The Good, Bad, and Ugly of the Over-the-Counter Hearing Aid Act of 2107

Victor Bray, MSC, PhD, FNAP

28 April 2022

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Abstract

The Food and Drug Administration released, for public comment, a proposed rule to establish over-the-counter hearing aids in October 2021.

Oct. 2021

This timeline suggests that over-the-counter hearing aids will become available in fall 2022.

Oct. 2022

Jan. 2022

The public comment period ended in January 2022, the FDA has is currently reviewing the comments, and will issue a final rule later this year which will become effective 60 days later.

EOY

Over-the-counter hearing aids are now a fact of life in the US and will become available in 2022.

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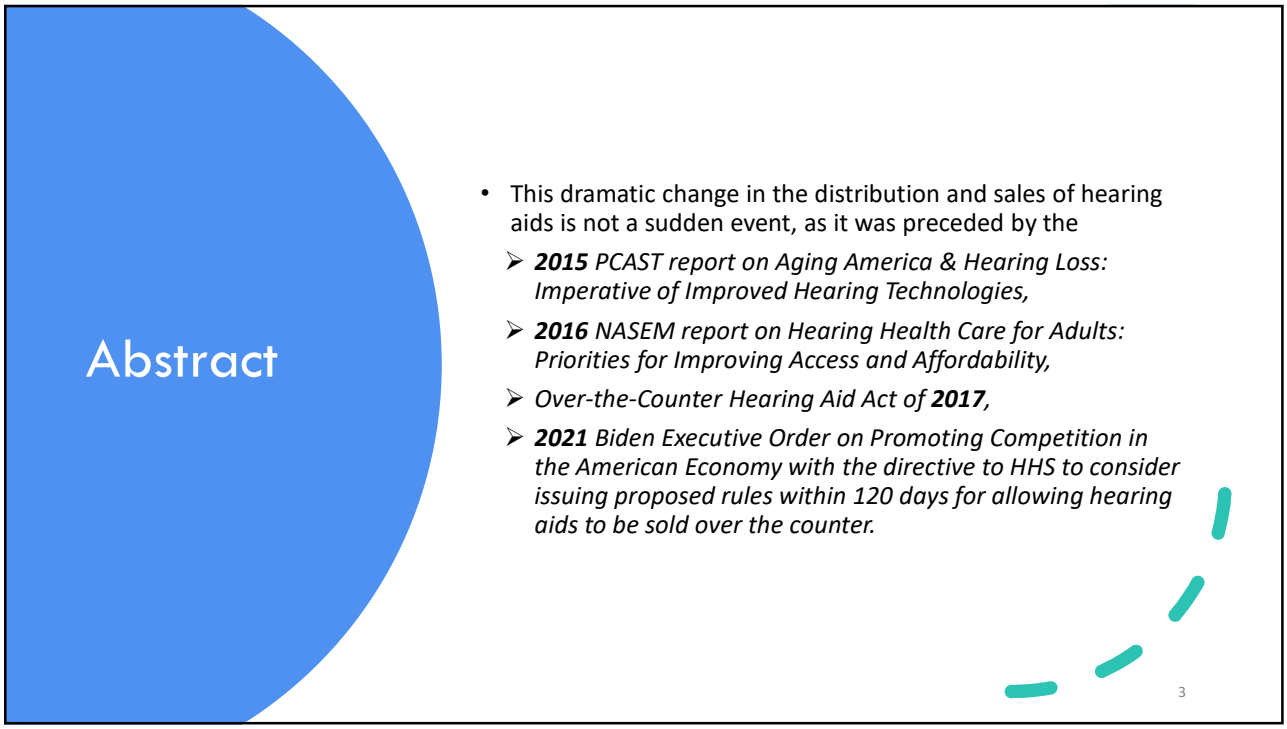
Abstract
• This dramatic change in the distribution and sales of hearing aids is not a sudden event, as it was preceded by the
➢ 2015 PCAST report on Aging America & Hearing Loss: Imperative of Improved Hearing Technologies,
➢ 2016 NASEM report on Hearing Health Care for Adults: Priorities for Improving Access and Affordability,
➢ Over-the-Counter Hearing Aid Act of 2017,
➢ 2021 Biden Executive Order on Promoting Competition in the American Economy with the directive to HHS to consider issuing proposed rules within 120 days for allowing hearing aids to be sold over the counter.
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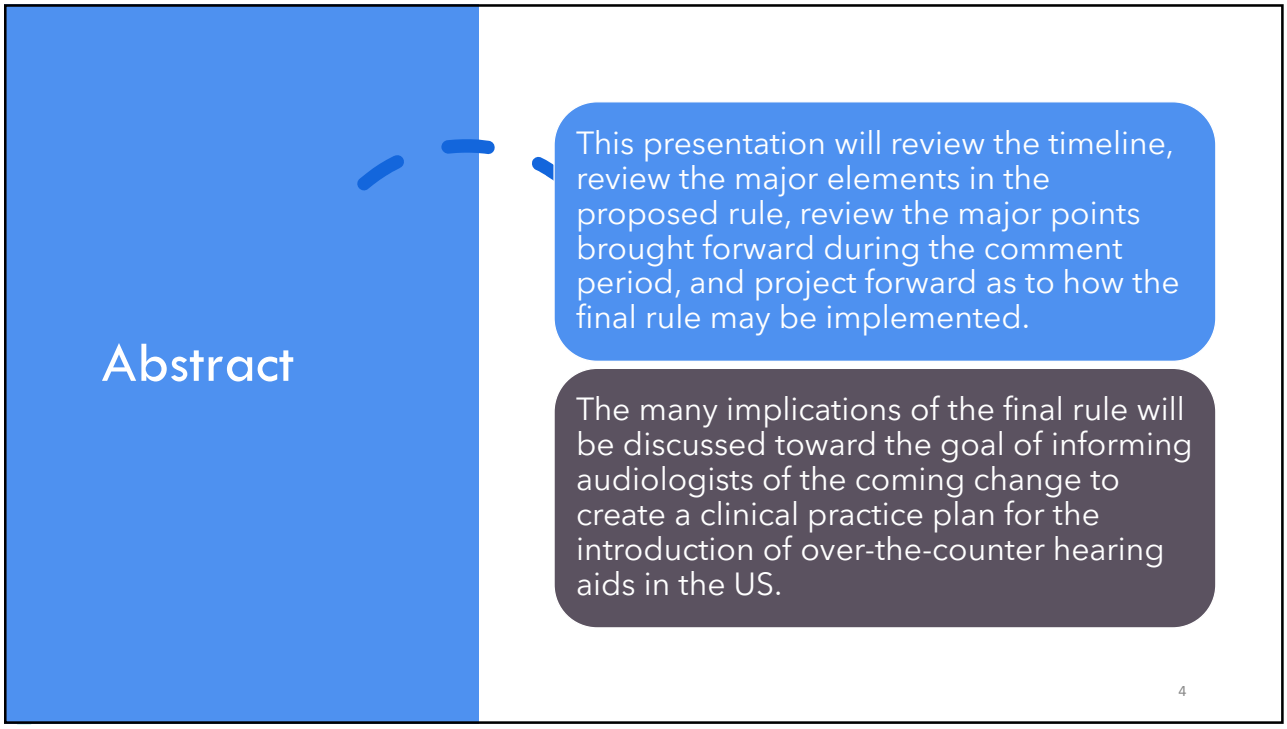
Abstract
This presentation will review the timeline, review the major elements in the proposed rule, review the major points brought forward during the comment period, and project forward as to how the final rule may be implemented.
The many implications of the final rule will be discussed toward the goal of informing audiologists of the coming change to create a clinical practice plan for the introduction of over-the-counter hearing aids in the US.
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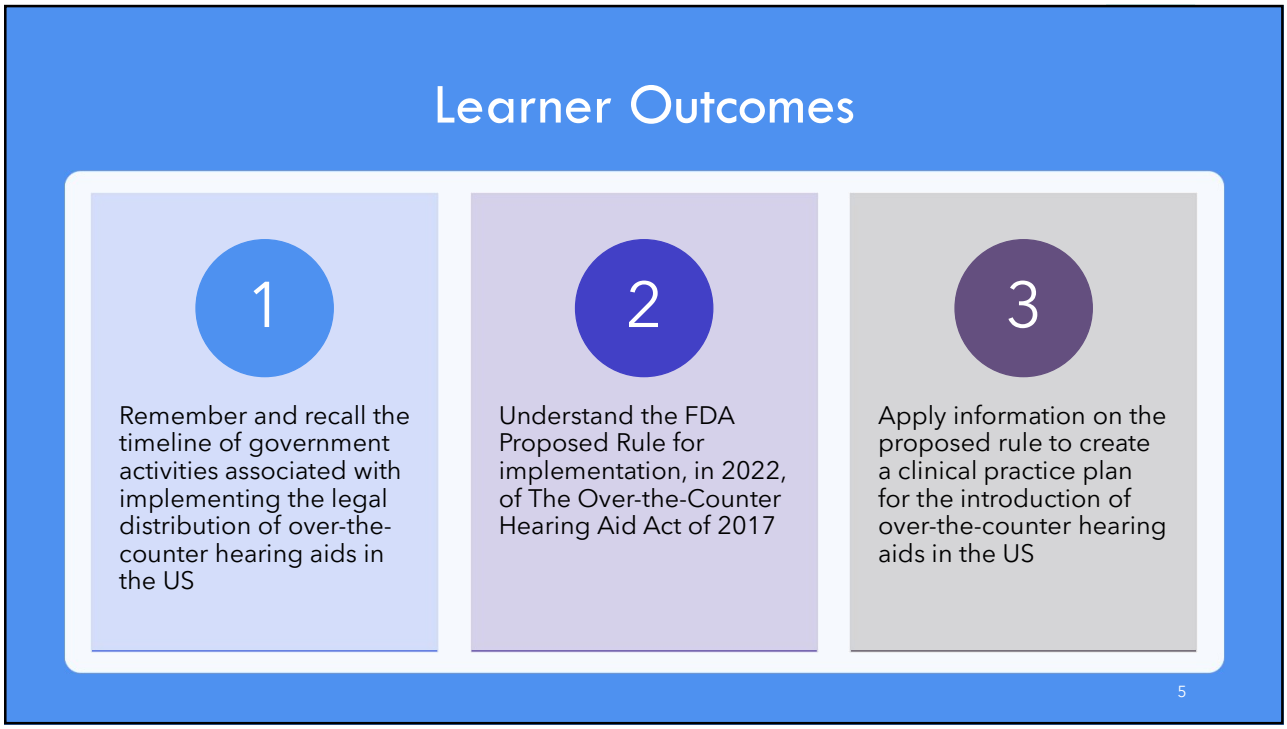
Learner Outcomes
1
Remember and recall the timeline of government activities associated with implementing the legal distribution of over-the-counter hearing aids in the US
2
Understand the FDA Proposed Rule for implementation, in 2022, of The Over-the-Counter Hearing Aid Act of 2017
3
Apply information on the proposed rule to create a clinical practice plan for the introduction of over-the-counter hearing aids in the US
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Topic One
The Timeline

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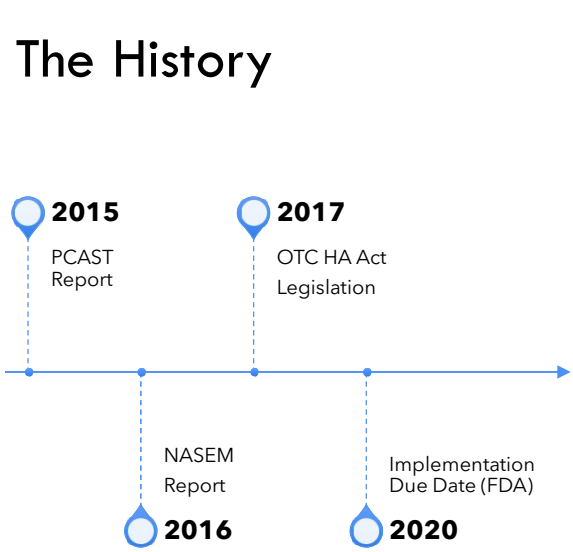
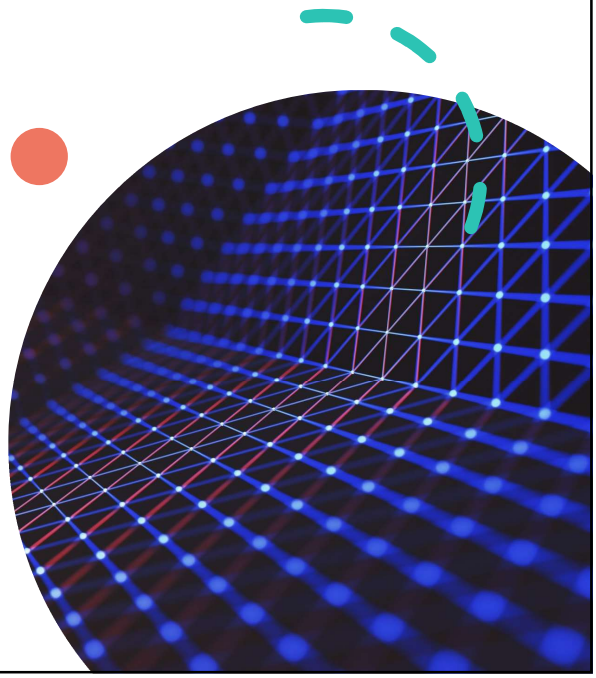
The History





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PCAST Report

President's Council of Advisors on Science and Technology

Aging America & Hearing Loss: Imperative of Improved Hearing Technologies

October 2015

Hearing Loss: Major Problem for Older Adults

- Major health and social problem
  - 30 million have difficulty hearing now
  - Hearing loss associated with social isolation, dementia, falls, depression, and other conditions.
- Growing importance with aging population
  - Nearly half of people over age 60 have hearing loss
  - Number of older Americans will rise from 46 to 82 million between 2014 and 2040
- Few adults with hearing loss use hearing aids
  - Only ~15-30% of older adults with hearing loss use hearing aids

President's Council of Advisors on Science and Technology 5

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PCAST Recommendations Open the Market

Recommendation 1. FDA should designate as a distinct category "basic" hearing aids—non-surgical, air-conduction hearing aids intended to address normal, bilateral, gradual onset, mild-to-moderate age-related hearing loss—and adopt distinct rules for such devices.

i. FDA should approve this class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser. FDA should also approve for OTC sale, both in stores and on-line, tests appropriate to the self-fitting and adjustment of these OTC devices by the end user. Such hearing treatments and tests meet the FDA requirements for OTC products, which are that consumers should be able to self-diagnose, self-treat, and self-monitor the condition.

ii. FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

President's Council of Advisors on Science and Technology

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Hearing Health Care for Adults: Priorities for Improving Access and Affordability

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Why Focus on Hearing Health Care Now?

- *Changing Demographics: Intersection of Hearing Loss and Aging*
- *Recognizing Hearing Loss as a Public Health Priority and a Societal Responsibility*
- *Rapidly Changing Technologies*
- *Changes in Health Care Paradigms*

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Goal 3: *Remove FDA Regulation fo*
Medical Evaluation or Waiver to Purchase a Hea

Recommendation 3: The Food and Drug Administration should remove the regulation that an adult seeking hearing aids be required to first have a medical evaluation or sign a waiver of that evaluation and should ensure consumers receive information about the medical conditions that could cause hearing loss through continued inclusion of that information in hearing aid user instructional brochures.

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Goal 7: *Implement a New FDA Device Category for Over-the-Counter Wearable Hearing Devices*

Recommendation 7: The Food and Drug Administration should establish a new category of over-the-counter (OTC) wearable hearing devices. This device classification would be separate from "hearing aids." OTC wearable hearing devices would be defined as wearable, OTC devices that can assist adults with mild to moderate hearing loss.

Specific actions detailed in bullet points that follow the recommendation.

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Over-the-Counter Hearing Aid Act of 2017

Summary: S.670 — 115th Congress (2017-2018)

All Information (Except Text)

Listen to this page

There is one summary for S.670. Bill summaries are authored by CRS.

Shown Here:
Introduced in Senate (03/21/2017)
Over-the-Counter Hearing Aid Act of 2017

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to categorize certain hearing aids as over-the-counter hearing aids and issue regulations regarding those hearing aids. The regulations for over-the-counter hearing aids must: (1) provide reasonable assurances of safety and efficacy; (2) establish output limits and labeling requirements; and (3) describe requirements for the sale of hearing aids in-person, by mail, or online, without a prescription.

State and local governments may not establish or continue in effect requirements specifically applicable to hearing products that are not identical to FDA requirements and that restrict or interfere with the servicing or sale of over-the-counter hearing aids.

The FDA must update and finalize its draft guidance on hearing products. The guidance must clarify which products are medical devices.

CONGRESS.GOV

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Over-the-Counter Hearing Aid Act of 2017

"(1) DEFINITION.—In this subsection, the term 'over-the-counter hearing aid' means a device—

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

"(B) that is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;

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

"(D) that may—

"(i) use wireless technology; or

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

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

"(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 2(b) of the Over-the-Counter Hearing Aid Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).".

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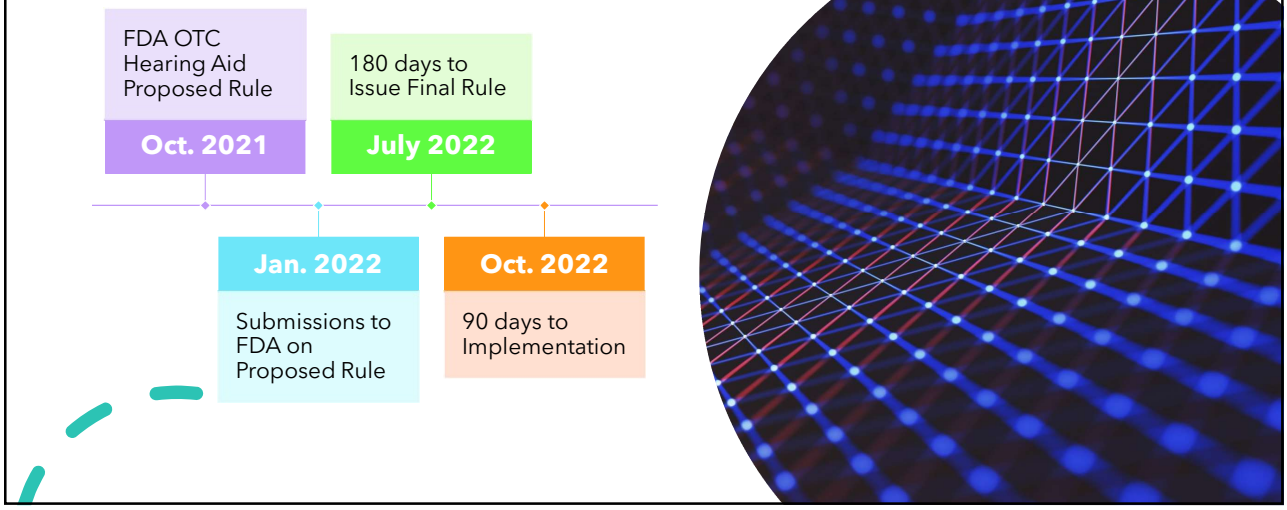
The Emerging Landscape



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Topic Two
Major Elements of the Proposed Rule

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FDA OTC HA Proposed Rule

- We propose to define OTC hearing aids and establish applicable requirements;
- Amend existing rules for consistency with a new OTC category;
- Aepeal the conditions for sale applicable to hearing aids;
- Amend the existing labeling requirements for hearing aids; and
- Update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements.

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FDA OTC HA Proposed Rule

- OTC hearing aids will be intended to address perceived mild to moderate hearing loss in people age 18 or older.
- Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category.
- This rulemaking also affects other existing regulations that apply to hearing aids.
- We are proposing to remove these device restrictions for hearing aids, and establish a new regulation for prescription hearing aid labeling.

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Current Framework vs. Proposed Rule

Table 1—Summary of Current Regulatory Framework

Classification regulation, 21 CFR section	874.3300	874.3305	874.3315	874.3325	874.3950
Device Restrictions	Restricted	Restricted	Restricted	Restricted	Restricted.
Class I, 510(k) exempt [1]	Air-conduction ("legacy")				
Class II, 510(k) exempt [1]		Wireless air-conduction			
Class II	Bone-conduction		Tympanic membrane contact hearing aid	Self-fitting air-conduction	Transcutaneous air-conduction hearing aid system.

Table 2—Outline of Proposed Hearing Aid Rule

800.30	801.422	874.3301	874.3305
Over-the-counter hearing aid controls [1]	**Prescription hearing aid labeling [1]**	**Bone-conduction hearing aid**	**Air-conduction hearing aid**

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Hearing aids, as defined in § 801.420(a)(1), are currently restricted class I and class II devices of multiple types.

- Wireless air-conduction hearing aid (§ 874.3305 (21 CFR 874.3305))
- Tympanic membrane contact hearing aid (§ 874.3315 (21 CFR 874.3315)).
- *Self-fitting air-conduction hearing aids (§ 874.3325 (21 CFR 874.3325)).*
- *Transcutaneous air conduction hearing aid system (§ 874.3950 (21 CFR 874.3950)).*

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Description of the Proposed Rule

- Add to part 800, subpart B (21 CFR part 800, subpart B), definitions and other rules for OTC hearing aids;
- Remove § 801.420 and repeal § 801.421;
- Add to part 801, subpart H (21 CFR part 801, subpart H), § 801.422, labeling requirements for prescription hearing aids;
- Amend part 874, subpart D (21 CFR part 874, subpart D), in multiple places to update classification regulations for hearing aids and align hearing aid types by sound-conduction technology; and
- Amend part 808, subparts A and C (21 CFR part 808, subparts A and C), by updating the Scope and removing most of the current regulations codifying previous decisions for exemption from Federal preemption for certain States.

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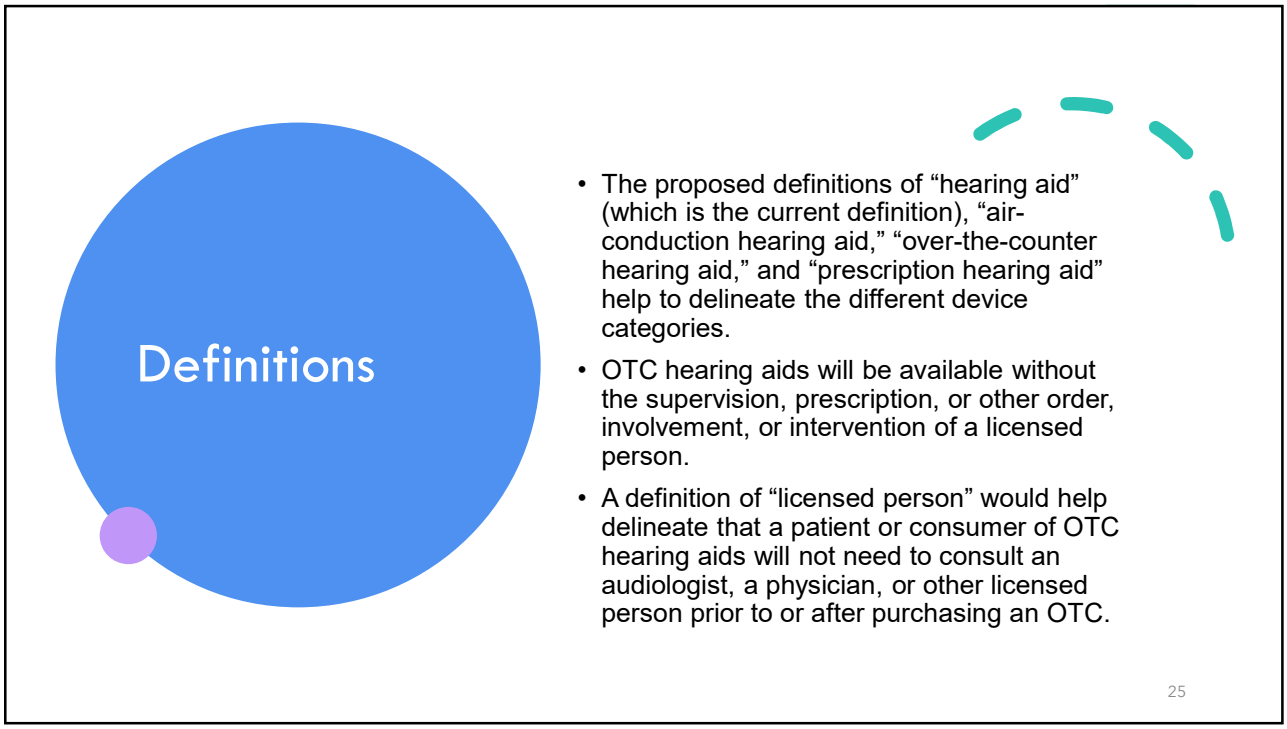
Definitions
• The proposed definitions of “hearing aid” (which is the current definition), “air-conduction hearing aid,” “over-the-counter hearing aid,” and “prescription hearing aid” help to delineate the different device categories.
• OTC hearing aids will be available without the supervision, prescription, or other order, involvement, or intervention of a licensed person.
• A definition of “licensed person” would help delineate that a patient or consumer of OTC hearing aids will not need to consult an audiologist, a physician, or other licensed person prior to or after purchasing an OTC.
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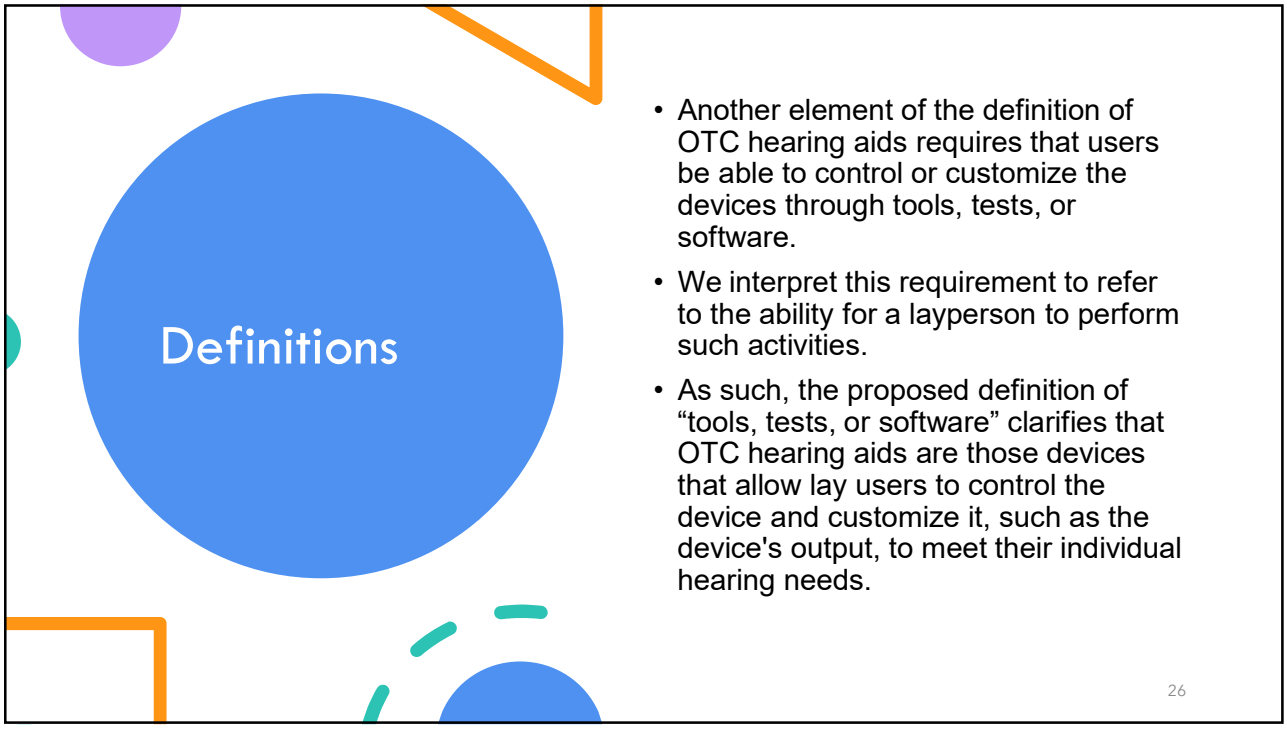
Definitions
• Another element of the definition of OTC hearing aids requires that users be able to control or customize the devices through tools, tests, or software.
• We interpret this requirement to refer to the ability for a layperson to perform such activities.
• As such, the proposed definition of “tools, tests, or software” clarifies that OTC hearing aids are those devices that allow lay users to control the device and customize it, such as the device's output, to meet their individual hearing needs.
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Package Labeling

- A conspicuous warning that the device is not for users younger than 18 years old;
- The symptoms of perceived mild-to-moderate hearing loss;
- Considerations for seeking a consultation with a hearing healthcare professional; and
- Red flag conditions: Warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician (preferably an ear specialist).

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Labeling Inside the Package

- Warnings, cautions, and notes, including a conspicuous statement warning against the use of the OTC hearing aid in people younger than 18 years old as well as a warning regarding “red flag” medical conditions to prompt consumers to consult with a licensed physician and a note about how to report adverse events to FDA;
- Illustration(s) of and information about the controls, user adjustments, and the battery compartment;
- A description of any accessory that accompanies the OTC hearing aid;

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Labeling Inside the Package

- Technical specifications to allow users, prospective users, and others to evaluate and compare the performance of OTC hearing aids;
- Description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid;
- Identification of known physiological side effects associated with using the OTC hearing aid that may warrant consultation with a physician, including but not limited to skin irritation and accelerated build-up of ear wax (cerumen accumulation);
- Information on repair services; and
- If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

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Labeling Inside the Package

- Frequency gain characteristics;
- Adequate directions for use;
- Communication challenges for which it may be helpful to seek professional consultation; and
- Medical situations, symptoms, or signs for which to consult with a physician.

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Overview of Proposed Output Limits

- We propose a maximum OSPL90 output level of **115 dB sound pressure level (SPL)** as a general rule to balance consumer safety with device performance.
- However, we would permit a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control (*i.e.,* volume adjustment).
- We are proposing not to limit the device gain because we believe that the proposed maximum output limit (together with the other proposed requirements) will provide reasonable assurance of safety and effectiveness without limiting the device gain also.
- Moreover, a gain limit may unduly constrain the design of effective devices.

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Electroacoustic Performance Requirements To Help Provide a Reasonable Assurance of Safety and Effectiveness

- Distortion control limits;
- Self-generated noise limits;
- Latency limit;
- Frequency response bandwidth; and
- Frequency response smoothness limits.

- *See ANSI/CTA-2051*

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Design Requirements To Ensure Proper Physical Fit and Prevent User Injury

- Maximum insertion depth;
- Eartip made from atraumatic materials;
- Proper physical fit; and
- Tools, tests, or software allowing the lay user to control the device and customize it to the user's hearing needs.

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Preemption Provisions

1. FDARA Preempts State Regulation of OTC Hearing Aids
   - State or local government requirements specifically related to hearing products not restrict or interfere with commercial activity involving OTC hearing aids.
2. Generally Applicable State and Local Requirements Are Not Necessarily Preempted Under FDARA
3. Requirements for Professionals and Establishments
   - A person that purports to be a specially licensed professional or establishment would be subject to applicable State and local requirements.

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Proposed Repeal of Conditions for Sale and Modifications for Prescription Labeling

1. Repeal of Conditions for Sale § 801.421
   - In light of the fact that FDA is proposing to clarify that non-OTC hearing aids would be prescription devices, such hearing aids would be subject to State and local requirements for obtaining written or oral authorization of a practitioner licensed by State law to administer the use of the devices.
2. Revised Labeling for Prescription Hearing Aids
   - We continue to believe that the labeling requirements are necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids.

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Topic Three
Major Points from the Comment Period

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LISTEN CAREFULLY

Over-the-Counter (OTC) Hearing Aids

On October 19, the U.S. Food and Drug Administration proposed rules for OTC hearing aids. This started a 90-day public comment period to ensure all voices are heard and lawmakers get these rules right.

A hearing aid is not a consumer electronics device; they are medical devices and should be regulated as such.

These rules are designed with the purpose to provide greater access to hearing assistance for those with perceived mild-to-moderate hearing loss. However, without proper guardrails in place to protect patient's long-term hearing health, these products could result in more harm than help.

The public comment period is now **closed** for further consideration before the final regulations are announced.

https://www.listencarefully.org/over-the-counter

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LISTEN CAREFULLY

Even short periods of excessively loud sound can leave lasting damage to a person's hearing. This is why adequate amplification parameters are needed to protect Americans' long-term hearing. As currently written, the FDA's proposed OTC Hearing Aid Rule allows amplification in OTC hearing aids of up to 120 decibels (dB), about the noise level of a chainsaw. The overwhelming consensus from hearing industry stakeholders is that **this must change**. Patient safety must be the priority for ***all*** hearing aids.

Ninety-one hearing organizations submitted formal comments to the FDA expressing concern that the proposed 120 dB maximum output limit and omission of a gain requirement will put patient safety at risk.

https://www.listencarefully.org/over-the-counter

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LISTEN CAREFULLY

Hearing Industries Association:

"HIA believes the maximum output limit at 115 dB SPL or 120 dB SPL coupled with the absence of a gain limit fails to 'balance consumer safety with device performance.' [I]ndividuals who use OTC hearing aids with no gain limit and 120 dB SPL maximum output levels (with or without input compression) as proposed by the draft OTC hearing aid rule are at a significant risk for developing noise-induced hearing loss."

https://www.listencarefully.org/over-the-counter

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2018 Consensus Paper

REGULATORY RECOMMENDATIONS FOR OTC HEARING AIDS: SAFETY & EFFECTIVENESS

CONSENSUS PAPER FROM HEARING CARE ASSOCIATIONS

August 2018

The Working Group recommends ***a high frequency average (HFA) full on gain limit of 25 dB as defined for measurement in a 2 cc coupler, with an input level of 50 dB SPL per ANSI S3.22-2014.***

The Working Group's recommendation is that ***the peak (or maximum) 2 cc coupler OSPL90, per ANSI S3.22-2014, not be greater than 110 dB SPL.***

The Working Group's recommendation is for the FDA to establish product specifications that include, as the minimum standard, input compression and a volume control *(in addition to the already recommended requirements for gain and maximum output limit).*

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STATEMENT FROM ADA ON THE FDA OTC HEARING AID PROPOSED RULE PROVISIONS FOR MAXIMUM SOUND OUTPUT AND GAIN

https://www.audiologypractices.org/statement-from-ada-on-the-fda-otc-hearing-aid-proposed-rule-provisions-for-maximum-sound-output-and-gain

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ADA ACADEMY of DOCTORS of AUDIOLOGY®

After a careful evaluation of the evidence, the ADA OTC task force and the ADA Board of Directors concluded the original methodologies used to justify the 25 dB (decibel) gain limit and the 110 dB output limit in the 2018 Consensus Paper—published as a consensus paper from several hearing healthcare organizations, including ADA—was flawed. In January 2022, ADA subsequently submitted the following recommendations to the FDA:

- ADA **supports** FDA's proposal to allow an output limit up to 120 dB OSPL90 for OTC hearingaids with input-controlled compression and user adjustable volume control.
- ADA **urges** the FDA to implement a general output limit for OTC hearing aids of 110 dB OSPL90 when the hearing aid *does not* include input-controlled compression and user adjustable volume control.
- ADA **supports** FDA's proposal to forgo gain limitations for OTC hearing aids.

ADA **does not** support the 2018 Consensus Paper recommendations regarding maximum gain and maximum output:

- The 2018 Consensus Paper working group recommended a high-frequency average full on gain (HFA-FOG) limit of 25 dB as defined for measurement in a 2cc coupler, with an input level of 50 dB SPL per ANSI standard S3.22-2014.
- The 2018 Consensus Paper working group recommended a peak (or maximum) 2cc coupler OSPL90, per ANSI S3.22-2014, not to exceed 110 dB SPL.

https://www.audiologist.org/item/analysis-of-fda-proposed-rule-to-establish-over-the-counter-hearing-aids

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What's the Fuss over 110/25?

- The larger issue, and one that is not being discussed, is what is the implication of lower or higher gain and output.
- In my opinion, the heated debate is not solely about safety or efficacy.
- It's really about the role of OTC hearing aids in the continuum of care for persons with impaired hearing.

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Topic Four
How Might the Final Rule be Implemented?

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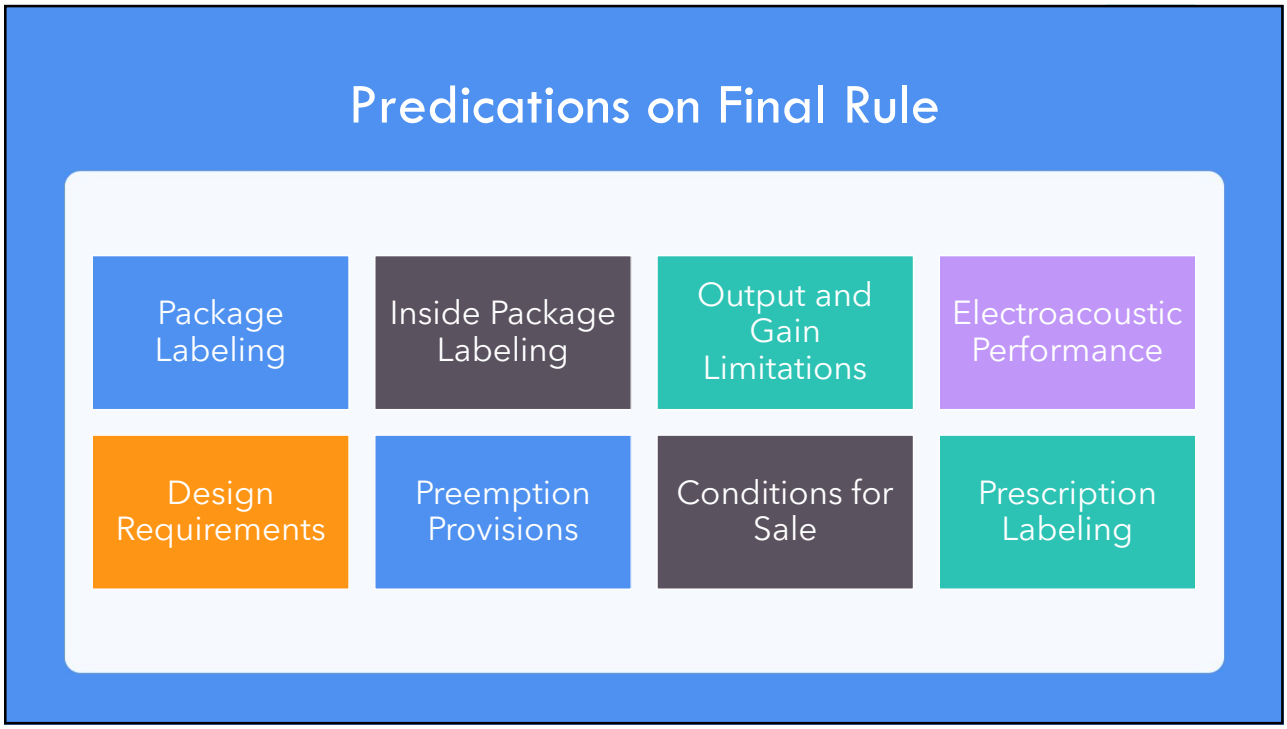

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Open Issues

Definitions

- FDA welcomes comments on the definitions pertinent to the regulation of OTC hearing aids (as well as any other portion of this proposal).
- In particular, we seek comments on the clarity of the definitions and ways to improve the definitions to encourage and support the broad availability of safe and effective devices.

Labeling

- FDA welcomes your comments on the proposed labeling requirements, including the placement or conspicuousness of statements, as well as whether the statements are clear and understandable.

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Open Issues

Package Labeling

- We welcome your comments on whether to require other information on the package labeling and whether you had any difficulty understanding the information (and if so, your suggestions for improvements.
- *Symptoms suggesting perceived mild to moderate hearing loss.*
- *Considerations for seeking consultation with a hearing healthcare professional.*
- *"Red flag" conditions.*
- *Other information.*

Labeling Inside the Package

- We will announce the availability of the draft of that guidance separately from this rulemaking, and the announcement will include information for submitting comments about that guidance, which will be separate and distinct from comments for this rulemaking.

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Open Issues

Data and Stakeholder Perspectives on the Proposed Output Limit

- We also note that the NASEM report does not recommend any limit on gain for OTC devices, only on maximum output.

Design Requirements To Ensure Proper Physical Fit and Prevent User Injury

- *Maximum insertion depth.* We welcome comments, particularly those with support from peer-reviewed sources, about other design requirements (*e.g.,* in terms of absolute length) to limit the insertion depth and prevent damage to the tympanic membrane or other injuries while also promoting device effectiveness.

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Open Issues

Condition for Sale

- FDA welcomes your comments on whether a prohibition of sales to or for people younger than 18 years, without the need to verify age, would best promote access to OTC hearing aids while protecting the hearing health of people younger than 18 years.

Removal of Regulations Codifying Exemption Decisions Affected by Amendments to § 801.420 and Repeal of § 801.421 if Finalized

- We specifically seek comments from the States regarding the proposed removal of the regulations in part 808, subpart C, codifying these exemption decisions.
- *§ 801.420 Hearing aid devices; professional and patient labeling.*
- *§ 801.421 Hearing aid devices; conditions for sale.*

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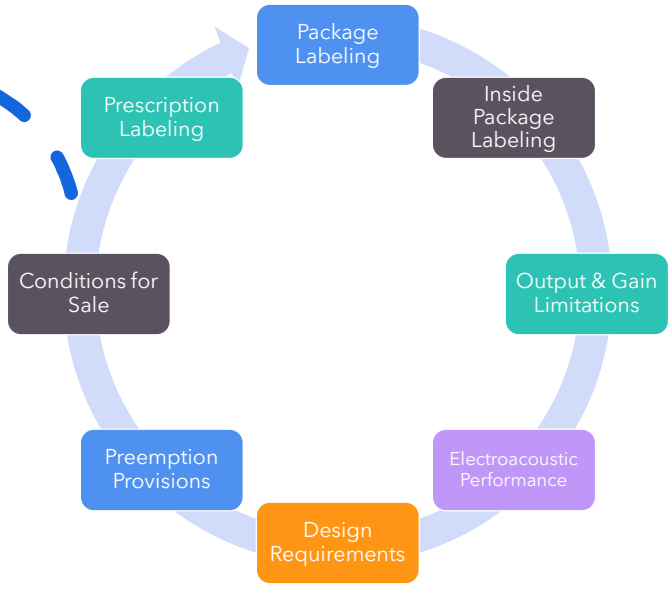
Predications on Final Rule



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Topic Five
Implications of the Coming Change?

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Market Disruption & Chaos

- New consumer avenue to purchase FDA-approved amplification devices.
- Non-professional distribution channels as source of devices.
- Device sales divorced from professional services.
- Consumers with devices in need of service and guidance.

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State Licensure Law Disruption & Chaos

- Hearing aids are redefined as OTC or Prescription.
- Licensure Acts do not have the new definitions.
- FDA has separate rules and regulations for OTC vs Prescription; States do not have separate rules and regs.
- Every State Licensure Act may need to be rewritten.
- Opportunity for 'bad actors' to alter the landscape.

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Federal Preemption over State Laws

- Restriction or interference with commercial activity involving OTC hearing aids.
- State Licensure Acts and licensed persons.
- Conditions for sale including labeling.
- Conditions for return for credit.

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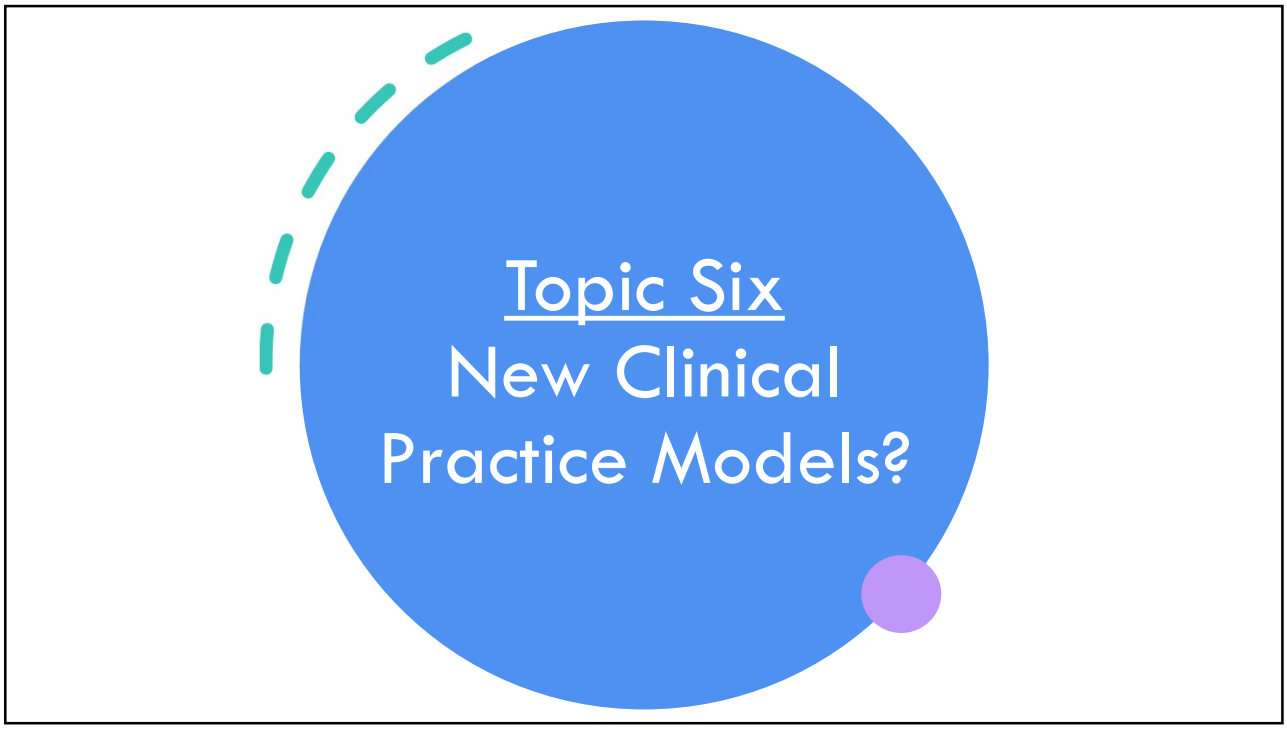

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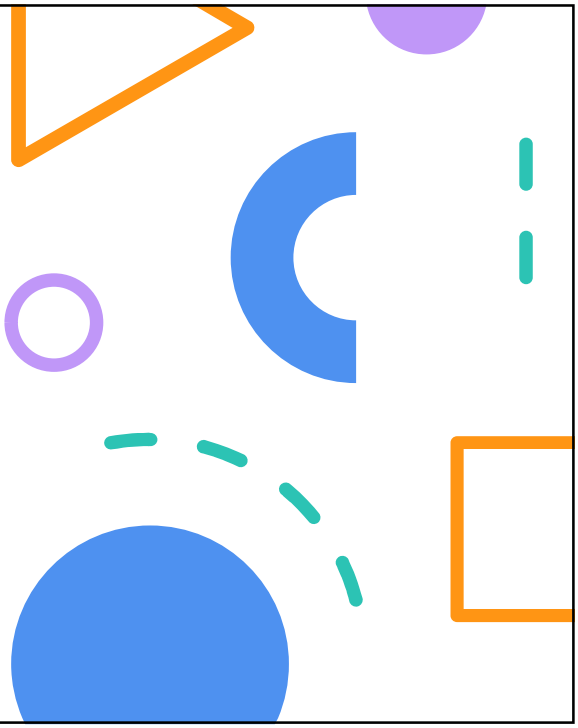
American Academy of Audiology

- https://www.audiology.org/news-and-publications/audiology-today/articles/embracing-change-in-audiological-treatment-over-the-counter-hearing-devices/
- Erin Miller, AuD



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American Academy of Audiology

- https://eaudiology.audiology.org/products/regulation-of-over-the-counter-hearing-aids-overview-part-1-of-2
- Catherine Palmer, PhD
- Susan Pilch, JD

- https://eaudiology.audiology.org/products/regulation-of-over-the-counter-hearing-aids-analysis-part-2-of-2
- Sarah Sydlowski, AuD, PhD, MBA
- Catherine Palmer, PhD
- Sumit Dhar, PhD
- Ryan McCreery, PhD

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American Academy of Audiology

- https://www.audiology.org/news-and-publications/audiology-today/articles/navigating-your-practice-now-that-mainstream-over-the-counter-hearing-aids-are-coming/

Amit Gosalia, AuD

Judy Huch, AuD

Heather Malyuk, AuD

Emily McMahan, AuD

Jackie Napoli, AuD

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American Speech-Language-Hearing Assn

- **Over-the-Counter Hearing Aids: Be the Change**
- https://leader.pubs.asha.org/doi/10.1044/leader.aea.25012020.18
- Tim Nanof, MSW

- Change is coming. Over-the-counter (OTC) and self-fitting hearing aids will likely be on the market by the fall.
- Indeed, OTC hearing aids present challenges and opportunities for audiologists in practices that dispense hearing aids and provide related services and supports. And several national pushes are moving OTCs and increased access to hearing health care closer to reality.

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American Speech-Language-Hearing Assn

- **Americans Want Professionals' Guidance on Hearing Care, Know Little About Coming Over-the-Counter Hearing Aids (OTCs)**
- https://www.asha.org/news/2021/americans-want-professionals-guidance-on-hearing-care-know-little-about-coming-over-the-counter-hearing-aids-otcs/

- "It is critical that the public understands what these products can and cannot do—and who should be using them and how," said Charles E. Bishop, AuD, PhD, CCC-A, ASHA Board Member at Large in Audiology.
- "We don't want people to further damage their hearing by purchasing a device that will over-amplify sound.
- We also don't want to see people purchasing devices that are not strong enough for their hearing loss."

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Academy of Doctors of Audiology

- To OTC or Not To OTC? How Audiologists Need to Respond to Over-The-Counter Hearing Aids
- https://www.audiologist.org/item/to-otc-or-not-to-otc-how-audiologists-need-to-respond-to-over-the-counter-hearing-aids?
- Nancy M. Williams

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Academy of Doctors of Audiology

A communications needs assessment provides a way for audiologists to differentiate themselves from online, drugstore, and other value channels offering OTC hearing aids.

Call out table: Communications Needs Assessment

- Patient's chief complaint
- Lifestyle and cosmetic needs
- Psychological, medical, social, and vocational impact of patient's chief complaint
- Diagnostic audiologic test results
- Loudness discomfort and speech-understanding- in-noise measures
- The Rear Ear Unaided Response (REUR)
- Dexterity & physical ability
- Cognitive status
- Self-confidence
- Family support

Source: Kim Cavitt, Au.D., Audiology Resources, Inc.

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Learning Outcomes

- Remember and recall the timeline of government activities associated with implementing the legal distribution of over-the-counter hearing aids in the US.
- Understand the FDA Proposed Rule for implementation, in 2022, of The Over-the-Counter Hearing Aid Act of 2017.
- Apply information on the proposed rule to create a clinical practice plan for the introduction of over-the-counter hearing aids in the US.

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Thank you

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