hearing aids as prescription devices, subject to 21 CFR § 801.109, rather than restricted devices (see 87 FR at 50755, removing § 801.421); and providing updated labeling requirements for such prescription hearing aids (see *id.*, adding new 21 CFR § 801.422).

We have received questions about some implications of these actions, including who may prescribe hearing aids and whether medical evaluations are necessary to obtain non-OTC hearing aids, which will be defined as prescription hearing aids under the rule. We clarify below that the final rule:

- Does not change the necessary qualifications of who may provide hearing healthcare with prescription hearing aids, including the recommendation, selection, fitting, and dispensing of these devices;
- Does not require an additional professional to take actions, for example, does not in any way require a physician's involvement prior to fitting these devices; and
- Does not require an examination of any kind to obtain a prescription hearing aid.

A State can authorize many kinds of practitioners to order the use of (or prescribe) a prescription device. Federal regulations in § 801.109 do not require that a prescriber be a physician (a person licensed to practice allopathic or osteopathic medicine), physician assistant, or nurse practitioner. Instead, the relevant requirements for prescription devices apply in the case of practitioners licensed by the law of the State to use or order the use of the device (see § 801.109). FDA's intent is that the same professionals who recommended, selected, fitted, and dispensed restricted hearing aids before the effective date would continue to do so for prescription hearing aids after the effective date. Further, the final rule does not require the involvement of an additional licensed practitioner such as a physician. A licensed audiologist, for example, would not need to consult a physician under FDA's final rule.

Similarly, Federal regulations in § 801.109 do not require that a prescriber provide or require a medical or other examination prior to using or ordering the use of a prescription device. As has been observed elsewhere, medically treatable causes of hearing loss are relatively rare, and while certain circumstances may warrant the involvement of a physician in some individual cases—for example, those included as “red flag conditions” in required labeling for prescription hearing aids—the final rule does not state or imply that a medical evaluation is generally necessary or generally more advisable for people 18 and older under Federal regulations to obtain a prescription hearing aid.<sup>1</sup>

Regarding terminology and the use of the word “prescription,” we note that FDA regulations for prescription devices refer to a “prescription *or other order*” (emphasis added) and a practitioner who is licensed “to use or order the use” of the device (see § 801.109). Therefore, the document or action to obtain a prescription hearing aid need not be called a “prescription” under State law. Thus, for example, if a hearing aid purchaser obtained a document called a “hearing aid use authorization” or a “hearing aid certificate of need” from an audiologist or hearing instrument specialist who had authority in that State to provide such a document, this would likely satisfy the practitioner-order requirements under § 801.109.

In conclusion, the final rule defining non-OTC hearing aids as prescription devices does not, and is not intended to, create barriers to accessing hearing aids, including prescription devices. It does not require the involvement of different or additional health care providers or examinations upon the effective date.

States or localities that have questions may contact FDA’s Intergovernmental Affairs Staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Sincerely,

Jeffrey Shuren, M.D., J.D.  
Director  
Center for Devices and  
Radiological Health

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<sup>1</sup> See reference 7 for the final rule, from the National Academies of Sciences, Engineering, and Medicine, “Hearing Healthcare for Adults: Priorities for Improving Access and Affordability,” Board on Health Sciences Policy, Committee on Accessible and Affordable Hearing Health Care for Adults; Blazer, D.G., S. Domnitz, and C.T. Liverman, Eds., 2016. DOI: 10.17226/23446. Available at: <https://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and>. Unlike conditions such as otitis media (an infection of the middle ear) or ear canal blockages, “most sensorineural hearing loss...cannot be repaired using current medical or surgical interventions,” (p. 22).