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ASHA's OTC Hearing Aid Town Hall

Monday, October 24, 2022

Town Hall Agenda

- ASHA Advocacy
- ASHA Supporting Audiologists
- Questions and Discussion

ASHA Audiology Practices & Gov't Affairs and Public Policy Team Members

Panelists:

Donna Smiley, Chief Staff Officer, Audiology, Standards & Ethics

Bria Collins, Associate Director, Audiology Practices

Lindsay Creed, Associate Director, Audiology Practices

Marquitta Merkison, Associate Director, Audiology Practices

Tim Boyd, Director, State Health Care & Education Affairs

Bill Knudsen, Director of Education Policy

Jeff Regan, Chief Advocacy Officer

Webinar Support

Regina Zappi, Associate Director, Audiology Practices

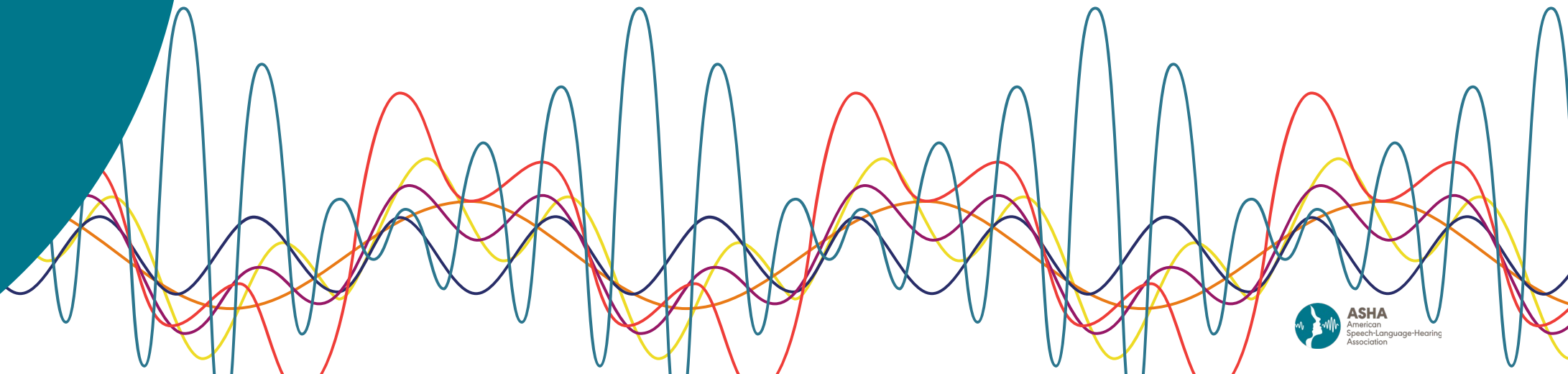
Tricia Ashby-Scabis, Senior Director, Audiology Practices

Maureen Salamat, Project Manager, Audiology Practices

Natalie Wilson, Director of Digital Products and UX Design

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ASHA Advocacy



Advocacy Overview To Date

Law enacted that required the Food and Drug Administration (FDA) to classify Over-the-Counter Hearing Aids (P.L. 115-52)

FDA issues proposed rule; ASHA submits comprehensive comments

ASHA advocates for FDA clarification on final rule's impact on conventional hearing aids

Aug. 2017

Aug. 2018

Oct. 2021

Aug. 2022

Oct. 2022

17 Oct. 2022

ASHA, AAA, ADA, and IHS release joint consensus recommendations concerning the safety and effectiveness of OTC hearing aids, and engage in direct advocacy with the FDA

FDA issues final rule

OTCs hit the market

Implications of FDA's Final Rule

In the final rule, the FDA:

Does:

Establish a new regulatory category for OTC hearing aids

Designate hearing aids that do not meet the requirements for the OTC category as prescription hearing aids

Repeal the conditions for sale applicable to hearing aids

Amend existing labeling requirements for hearing aids

Does NOT:

Place any direct restrictions on audiologists (e.g. selling, dispensing, marketing, and servicing of OTC or prescription hearing aids)

Require states to change their medical evaluation requirements for prescription hearing aids

FDA Background

On October 20, 2021, the FDA officially published proposed regulations to establish over-the-counter (OTC) hearing aids. The public comment period ended January 18, 2022.



The primary issues covered included:

clarifying preemption of state laws;	conditions of sale (e.g., no direct sale to minors);	design;	electroacoustic performance;	labeling;	output limits; and	scope.
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Selected Provisions of Note from the Final Regulations

A maximum output (MPO) of 115 dB SPL or 120 dB SPL if the device is equipped with a volume control, and input-controlled compression to 111 dB SPL or 117 dB SPL if the device is equipped with activated input-controlled compression;

A user-adjustable volume control;

A maximum insertion depth defined as 10 mm from the tympanic membrane;

Updated labeling requirements to improve readability and accessibility for the general public; and

Updated clarification on preemption of state laws and ensuring adequate provisions for consumer protection.

“Prescription” Devices

- The FDA redesignated traditional (non-OTC) hearing aids as "prescription devices."
- The FDA confirmed:
 - Rx designation *“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;”* and
 - *“[T]he 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.”*
- If your state licensing board makes any changes to its rules, it must notify licensees.



Medical Evaluation Requirement



- The FDA gave authority back to the states to implement medical evaluations as part of hearing aid dispensing for non-OTC hearing aids.
- In select cases, old laws that are more onerous than FDA rules are now legal again.
 - E.g., RI law requires patients to obtain a certificate of need from a physician (without the option of a waiver) before they can obtain a hearing aid from a licensed audiologist.
- The FDA confirmed:
 - The final rule “does not in any way require a physician’s involvement prior to fitting [prescription hearing aids];” and
 - “[d]oes not require an examination of any kind to obtain a prescription hearing aid.”
- IA, OH, and RI and others have already indicated there will be no changes to their rules.

Likely State Actions on OTCs

- Under the final rule, a state law cannot *"restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids"* differently from FDA rules.
- Some states may need to explicitly exempt OTCs from their licensing acts.
 - Mail-order (online sale) bans of OTC hearing aids are now illegal.
 - States cannot require someone seeking an OTC device to undergo a hearing screening.
- To enable audiologists to service OTC hearing aids via telehealth, licensing boards may need to alter hearing screening requirements.



Government Affairs and Public Policy Contact Information

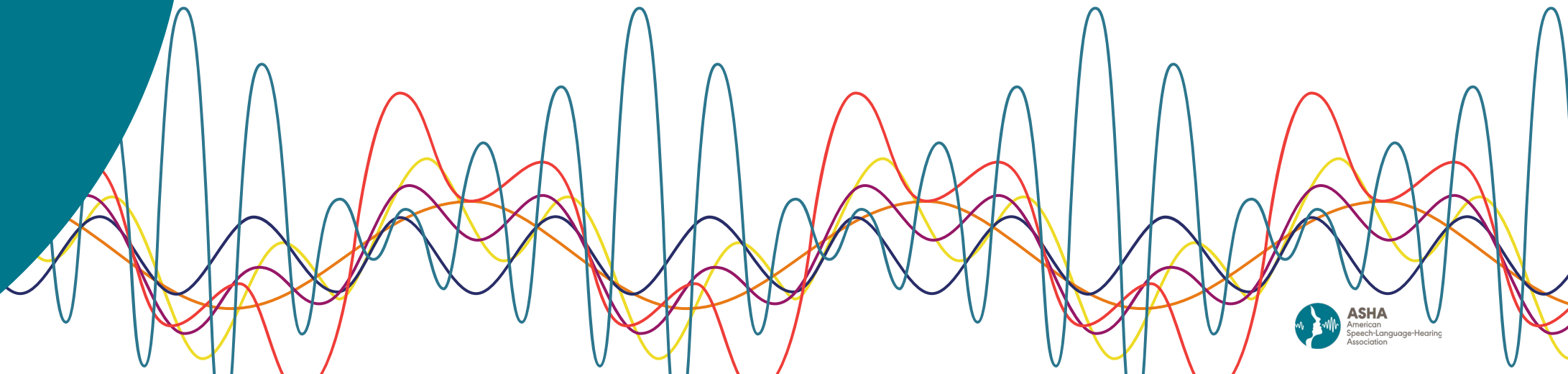
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ASHA Supporting Audiologists



ASHA Supporting Audiologists

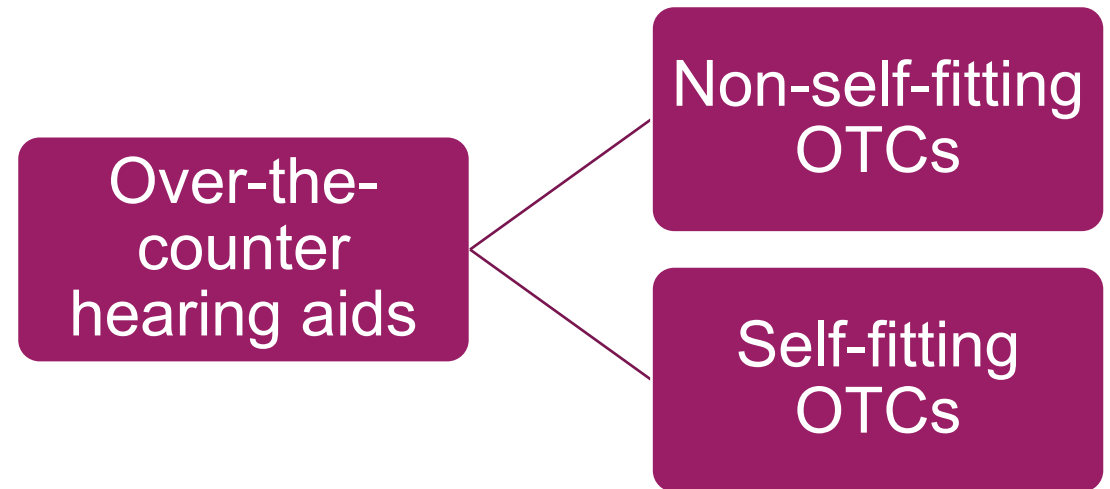
ASHA respects the professional autonomy of audiologists to make decisions about their practice, which includes what devices they offer and what services they provide to their patients.

We do expect audiologists will have various approaches to addressing OTC hearing aids.

Our goal at ASHA is to help our members pre-position themselves and their practices to navigate these changes in a way that best aligns with their values and goals.

What to Expect

- The OTC final rule took effect October 17, 2022. We are already seeing devices enter the marketplace.
- All OTC hearing aids must be customizable, some will be “self-fitting”
 - “Self-fitting hearing aids incorporate technology, including software, that integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.” p. 50703



Self-Fitting OTC Hearing Aids

- [510\(k\) pre-market notifications](#) can be monitored through the FDA's Medical Device Database.
 - QDD is the device code for self-fitting air-conduction hearing aids

ProductCode: QDD Decision Date To: 10/10/2022 Results per Page 10

New Search Export to Excel Download Files More About 510(k)			
Device Name	Applicant	510(K) Number	Decision Date
Vibe Sf Self-Fitting Hearing Aid	WSAUD A/S	K220403	08/12/2022
Mdhearingaid App, Mdhearingaid Smart Hearing Aids	MDHearingAid	K220303	08/04/2022
Jabra Enhance Plus	GN Hearing A/S	K213424	01/19/2022
Bha100 Series Braun Clear Hearing Aid	Kaz USA, Inc., A Helen Of Troy Company	K212609	01/05/2022
Bose Soundcontrol Hearing Aids	Bose Corporation	K211008	05/05/2021

hearX USA	DE/USA	3015246392	2022
<ul style="list-style-type: none"> • Self-Fitting Air-Conduction Hearing Aid - Lexie B1 Hearing Aids, Powered By Bose; Lexie B1 Powered By Bose; Lexie B2 Hearing Aids, Powered By Bose; Lexie B2 Powered By Bose 			Specification Developer

Non-Self-Fitting OTC Hearing Aids

Establishment Registration & Device Listing

[FDA Home](#)
[Medical Devices](#)
[Databases](#)

1 to 6 of 6 Results for Product Code : QUF

Results per Page

[New Search](#)

Establishment Name		Registration Number	Current Registration Yr
HEARING LAB TECHNOLOGY, LLC	TX/USA	3012213704	2023
<ul style="list-style-type: none"> Hearing Aid, Air-Conduction, Over The Counter - Enrich, Enrich Pro, Enlite, Enlite Plus 			Repackager/Relabeler; Complaint File Establishment
Hearing Lab Technology, LLC	PA/USA	2523532	2023
<ul style="list-style-type: none"> Hearing Aid, Air-Conduction, Over The Counter - Enrich Pro, Enrich 			Repackager/Relabeler; Specification Developer; Complaint File Establishment
HEARX SA	SOUTH AFRICA	3014337591	2023
<ul style="list-style-type: none"> Hearing Aid, Air-Conduction, Over The Counter - Go Hearing Lite [C400]; Go Hearing Prime [C600]; Go Lite OTC Hearing Aids; Go Prime OTC Hearing Aids 			Repackager/Relabeler
hearX USA	DE/USA	3015246392	2023
<ul style="list-style-type: none"> Hearing Aid, Air-Conduction, Over The Counter - Go Hearing Lite [C400]; Go Hearing Prime [C600]; Go Lite OTC Hearing Aids; Go Prime OTC Hearing Aids 			Repackager/Relabeler
MDHearingAid	IL/USA	3008941158	2022
<ul style="list-style-type: none"> Hearing Aid, Air-Conduction, Over The Counter - MDHearing NEO; MDHearing VOLT; MDHearingAid AIR; MDHearingAid CONTROL; MDHearingAid LUX; MDHearingAid PRO; MDHearingAid VOLT; MDHearingAid VOLT+ 			Manufacturer
XIAMEN RETONE HEARING TECHNOLOGY CO., LTD.	CHINA	3010408889	2023
<ul style="list-style-type: none"> Hearing Aid, Air-Conduction, Over The Counter - Behind-The-Ear Hearing Aid; In-The-Ear Hearing Aid 			Contract Manufacturer; Foreign Exporter; Manufacturer

- QUF is the device code for self-fitting air-conduction hearing aids
- OSM is the device code for prescription air-conduction hearing aids with wireless technology

What do OTC Hearing Aids Cost?



HSA/HRA/FSA eligible

Hearing Assist - ReCharge! HA-302 Behind the Ear Hearing Aids (Both Ears) - Beige

Model: HA-302BKT SKU: 6501425

Color: Beige



★★★★★ (1)

Get it in 3 days

Pickup: Order now for pickup on Tue, Oct 25 at Salisbury

[See all pickup locations](#)

FREE Shipping: Get it by Fri, Oct 21

[See all shipping options for 19951](#)

\$499.99

[Add to Cart](#)

HSA/HRA/FSA eligible

New! Go Hearing - Go Lite OTC Hearing Aids - Black

Model: GH00001BL SKU: 6513096

☆☆☆☆☆ Not Yet Reviewed

Get it in 7 days

Pickup: Order now for pickup on Wed, Oct 26 at Salisbury

[See all pickup locations](#)

FREE Shipping: Get it by Tue, Oct 25

[See all shipping options for 19951](#)

Compare Save

\$199.00

[Add to Cart](#)



Jabra - Enhance Plus Self-fitting OTC Hearin...

Not yet reviewed

\$799.99

New

Lexie Lumen
Premium hearing aids with remote expert care

Behind-the-ear, Over-the-counter, Digital Hearing Aids, Bronze Bronze - 1 pr

\$799.00

Spend \$25 on select Health&Wellness, Earn \$7 W Cash rewards

NEW
CREC10 Self-Fitting OTC Hearing Aids
Model: CRE-C10
Est. Delivery Oct 26-27

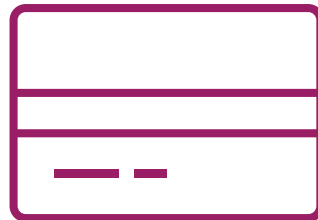
\$999.99

CRE-E10 Self-Fitting OTC Hearing Aids
Model: CRE-E10

\$1,299.99

Will Insurance Cover OTC Hearing Aids?

This will be payer and plan specific



If an individual's plan has a hearing aid benefit- it will be up to the payer to decide whether it can apply to OTC hearing aids and if so, what requirements must be met.



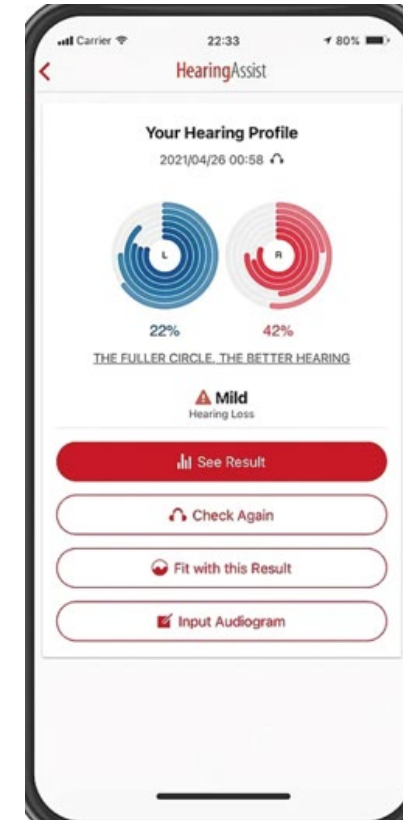
“Aetna considers the Bose Hearing Aid and other FDA-cleared hearing aids available over the counter without a prescription as medically necessary **equally effective alternatives** to hearing aids available only by prescription for persons whose hearing has been evaluated and meet medical necessity criteria for air conduction hearing aids, and the member has a **prescription** for the hearing aid from a physician or provider licensed to prescribe hearing aids.

Note: **Most Aetna benefit plans exclude coverage of hearing aids.** Any applicable benefit plan exclusions and limitations for coverage of hearing aids would apply to air conduction hearing aids, implantable hearing aids and semi-implantable hearing aids. Please check benefit plan descriptions for details.

For plans that do not exclude hearing aids, either OTC and prescription hearing aids are eligible for coverage if they are cleared by the FDA and prescribed by a qualified healthcare provider and medical necessity criteria for hearing aids above are met.”

What Role Can Audiologists Play in Fitting and Adjustment of OTC Hearing Aids?

- Will users be able to upload audiograms obtained from audiologists or HIS' into their OTC devices?
 - “For devices intended for fitting based off of a user-supplied audiogram, a requirement for the involvement of a licensed person to produce the audiogram may cause the device not to be an OTC hearing aid as defined in section 520(q)(1)(A) of the FD&C Act.”
 - We’re guessing it *may* be an **option** for some devices



What Role Can Audiologists Play in Fitting and Adjustment of OTC Hearing Aids?

- Will audiologists be able to adjust the output of OTC hearing aids?
 - “If a manufacturer markets an OTC hearing aid that meets the OTC hearing aid definition and complies with all applicable requirements of the OTC Hearing Aid Controls—but also offers an additional separate feature, a software interface for professionals that allows only licensed persons to adjust the device output—FDA likely would not consider the hearing aid to be a prescription device, but the software interface for professionals would be a prescription device and therefore must comply with §§ 801.422 and 801.109.”
 - It is possible- the software would however have to be a prescription “device”

Opportunities for Patient Education

- Meet your local audiologist
- What is an audiologist?
- Prevalence of hearing loss
- Why is treatment important?
- First step: consult an audiologist
- Functional communication assessment
- OTC vs. prescription hearing aids- what is the difference?
- Who is a candidate for OTC hearing aids?
- Red flag symptoms
- Where do I buy an OTC hearing aid?
- When to stop using an OTC hearing aid?



- Educational Presentation for the Community [PPTX]



Considering OTC Hearing Aids?
HLAA's OTC Tip Sheet Can Help



Clinical Integration of OTCs



ASHA
OTC Hearing Aid Toolkit

ASHA has compiled these resources to help you:

- Educate patients about OTC hearing aids
- Promote the continued value of an audiologist
- Collaborate with and market your practice to other trusted professionals influencing OTC hearing aid decisions



ASHAWIRE
SPECIAL COLLECTION

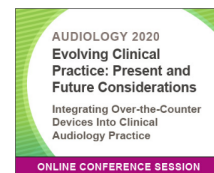
Over-the-Counter Hearing Devices

A special collection of resources from across ASHA publications

The Practice Portal

- **Unbundling Hearing Aid Sales**

Integrating Over-the-Counter Devices Into Clinical Audiology Practice (WEB19729)



AUDIOLOGY 2020
Evolving Clinical Practice: Present and Future Considerations
Integrating Over-the-Counter Devices Into Clinical Audiology Practice
ONLINE CONFERENCE SESSION

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Presenter(s): Meaghan Reed, AuD, CCC-A
Credit(s): PDHs: 0.5, ASHA CEUs*: 0.05
Summary: It is unclear how over-the-counter hearing devices will impact our patients and our practices in the coming years. This session will discuss practical strategies for incorporating OTC devices, deciding when to offer alternative rehabilitation options to patients, and offering a wider variety of solutions to meet our patients' needs.



MC37: OTCs for the Audiologist's Toolbox (2-Hour Master Class (In-Person))

CC/R5

1:15 PM - 3:15 PM
Nov 18, 2022



We're Here to Support You

Contact Information

- Audiology Practices Team
 - audiology@asha.org

What questions do you have for us?