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International Hearing Society
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July 31, 2020

VIA EMAIL AND FIRST CLASS MAIL

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: Amended Petition to Repeal or Amend
OAR 331-670-0010(11) and 331-670-0020(1)(c)

Dear Ms. Donaldson,

We, the petitioners, are writing to petition the Oregon Health Licensing Office to amend or alternatively repeal the administrative rule changes to OAR 331-670 adopted on June 15, 2018. Specifically, we are requesting that the Health Licensing Office repeal or revise OAR 331-670-0010(11) and 331-670-0020(1)(c), which concern restrictions on hearing aid specialists' ability to activate tinnitus masking features of hearing aid devices and require hearing aid specialists to refer clients to a physician for tinnitus management.

I. Petitioners' Names & Addresses:

Richard W. Giles, ACA, BC-HIS, Oregon HAS Licensee
6132 Broadview Lane
Vancouver, WA 98661

Todd Beyer, ACA, BC-HIS, President, International Hearing Society
110237 Mann Street
Marshfield, WI 54449

Cheryl Blackman, BC-HIS, Secretary, Oregon Hearing Society
39371 Golden Valley Drive
Lebanon, OR 97355-9469

Any Other Person Interested in the Rule & Address:
All citizens of Oregon, at their mailing addresses registered in Oregon.

All hearing aid specialists licensed by the State of Oregon, at their mailing addresses registered in Oregon.

II. The rule petitioner requests the agency adopt, amend, or repeal:

Petitioners request that the agency repeal OAR 331-670-0010(11) and 331-670-0020(1)(c). In the alternative, petitioners request that the agency amend OAR 33-670-0010(11) and 331-670-0020(1)(c) as follows:

331-670-0010 - Practice Standards

(1) The Council recognizes and adopts the following uniform set of hearing loss measurement standards required for use when interpreting audiograms: 0-110 for degrees of decibel hearing loss (dB HL) and 125-8000Hz for frequency. A licensee must use the uniform measurement standards for advising clients on peripheral or cochlear hearing loss. The uniform measurement standards are available on the Office website.

(2) Testing requirements prior to fitting a hearing aid:

(a) A licensee must verify and document the following tests were completed:

(A) Puretone Air Conduction Threshold testing (should include at a minimum, the following frequencies – 250, 500, 1000, 2000, 3000, 4000, and 6000 or 8000 Hz);

(B) Puretone Bone Conduction Threshold testing (should include at a minimum, the following frequencies – 500, 1000, 2000, and 4000 Hz);

(C) Speech Recognition Threshold testing (SRT);

(D) Word Recognition Score (WRS) also known as speech discrimination testing;

(E) Most Comfortable Listening Level (MCL); and

(F) Uncomfortable Listening Level (UCL).

(b) If all the tests in (2)(a) of this rule were completed by a licensee, or an individual who is licensed and has hearing tests in their scope of practice, within 90 days of the hearing aid fitting, the licensee does not need to repeat the tests before fitting a hearing aid.

(c) If any of the tests in (2)(a) of this rule were completed by a licensee, or an individual who is licensed and has hearing tests in their scope of practice, more than 90 days and fewer than 180 days from the hearing aid fitting, Puretone Air

Conduction Threshold testing as described in (2)(a)(A) of this rule must be completed before fitting a hearing aid.

(A) If Puretone Air Conduction Threshold testing as described in (2)(a)(A) shows a threshold shift of less than 10 decibels at any frequency, the licensee does not need to complete the tests in (2)(a)(B-F) before fitting a hearing aid.

(B) If Puretone Air Conduction Threshold testing as described in (2)(a)(A) shows a threshold shift of 10 decibels or more at any frequency, then the tests in (2)(a)(B-F) also must be completed prior to fitting a hearing aid.

(d) If any tests were completed more than 180 days prior to hearing aid fitting, all the tests in (2)(a)(A-F) this rule must be performed before fitting a hearing aid.

(e) The only circumstances under which a hearing aid may be fitted without the verification of the completion of the tests described in (2)(a)(B-F), are:

(A) There is a documented and fully explained client language barrier that prevents the completion of tests (2)(a)(C) and (D). The licensee still must complete and document the results of the tests described in (2)(a)(A),(B),(E) and (F), and verify that the hearing aid is giving a benefit.

(B) There is a documented and fully explained client medical reason that prevents the completion of one or more of the tests in (2)(a)(B-F). The licensee still must complete and document the results of the test described in (2)(a)(A), and verify that the hearing aid is giving a benefit.

(f) All licensees completing the tests described in (2)(a)(A-F) must perform the tests to industry standards.

(3) A licensee must perform at least one of these verification procedures within the 30-day rescission period:

(a) Soundfield testing for puretone thresholds; or

(b) Real-ear probe microphone measurements; or

(c) Speech mapping.

(4) A licensee must abide by the IHS Code of Ethics (2009).

(5) A licensee must provide the client with the Statement to the Prospective Hearing Aid Purchaser Form, or a form that includes all of the information required in ORS 694.036(1). The licensee must complete the form, and then the form must be signed by both the client and licensee prior to the consummation of the hearing aid sale. The form is available at the Office website.

(6) A licensee must provide the client with a new Statement to the Prospective Hearing Aid Purchaser Form for each hearing aid or set of hearing aids.

(7) A licensee must refund all monies paid by or on behalf of the client if the hearing aid purchase is canceled prior to the consummation of the sale. The client shall incur no additional liability for the cancellation.

(8) The 30-day rescission period begins at the consummation of the sale.

(9) A licensee must conduct and document at least one post-consummation of sale appointment with the client before the 30-day rescission period expires. The licensee must document in the client's record any change to the agreed-upon location or date of the appointment, if the licensee is unable to contact the client, or if the licensee is unable to provide the follow-up appointment.

(10) Under provisions of ORS 694.042(4), a licensee may retain no more than 10 percent of the purchase amount, or $250 per hearing aid, whichever amount is less, if the cancellation of the sale occurs during the 30-day rescission period.

(11) ~~A licensee must have a written recommendation from a licensed physician as defined in ORS 694.142(2) prior to activating or adapting the masking features of a hearing aid when a client has tinnitus or has signs or symptoms of tinnitus. The licensee must provide services within the scope of the written recommendation only. For instance, a licensee cannot activate a hearing aid masking feature when a client has tinnitus or signs or symptoms of tinnitus unless the written recommendation recommends activation. A licensee cannot adjust a hearing aid masking feature when a client has tinnitus or signs or symptoms of tinnitus unless the written recommendation recommends the specific setting needed for adaption of the hearing aid. A licensee shall refer a client back to the licensed physician if the client needs services outside of the written recommendation. A licensee must have obtained manufacturer-specific training on their equipment as well as a comprehensive course on tinnitus and the masking function of a hearing aid prior to activating the masking function of a hearing aid.~~

A licensee shall be responsible for obtaining the training, knowledge, and skills necessary to perform tinnitus-related services, such as assessment of tinnitus symptoms, and advising patients on sound therapy techniques and other strategies to address tinnitus symptoms.[1]

(12) A licensee must use the federal disclosure statement available on the Office website for in home sales. This form must be completed and affixed to the Statement to the Prospective Hearing Aid Purchaser.

(13) A licensee must post the following statement in public view on the business premises or provide the client with a written notice stating: "Individuals are entitled

[1] The existing rule language is indicated by "strikethrough" text and the proposed amendment is in red, bold, underlined text.

to a copy of the audiogram used to conduct hearing evaluations and any test results."

(14) A licensee must provide a client with a copy of the audiogram used to conduct hearing evaluations and any test results, when requested by the client.

(15) A licensee must abide by the standards of practice set forth in ORS 694.142.

Rule 331-670-0020 - Additional Conditions For Referral

(1) In addition to the conditions listed in ORS 694.142(1), a licensee must refer the client to a physician as required under ORS 694.142(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.~~ **If the licensee determines a client is exhibiting pulsatile tinnitus, unilateral tinnitus, any of the U.S. Food and Drug Administration conditions for referral outlined in 21 CFR 801.420, or, relying on findings from the client's comprehensive assessment, case history, and any tinnitus questionnaires, in his/her professional judgment believes the client's tinnitus warrants referral to a physician.**[2]

(2) If the client, or the parent or guardian of the client, refuses to seek a medical opinion from a licensed physician as defined in ORS 694.042(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(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) Licensees name;

(b) Licensees license number;

(c) Clients name;

(d) Clients 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;

[2] The existing rule language is indicated by "strikethrough" text and the proposed amendment is in red, bold, underlined text.

(g) The signature of the person who is refusing; and

(h) The date that the person signed the form.

III. <u>Facts or arguments in sufficient detail to show the reasons for and effects of adoption, amendment, or repeal of the rule</u>:

These newly adopted rules improperly restrict activities that are within the scope of the services provided by hearing aid specialists, specifically the "adaptation" of hearing aids in conjunction with "the evaluation or measurement of the powers or range of human hearing" pursuant to ORS 694.015(2). Historically, hearing aid specialists have provided tinnitus management services as part of their practice of selecting, fitting, and adapting hearing aids for clients experiencing hearing loss. Erecting barriers to the ability of those experiencing tinnitus to obtain the relief provided by tinnitus masking features of hearing aids by requiring a physician to recommend not only the activation of the tinnitus masking feature(s) but the exact setting of said feature is unnecessary, unsupported by evidence, and will cause those who suffer from tinnitus in addition to hearing loss to go without the help they seek. Any professional who has assisted a hearing-impaired individual with a tinnitus masker knows that ultimately it is the user who, after listening to multiple settings, determines which setting works best for them. To fit a masker properly, a professional generally needs to spend at least 45-60 minutes, spread out over two visits, to activate and adjust the settings in consultation with the user to arrive at the preferred setting. Many hearing-impaired individuals are reluctant to seek help, and enacting a medically unsupported hurdle to obtain relief is inconsistent with the public interest and should be remedied.

As many as 50 million adults in the United States have reported experiencing tinnitus. The incidences of tinnitus are commonly associated with advanced age and hearing loss.[1] It is estimated that 10 to 15 percent of the U.S. population experiences chronic tinnitus, and a 2008 study indicated that 50% of all persons seen by hearing care professionals report experiencing tinnitus.[2] Nearly everyone who experiences chronic tinnitus also experiences hearing loss. Tinnitus can be addressed along with the underlying hearing loss through amplification.[3] A survey of 230 hearing care professionals indicated that 6 out of 10 clients experience relief of tinnitus when wearing hearing aids, and 1 in 5 reported receiving major relief.[4] When evaluating clients' hearing levels, hearing aid specialists can use tools such as the Tinnitus Handicap Inventory questionnaire[5] to determine the extent of a person's tinnitus, whether tinnitus can be alleviated by the use of tinnitus masking features of a hearing aid, or whether the particular incidence of tinnitus warrants referral to an otolaryngologist. Such a process is a standard practice for hearing aid specialists that has been utilized in Oregon and across the country for many years.

A tinnitus masker is built-in as standard equipment in most hearing aids today, making hearing aids impossible to order without the masker. A tinnitus masker can be used to provide improved hearing to the end user. Prohibiting hearing aid specialists from utilizing features of a hearing aid that are used to accurately fit and adapt the hearing aids for the end user erroneously restricts the services that hearing aid specialists otherwise provide, and have provided for decades. Moreover, using a tinnitus masker that is fully integrated

into devices, which hearing aid specialists unquestionably are permitted to recommend, select, and adapt, is an allowable "adaptation" of the device pursuant to ORS 694.015(2).

It is our collective belief that much of the disagreement and confusion surrounding the management of tinnitus during the course of services provided by hearing aid specialists, and the apparent effort to stop hearing instrument specialists from managing tinnitus, can be traced back to an email to the Advisory Council by audiologist Scot Frink dated March 9, 2015.[6] This email is part of the public record of the Advisory Council.[7] Concerns over inaccuracies in this email were raised by IHS in a December 15, 2015 letter to Dr. Gary Harris who was the Chair of the Oregon Advisory Council on Hearing Aids. The Council was advised as follows:

In developing the FAQ document, IHS understands that the Advisory Council and the Health Licensing Office considered an email from Oregon-licensed audiologist and hearing aid specialist Scot Frink, MS, dated March 9, 2015, that includes comments from an unnamed source. The actual source was a California audiologist, Randall Bartlett, MA, of the Tinnitus & Audiology Center of Southern California, who had posted his comments on a forum hosted by the American Academy of Audiology. Mr. Frink's email was included in the Meeting Materials for the March 20, 2015, Council Meeting.[8] The information in the email contains several inaccuracies. It is also worth noting that, upon information and belief, during at least a portion of the time period that the FAQ's were being developed and implemented by the Advisory Council, two of the Council members, Randy Lerner and Jonathan Hamm, had a business relationship with Mr. Frink. In fact, both Mr. Lerner and Mr. Hamm were on the Council and in attendance at the March 20, 2015 meeting when "Policy Analyst, Anne Thompson, **read Scott Frink's emailed comments concerning tinnitus as it relates to hearing instrument specialists' scope of practice in to the record."**[9] (Emphasis added.) At no point in the record is there a disclosure by any of the parties involved of their business relationship, nor was there a request to recuse or offer to recuse themselves from discussion or subsequent vote.

Mr. Frink states that **an anonymous individual** had a conversation with FDA ENT Section Chief Cesar Perez in which it was stated that the "use of maskers is regulated and intended by the FDA to only be dispensed by audiologists. Hearing aid practitioners are not allowed by FDA statute to fit them." While we cannot deny that a conversation may have taken place between these two parties, **the statement that hearing aid practitioners are not allowed under the FDA statute to fit a hearing aid masker is simply inaccurate**. One need look no further than the FDA statute to see the falsity of that claim.

IHS spoke with Srinivas Nandkumar, Ph.D., Branch Chief, Ear, Nose, and Throat Devices Branch with the U.S. Food and Drug Administration (FDA) in both June and August of 2015 to discuss the federal regulations covering hearing instruments and tinnitus masking devices, and to clarify the issues raised in Mr. Bartlett's message. The information provided by the FDA during the conversations with IHS directly contradicts the information provided by Bartlett, to which Mr. Frink makes reference and bases his request for the

Advisory Council to issue a position statement. The FDA affirmed that regardless of the class of the hearing aid or tinnitus management device, **the FDA statute does not restrict who can fit or use them**. Some can be purchased for use directly by the consumer (i.e. tinnitus masking sound pillows, white noise machines, and other sound producing devices). In this case, the consumer is able to bypass the provider altogether, and self-identify and attempt to self-manage their tinnitus. For those that require the involvement of a professional, which professionals are considered appropriate dispensers is determined by the manufacturer's intended use of the device as delineated in their 510(k) application or premarket notification. For example, if an FDA-registered or -approved tinnitus masker or sound therapy device is intended to be dispensed by an audiologist, hearing aid specialist, and/or hearing care professional in general, per the manufacturer's submission, as long as the professional is appropriately trained to use/dispense the device, no FDA regulations would prohibit the use of the device by that professional. The FDA further asserts that a provider should be licensed by law to use or order the use of a tinnitus management device — in this case, a hearing aid with a tinnitus masking feature - in accordance with the prescription device regulation.

As an illustrative example, in 2013 Oticon submitted a 510(k) application for its new SoundSupport software module, which is used in conjunction with its wireless air-conduction hearing aids. Oticon's application states the device is to be used by audiologists, hearing aid specialists, and otolaryngologists as part of a tinnitus management program. The application itself, which was subsequently found by the FDA to be substantially equivalent to legally marketed predicate devices, cites two other maskers from ReSound and Phonak that may be used by hearing aid specialists as well as audiologists and otolaryngologists as part of a tinnitus management program, for which applications had been previously submitted. Another device, the Widex IE-Zen Program in the CLEAR Series Hearing Aids, includes the feature that, according to the manufacturer, "may be used as a sound therapy tool in a tinnitus treatment program that is programmed by a licensed hearing healthcare professional (audiologists, hearing aid specialists, otolaryngologists) who is trained in tinnitus management." According to the FDA's letter to Widex USA dated May 5, 2011, the device was considered substantially equivalent to legally marketed predicated devices and may therefore be marketed. These examples directly contradict Mr. Bartlett's statement that the "FDA was not aware that devices existed with open software programming, allowing non-audiologists to potentially access and operate [tinnitus] masking circuits; no manufacturer ever told them they had done this..."[10]

Additionally, the assertion that the management of tinnitus by adjusting a tinnitus masker is actually “treatment of tinnitus” or otherwise the practice of medicine, thus outside the scope of practice of a Hearing Aid Specialist is self-serving and flawed.[11] Setting aside for the moment the fact that if management of tinnitus equaled treatment of tinnitus, every audiologist in the state of Oregon would also be prohibited from adjusting a tinnitus masker on a hearing aid; there is absolutely no scientific or medical basis for this position. (Audiologists, who may hold a doctor of audiology (AuD) or master’s degree (MS) are not medical physicians, and are not regulated under the medical practice act.) Just saying “it is so,” over and over, does not make it fact. As has been explained to the Health Licensing

Office's Advisory Council on Hearing Aids in great detail, and on multiple occasions, by ourselves, fellow members of the Oregon Hearing Society, and the International Hearing Society (IHS)[12], activating the integrated tinnitus masking feature of a hearing aid device does not constitute the practice of medicine. Pursuant to Oregon Revised Statute 677.085, to "offer or undertake to diagnose, cure, or treat in any manner, or by any means, methods, devices or instrumentalities, any disease, illness, pain, wound, facture, infirmity, deformity, effect or abnormal physical or mental condition of any person," constitutes the practice of medicine. Hearing Aid Specialists provide management services and tinnitus care—not treatment. Management of tinnitus is consistent with the permissible services currently and historically provided by hearing aid specialists in Oregon and across the United States. Further, the Oregon Department of Health clearly does not define management of tinnitus as "treatment" because if it did**, every audiologist who activates a tinnitus masker in the State of Oregon is violating the law on a daily basis**.

Neither Oregon statutes governing hearing aid specialists and their scope of practice nor statutes governing audiologists and their scope of practice make reference to tinnitus or tinnitus masking features of hearing aids.[13] Oregon statutes, therefore, are silent as to the management of tinnitus, neither positively delineating tinnitus management as a part of any profession's scope of practice nor restricting any profession from tinnitus management.[14]

Federal regulations also do not make any reference to tinnitus as one of the conditions for which a hearing aid specialist should advise a person to consult with a licensed physician prior to obtaining a hearing aid.[15] Oregon statues and administrative rules concerning the conditions for which a hearing aid specialist must refer a person to a physician are the exact same conditions delineated in the federal rules, with one material difference: the newly enacted Oregon administrative rule includes tinnitus as a condition requiring a referral, where the federal rules remain silent.[16] The new Oregon rule, therefore, is inconsistent with and a departure from the federal rules governing hearing aid specialists.

It is well-accepted that it is within the proper scope of services provided by a hearing aid specialist for the specialist to perform "evaluation or measurement of the powers or range of human hearing," and, based on the evaluation, to recommend, select, and adapt hearing aids that will increase a person's hearing ability.[17] Because it also is well-accepted that hearing aid specialists may not diagnose and treat patients, it follows that such services do not constitute the diagnosis and treatment of patients. If a hearing aid specialist is permitted to evaluate a person for hearing loss, perform tests to determine the nature and degree of the person's hearing loss, recommend and fit the person for a hearing aid that will provide the person with relief, and adapt the hearing aid to fit the person's individual needs, then it is contradictory and unduly restrictive to prohibit a hearing aid specialist from activating the tinnitus masking feature of a hearing aid during the above process if the feature will increase a person's hearing benefit from the device.[18]

The concept of tinnitus masking and hearing aid specialists providing tinnitus management is not new in Oregon, but rather historically has been a common practice.

Many hearing aid specialists have received training and continuing education instruction in tinnitus management and products offering tinnitus masking for many years from professional healthcare associations, hearing aid device manufacturers, and other education providers. It is clear that such practical knowledge is necessary to provide proper tinnitus management, and we believe that only hearing aid specialists who are sufficiently trained and properly educated as to tinnitus management should be providing such services. To that end, IHS offers a Tinnitus Care Provider Certificate Program, which is a comprehensive training program and workshop that focuses on physiology, psychology, measurement, and management of tinnitus, and also requires passing an assessment in order to successfully complete the program.[19] The program was developed by and includes instructors who are audiologists who are experts in tinnitus management, and who agree that properly trained hearing aid specialists should be permitted to provide tinnitus management services when fitting and adapting hearing aids.

From a practical perspective, requiring hearing aid specialists to make a referral to a physician when a person presents with tinnitus and prohibiting hearing aid specialists from activating tinnitus masking features of hearing aid devices without a specific written recommendation from a physician regarding tinnitus is a significant departure from traditional and current practices in Oregon, is not a requirement in any other State, and is a needless hurdle that will create an unnecessary hardship on many people suffering from hearing loss. Appropriately trained and licensed hearing aid specialists are able to safely and effectively activate and calibrate tinnitus masking features of hearing aids without a specific written referral from a licensed physician, and in many cases are more qualified to determine whether a masking feature on a particular device is appropriate and calibrate the feature for optimal effectiveness. Manufacturers specifically provide training on their product line directly to providers (hearing aid specialists) so that subtle nuances in the tinnitus management features can be more fully understood and utilized to achieve maximum benefit to the patient. There are literally hundreds of devices with tinnitus maskers on the market, and it would be impossible for a physician to have a working understanding of every possible device. Moreover, the new rule also only states that a hearing aid specialist must refer a client with tinnitus to a “physician”; not an otolaryngologist (who is a specialist) - just any “physician.” Accordingly, under the rule a referral to a psychiatrist or a radiologist is acceptable, yet neither of whom presumably would have any knowledge or experience regarding tinnitus or hearing loss in general.

Importantly, Hearing aid specialists are able to identify when a medical referral is necessary based on standards set forth by the FDA and Oregon law, and activation of a tinnitus masking feature does not create the risk of harm that necessitates referral to and evaluation by a licensed physician under Federal or State law. Requiring all persons with tinnitus to schedule a separate appointment with a physician (any physician) who may or may not be familiar with tinnitus masking features, followed by a repeat appointment with a hearing aid specialist, will add unnecessary time and cost to the common practice of testing and fitting hearing aids such that many people suffering from hearing loss and/or tinnitus will go untreated. **This requirement also adds significant, and unnecessary, costs to the healthcare system.** While the device may not be covered by Medicare (or

other private insurances), the physician visit will likely be billed to Medicare. Such a result is unacceptable, entirely avoidable, and is a clear and blatant barrier to access.

Nationally, the trend for management of hearing loss is away from burdensome physician referral requirements and toward a lack of restriction on the ability to obtain hearing aid devices. In **2013**, North Carolina modernized its scope of practice for hearing aid specialists and, among other changes, added: "Determining candidacy for hearing aids, **tinnitus management devices**, and other assistive listening devices; providing hearing aid, **tinnitus management device, and assistive device recommendations and selection**; and administering **cerumen management** in the course of examining ears."[3]

On December 12, **2016**, the FDA issued a guidance document regarding its enforcement of certain conditions for the sale of hearing aid devices, in which the FDA indicated that it no longer would enforce the need for a person 18 or older to undergo a medical evaluation prior to permitting a hearing aid dispenser to provide that person with a class I air-conduction hearing aid or a class II wireless air-conduction hearing aid.[20] The guidance conceded that only one-fifth of people who could benefit from a hearing aid seek assistance, and that recent studies have concluded "the requirement for a medical examination (or a written waiver of such examination) provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance."[21] For those reasons, the FDA reduced the medical intervention necessary for obtaining hearing aids in the interest of making access to hearing aids easier and less burdensome.

In **2017**, Congress went a step further and enacted the FDA Reauthorization Act of 2017, which amended the Federal Food, Drug, and Cosmetic Act to require the FDA to promulgate rules to establish certain hearing aids as over-the-counter hearing aids and regulate their use and requirements.[22] The FDA has yet to publish its proposed rules but must do so by August 18, 2020. The FDA Reauthorization Act of **2017** also amended 21 U.S.C. § 360j, the statute regulating medical devices, to include a new section defining the term "over-the-counter hearing aid," which is defined as a device that (i) uses the same fundamental scientific technology as air conduction hearing aids or wireless air conduction hearing aids; (ii) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment; (iii) 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; (iv) may use wireless technology or include tests for self-assessment of hearing loss; and (v) 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.[23] While it remains to be seen whether over-the-counter hearing aids will include tinnitus maskers, the new laws and regulations clearly evidence the federal government's desire to reduce restrictions on the public's access to hearing aids, and the new rules enacted in Oregon are antithetical to the public interest demonstrated by recent changes in federal law.

In April **2018**, the U.S. Department of Labor adopted national guidelines for a hearing aid specialists apprenticeship program. Within the DOL guidelines, the DOL explained the

[3] The full definition of hearing aid specialist scope of practice can be found at https://nchalb.org/regulatory/93D.pdf.

profession as: “In a manner consistent with the individual licensee’s state law: Elicit patient case histories; perform otoscopy for the purpose of identifying contraindications to testing or ear impression; administer cerumen management if properly trained; perform audiometric testing to determine candidacy for hearing aids or assistive devices; take ear impressions; refer to other healthcare providers for appropriate clinical, rehabilitative, or medical interventions; select and fit appropriate hearing aids and assistive devices; assess hearing aid efficacy; design and modify ear molds and auditory equipment; provide counseling and aural rehabilitative services; **provide tinnitus management to clients who exhibit symptoms of tinnitus during an evaluation of hearing loss conducted for the purpose of determining the appropriateness of hearing aids and/or tinnitus devices**; provide supervision and in-service training of those entering the dispensing profession; and provide ongoing hearing aid care and repair services.” (Emphasis added.)

Together, we have made every effort short of this step in an attempt to convince this office to amend or rescind the new rules related to tinnitus, for the reasons stated above. There is substantial evidence to support the proposition that the promulgated rules, which clearly shift services that were safely and effectively being provided by hearing aid specialists to audiologists, was initiated by one audiologist, without any reasonable medical or public interest justification. Rather, it is our belief that the record demonstrates that the rule changes **were motivated by anticompetitive and discriminatory intent against hearing aid specialists, in blatant violation of federal antitrust laws.** As detailed above, the issue was raised by an audiologist to a Council that included two of his business associates. While it is true that the Advisory Council does not dictate policy to audiologists, the creation of a baseless barrier for hearing aid specialists will have the very foreseeable effect of driving consumers to audiologists (who do not have to refer to a physician to manage tinnitus), financially benefitting audiologists, and harming hearing aid specialists.

The United States Supreme Court has made it clear that state agencies and their individual members can be held **personally liable** for unreasonably restraining trade in violation of antitrust law by taking concerted actions to unfairly stifle competition, despite appearing to be acting pursuant to statutory authority.[24] This is especially true where, like the Advisory Council on Hearing Aids, the decision makers are active market participants in the profession that the agency regulates. We are further emboldened by the fact the **Advisory Council admittedly did not consider any complaints against hearing aid specialists during the rule making process**. Based on correspondence from the Attorney General’s office, we understand that the Health Licensing Office has received only three complaints related to tinnitus, which **HLO investigated and did not substantiate**. Additionally, no complaints involving hearing aid specialists and tinnitus management have been received by the Board of Examiners for Speech-Language Pathology and Audiology.[25] The complete lack of evidence or medical justification supporting the ban on hearing aid specialists’ management of tinnitus leads to the only logical conclusion that can be drawn; that the new rules were adopted for one purpose—to drive consumers away from hearing aid specialists and towards audiologists. Such a practice is a violation of the Federal Trade Commission Act.

IV. All propositions of law to be asserted by petitioner:

In the absence of action by the Health Licensing Office to amend or repeal the rules, it is the signatories' intention to move forward with an antitrust action against the Advisory Council and its members supported by the statutory and regulatory authority cited above.

V. Comments on options for achieving the existing rule's substantive goals while reducing the negative economic impact on businesses:

The HLO record is completely devoid of any goal the rule changes were targeted at achieving. On the contrary, the absence of any stated goal by the HLO for the rule change shines a bright light on the apparent motivation of the authors of the rule change – to take business away from hearing aid specialists and direct it to audiologists. Regardless, while the substantive goals for the rule changes were not part of the original record, we believe the proposed amendment language above serves as a wholly adequate option to address any competency concerns of licensees and any conditions for referral concerns.[26] We are unaware what the problem was before the rules were promulgated, including any "negative economic impact." We also find it important to note that touting "public safety" today, in saying that "public safety was in the forefront of the decision-making" to promulgate the rules, is fallacious. It simply is not supported by the record, which is void of any actual public safety concerns.

If the proposed amendment language is adopted or the rules at issue are repealed, the unnecessary spending of federal, state, private insurance, as well as consumer dollars will be reduced, by removing the unnecessary hurdles imposed by the rules as currently written.

VI. Comments on the continued need for the existing rule:

We do not believe there is a need for the specific sections of the rules at-issue here, OAR 331-670-0010(11) and 331-670-0020(1)(c). However, there is a need for the remaining rules under the Practice Standards and Conditions for Referral.

VII. Comments on the complexity of the existing rule:

The existing rule is not so complex to cause a significant delay in any amendment or repeal of same.

VIII. Comments on the degree to which technology, economic conditions, or other factors have changed in the subject area affected by the existing rule, since the agency adopted the rule:

Now, more than ever, during the international public health emergency created by the COVID-19, novel coronavirus, we believe unnecessary hurdles for consumers to manage their tinnitus should be eliminated. Further, as hearing aid technology continues to advance, it will become even more of a challenge to involve any "licensed physician," as OAR 331-670-0010(11) currently requires, and expect these clinicians who may never work with hearing aids to provide the "specific setting needed for adaption of the hearing

aid." The consumer who is in need of the tinnitus masker will suffer through the burdensome and impossible process in place under the existing rule cited.

IX. Conclusion

In conclusion, the restrictions on services provided by hearing aid specialists in OAR 331-670-0010(11) and 331-670-0020(1)(c) are not based in medical science, are inconsistent with the public interest, disparately and unfoundedly favor audiologists over hearing aid specialists, unnecessarily burden hearing aid specialists and persons suffering from hearing loss who are seeking relief, and counteract recently enacted federal rules regarding eliminating barriers to the public's ability to obtain hearing aid devices. Furthermore, with CMS projecting that physician and clinical services spending is expected to grow by 5.4 percent per year between 2020 and 2027[27], it is simply irresponsible to add to the rising cost of healthcare by requiring physician involvement (and all related costs) **without a shred of evidence** to support medical necessity. Rather than continuing to follow the recently enacted unnecessary and inappropriate rules, the Health Licensing Office should amend or repeal the rules and promulgate new rules that ensure the safety of the public who experience hearing loss, but also do not unduly restrict the services offered by hearing aid specialists. Consistent with recently enacted federal rules, the Oregon rules also should promote greater access to hearing aid devices, rather than restrict the public's ability to obtain relief from hearing loss and restrict their ability to communicate.

We thank you for your consideration of our request and look forward to hearing from you. Please do not hesitate to contact us with any questions or concerns.

Sincerely,

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[1] Shargorodsy, et al., "Prevalence and characteristics of tinnitus among US adults," 123 AM J MED 711 (2010), https://www.amjmed.com/article/S0002-9343(10)00344-X/fulltext.

[2] The Hearing Review, *Tinnitus Treatment and the Effectiveness of Hearing Aids: Hearing Care Professional Perceptions*, (Dec. 1, 2008), http://www.hearingreview.com/2008/12/tinnitus-treatment-and-the-effectiveness-of-hearing-aids-hearing-care-professional-perceptions/.

[3] *Id.*

[4] *Id.*

[5] The client uses the questionnaire to self-report on a variety of situations/attitudes.

[6] The position that Mr. Frink's email "was submitted as public comment and was not involved in the crafting of the FAQ," is interesting when Mr. Frink's email was dated March 9, 2015; the Tinnitus FAQs were published July 15, 2015 (with the first draft completed on April 30, 2015); the proposed administrative rule changes for OAR, Chapter 331, Divisions 360-680 were published in the November 1, 2016 edition of the Oregon Bulletin; and the Notice of Proposed Rulemaking for the rules at issue was published February 16, 2018. The July 15, 2015, Tinnitus FAQ indicates "The Health Licensing Office (HLO) has received several inquiries regarding tinnitus and hearing aid specialists "treating" the condition with the new technology available in hearing aids with masking functions." **Yet the response to International Hearing Society's public records request is noticeably lacking any of these "inquiries" except for Mr. Frink's email dated March 9, 2015**. Further, it is our understanding that Scot Frink also served on the Rules Advisory Committee to provide input to Oregon Health Authority and the Health Licensing Office about the administrative rules at issue.

[7] See the public records request response with Bates Stamp 2019-0058 025 03/05/2019.

[8] Mr. Frink's email is part of the public record which has served, in part, to support the rule change.

[9] March 20, 20 15 HLO Advisory Council on Hearing Aids minutes, page 2.

[10] December 21, 2015 letter from Alissa Parady, Government Affairs Director, IHS, to Dr. Garry Harris, MD, Chair, Oregon Advisory Council on Hearing Aids.

[11] During the October 10, 2018 Health Licensing Office Advisory Council on Hearing Aids, Ms. Donaldson, along with Randy Lerner, an audiologist, repeatedly stated that because Hearing Aid Specialists cannot diagnose and treat tinnitus, they cannot adjust a tinnitus masked without specific guidance from a physician.

[12] The International Hearing Society (IHS) is a membership association that represents hearing healthcare professionals worldwide. IHS members are engaged in the practice of testing human hearing and selecting, fitting and dispensing hearing instruments and counseling patients. Founded in 1951, the Society continues to recognize the need for promoting and maintaining the highest possible standards for its members in the best interests of the hearing impaired it serves. As the membership organization for thousands of independent specialists, IHS conducts programs in competency accreditation, education and training and encourages specialty-level certification for its members.

[13] ORS 681.205; ORS 694.015.

[14] While we appreciate the Health Licensing Office's remarks indicating it is open to a statutory change, that is not what the petitioners are seeking. Again, the scope of practice does not preclude hearing aid specialists from tinnitus management. The statute is not what is at issue here. We hope the Health Licensing Office will be amenable to this petition and refrain from offering legislative changes to the scope of practice as its solution.

[15] 21 CFR 801.420

[16] ORS 694.142(1); OAR 331-670-0020(1).

[17] ORS 694.015(2).
[18] Id.
[19] The International Hearing Society, *Tinnitus Care Provider Certificate Program*, (Nov. 26, 2018), https://www.ihsinfo.org/IhsV2/tinnitus/. The program is accredited by the Institute for Credentialing Excellence and is approved for continuing education units by the American Academy of Audiology.
[20] Immediately in Effect Guidance Document: Condition for Sale for Air-Conduction Hearing Aids, 81 Fed. Reg. 89469 (Dec. 12, 2016).
[21] *Id.*
[22] 115 P.L. 52, 131 Stat. 1005, 2017 Enacted H.R. 2430, 115 Enacted H.R. 2430.
[23] 21 U.S.C. § 360j(q).
[24] *N.C. State Bd. of Dental Exam'rs v. FTC*, 574 U.S. 494, 135 S. Ct. 1101, 1104 (2015)
[25] Erin K. Haag, Executive Director, Board of Examiners for Speech-Language Pathology & Audiology
July 28, 2020 response to FOIA request from Kitch/IHS.
[26] Again, the record is wholly devoid of ANY competency complaints, or referral complaints related to tinnitus.
[27] National Health Expenditure Projections 2018-2027, www.cms.gov/.../Downloads/ForecastSummary.pdf