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Over the Counter Hearing Aids: Misperceptions and Misinformation

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Disclosures

- **Presenter Disclosure:** Financial: Thomas Powers is the Founder and Managing Member of Powers Consulting, LLC. He serves as an expert audiology consultant for Hearing Industries Association and is a Partner in Amplifi Hearing, LLC. He is also an Executive consultant for Healthcare Technologies and Methods, LLC, Market consultant for Audio Focus, Inc., and an Adjunct research professor at Ohio University. He received an honorarium for this course. Non-financial: Thomas Powers has no relevant non-financial relationships to disclose.
- **Content Disclosure:** This learning event does not focus exclusively on any specific product or service.
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Learning Outcomes

After this course, participants will be able to:

1. Describe and discuss the FDA regulations for OTC devices and changes to hearing aid distribution.
2. Compare the facts and misconceptions regarding OTC devices.
3. Review hearing professional choices of OTC hearing devices and personal sound amplification devices (PSAP).

The Path to OTC Hearing Aids

Perceptions

- Cost
- Access through a professional
- Growing bodies of research and awareness around associated comorbidities

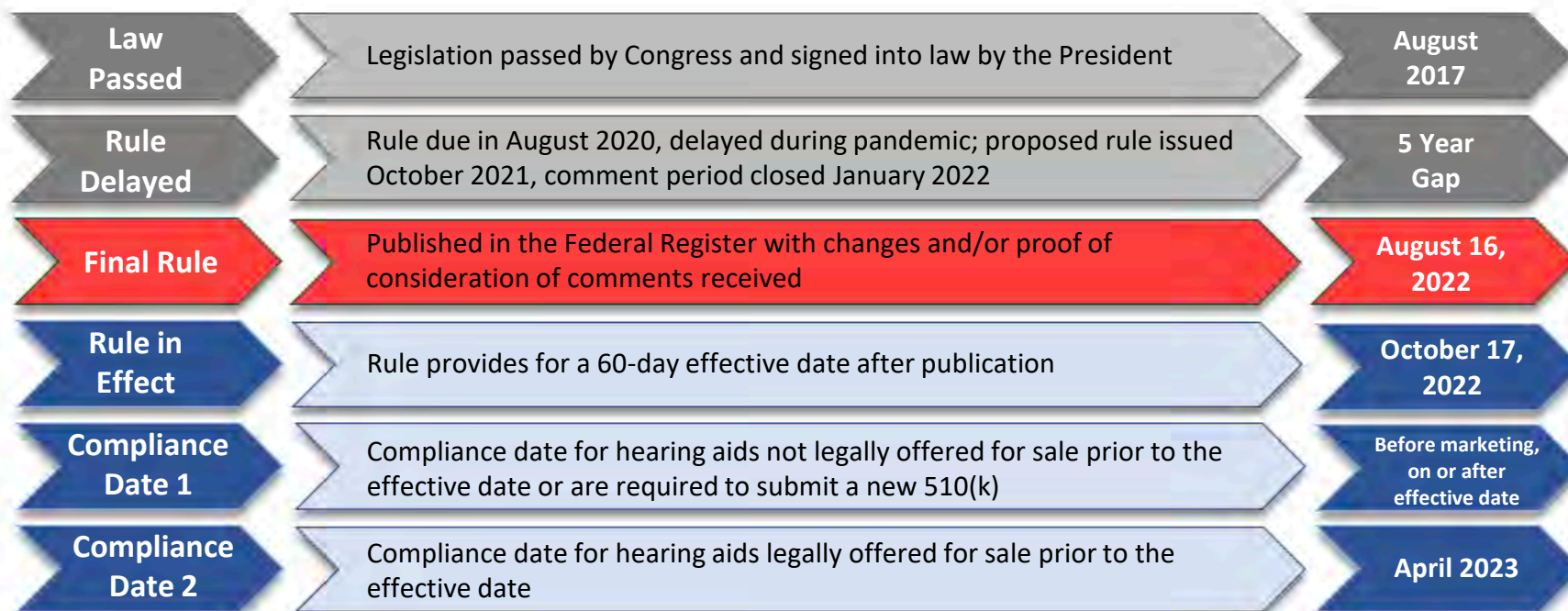
Medicare

- Since 1965, original Medicare has statutorily excluded hearing aids and hearing aid-related services from coverage
- Coverage limited to diagnostic hearing and balance exams, cochlear implantation, and osseointegrated devices for those who meet selection criteria

Insurance Coverage

- No minimum national coverage requirements for hearing health
- Few states require hearing health coverage options

OTC Timeline



Regulatory

- FDA
 - Safety
 - Efficacy
 - Enforcement
- FTC
 - Mandate is to prevent “unfair or deceptive acts or practices.”
 - Health Products Compliance Guide (Dec 2022)
 - Enforcement
- State regulations

Regulatory

Premarket Approval (510(k))

- 510(k) **not** required for OTC hearing aids but **required** for self-fitting hearing aids.
- Specifies compliance dates for OTC hearing aids and hearing aids currently on the market:
 - **Hearing aids not previously offered for sale OR hearing aids required to submit a 510(k)**
 - Must comply before marketing devices on or after effective date of the Final Rule (17 October)
 - **Hearing aids legally offered for sale prior to 17 October, including those with a 510(k) clearance**
 - Must comply with the new or revised requirements within 180 days of the Final Rule (April 2023)
 - Non-enforcement if hearing aid meets certain criteria

Primary Technical Specifications

Amplification

- Output is 111 dB SPL, with 117 dB SPL allowed for devices with input-controlled compression. No limit on gain.

Insertion Depth

- Most medial component of OTC device must be reasonably expected to remain at least 10 mm from the tympanic membrane.

Self-Fit vs. OTC

- Self-fit enables users to independently derive and customize their hearing aids and settings in a manner that is more personalized to their audiometric profile through the use of presets. Subject to additional regulatory measures (i.e., 510(k)).

Definitions

- Mild to moderate hearing loss is not defined
- Creates two categories of hearing aids: OTC and "prescription hearing aids"

OTC classification*

Product Code	Regulation Number	OTC	Description
QUF	874.3300	Yes	Preset-based OTC hearing aid, air-conduction
QUG	874.3305	Yes	Preset-based OTC hearing aid, air-conduction with wireless technology
QDD	874.3325	No	Self-fitting hearing aid that may be sold online
QUH	874.3325	Yes	Wireless self-fitting OTC hearing aid that may be sold online AND in stores, pharmacies, etc.
OSM	874.3305	No	Prescription wireless air-conduction hearing aids

* Hearing Tracker 2022

Where OTC's will be sold

- **Hearing Care Professionals** – may dispense both OTC and prescription devices
- **Retail Stores** – offer several models in various price points
- **Pharmacies** – offer several models in various price points
- **Online** – OTC models only, NOT PSAP'S OR HEARABLES as these are “not intended” for hearing loss

Support for OTC

- Professional office
 - Testing of devices will require update to test box for ANSI/CTA-2051-2017
 - Understanding of pre-sets and self-fitting process
- Online or Retail
 - Many OTC companies have customer support and fitting support (audiologists or dispensers)

Support for OTC

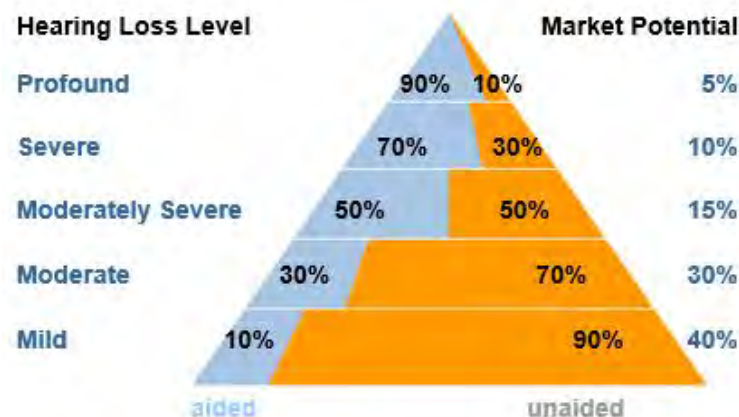
- Programming or adjustment will be made by
 - Professional
 - Consumer
 - Seller of the device

Definitions

- Misinformation – providing inaccurate information
- Misperceptions – confusion about information
- Misinforceptions – What happens when both occur

Mis-

- About 48 million people in the U.S. alone need hearing aids.
- Also, the lion's share of those, 94%, have mild to moderate hearing loss, which is the target market for OTC hearing aids.



Mis-

- “One thing that's really interesting about the OTC devices, and this was one of the rules that was part of the FDA guidelines was that they have to be sold for the same price wherever they are sold.
- So, if you go into BestBuy or Walgreens or CVS or any place that's selling these devices, they should be the same price wherever you go.”

Mis-

- “Someone came into my audiology office with an OTC from a company that has been selling in the DTC channel but now is OTC.
- “None of the packaging has the require labeling from the FDA regulations. Should I report them?

Mis-

- These devices are basically small earbud amplifiers and have been on-the-market for a while but could not previously be marketed as “hearing aids”.
- There is a standard of care that comes with these high-quality devices. This includes a complete hearing screening and exam, special fittings, adjustments, and expert assistance throughout the journey for hearing correction.
- OTC devices do not; users are on their own.
- “There is no ongoing care after purchase”

Mis-

- There's evidence that self-programmed technology or one-size-fits-all solutions can be harmful.
- Hearing technology that amplifies sound too much can further damage your hearing, and an ill-fitting hearing aid can create discomfort.
- Inappropriate amplification will not help enough and will not slow down the progression of your hearing loss.

Mis-

- Consumers may think they loss is mild, but I really don't know. And then you pick something with an amplification level that is three, four or five times, 10 times more than you need.
- You put that OTC device in your ear , you're actually causing damage.
- Irreversible damage.

Mis-

- To maximize comfort and functionality, hearing aids must be custom fitted to each individual and programmed to support their listening lifestyle.
- Only a trained audiologist or hearing instrument specialist can do this.
- Additionally, audiologists can verify the improvement of your hearing with amplification, they can monitor your progress over time, and they can make fine-tuning adjustments to meet your personal listening needs.

Choosing OTC devices

- Existing prescription manufacture/supplier
- New OTC companies
- Exclude PSAP devices for those with hearing loss as not the “intended use”

Customer experience*

- **Pharmacy –**

- Yes, we have them and they're in the pharmacy department
- Oh, we have one box of them, I don't know why, we don't sell them.
- No, why would I be trained? We don't sell hearing aids."

- **Electronics store**

- I told him I was interested in smart hearing aids and to use with my smartphone
- I can't tell you much, they're something new for us.
- There's a video training course but it's not required so I haven't taken it.

- **Mobile phone store**

- I asked how many hearing aids they had in stock and was told there was only a single pair, and they were not for sale, that the test taker would be contacted

Summary

- Read the FDA regulations
- Decide if OTC devices are right for your practice
- Develop a pricing model for OTC



Thank You!

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