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

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Today’s Speakers

Alicia D.D. Spoor, Au.D.
President
Designer Audiology, LLC

Michael Belaen, J.D.
Senior Vice President, Regulatory Affairs and Deputy General Counsel
Amplifon Americas

Shruti Kulkarni, J.D.
Senior Director, Regulatory Affairs and Associate General Counsel
Amplifon Americas

Thomas Tedeschi, Au.D.
Chief Audiology Officer
Amplifon Americas

Stephanie Czuhajewski, MPH, CAE
Executive Director
Academy of Doctors of Audiology
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**

- **1967**
  - FLA. STAT. ANN. § 480.120, 126 (West 1977).

- **1968**

- **1969**

- **1970**

- **1977**
  - ARIZ. REV. STAT. § 14-1001 to 1006 (1956).

- **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

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.

Final Regulatory Changes

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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended For</td>
<td>Both Adults with perceived mild to moderate hearing loss</td>
</tr>
<tr>
<td>Types (2)</td>
<td>(1) Preset-Based and (2) Self-Fitting</td>
</tr>
<tr>
<td>Amplification</td>
<td>111 dB SPL unless device features active input compression, then 117 dB SPL</td>
</tr>
<tr>
<td>Sold Online</td>
<td>Yes</td>
</tr>
<tr>
<td>Labels</td>
<td>Specific Labels Required</td>
</tr>
<tr>
<td>Consumer Protections</td>
<td>Limited due to issues surrounding federal preemption</td>
</tr>
<tr>
<td>Design &amp; Performance Requirements</td>
<td>Yes, specific requirements apply</td>
</tr>
<tr>
<td>Prescription Required</td>
<td>No, OTC devices may be sold without involvement of a professional.</td>
</tr>
</tbody>
</table>
## Overview of Prescription Hearing Aid Regulation

**Prescription Hearing Aids**

<table>
<thead>
<tr>
<th>Intended For</th>
<th>Both Adults and Children</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplification</td>
<td>No Limits</td>
</tr>
<tr>
<td>Sold Online</td>
<td>Depends on State Law. If Allowed, Prescription Required</td>
</tr>
<tr>
<td>Labels</td>
<td>Specific Labels Required</td>
</tr>
<tr>
<td>Consumer Protections</td>
<td>Existing Federal and State Protections Apply</td>
</tr>
<tr>
<td>Prescription Required</td>
<td>Yes, pursuant to 21 CFR §801.109.</td>
</tr>
</tbody>
</table>
Ambiguity Leads to Stakeholder Request for Guidance from FDA

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.

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

“*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**

Federal law defines an over-the-counter (OTC) hearing aid as:

1. A device that is a prescription hear aid.
2. A device that is used by adults age 16 and older.
3. A device that is included in the OTC hearing aid category and is not included in the professional practice category.
4. A device that is not prescribed by a physician.

**REDOH Guidance Regarding FDA Final Rule on OTC Hearing Aids**

On August 17, 2022, the US Food and Drug Administration (FDA) published the 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 may change the current State law, went into effect on October 17, 2022. The FDA rule may be accessed here: [link to FDA.gov]

Legislative Proposals

2453 SESSION

HOUSE BILL 401

INTRODUCED

Dr. James S. Smith

November 15, 2022

Bill introduced and referred to committee on January 27, 2023

A BILL ENTITLES

1. An Act establishing uniform standards for the prescription of hearing aids.
2. An Act creating a uniform standard for the prescription of hearing aids.
3. An Act establishing uniform standards for the prescription of hearing aids.

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)**
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)*

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.

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.

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.
### Challenges Facing State Advocacy Efforts

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Examples</th>
</tr>
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<tbody>
<tr>
<td>Lack of Awareness Surrounding Implications of FDA’s Changes</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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.

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.

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.

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!