Counter Steer – OTC Updates: Its Impact on State Licensure Boards

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National Council of State Boards of Examiners, 36th Annual Conference, Charlotte, NC, October, 2023

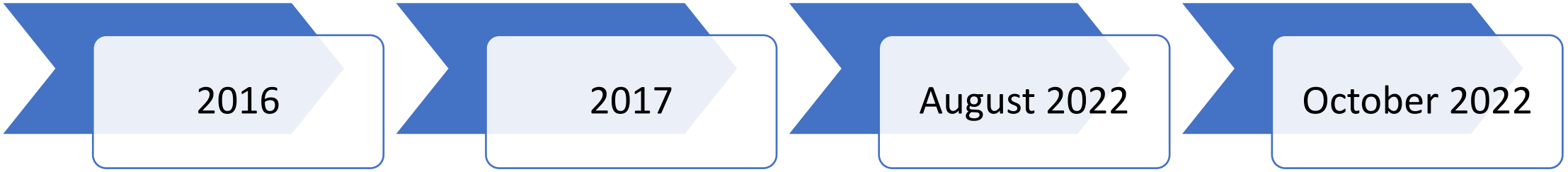
Disclosures & Disclaimers

- Audiology member on the NC State Board of Examiners for Speech Language Pathology and Audiology
  - Providing travel support to NCSB meeting
- Member of Audiology and SLP Interstate Compact

- Salary from Duke University and Department of Veterans Affairs
- Funding from NIH, PCORI, VA

- My views are my own and do not represent those of my employers or funders or boards

Over-the-Counter (OTC) Hearing Aids



President's Council of Advisors on Science and Technology (PCAST) and the National Academies of Sciences, Engineering, and Medicine (NASEM) reports on hearing loss

Congress passed bipartisan legislation requiring the FDA to create a category of OTC hearing aids

Final FDA ruling on OTC hearing aids

OTC hearing aids available in retail and online markets in US

Impact for Board and Licensees

Impact for Board and Licensees

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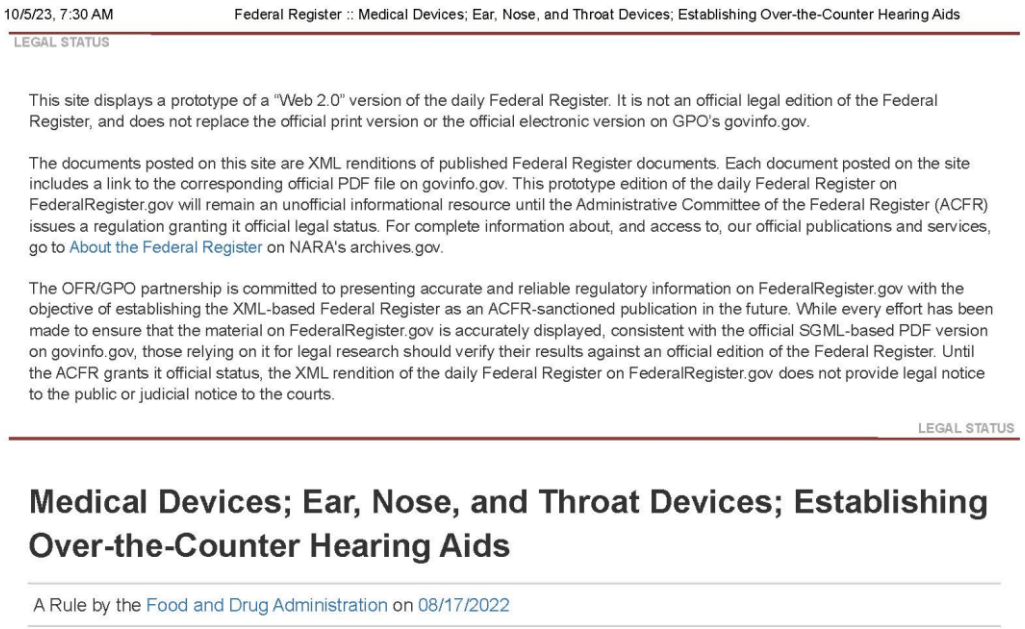

10/5/23, 7:30 AM Federal Register :: Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

LEGAL STATUS

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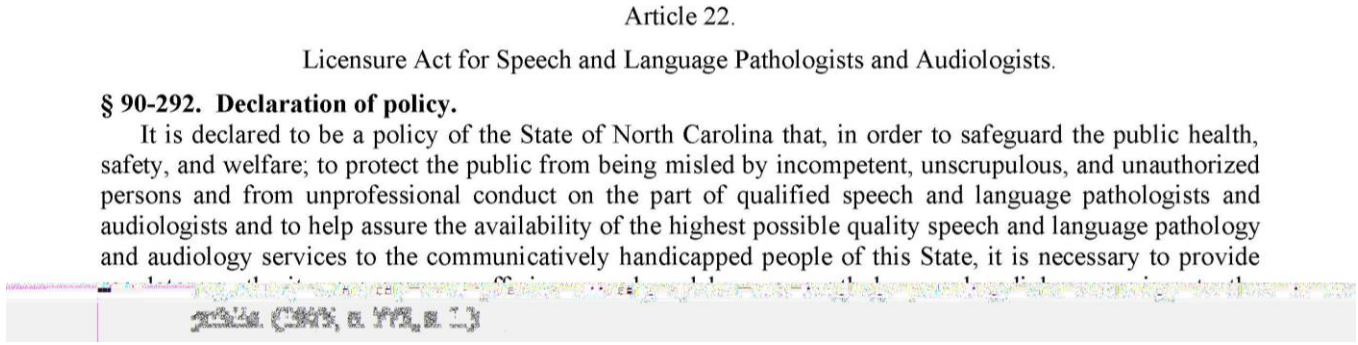
LEGAL STATUS

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

A Rule by the Food and Drug Administration on 08/17/2022



Article 22.

Licensure Act for Speech and Language Pathologists and Audiologists.

§ 90-292. Declaration of policy.

It is declared to be a policy of the State of North Carolina that, in order to safeguard the public health, safety, and welfare; to protect the public from being misled by incompetent, unscrupulous, and unauthorized persons and from unprofessional conduct on the part of qualified speech and language pathologists and audiologists and to help assure the availability of the highest possible quality speech and language pathology and audiology services to the communicatively handicapped people of this State, it is necessary to provide

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PART XII. UPDATE GENERAL STATUTES GOVERNING THE PRACTICE OF AUDIOLOGY TO BETTER REFLECT THE CHANGES IN EDUCATION, EXPERIENCE, AND PRACTICE OF THE PROFESSION TO ENHANCE THE HEALTH AND WELFARE OF NC CITIZENS.

SECTION 12.1.(a) G.S. 90-292 reads as rewritten:

"**§ 90-292. Declaration of policy.**

It is declared to be a policy of the State of North Carolina that, in order to safeguard the public health, safety, and welfare; to protect the public from being misled by incompetent, unqualified, unscrupulous, and unauthorized persons and from unprofessional conduct on the part of qualified speech and language pathologists and audiologists and to help assure the availability of the highest possible quality speech and language pathology and audiology services to the

f. Assessing the candidacy of persons with hearing loss for cochlear implants, auditory brainstem implants, middle ear implantable hearing aids, fully implantable hearing aids, bone-anchored hearing aids, and post-surgery audiologic testing, follow-up assessment, and nonmedical management.

g. Offering audiologic decision making for treatment for persons with impairment of auditory function utilizing amplification or other hearing impairment assistive devices, or auditory training.

h. Ordering the use of, selecting, fitting, evaluating, and dispensing hearing aids and other amplification or hearing-assistive or hearing-protective systems and audiologic rehabilitation to optimize use. The sale of an over-the-counter hearing aid is solely a financial transaction and, without additional services, does not constitute treatment by an audiologist.

i. Fitting and mapping of cochlear implants and audiologic rehabilitation to optimize device use.

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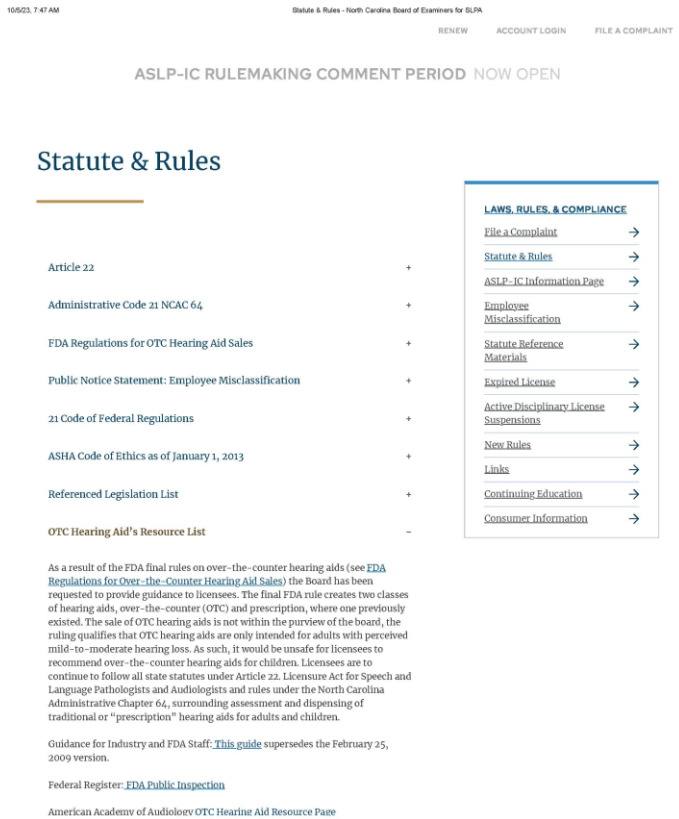

10/5/23, 7:47 AM Statute & Rules - North Carolina Board of Examiners for SLPA

RENEW ACCOUNT LOGIN FILE A COMPLAINT

ASLP-IC RULEMAKING COMMENT PERIOD NOW OPEN

Statute & Rules

Article 22 +

Administrative Code 21 NCAC 64 +

FDA Regulations for OTC Hearing Aid Sales +

Public Notice Statement: Employee Misclassification +

21 Code of Federal Regulations +

ASHA Code of Ethics as of January 1, 2013 +

Referenced Legislation List +

OTC Hearing Aid's Resource List –

As a result of the FDA final rules on over-the-counter hearing aids (see FDA Regulations for Over-the-Counter Hearing Aid Sales) the Board has been requested to provide guidance to licensees. The final FDA rule creates two classes of hearing aids, over-the-counter (OTC) and prescription, where one previously existed. The sale of OTC hearing aids is not within the purview of the board, the ruling qualifies that OTC hearing aids are only intended for adults with perceived mild-to-moderate hearing loss. As such, it would be unsafe for licensees to recommend over-the-counter hearing aids for children. Licensees are to continue to follow all state statutes under Article 22. Licensure Act for Speech and Language Pathologists and Audiologists and rules under the North Carolina Administrative Chapter 64, surrounding assessment and dispensing of traditional or "prescription" hearing aids for adults and children.

Guidance for Industry and FDA Staff: This guide supersedes the February 25, 2009 version.

Federal Register: FDA Public Inspection

American Academy of Audiology OTC Hearing Aid Resource Page

LAWS, RULES, & COMPLIANCE

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Statute & Rules →

ASLP-IC Information Page →

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Links →

Continuing Education →

Consumer Information →

OTC Hearing Aid's Resource List –

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Guidance for Industry and FDA Staff: This guide supersedes the February 25, 2009 version.

Federal Register: FDA Public Inspection

American Academy of Audiology OTC Hearing Aid Resource Page

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Online sale of hearing aid policy for website Draft

The online sale and fitting of a traditional or "prescription" hearing aid falls under the jurisdiction of NC Administrative Code Title 21, Chapter 64 sections .0215 Standard of Practice for Audiological Evaluations and .0220 Standards for Audiologists who Dispense Hearing Aids. Licensees are required to follow all rules related to dispensing prescription hearing aid no matter the service delivery model.

As a result of the Food and Drug Administration (FDA) Over-the-Counter (OTC) Hearing Aid Regulations, the Board is providing additional guidance to Licensees regarding the state's statutory requirements. It will be the Board's policy that the sale of OTC hearing aids without fitting and maintenance by an audiologist shall not require an examination of the ear canal.

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Fitting and maintaining OTC Hearing Aid Policy for website Draft

If an Audiologist fits and maintains the OTC Hearing Aid for a patient; it falls under the practice of Audiology and the jurisdiction of the NC Board of Examiners for Speech and Language Pathologists and Audiologists.

Fitting and maintaining "Prescription" Hearing Aids Policy for website Draft

For "prescription" hearing aids licensees are to continue to follow all state statutes under Article 22 Licensure Act for Speech and Language Pathologists and Audiologists and rules under the North Carolina Administrative Code Title 21, Chapter 64, surrounding the assessment and dispensing of traditional or "prescription" hearing aids for adults and children.

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Reminder for Licensees website Draft

OTC hearing aids are only intended for adults with perceived mild-to-moderate hearing loss. As such, it would be unsafe for licensees to recommend OTC hearing aids for children (less than the age of 18).

Counter Steer – OTC Updates: Its Impact on State Licensure Boards

Tammy Brown (OH)

Disclosures

Financial – Conference registration and travel to attend the conference is being covered by my licensure board

Non-Financial – I am a licensed dispensing audiologist and serve as board president on the Speech and Hearing Professionals Board, president of NCSB, and serve on the ASLP-ICC's Executive Committee

OTC Hearing Aids – Impact on Ohio

- Developed real time working FAQs

- With AAG Office of AG Yost; addressed confusion between “prescription” and “OTC” hearing aids
  - At Ohio and board level, at national level
  - FDA clarified intent of “prescription” hearing aids

- Met with board’s Assistant Attorney General, Crystal Richie
  - Connected with Ohio Attorney General’s Office Consumer Protection Section
  - Hearing aid sales, including refunds are covered under Ohio’s Consumer Sales Practice Act (CSPA)
  - Board’s rules and CSPA’s rules mirrored each other and FDA regulations

OTC Hearing Aids – Impact on Ohio

- Drafted rules for public comment
  - Based on new FDA regulations
  - Based on scope of practice – freedom for dispensers acknowledging transparency of scope practice(s) and types of hearing aids
  - Public comment lasted for 6 months with no comments
    - Shared with stakeholders in advance

- Focus of rules
  - Definitions to distinguish OTCs from prescription hearing aids
  - OTCs are not covered under scope of practice(s)
  - Rescinded medical clearance and medical waiver language for persons 18 years of age or older
  - Red flag conditions still exist and require referral to physician

- Rules hearing in October; will go into effect on January 1, 2024

Note: The current rule appears below. Blue underlined text is proposed new language. Red text with strikethrough is proposed deleted language.

4747-1-02 **Definitions and interpretations.**

(A) The statement "includes the making of ear impressions for earmolds" shall apply only to earmolds that are used with devices as defined in division (A) of section 4747.01 of the Revised Code.

(B) "Obtained any fee or made any sale of a hearing aid by fraud or misrepresentation" means that any person who obtains a fee, i.e., the owner of the business, the hearing aid dealer or fitter, the supervisor, or trainee shall be held responsible for the sale of a hearing aid by fraud or misrepresentation regardless of whether or not that person was directly involved with the fitting or sale of the aid.

(C) The practice of dealing in or fitting of a hearing aid shall only apply to prescription hearing aids and includes hearing screening of individuals, provided they are advised that the screening is to determine if they are a candidate for a hearing aid, and the results are reported as either pass or fail. The practice of dealing in or fitting of a hearing aid does not apply to the category of hearing aids defined by the U.S. Food and Drug Administration as over-the-counter hearing aids.

(D) "Contact hours" means the actual time a trainee or trainees spend under the direct an immediate supervision of a licensed hearing aid dealer or fitter acting as a supervisor.

(E) "Supervision" means the availability and responsibility of the supervisor for direction of the actions of the person supervised.

(F) "Mail" means send a notification/service in the form of paper or electronic including notification by email or public posting by website or electronic notification board or page.

Note: The current rule appears below. Blue underlined text is proposed new language. Red text with strikethrough is proposed deleted language.

*** DRAFT - NOT YET FILED ***

4747-1-19 **Rules on appropriate test procedures.**

~~(I)Except as noted in paragraph (J) of this rule, a licensee shall not sell a hearing aid unless the prospective user has presented to the licensee a written statement signed by a licensed physician that states the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding six months.~~

~~(J)An exception to medical referral can be made only if the prospective hearing aid user is eighteen years of age or older and following viewing of the ear canals, taking a case history and completing appropriate testing. The licensee may, in such cases, afford the prospective user an opportunity to waive the medical evaluation provided that the licensee:~~

~~(1)Informs the prospective user that the exercise of the waiver is not in the user's best health interest;~~

~~(2)Does not in any way actively encourage the prospective user to waive such medical evaluation; and~~

~~(3)Affords the prospective user the opportunity to sign a wavier stipulating to the above. The waiver shall be printed in bold face type of the minimum size of ten points to include the following statements:~~

~~" I have been advised by~~

~~_____~~

~~(Hearing Aid Dispenser's Name)~~

~~that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid."~~

~~The licensee or trainee must provide the prospective hearing aid user with a copy of this signed waiver.~~

Note: The current rule appears below. Blue underlined text is proposed new language. Red text with strikethrough is proposed deleted language.

4753-8-01 **Definitions.**

(A) "Hearing aid" means any wearable instrument or device, classified as a prescription hearing aid, designed or offered for the purpose of aiding or compensating for impaired human hearing, including all attachments, accessories, and parts thereof, except batteries and cords. This definition does not include over-the-counter hearing aids as defined by the U.S. Food and Drug Administration.

(B) "Practice of dispensing" or "fitting" of hearing aids means the sale of a prescription hearing aid, and the measurement and testing of human hearing by means of an audiometer or by any other means for the purpose of selecting, adapting, and selling a prescription hearing aid to any person, and includes the making of impressions for earmolds. This definition does not apply to over-the-counter hearing aids as defined by the U.S. Food and Drug Administration.

(C) "Dispensing audiologist" means an audiologist who is licensed pursuant to Chapter 4753. of the Revised Code and who is engaged in the practice of dispensing or fitting of prescription hearing aids.

(D) "Dispense," "sell" or "sale" means the retail transfer of title or of the right to use by lease, bailment, or any other contract, but does not include a wholesale sale to a distributor or dealer.

(E) "Assistive listening device" means an auxiliary aid which enhances ease of communication, telephone communication, and reception of important warning signals.

(F) "Advertising" includes all advertisements to the general public offering replicas, descriptive literature on assistive listening devices, wearable hearing aids or hearing loss, etc., placed by an audiologist licensed under Chapter 4753. of the Revised Code or an organization whose business includes the merchandising of hearing aids and assistive listening devices for sale.

Note: The current rule appears below. Blue underlined text is proposed new language. Red text with strikethrough is proposed deleted language.

*** DRAFT - NOT YET FILED ***

4753-8-03 **Rules on appropriate hearing aid test procedures.**

(A) An audiologist is responsible for the accuracy of an evaluation and shall utilize the results of appropriate evaluative procedures on every individual to whom he/she sells or fits a prescription hearing aid. He/she shall retain the results on file for a period of at least three years for adult patients, or in the case of patients under the age of twenty-one years, three years past the date of the patient's twenty first birthday, or as required by federal or state laws and regulations.

(B) An audiologist shall advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if medical intervention is indicated by documented case history, actual observation, or review of any diagnostic audiological or other available information concerning the prospective user.

~~(C) An audiologist shall only sell hearing aids to a prospective user who has presented one of the following types of documentation, which document shall be retained by the audiologist for three years after the dispensing of a hearing aid:~~

~~(1) A written statement, signed by a licensed physician, that states the prospective user is his/her patient, the patient's hearing loss has been medically evaluated on a date that is within the six months preceding the sale, and the patient may be considered a candidate for a hearing aid.~~

~~(2) A written waiver of the medical evaluation signed by the prospective user provided all of the following conditions are met:~~

~~(a) The prospective user is at least eighteen years of age;~~

~~(b) The audiologist informs the prospective user that the exercise of the waiver is not in the user's best health interest;~~

~~(c) The audiologist does not in any way actively encourage the prospective user to waive such a medical evaluation;~~

~~(d) The waiver consists of the following statement printed in boldface type of the minimum of ten points:~~

~~"I have been advised by (Audiologist's name) that the food and drug administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid."; and~~

~~(e) The audiologist provides the prospective user with a copy of the signed waiver.~~

OTC Hearing Aids – Impact on Ohio

- Ohio Pharmacy Board Inquiry
  - Collaborative education between respective licensure boards
  - E-mail blast to licensed pharmacists
  - Shared in-state and national association education FAQs

- Anecdotal reflection on consumer's embracing OTCs
  - OTC manufacturers already dropping out; return rate

Speaker Contact:
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Counter Steer- OTC Updates: Its Impact on State Licensure Boards-Louisiana

Dr. Jerrilyn Frasier-Vaughan

Where to Begin?

The Food and Drug Administration (FDA) established an Over-the-Counter (OTC) Hearing Aid category by Rule in August 2022. This rule does not change the necessary qualifications of those who may provide hearing healthcare with prescription hearing aids.

Proposed law revisions are being put forth by the Louisiana Academy of Audiology (LAA), in consultation with the Louisiana Board of Examiners for Speech-Language Pathology and Audiology.

A letter of support has also been received from the Louisiana Speech Language Hearing Association (LSHA).

Proposed Legislative Changes….

- An audiologist, by definition of scope of practice, may sell and dispense hearing aids as defined by the Food and Drug Administration in accordance with this Chapter.

OTC Defined

- Over the counter hearing aid” means a hearing instrument or hearing aid that meets the current Food and Drug Administration’s requirements for this class of device and which may be dispensed or sold without a hearing assessment, licensed hearing instrument professional fitting and dispensing engagement, or return for credit privileges as provided by federal law.

PSAP

- Personal Sound Amplification Product” means an amplification device, as defined by the Food and Drug Administration or the Federal Trade Commission that is not labeled as a hearing aid and is not intended to treat hearing loss.

Prescriptive Hearing Aids

- Prescription hearing aid means a hearing instrument or hearing aid that meets the Food and Drug Administration's requirements for this class of device and which requires: (a) a hearing assessment and prescription for medically necessary hearing aids prior to purchase, (b) fitting and dispensing by a licensed hearing instrument professional.

All Classifications of Hearing Aids

In the Meantime….

Differences between Over-The-Counter (OTC) and Prescriptive Hearing Devices

Over-the-counter (OTC) hearing devices are now available to the public. As of October 2022, consumers can purchase over-the-counter hearing devices online, in pharmacies, big-box stores, and even through audiologists. Using over-the-counter devices may be a starting point for adults with perceived mild to moderate hearing loss. As the licensure board, it is our mission to protect the consumers of Louisiana, so we want to ensure that they receive necessary information to assist in making an informed decision when beginning their hearing healthcare journey.

We have adapted the following chart, originally created by our colleagues at the ***Louisiana Academy of Audiology (LAA***). Please feel free to share.

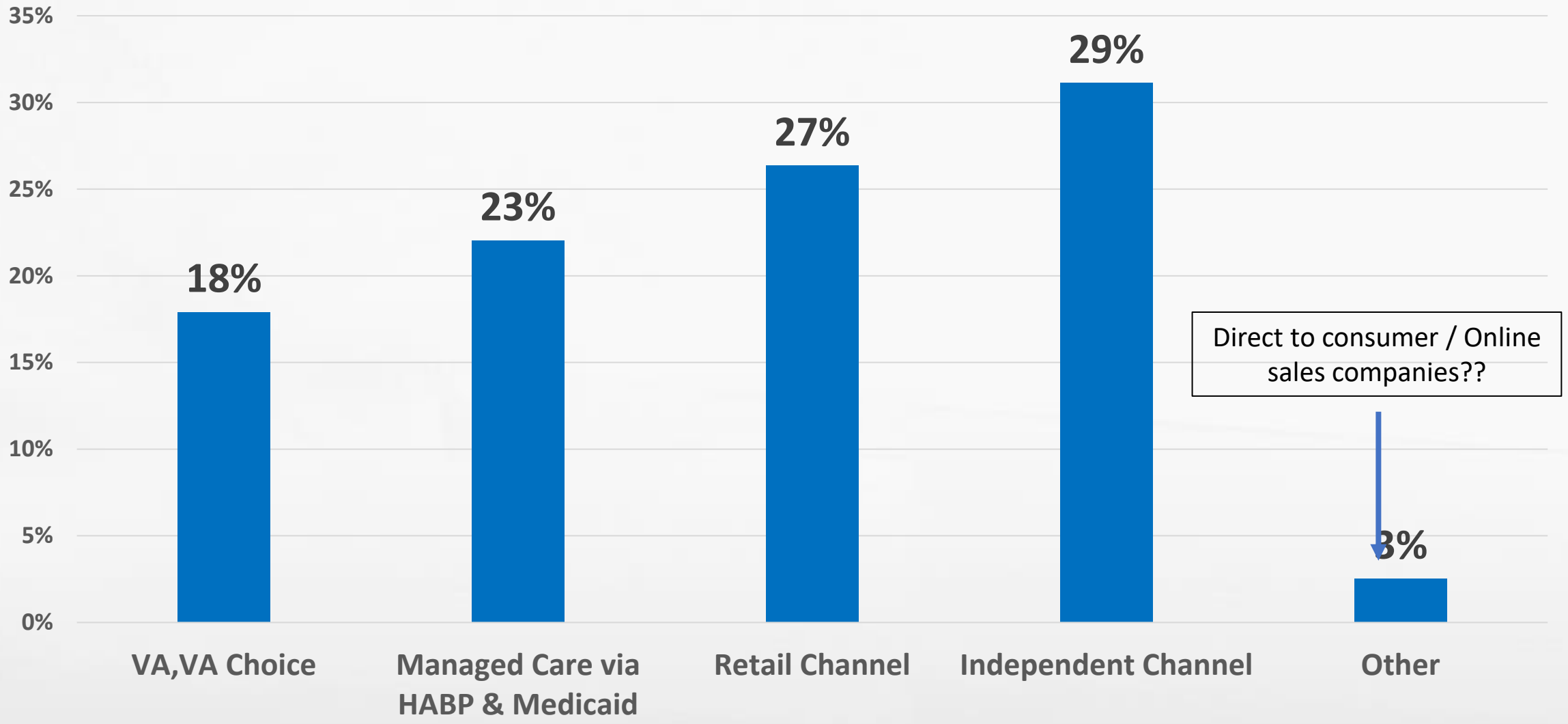
	Over-the-Counter (OTC) Hearing Devices	Prescriptive Hearing Aids (Dispensed by a licensed hearing healthcare professional)
PRICE	Wide Range	Average $2000-$8000. May be eligible for some insurance coverage or state funded plans.
AGE	18 years+	Any Age
HEARING RANGE	Mild to Moderate Hearing Loss	All degrees of hearing loss.
HEARING HEALTH	No medical evaluation or diagnosis to rule out medically treatable hearing disorders.	Continued medical management for evaluation and treatment of hearing loss following otolaryngological referral for medically treatable hearing disorders.
EVALUATION	Patients fit themselves with devices. Can be done with pre-set programs/ smartphone app guided self-programming.	Comprehensive audiological examination. Otoscopic examination of ears (wax removal if needed). Appropriate referral made for medical treatment of diseased ear(s) if applicable.
FITTING	Relies on the patient's self-perception of their hearing loss. Some devices provide a self-assessment of hearing through a smartphone application.	Programmed to individual prescriptive hearing thresholds by licensed hearing professionals (Audiologists or hearing aid specialists). Noise reduction technology and tinnitus management available.
CUSTOMIZATION	None	Fit to the unique needs of the patient.
STYLE OPTIONS AND SELECTION	Typically, one-size-fits-most. Some devices provide a small selection of sizes (consumer selects the fit). Most choose devices based on consumer research and reviews.	Hearing healthcare providers will discuss appropriate devices based on individual patient needs. Includes customized, discreet options.
HELP WITH USER TRAINING	None	In-person training on use/care of devices with a licensed professional. Ongoing support with adjustment to new sounds and new technology, including troubleshooting with accessories and smart phone apps.
HELP WITH DEVICE MAINTENANCE	Typically, none. Some packages may provide a contact number for assistance, but this is not required by the FDA.	On-going cleaning, device checks, and adjustments – some fees may apply.
VERIFICATION OF AMPLIFICATION	None	Real-Ear measurements to confirm individual prescriptive targets are met.
DEVICE LIFESPAN	Unknown	Approximately 5 years.
RETURN POLICY	No requirement proposed by the FDA.	Minimum 30 days. Most clinics range from 30-75 days.

How Concerned Should We Be?

- Only 2% of American adults ages 40 and older who have hearing difficulties reported that they have purchased them, and only4% reported that they are likely to purchase OTCs in the next year.
- Further substantiated by manufacturer's data.

Who is buying all the Hearing Aids?

Estimated OTC sales Y1
~1,000,000 units



- Source: Manufacturer data 2022

Manufacturer Response….