Oregon Academy of Audiology

19 November 2021

Sylvie Donaldson
Director, Oregon Health Authority – Health Licensing Office
1430 Tandem Avenue NE, Suite 180
Salem, OR 97301
Sylvie.Donaldson@dhsoha.state.or.us

Re: Petition to Amend OAR 331-670-0020(2)

Dear Ms. Donaldson,

I write to you on behalf of the Oregon Academy of Audiology (OAA), its Board of Directors, and its membership, to request the amendment of OAR 331-670-0020(2). We are requesting the removal of language which allows the parents of minor patients to waive the medical examination requirement associated with the dispensing of hearing aids. As written, this rule is not in compliance with federal regulations which preempt state rules, and presents a significant risk to patient safety.

1. Petitioners Names and Addresses:

Bryan Greenaway, Au.D., CH-TM
Chair, Legislation and Policy Committee
Oregon Academy of Audiology
333 SE 7th Ave, Ste 4450
Hillsboro, OR 97123

2. Other individuals and groups who may be interested in the proposed rule change:

All licensed hearing aid dispensers in the state of Oregon.
Addresses can be found in the HLO licensee database.

Oregon Hearing Society
PO Box 30404
Portland, OR 97294

Hearing Loss Association of America - Oregon Chapter
PO Box 22501
Eugene, OR 97402

AG Bell Association (which has an Oregon Chapter)
3417 Volta Place NW
Washington, D.C. 20007

Oregon Medical Association
11740 SW 68th Parkway, Suite 100
Portland, OR 97223

Oregon Academy of Otolaryngology - Head and Neck Surgery
No mailing address found
oregonacademyoto@gmail.com

3. The Rule The Petitioner is Requesting be Amended:

The petitioner requests the Health Licensing Office amend OAR 331-670-0020 as follows. Changed language is highlighted yellow and removed language is denoted with a strikethrough:

Rule 331-670-0020
Additional Conditions For Referral

(1) In addition to the conditions listed in ORS 694.142 (Standards of practice)(1), a licensee must refer the client to a physician as required under ORS 694.142 (Standards of practice)(2) for the following:

(a) Cerumen accumulation in the auditory canal preventing visual inspection of the external auditory canal or external auditory meatus and tympanic membrane or foreign body in the ear canal;
(b) Pain or discomfort in the ear;
(c) Tinnitus.

(2) If the client, ~~or the parent or guardian of the client~~ who is eighteen years of age or older, refuses to seek a medical opinion from a licensed physician as defined in ORS 694.042 (Right to rescind hearing aid purchase)(1)(a), the licensee must obtain written refusal from the client ~~or the parents or guardian of the client~~ on a Waiver of Medical Opinion form as required by ORS 694.142 (Standards of practice)(6). The licensee must obtain the written refusal prior to the fitting or dispensing of a hearing aid. The Waiver of Medical Opinion form must include:

(a) Licensee's name;
(b) Licensee's license number;
(c) Client's name;

(d) Client's address;
(e) Client contact information;
(f) A statement that the person signing the form is refusing to seek a medical opinion from the physician to whom the client has been referred;
(g) The signature of the person who is refusing; and
(h) The date that the person signed the form.

4. <u>Facts and Arguments for Amendment of the Rule:</u>

Chapter 331-670-0020(2)[1] defines a patient's ability to waive the mandatory medical evaluation when getting hearing aids, as allowed by the Food and Drug Administration's (FDA) regulations (21CFR801.420). However, the FDA states that only adult patients may waive the medical examination requirement. It remains a requirement for pediatric patients. OAR 331-670-0020(2), as quoted above, explicitly states that a parent or guardian may waive the medical examination for their child.

The Oregon language is in direct contrast to FDA regulation 21CFR801.420[2], stating:

*Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits **<u>a fully informed adult</u>** to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.*

According to US Code 21USC360(k)[3], which relates to the above quoted FDA regulation:

(a)General rule: Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use [including hearing aids] any requirement—
(1)which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2)which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In effect, no state or state department may create laws which differ from, or are in addition to, the FDA's written regulations, a concept known as federal preemption. Thus, the Health Licensing Office's rule allowing the parents or guardians of pediatric patients to waive the medical examination is in violation of federal law.

While there is a process to request an exemption to 21USC360(k), such requests are rarely granted unless they can show a necessary improvement to patient safety. A somewhat similar exemption request was made to the FDA in 1980 by three states and the District of Columbia, which would have allowed pediatric patients to be evaluated by an audiologist instead of a physician[4]. This

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OREGONAUDIOLOGY@GMAIL.COM

request was denied because it would have created a state law less strict than the federal law by allowing something other than a physician examination of a pediatric patient. Thus, not only is there the letter of the law, but also precedent in the form of a similar case, which suggests the current Oregon rule is not in alignment with federal law.

Beyond ensuring Oregon is in compliance with federal law, we also view this as an issue of patient safety. Most adults with hearing loss have permanent, stable, sensorineural hearing losses caused by factors such as age and noise exposure. In contrast, children tend to have much more complicated hearing loss cases, or cases which can otherwise be treated surgically or pharmaceutically. It is vital that such cases are examined by a qualified physician, preferably one specializing in the ear, to determine the best course of action for the patient. Pediatric patients are also more likely to have undiagnosed genetic or congenital hearing losses with complicated or varied prognoses. In these cases, it is extremely important that a family receive as much medical information on their child's hearing loss as possible to ensure the family can plan for the child's educational, social, and medical needs based on their prognosis.

5. Options for Achieving the Existing Rules Goals While Reducing Economic Impact

The amendment of this OAR 331-670-0020 should not add any significant economic burden to businesses. The approval of amplification by a licensed physician represents a minimal burden to both the patient and the dispenser and is a vitally important measure of patient safety. Other dispensing professionals in Oregon, including doctors of audiology, adhere to this rule without substantial economic burden. Further, regardless of the economic impact, the existing language is out of compliance with federal law and must be amended.

6. The Continued Need for The Existing Rule:

The language of OAR 331-670-0020, with the exception of the language in question, is necessary and legally sound. It provides a reasonable option for adult patients to forego the medical evaluation. Only the language allowing for pediatric exception to evaluation needs amendment.

7. The Complexity of the Existing Rule:

The existing rule is not significantly complex and is consistent with the language used in the FDA regulations, with the exception of the pediatric exemption.

8. The Extent to Which the Existing Law Conflicts with State or Federal Rules:

As stated above, OAR 331-670-0020 as written is in direct conflict with FDA regulation 21CFR801.420 and US Code 21USC360(k).

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9. <u>The Extent to Which Conditions Have Changed Since the Agency Adopted the Rule:</u>

This writer is unaware of when this rule was adopted, but there has been precedent in the Federal Register showing this rule is in violation of federal law since 1980.

10. <u>Conclusion:</u>

We ask that the Health Licensing Office immediately amend paragraph (2) of chapter 331-670-0020 to realign state regulations with federal regulations and ensure the highest standard of safety for Oregon's pediatric patients. Please do not hesitate to reach out with any questions regarding our request. Oregon Academy of Audiology is happy to offer its assistance in resolving this matter, at the Health Licensing Office's request.

Sincerely,

Bryan Greenaway, Au.D., CH-TM
Chair, Legislation and Policy Committee
On behalf of the Board and Membership of Oregon Academy of Audiology

[1]OAR 331-670-0020: https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=246894
[2]21CFR801.420: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=801.420
[3]21USC360(k): https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section360k&num=0&edition=prelim
[4]Federal Register Vol. 45, No. 199, Friday, October 10, 1980, page 67333, heading "Maine": https://www.govinfo.gov/content/pkg/FR-1980-10-10/pdf/FR-1980-10-10.pdf

*Bold and underline added for emphasis of relevant language

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