A Prescription for Change – How to Conform State Laws to Align with FDA Prescription Hearing Aid Regulations and Protect Consumer Access to Care

April 11, 2023

ADA ACADEMY of DOCTORS of AUDIOLOGY®

amplifon

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Historical Perspective on Hearing Aid Regulations in the United States

Pre-1959

No federal or state regulation

1959 - 1977

States begin to regulate hearing aid sales and dispensing practices

1959: Or. Rev. Stat. § 694.015-.991 (1975).
1966: Mich. Comp. Laws Ann. § 338.1451-.1466 (1976).
1967: Fla. Stat. Ann. § 468.120-.138 (West 1977).
Ind. Code Ann. § 25-20-1-1 to 24. (Burns 1974) (amended 1976).
Tenn. Code Ann. § 63-1501 to 1521 (1976).
1968: Kan. Stat. Ann. § 74-5801 to 5824 (1972) (amended 1976).
La. Rev. Stat. Ann. § 37:2441-:2465 (West 1974).
S.D. Compiled Laws Ann. § 36-24-1 to 43 (1972) (amended 1976).
1969: Ark. Stat. Ann. § 72-1701 to 1717 (Supp. 1975).
Md. Ann. Code art. 43, §§ 737-754A (1971) (amended 1976).
Mont. Rev. Codes Ann. § 66-3003 to 3022 (Supp. 1975).
Neb. Rev. Stat. § 71-4701 to 4719 (1976).
N.M. Stat. Ann. § 67-36-1 to 18 (1974).
N.C. Gen. Stat. § 93D-1 to 16 (Supp. 1975).
N.D. Cent. Code § 43-33-01 to 19 (Supp. 1977).
Ohio Rev. Code Ann. § 4747.01-.99 (Page 1977).
Tex. Rev. Civ. Stat. Ann. § 4566-1.01 to 1.22 (Vernon 1976).
Wisc. Stat. Ann. § 459.01-.14 (West 1974) (amended 1976).
1970: Ariz. Rev. Stat. § 36-1901 to 1938 (1974).
Cal. Bus. & Prof. Code §§ 3300-3456 (West 1974).
Ga. Code Ann. § 84-5601 to 5620 (1975).
Va. Code § 54-524.110-.116 (1976).
1971: Ala. Code, tit. 46, § 150(21)-(39) (Supp. 1974).
Idaho Code § 54-2901 to 2919 (Supp. 1977).
S.C. Code § 40-25-10 to 190 (1977).
1972: Conn. Gen. Stat. Ann. § 20-396 to 407 (West Supp. 1976).
Ky. Rev. Stat. § 334.010-.990 (Supp. 1976).
Miss. Code Ann. § 73-14-1 to -47 (Supp. 1977).
1973: Del. Code tit. 16, §§ 2001-2020 (1975) (amended 1976).
Minn. Stat. Ann. § 145.43-.45 (West Supp. 1976).
Mo. Rev. Stat. § 346.010-.135 (Vernon Supp. 1976).
Nev. Rev. Stat. § 637A.010-.360 (1975).
N.J. Stat. Ann. § 45:9A-1 to-28 (West Supp. 1977).
Okla. Stat. Ann. tit. 59, §§ 1551-1569 (West Supp. 1976).
R.I. Gen. Laws § 5-49-1 to 20 (1976).
Wash. Rev. Code Ann. § 18.35.010-.900 (Supp. 1977).
W. Va. Code § 16-24-1 to 20 (Supp. 1976).
1974: Haw. Rev. Stat. § 451A-1 to 19 (Supp. 1975).
Iowa Code Ann. § 154A.1-.27 (West Supp. 1977).
1975: Colo. Rev. Stat. § 12-65-101 to 121 (Supp. 1976).
Me. Rev. Stat. tit. 32, §§ 1658 to 1660-F (Supp. 1976).
N.Y. Gen. Bus. Law §§ 780-787 (McKinney Supp. 1976).
Vt. Stat. Ann., tit. 18, §§ 4581-4586 (Supp. 1977).
1976: Pa. Stat. Ann. tit. 35 § 6700-101 to 802 (Purdon Supp. 1977).
1977: Wyo. Sess. Laws Ch. 163 (1977).

1977 - 2022

FDA promulgates first-ever regulations governing hearing aids at federal level

1977

FDA begins regulating hearing aids "restricted devices" subject to various restrictions on sale, distribution, and use.

August 16, 2022

FDA transforms federal regulatory landscape by:

- Establishing OTC hearing aid category
- Reclassifying all non-OTC hearing aids as "prescription devices."

Overview of FDA's Regulatory Changes Governing Hearing Aids

FDA NEWS RELEASE

FDA Finalizes Historic Rule Enabling Access to Over-the-Counter Hearing Aids for Millions of Americans

More Affordable Hearing Aids Could Be in Stores as Soon as Mid-October

Share | Tweet | Linkedin | Email | Print

For Immediate Release: August 16, 2022

Final Regulatory Changes

OTC Hearing Aids

Hearing aids meeting certain regulatory controls may be sold to adults with "**perceived mild to moderate**" hearing loss without involvement of hearing care professional.

Prescription Hearing Aids

Non-OTC hearing aid available with a "prescription or other order from a state-licensed practitioner."

Changes Became Effective October 17, 2022

Overview of Prescription Hearing Aid Regulation

OTC Hearing Aids

Intended For	Both Adults with perceived mild to moderate hearing loss
Types (2)	(1) Preset-Based and (2) Self-Fitting
Amplification	111 dB SPL unless device features active input compression, then 117 dB SPL
Sold Online	Yes
Labels	Specific Labels Required
Consumer Protections	Limited due to issues surrounding federal preemption
Design & Performance Requirements	Yes, specific requirements apply
Prescription Required	No, OTC devices may be sold without involvement of a professional.

Overview of Prescription Hearing Aid Regulation

Prescription Hearing Aids

Intended For	Both Adults and Children
Amplification	No Limits
Sold Online	Depends on State Law. If Allowed, Prescription Required
Labels	Specific Labels Required
Consumer Protections	Existing Federal and State Protections Apply
Prescription Required	Yes, pursuant to 21 CFR §801.109.

Ambiguity Leads to Stakeholder Request for Guidance from FDA

Stakeholders Request FDA Guidance from FDA on Prescription Devices

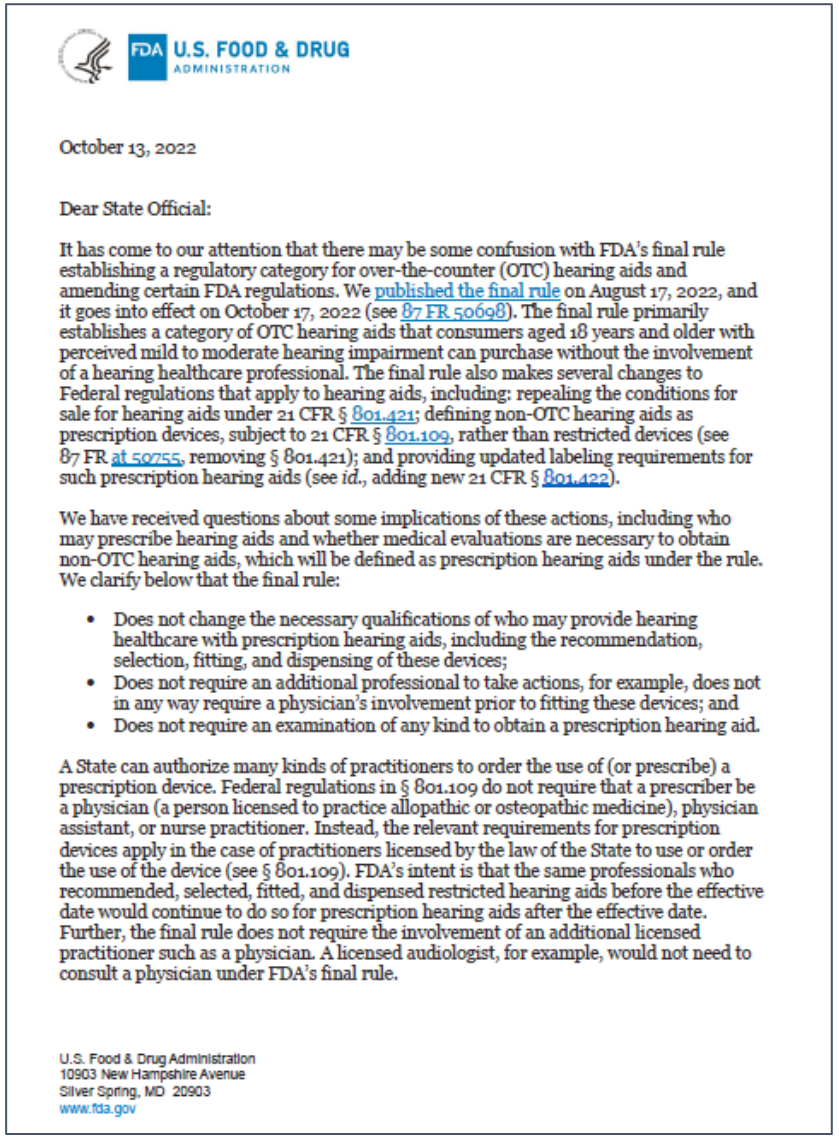
ADA ACADEMY of DOCTORS of AUDIOLOGY

AMERICAN ACADEMY OF AUDIOLOGY

HLAA Hearing Loss Association of America

HIA Hearing Industries Association

IHS International Hearing Society



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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

"We clarify 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."

"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."

But…

FDA does not have jurisdiction over state licensure. As such, each state will need to adopt necessary policy changes to align with the federal changes to avoid any unintended consequences.

Practical Implication of Shift to "Prescription Device" Regulation

FDA's Prescription Device Regulation

§ 801.109 Prescription devices.

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)

(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

What Does this Mean?

1. **Prescription hearing aids may only be dispensed to patients with a "prescription or other order" from a state-licensed practitioner.**

2. **While FDA's "Dear State Official Letter" was helpful in clarifying federal intent, FDA ultimately lacks jurisdiction to regulate the scope of state practitioner licensure.**

3. **Ultimately, states must define which specific practitioners have the authority to "prescribe" or "order" non-OTC hearing aids to protect patient access to prescription hearing aids.**

4. **Problematically, few states include the terms "prescribe" or "order" in the scope of practice for audiologists and hearing aid specialists.**

To ensure patient access to prescription hearing aids, the audiology and dispensing professions should proactively pursue appropriate policy changes under state laws and regulations.

State Policy Solutions: Two Options

States must clarify that both audiologists and hearing aid specialists have the authority to "prescribe or order the use of" prescription hearing aids.

Legislation (Preferred Option)

Enact legislation amending existing laws to insert specific authorizing language in relevant statutes for both professions

Appropriate Language is Key. It is important to ensure that specific language is used when amending existing laws to ensure satisfactory clarification is achieved. Relevant definitions, and in some cases, scope of practice provisions should be amended to include professional authority to "prescribe" or "order the use of" non-OTC devices.

Guidance (Alternative Option)

Publication of administrative guidance by state regulatory bodies overseeing dispensing professionals

Note. Depending on status of a particular state's legislative session, this may be the only option to secure an immediate clarification. If guidance is obtained, it should be viewed only as a temporary clarification until a permanent resolution is obtained through legislation.

Importantly, the audiology and dispensing professions should **proactively** pursue these changes **collaboratively** to ensure unintended consequences of impacting patient access.

"Casus Omissus" and "Expressio Unius": Collaboration Between the Audiology and Dispensing Professions is Important to Protect Patient Access

Casus Omissus: A matter not covered by a statute should be treated as intentionally omitted.

266 U.S. 548 (1925)

EBERT ET AL.

v.

POSTON.

No. 153.

Supreme Court of United States.

"The judicial function to be exercised in construing a statute is limited to ascertaining the intention of the legislature therein expressed. A *casus omissus* does not justify judicial legislation. This Act is so carefully drawn as to leave little room for conjecture (internal citations omitted).

Expresio Unius: The expression of one thing implies the exclusion of others.

THE STATE OF SOUTH CAROLINA
In The Supreme Court

City of Rock Hill, Respondent,

v.

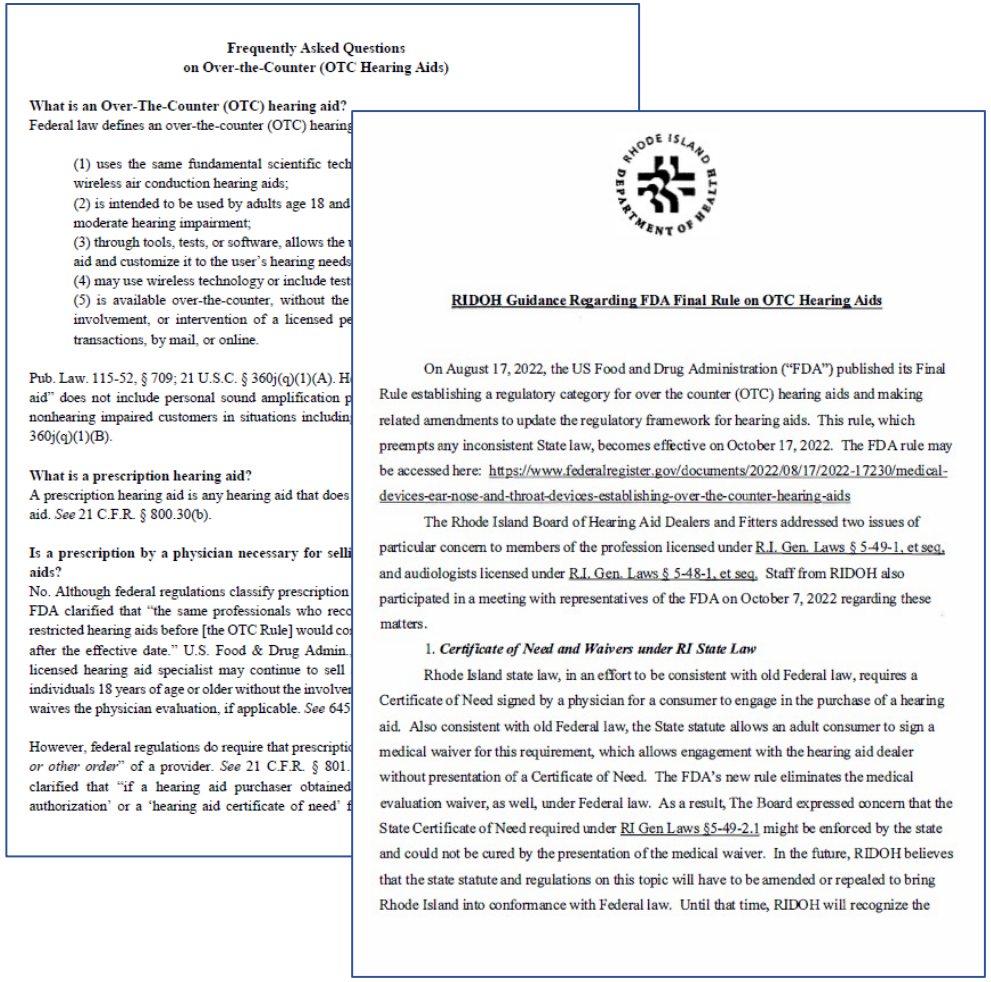
Tyler M. Harris, Appellant.

Appeal from York County
Lee S. Alford, Circuit Court Judge

"The power of our state legislature is plenary, and therefore, the authority given to the General Assembly by our Constitution is a limitation of legislative power, not a grant. [W]hen determining the effect of statutory language, the canon of construction expressio unius est exclusio alterius holds that to express or include one thing implies the exclusion of another, or the alternative" (internal citations omitted).

How are States Responding?

Issuing Administrative Guidance



Frequently Asked Questions
on Over-the-Counter (OTC Hearing Aids)

What is an Over-The-Counter (OTC) hearing aid?
Federal law defines an over-the-counter (OTC) hearing

(1) uses the same fundamental scientific tech
wireless air conduction hearing aids;
(2) is intended to be used by adults age 18 and
moderate hearing impairment;
(3) through tools, tests, or software, allows the
aid and customize it to the user's hearing needs
(4) may use wireless technology or include test
(5) is available over-the-counter, without the
involvement, or intervention of a licensed pe
transactions, by mail, or online.

Pub. Law. 115-52, § 709; 21 U.S.C. § 360j(q)(1)(A). H
aid" does not include personal sound amplification p
nonhearing impaired customers in situations includin
360j(q)(1)(B).

What is a prescription hearing aid?
A prescription hearing aid is any hearing aid that does
aid. *See* 21 C.F.R. § 800.30(b).

Is a prescription by a physician necessary for selli
aids?
No. Although federal regulations classify prescription
FDA clarified that "the same professionals who reco
restricted hearing aids before [the OTC Rule] would co
after the effective date." U.S. Food & Drug Admin.
licensed hearing aid specialist may continue to sell
individuals 18 years of age or older without the involve
waives the physician evaluation, if applicable. *See* 645

However, federal regulations do require that prescripti
or other order" of a provider. *See* 21 C.F.R. § 801.
clarified that "if a hearing aid purchaser obtained
authorization' or a 'hearing aid certificate of need' f

RHODE ISLAND DEPARTMENT OF HEALTH

RIDOH Guidance Regarding FDA Final Rule on OTC Hearing Aids

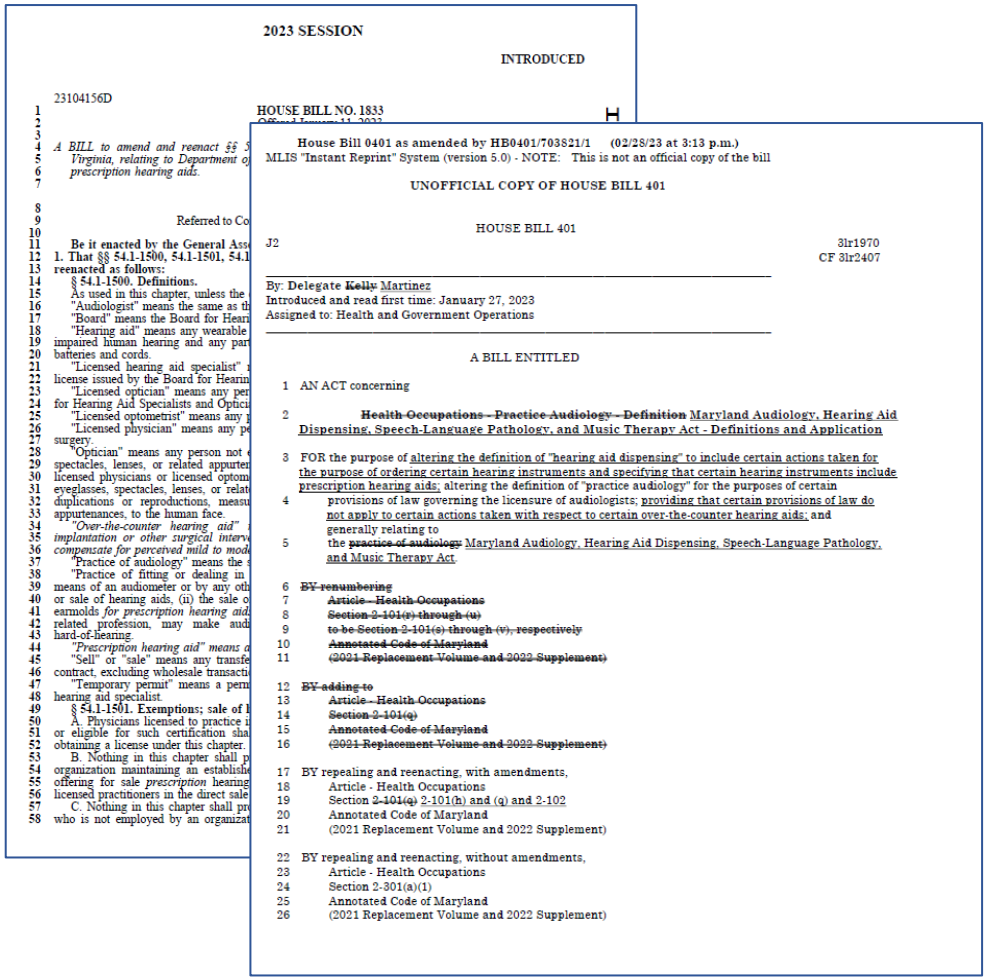
On August 17, 2022, the US Food and Drug Administration ("FDA") published its Final Rule establishing a regulatory category for over the counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids. This rule, which preempts any inconsistent State law, becomes effective on October 17, 2022. The FDA rule may be accessed here: https://www.federalregister.gov/documents/2022/08/17/2022-17230/medical-devices-ear-nose-and-throat-devices-establishing-over-the-counter-hearing-aids

The Rhode Island Board of Hearing Aid Dealers and Fitters addressed two issues of particular concern to members of the profession licensed under R.I. Gen. Laws § 5-49-1, et seq. and audiologists licensed under R.I. Gen. Laws § 5-48-1, et seq. Staff from RIDOH also participated in a meeting with representatives of the FDA on October 7, 2022 regarding these matters.

1. ***Certificate of Need and Waivers under RI State Law***

Rhode Island state law, in an effort to be consistent with old Federal law, requires a Certificate of Need signed by a physician for a consumer to engage in the purchase of a hearing aid. Also consistent with old Federal law, the State statute allows an adult consumer to sign a medical waiver for this requirement, which allows engagement with the hearing aid dealer without presentation of a Certificate of Need. The FDA's new rule eliminates the medical evaluation waiver, as well, under Federal law. As a result, The Board expressed concern that the State Certificate of Need required under RI Gen Laws §5-49-2.1 might be enforced by the state and could not be cured by the presentation of the medical waiver. In the future, RIDOH believes that the state statute and regulations on this topic will have to be amended or repealed to bring Rhode Island into conformance with Federal law. Until that time, RIDOH will recognize the

Legislative Proposals



2023 SESSION

INTRODUCED

23104156D

HOUSE BILL NO. 1833

A BILL to amend and reenact §§ 5
Virginia, relating to Department o
prescription hearing aids.

Referred to Co

Be it enacted by the General Ass
1. That §§ 54.1-1500, 54.1-1501, 54.1
reenacted as follows:
§ 54.1-1500. Definitions.
As used in this chapter, unless the
"Audiologist" means the same as th
"Board" means the Board for Heari
"Hearing aid" means any wearable
impaired human hearing and any par
batteries and cords.
"Licensed hearing aid specialist"
license issued by the Board for Hearin
"Licensed optician" means any per
for Hearing Aid Specialists and Optici
"Licensed optometrist" means any
"Licensed physician" means any pe
surgery.
"Optician" means any person not
spectacles, lenses, or related appurte
licensed physicians or licensed optom
eyeglasses, spectacles, lenses, or relat
duplications or reproductions, measu
appurtenances, to the human face.
"Over-the-counter hearing aid"
implantation or other surgical interv
compensate for perceived mild to mod
"Practice of audiology" means the
"Practice of fitting or dealing in
means of an audiometer or by any oth
or sale of hearing aids, (ii) the sale o
earmolds *for prescription hearing aid*
related profession, may make aud
hard-of-hearing.
"Prescription hearing aid" means a
"Sell" or "sale" means any transfe
contract, excluding wholesale transacti
"Temporary permit" means a perm
hearing aid specialist.
§ 54.1-1501. Exemptions; sale of
A. Physicians licensed to practice
or eligible for such certification sha
obtaining a license under this chapter.
B. Nothing in this chapter shall p
organization maintaining an establish
offering for sale *prescription* hearing
licensed practitioners in the direct sale
C. Nothing in this chapter shall pr
who is not employed by an organiza

House Bill 0401 as amended by HB0401/703821/1 (02/28/23 at 3:13 p.m.)
MLIS "Instant Reprint" System (version 5.0) - NOTE: This is not an official copy of the bill

UNOFFICIAL COPY OF HOUSE BILL 401

HOUSE BILL 401

J2 3lr1970
CF 3lr2407

By: Delegate ~~Kelly~~ Martinez
Introduced and read first time: January 27, 2023
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

~~Health Occupations - Practice Audiology - Definition~~ Maryland Audiology, Hearing Aid Dispensing, Speech-Language Pathology, and Music Therapy Act - Definitions and Application

FOR the purpose of altering the definition of "hearing aid dispensing" to include certain actions taken for the purpose of ordering certain hearing instruments and specifying that certain hearing instruments include prescription hearing aids; altering the definition of "practice audiology" for the purposes of certain provisions of law governing the licensure of audiologists; providing that certain provisions of law do not apply to certain actions taken with respect to certain over-the-counter hearing aids; and generally relating to the ~~practice of audiology~~ Maryland Audiology, Hearing Aid Dispensing, Speech-Language Pathology, and Music Therapy Act.

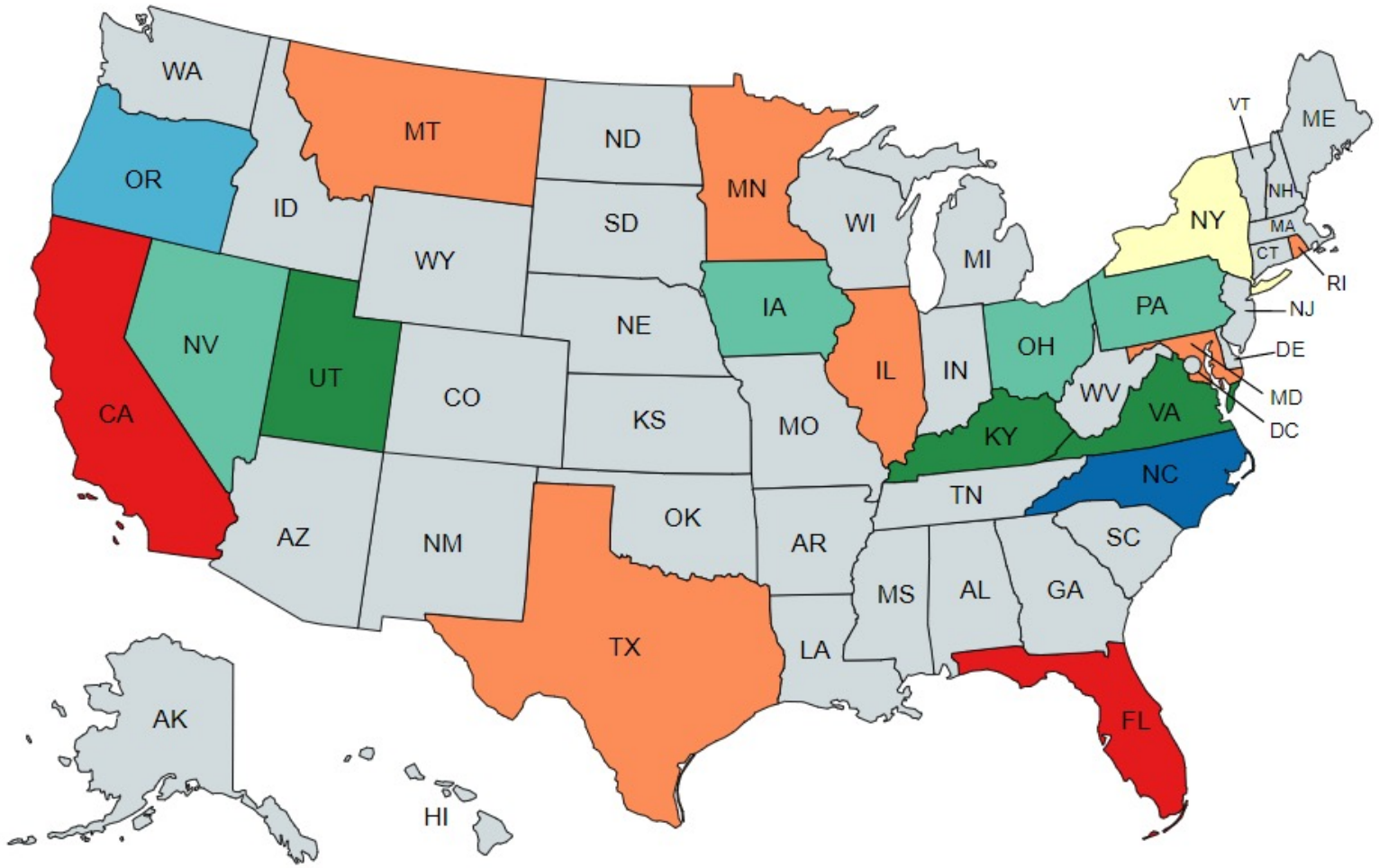
~~BY renumbering~~
~~Article - Health Occupations~~
~~Section 2-101(r) through (u)~~
~~to be Section 2-101(s) through (v), respectively~~
~~Annotated Code of Maryland~~
~~(2021 Replacement Volume and 2022 Supplement)~~

~~BY adding to~~
~~Article - Health Occupations~~
~~Section 2-101(q)~~
~~Annotated Code of Maryland~~
~~(2021 Replacement Volume and 2022 Supplement)~~

BY repealing and reenacting, with amendments,
Article - Health Occupations
Section ~~2-101(q)~~ 2-101(h) and (q) and 2-102
Annotated Code of Maryland
(2021 Replacement Volume and 2022 Supplement)

BY repealing and reenacting, without amendments,
Article - Health Occupations
Section 2-301(a)(1)
Annotated Code of Maryland
(2021 Replacement Volume and 2022 Supplement)

Status of State Policy Changes



Legislation

- Enacted legislation with appropriate policy solution for both audiology and dispensing professions (3)
- Pending legislation with appropriate policy solution for both audiology and dispensing professions (7)
- Pending legislation with appropriate policy solution (audiologists only) (1)
- Pending legislation with appropriate policy solution (dispensers only) (1)
- Pending legislation without appropriate policy solution (2)

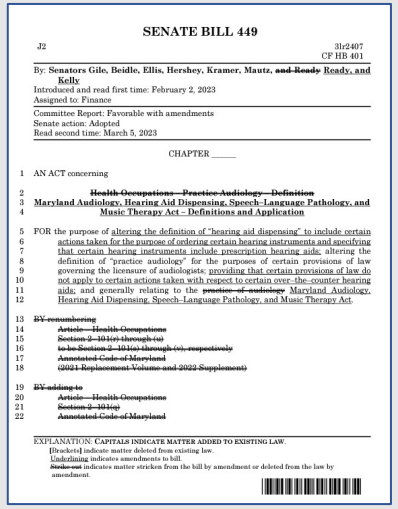
Administrative Guidance

- Regulatory guidance in place with appropriate policy solution for both audiology and dispensing professions (4)
- Regulatory guidance in place without clarification of which practitioners may “prescribe or order the use of” prescription hearing aids (1)

Case Studies

Maryland

- *Legislation pending amending audiology and dispensing laws to align with FDA regulations (HB 401/SB 449).
- Legislation includes language clarifying prescriptive authority of audiologists and dispensers.
- *Note: HB 401/SB 449 is scheduled to be signed into law TODAY (4/11/23)



SENATE BILL 449

J2 3lr2407
CF HB 401

By: Senators Gile, Beidle, Ellis, Hershey, Kramer, Mautz, ~~and Ready~~ Ready, and Kelly
Introduced and read first time: February 2, 2023
Assigned to: Finance

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 5, 2023

CHAPTER _____

AN ACT concerning

~~Health Occupations – Practice Audiology – Definition~~
Maryland Audiology, Hearing Aid Dispensing, Speech–Language Pathology, and Music Therapy Act – Definitions and Application

FOR the purpose of altering the definition of "hearing aid dispensing" to include certain actions taken for the purpose of ordering certain hearing instruments and specifying that certain hearing instruments include prescription hearing aids; altering the definition of "practice audiology" for the purposes of certain provisions of law governing the licensure of audiologists; providing that certain provisions of law do not apply to certain actions taken with respect to certain over–the–counter hearing aids; and generally relating to the ~~practice of audiology~~ Maryland Audiology, Hearing Aid Dispensing, Speech–Language Pathology, and Music Therapy Act.

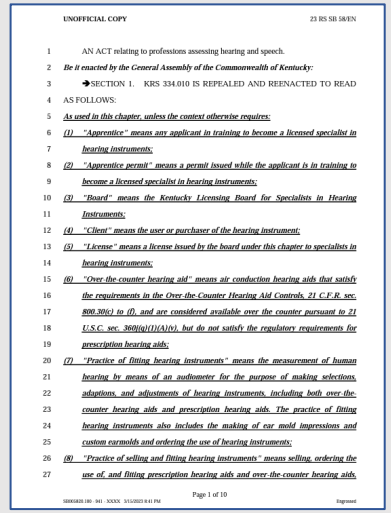
~~BY renumbering~~
~~Article – Health Occupations~~
~~Section 2–101(r) through (u)~~
~~to be Section 2–101(s) through (v), respectively~~
~~Annotated Code of Maryland~~
~~(2021 Replacement Volume and 2022 Supplement)~~

~~BY adding to~~
~~Article – Health Occupations~~
~~Section 2–101(r)~~
~~Annotated Code of Maryland~~

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.
[Brackets] indicate matter deleted from existing law.
Underlining indicates amendments to bill.
~~Strike–out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Kentucky

- Legislation signed into law amending audiology and dispensing laws to align with FDA regulations (SB 58).
- Legislation includes language clarifying prescriptive authority of audiologists and dispensers.



UNOFFICIAL COPY 23 RS SB 58/EN

AN ACT relating to professions assessing hearing and speech.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔SECTION 1. KRS 334.010 IS REPEALED AND REENACTED TO READ AS FOLLOWS:

As used in this chapter, unless the context otherwise requires:

(1) "Apprentice" means any applicant in training to become a licensed specialist in hearing instruments;

(2) "Apprentice permit" means a permit issued while the applicant is in training to become a licensed specialist in hearing instruments;

(3) "Board" means the Kentucky Licensing Board for Specialists in Hearing Instruments;

(4) "Client" means the user or purchaser of the hearing instrument;

(5) "License" means a license issued by the board under this chapter to specialists in hearing instruments;

(6) "Over-the-counter hearing aid" means air conduction hearing aids that satisfy the requirements in the Over-the-Counter Hearing Aid Controls, 21 C.F.R. sec. 800.30(c) to (f), and are considered available over the counter pursuant to 21 U.S.C. sec. 360l(q)(1)(A)(v), but do not satisfy the regulatory requirements for prescription hearing aids;

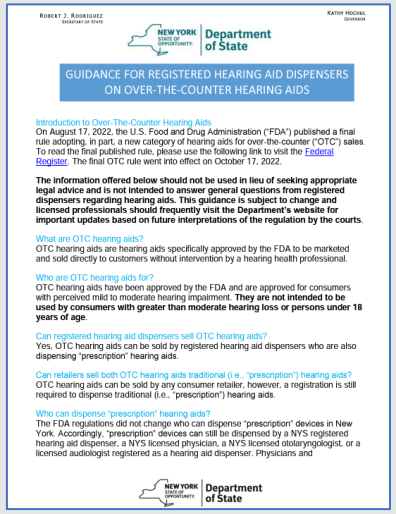
(7) "Practice of fitting hearing instruments" means the measurement of human hearing by means of an audiometer for the purpose of making selections, adaptions, and adjustments of hearing instruments, including both over-the-counter hearing aids and prescription hearing aids. The practice of fitting hearing instruments also includes the making of ear mold impressions and custom earmolds and ordering the use of hearing instruments;

(8) "Practice of selling and fitting hearing instruments" means selling, ordering the use of, and fitting prescription hearing aids and over-the-counter hearing aids.

Page 1 of 10

New York

- Administrative guidance recently issued.
- Guidance does not clarify prescriptive authority of registered dispensers (audiologists and fitters).
- Guidance does not clarify issues surrounding existing medical clearance/waiver law.



ROBERT J. RODRIGUEZ, SECRETARY OF STATE
KATHY HOCHUL, GOVERNOR

NEW YORK STATE OF OPPORTUNITY. Department of State

GUIDANCE FOR REGISTERED HEARING AID DISPENSERS ON OVER-THE-COUNTER HEARING AIDS

Introduction to Over-The-Counter Hearing Aids
On August 17, 2022, the U.S. Food and Drug Administration ("FDA") published a final rule adopting, in part, a new category of hearing aids for over-the-counter ("OTC") sales. To read the final published rule, please use the following link to visit the Federal Register. The final OTC rule went into effect on October 17, 2022.

The information offered below should not be used in lieu of seeking appropriate legal advice and is not intended to answer general questions from registered dispensers regarding hearing aids. This guidance is subject to change and licensed professionals should frequently visit the Department's website for important updates based on future interpretations of the regulation by the courts.

What are OTC hearing aids?
OTC hearing aids are hearing aids specifically approved by the FDA to be marketed and sold directly to customers without intervention by a hearing health professional.

Who are OTC hearing aids for?
OTC hearing aids have been approved by the FDA and are approved for consumers with perceived mild to moderate hearing impairment. **They are not intended to be used by consumers with greater than moderate hearing loss or persons under 18 years of age.**

Can registered hearing aid dispensers sell OTC hearing aids?
Yes, OTC hearing aids can be sold by registered hearing aid dispensers who are also dispensing "prescription" hearing aids.

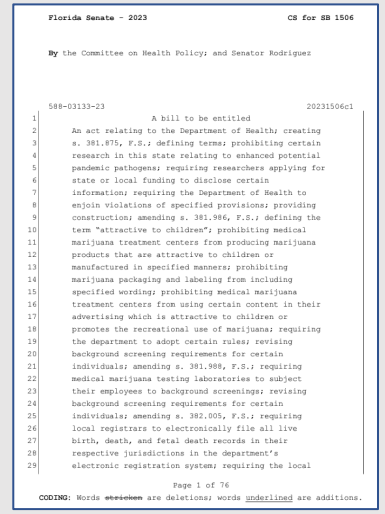
Can retailers sell both OTC hearing aids traditional (i.e., "prescription") hearing aids?
OTC hearing aids can be sold by any consumer retailer, however, a registration is still required to dispense traditional (i.e., "prescription") hearing aids.

Who can dispense "prescription" hearing aids?
The FDA regulations did not change who can dispense "prescription" devices in New York. Accordingly, "prescription" devices can still be dispensed by a NYS registered hearing aid dispenser, a NYS licensed physician, a NYS licensed otolaryngologist, or a licensed audiologist registered as a hearing aid dispenser. Physicians and

NEW YORK STATE OF OPPORTUNITY. Department of State

Florida

- Legislation pending amending audiology and dispensing laws to align with FDA regulations (HB 1387/SB 1506).
- Legislation does not include language clarifying prescriptive authority of audiologists or dispensers.



Florida Senate - 2023 CS for SB 1506

By the Committee on Health Policy; and Senator Rodriguez

588-03133-23 20231506c1

A bill to be entitled

An act relating to the Department of Health; creating s. 381.875, F.S.; defining terms; prohibiting certain research in this state relating to enhanced potential pandemic pathogens; requiring researchers applying for state or local funding to disclose certain information; requiring the Department of Health to enjoin violations of specified provisions; providing construction; amending s. 381.986, F.S.; defining the term "attractive to children"; prohibiting medical marijuana treatment centers from producing marijuana products that are attractive to children or manufactured in specified manners; prohibiting marijuana packaging and labeling from including specified wording; prohibiting medical marijuana treatment centers from using certain content in their advertising which is attractive to children or promotes the recreational use of marijuana; requiring the department to adopt certain rules; revising background screening requirements for certain individuals; amending s. 381.988, F.S.; requiring medical marijuana testing laboratories to subject their employees to background screenings; revising background screening requirements for certain individuals; amending s. 382.005, F.S.; requiring local registrars to electronically file all live birth, death, and fetal death records in their respective jurisdictions in the department's electronic registration system; requiring the local

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

Challenges Facing State Advocacy Efforts

Challenges	Examples
Lack of Awareness Surrounding Implications of FDA's Changes	Stakeholders, public officials, and policymakers understand the establishment of OTC but often fail to recognize the regulatory changes related to prescription devices and what this means practically.
Mistaken Belief that Policy Changes are Not Needed	**"Selling" ≠ "Prescribing"** / **Attorney General Opinions Helpful But Can Change** / **FDA Lacks Jurisdiction Over State Licensure**
Policy Changes Not Being Pursued Proactively	Legislation is being introduced to align state and federal laws related to OTC hearing aids but typically fails to include necessary changes for prescription devices, forcing stakeholders to pursue changes quickly and with limited time to properly educate policymakers.
Lack of Coordination and Collaboration Among Interested Stakeholders	The audiology and dispensing professions are often engaging in these issues separately and without coordinating, putting each other at an increased risk of losing the authority to "prescribe or order the use of" prescription devices if one profession fails to obtain proper clarification.

Key Considerations

Protecting Future of the Profession

Without appropriate changes under state laws and regulations in place, heightened risk of professions losing authority to prescribe non-OTC hearing aids.

Third-Party Reimbursement

Practitioners should monitor changes to health plans providing funded hearing benefits as coverage may be limited to “prescription hearing aids” or require a “prescription” to access the benefit.

Ensuring Strong Patients Access

If either audiology or dispensing professions lose authority to prescribe non-OTC hearing aids, patients will lose critical access to hearing care.

Each State is Unique

While model legislation would be convenient, each state is unique and ultimately requires narrowly crafted policy changes.

Next Steps and How You Can Help

Proactively Consult with ADA on Strategy and Ways to:

- Educate Fellow Audiologists and Dispensers and Encourage Collaboration
- Educate State Boards and State Agencies
- Pursue Appropriate Regulatory Guidance
- Pursue Appropriate Legislation

Thank You!