



## HEALTH LICENSING OFFICE

Kate Brown, Governor

Oregon  
**Health**  
Authority

700 Summer St NE, Suite 320  
Salem, OR 97301-1287  
Phone: (503)378-8667  
Fax: (503)585-9114

**WHO:** Health Licensing Office  
Advisory Council on Hearing Aids

**WHEN:** 1 p.m. March 25, 2016

<http://www.oregon.gov/OHLA/Pages/index.aspx>

**WHERE:** Health Licensing Office  
Rhoades Conference Room  
700 Summer St. NE, Suite 320  
Salem, Oregon

### **What is the purpose of the meeting?**

The purpose of the meeting is to conduct board business. Please use appropriate language, manners and protocols when conducting board business. A working lunch may be served for board members and designated staff in attendance. A copy of the agenda is printed with this notice. Please visit <http://www.oregon.gov/OHLA/LD/Pages/Meetings2.aspx> for current meeting information.

### **May the public attend the meeting?**

Members of the public and interested parties are invited to attend all board/council meetings. All audience members are asked to sign in on the attendance roster before the meeting. Public and interested parties' feedback will be heard during that part of the meeting.

### **May the public attend a teleconference meeting?**

Members of the public and interested parties may attend a teleconference board meeting **in person** at the Health Licensing Office at 700 Summer St. NE, Suite 320, Salem, OR. All audience members are asked to sign in on the attendance roster before the meeting. Public and interested parties' feedback will be heard during that part of the meeting.

### **What if the board/council enters into executive session?**

Prior to entering into executive session the board/council chairperson will announce the nature of and the authority for holding executive session, at which time all audience members are asked to leave the room with the exception of news media and designated staff. Executive session would be held according to ORS 192.660.

No final actions or final decisions will be made in executive session. The board/council will return to open session before taking any final action or making any final decisions.

### **Who do I contact if I have questions or need special accommodations?**

The meeting location is accessible to persons with disabilities. A request for accommodations for persons with disabilities should be made at least 48 hours before the meeting. For questions or requests contact a board specialist at (503) 373-2049.

All board members are asked to please give at least 24-hour notice if they are unable to attend the meeting so arrangements may be made.

# **Items for Board Action**

# **Approval of Agenda**



Health Licensing Office  
Advisory Council on Hearing Aids



1 p.m. March 25, 2016  
700 Summer St. NE, Suite 320  
Salem, Oregon

1. **Call to order**
2. **Items for board action**
  - ◆ Approval of agenda
  - ◆ Approval of minutes from March 20, 2015
  - ◆ Approval of meeting dates for 2016
  - ◆ Election of chair and vice chair
3. **Practical exam discussion** - Roz Sinclair, Dave Montross and Christopher Gustafson, examination proctors, and Mitchell Tudorache, Crystal Clear Audio-Medical, Inc.
4. **Reports**
  - ◆ Director report
  - ◆ Licensing and fiscal statistical reports
  - ◆ Regulatory report
  - ◆ Policy
    - Rule schedule discussion
    - What professions/stakeholders should be at the rules advisory committee meeting?
  - ◆ New website
5. **Items for board action II**
  - ◆ Approve rulemaking schedule
6. **Public/interested parties' feedback**
  - ◆ 12/21/15 letter from the International Hearing Society
7. **Executive session** - Pursuant to ORS 192.660(2)(f) for the purpose of considering information or records exempt from public inspection. (Investigation cases)
8. **Other board business**

# **Approval of Minutes**



Health Licensing Office  
Advisory Council on Hearing Aids



March 20, 2015  
700 Summer St. NE, Suite 320  
Salem, Oregon

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**MINUTES**

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**MEMBERS PRESENT**

Dr. Garry Harris, Chair  
Shelly Boelter (joined at 1:10 p.m.)  
Rodney Walker  
Jonathan Hamm  
Randy Lerner

**MEMBERS ABSENT:**

Tiffany Parret  
Cheryl Blackman

**GUESTS PRESENT:**

Mark Pierce, Avada Hearing  
Linda Pierce, Avada Hearing  
Andrea Bartling, Avada Hearing

**STAFF PRESENT**

Sylvie Donaldson, Fiscal Services and Licensing Manager  
Bob Bothwell, Regulatory Operations Manager  
Joanna Tucker Davis, Assistant Attorney General, Oregon  
Department of Justice  
Anne Thompson, Policy Analyst  
Sarah Kelber, Communications Coordinator  
Debby Daniels, Qualification Specialist

**Call to order**

Garry Harris called the meeting of the Advisory Council on Hearing Aids to order at 1:03 p.m., on March 20, 2015, at the Health Licensing Office (HLO), in Salem. Roll was called.

**Items for council action**

◆ **Approval of agenda**

Rodney Walker made a motion, with a second by Jonathan Hamm, to approve the agenda. Motion passed unanimously.

◆ **Approval of minutes**

Randy Lerner made a motion, with a second by Jonathan Hamm, to approve the minutes for March 21, 2014. Motion passed unanimously.

◆ **Meeting date selection**

Jonathan Hamm made a motion, with a second by Randy Lerner, to accept Aug. 28, 2015, for the next meeting date.

◆ **Chair and vice chair selection**

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Shelly Boelter made a motion, with a second by Jonathan Hamm, to have Garry Harris continue as chair and for Rodney Walker to serve as vice chair for 2015.

### **Reports**

#### **◆ Director report**

Sylvie Donaldson, Fiscal Services and Licensing Manager, spoke on behalf of Director Holly Mercer.

Donaldson introduced Sarah Kelber, HLO's new communications coordinator, and asked new Council members Randy Lerner and Jonathan Hamm to introduce themselves.

She outline legislation that may affect HLO and its boards, including the new advanced esthetics board and the new program to license music therapists.

She said the transition to the Oregon Health Authority was going smoothly, although some processes took longer than they did before HLO became part of the large agency.

Donaldson showed the Council the communication developed by staff to quickly explain how to become a hearing aid specialist and an FAQ for continuing education requirements.

#### **◆ Licensing and fiscal statistical reports**

Donaldson then outlined licensing trends and pass/fail rates for exams. The majority of permanent license holders are older and male. The number of temporary licenses is declining, which she said is a good thing, as it indicates that these people are finishing their training, passing exams and getting permanent licenses.

#### **◆ Policy report**

Donaldson showed the Council the changes and 2015 schedule for the written and practical examinations.

#### **◆ Regulatory report**

Regulatory Operations Manager Bob Bothwell told the Council that in the last biennium, 43 complaints were received; 36 are closed. In the current biennium, 22 complaints were received; four are closed.

### **Public/interested parties' feedback**

Mark Pierce addressed the Council, saying he was a hearing aid dispenser and he noticed that license holders were older and asked if young people were entering the profession. Donaldson said the Council's job is licensing and regulation; any promotion or recruitment efforts for the profession would have to come from associations.

Policy Analyst Anne Thompson read Scot Frink's emailed comments concerning tinnitus as it relates to hearing instrument specialists' scope of practice into the record.

Pierce said that there are new instruments with "masking" features and said he wasn't sure about how the new technology fit with scope of practice.

### **Executive session**

Garry Harris called for the Advisory Council on Hearing Aids to enter executive session pursuant to

ORS 192.660(2)(f) at 1:34 p.m. on March 20, 2015, for the purpose of considering information or records exempt from public inspection.

Harris concluded executive session and the council reconvened regular session at 2:31 p.m. It was noted that no final decisions were made and no votes were made in executive session.

**Other council business**

None.

The meeting adjourned at 2:33 p.m.

Minutes prepared by: Anne Thompson, Policy Analyst

DRAFT

# **2016 Meeting Dates**



HEALTH LICENSING OFFICE

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## 2016 meeting dates

### BACKGROUND AND DISCUSSION

The Advisory Council on Hearing Aids (Council) usually meets twice a year.

### ISSUE

The Council must approve 2016 meeting times and dates. The Health Licensing Office proposes:

- 1 p.m. Friday, March 25
- 1 p.m. Friday, Aug. 26

### BOARD ACTION

The Council approves 2016 meeting times and dates:

**2016 Chair  
and Vice Chair**



## Chair and vice chair – 2016

### BACKGROUND AND DISCUSSION

Garry Harris has served as chair for the Advisory Council on Hearing Aids (Council), and Rodney Walker has served as vice chair during 2015.

### ISSUE

The Council must nominate and elect a chair and vice chair for 2016.

#### **Role of the chair in meetings**

- Officially call the meeting to order.
- Keep order and impose any necessary restrictions for the efficient and orderly conduct of the meeting.
- Direct the “flow” of the meeting and to ensure the meeting is conducted in a professional manner.  
Some key points regarding meeting protocol include:
  - Board members wishing to speak must wait to be addressed by the chair.
  - Once addressed by the chair, the board member must state their last name for the record before speaking.
  - The chair guides members through the motion-making process.
  - If public comment is being accepted by the Board, audience members must wait to be addressed by the chair and state their full name and affiliation to the Board.
- Officially enter/exit executive session.
- Officially adjourn the meeting.

#### **Role of the chair outside of meetings**

- Collaborate with the director regarding the Board budget. The director may contact the chair to discuss the Board budget regarding revenue, expenditures and possible fee changes.
- Assist in generating meeting agendas. The board specialist or analyst may contact the chair to discuss the agenda for an upcoming meeting. The chair may be asked to comment on topics to be discussed and the format or order in which the topics should be presented at the meeting.

#### **Role of the vice chair**

The vice chair must assume the responsibilities of the chair if there is an absence or if the chair is no longer a member of the Board.

### COUNCIL ACTION

The Council nominates and elects:

Chair:

Vice chair:

# **Practical Exam Discussion**

# **Director's Report**



## Advisory Council on Hearing Aids

### Member Appointment Status Update

#### Council Membership in General:

Pursuant to ORS 694.165 the Advisory Council on Hearing Aids consists of seven members appointed by the governor including:

- One member who is licensed to practice medicine in Oregon and holds a certificate of qualification from the American Board of Otolaryngology;
- One member who holds a clinical certification in audiology with the American Speech-Language-Hearing Association and is a member in good standing;
- Four members who are experienced in the fitting of hearing aids and possess the qualifications provided in ORS 694.055; and
- One member who is a consumer of hearing aids and does not possess the professional qualifications of the other members.

Terms in office are four years; with an appointee eligible to serve a maximum of two consecutive terms or until a successor is appointed.

#### Current Appointment Information:

Member Position Type	Member Name	Full Term # or Partial Term	Start of Current Term	Term Expiration
Hearing Aid Specialist	VACANT			
Audiologist	Randy Lerner	1 <sup>st</sup> Full after partial	08/01/2015	07/31/2019
Hearing Aid Specialist	Cheryl Blackman	1 <sup>st</sup> Full	03/01/2014	02/28/2018
Otolaryngologist	Garry Harris	2 <sup>nd</sup> Full	11/01/2014	10/31/2018
Hearing Aid Specialist	Jonathan Hamm	1 <sup>st</sup> Full	10/01/2014	09/30/2018
Hearing Aid Specialist	Tiffany Parret	1 <sup>st</sup> Full	01/01/2013	12/31/2016
Consumer	Rodney Walker	1 <sup>st</sup> Full	12/10/2012	12/09/2016

#### How to Apply to be a Member:

Helpful information on how to apply to be a member is available online at:

<http://www.oregon.gov/gov/Pages/boards.aspx>

In general, interested applicants are asked to review the membership handbook and submit a completed interest form to the Governor’s Office of Executive Appointments. (Interest form attached) Completed interest forms can be submitted by any of the following methods:

- Fax interest form to 503-373-0840 (secure fax);

- Email scanned interest form to [executive.appointments@das.state.or.us](mailto:executive.appointments@das.state.or.us); or

- Mail interest form to:

Office of the Governor

Executive Appointments

900 Court Street NE, Room 160

Salem, OR 97301-4075

Please contact the Office of Executive Appointments if you have questions about the appointment process or about the status of your application.

# **Licensing and Fiscal Statistical Reports**

# Health Licensing Office

## Advisory Council on Hearing Aids

*Licensing Division Statistics as of March 14, 2016*

*2015 - 2017 Biennium*

<b>Quarter</b>	<b>Permanent Licenses Issued</b>	<b>Temporary Licenses Issued</b>	<b>Trainee Registrations Issued</b>	<b>Renewals Processed</b>
<b>1st</b>	2	4	14	73
<b>2nd</b>	4	3	8	50
<b>3rd</b>	4	4	3	53
<b>4th</b>	-	-	-	-
<b>5th</b>	-	-	-	-
<b>6th</b>	-	-	-	-
<b>7th</b>	-	-	-	-
<b>8th</b>	-	-	-	-
<b>Total</b>	<b>10</b>	<b>11</b>	<b>25</b>	<b>176</b>

# Health Licensing Office

## Advisory Council on Hearing Aids

Examination Statistics as of March 14, 2016

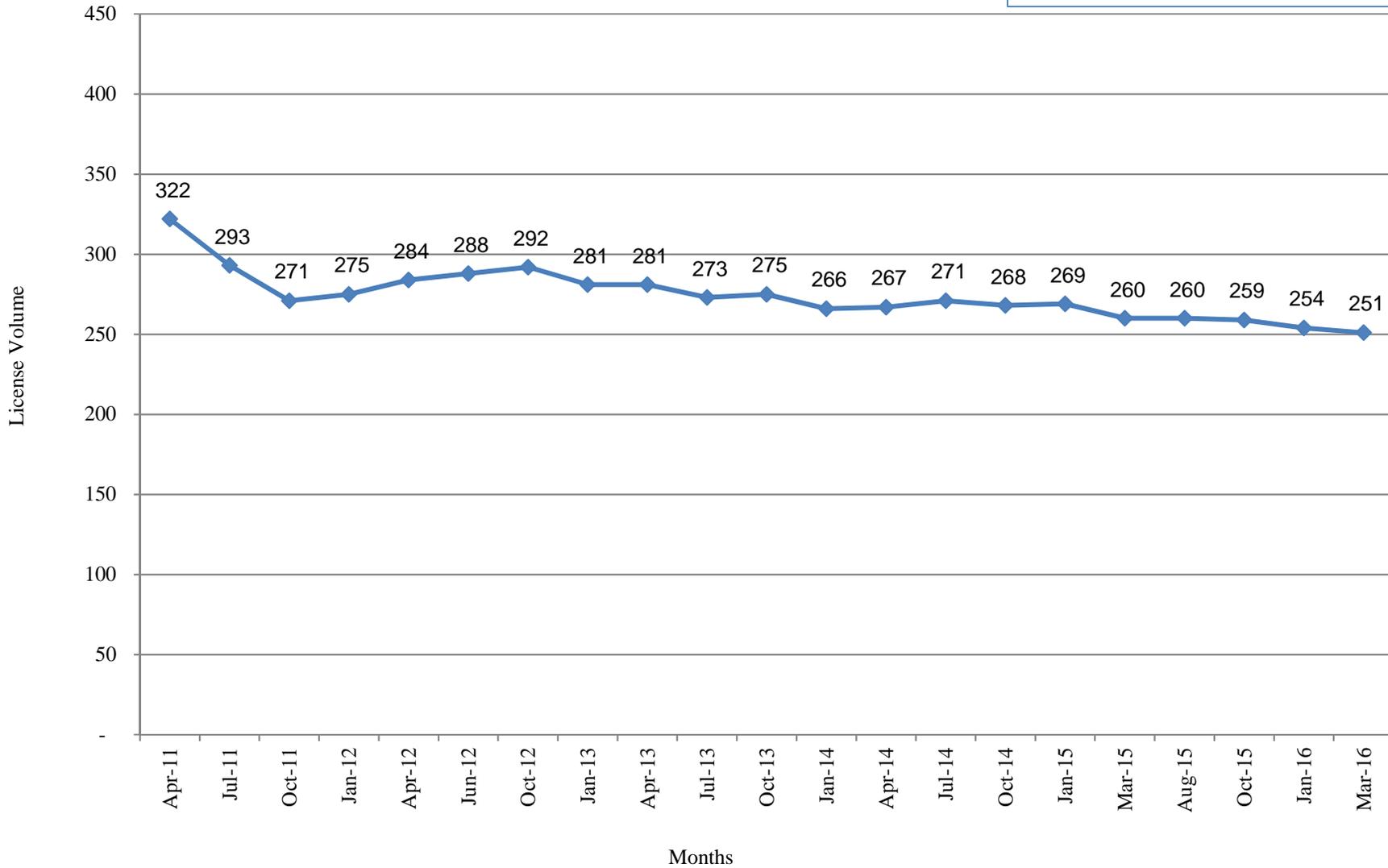
2015 - 2017 Biennium

Quarter	Oregon Laws and Rules			Quarter	Practical Exam 1A, Audiometrics		
	Passed	Failed	% Passed		Passed	Failed	% Passed
1st	5	-	100%	1st	5	-	100%
2nd	3	-	100%	2nd	2	-	100%
3rd	3	-	100%	3rd	1	1	50%
4th	-	-		4th	-	-	
5th	-	-		5th	-	-	
6th	-	-		6th	-	-	
7th	-	-		7th	-	-	
8th	-	-		8th	-	-	
<b>Total</b>	<b>11</b>	<b>-</b>	<b>100%</b>	<b>Total</b>	<b>8</b>	<b>1</b>	<b>89%</b>
Quarter	Practical Exam 1B, Audiometrics			Quarter	Practical Exam 2, Ear molds		
	Passed	Failed	% Passed		Passed	Failed	% Passed
1st	5	-	100%	1st	5	-	100%
2nd	2	-	100%	2nd	2	-	100%
3rd	1	1	50%	3rd	2	-	100%
4th	-	-		4th	-	-	
5th	-	-		5th	-	-	
6th	-	-		6th	-	-	
7th	-	-		7th	-	-	
8th	-	-		8th	-	-	
<b>Total</b>	<b>8</b>	<b>1</b>	<b>89%</b>	<b>Total</b>	<b>9</b>	<b>-</b>	<b>100%</b>
Quarter	Practical Exam 3, Audio diagrams			Quarter	NIHIS Written Exam		
	Passed	Failed	% Passed		Passed	Failed	% Passed
1st	3	3	50%	1st	1	1	50%
2nd	2	2	50%	2nd	4	-	100%
3rd	3	-	100%	3rd	1	-	100%
4th	-	-		4th	-	-	
5th	-	-		5th	-	-	
6th	-	-		6th	-	-	
7th	-	-		7th	-	-	
8th	-	-		8th	-	-	
<b>Total</b>	<b>8</b>	<b>5</b>	<b>62%</b>	<b>Total</b>	<b>6</b>	<b>1</b>	<b>86%</b>

# Advisory Council on Hearing Aids

Active Permanent License Trend  
April 2011 - March 2016

-3.5% change in growth over 1 year  
-22.0% change in growth over 5 years

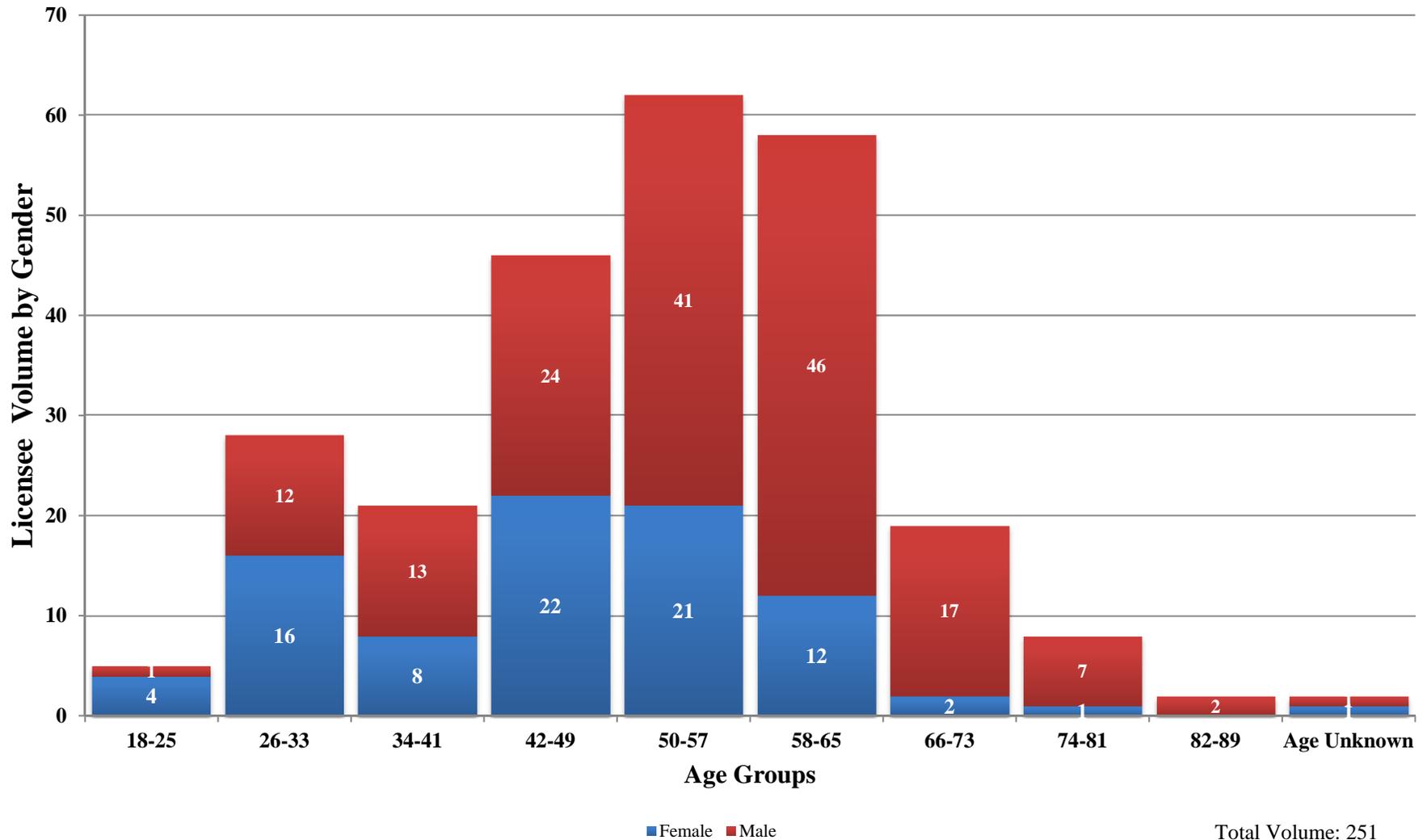


# Advisory Council on Hearing Aids

## Active Permanent Licensee Volume

Statistics grouped by Gender and Age Group as of March 14, 2016

2015 - 2017 Biennium

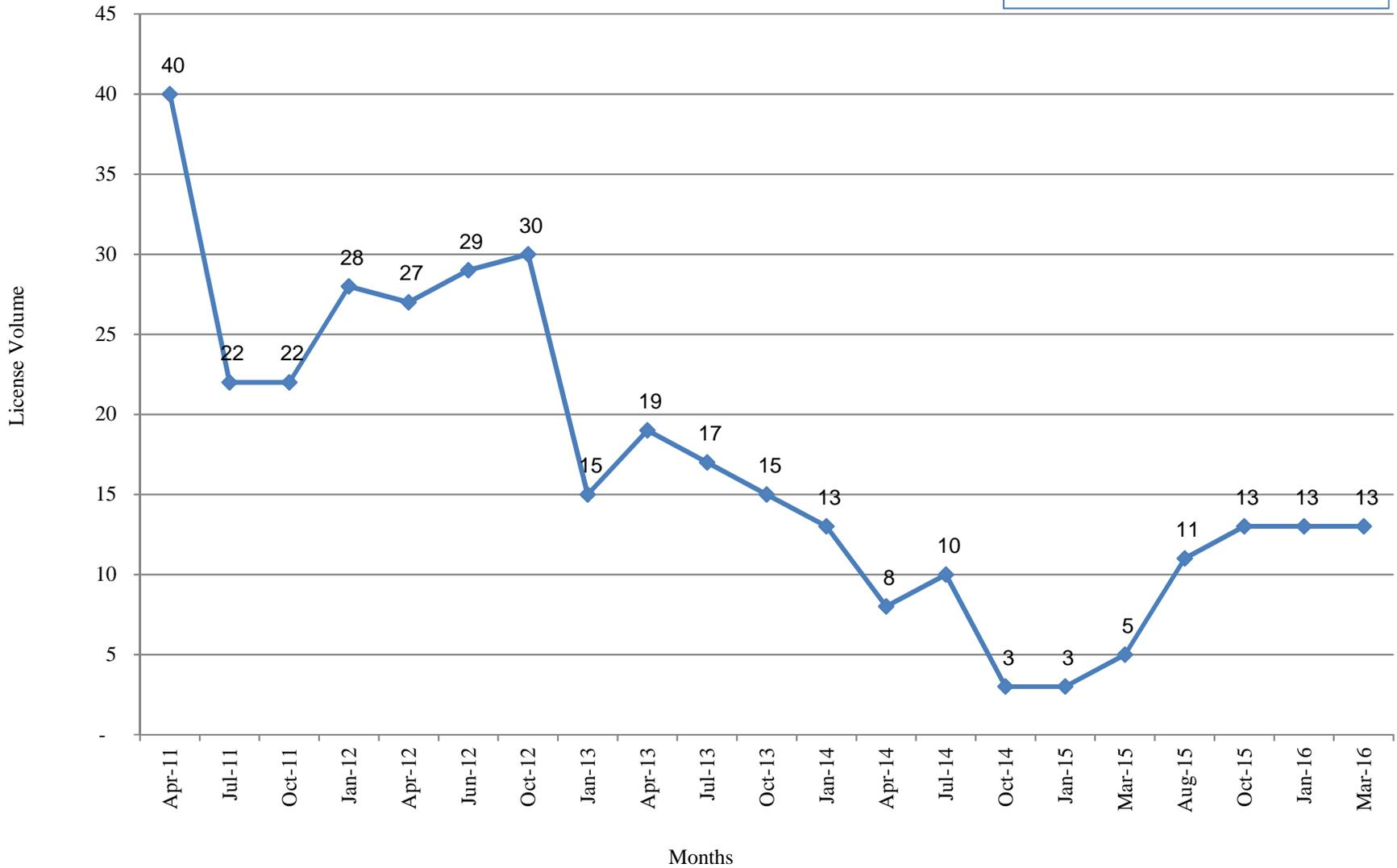


Total Volume: 251

# Advisory Council on Hearing Aids

Active Temporary License Trend  
April 2011 - March 2016

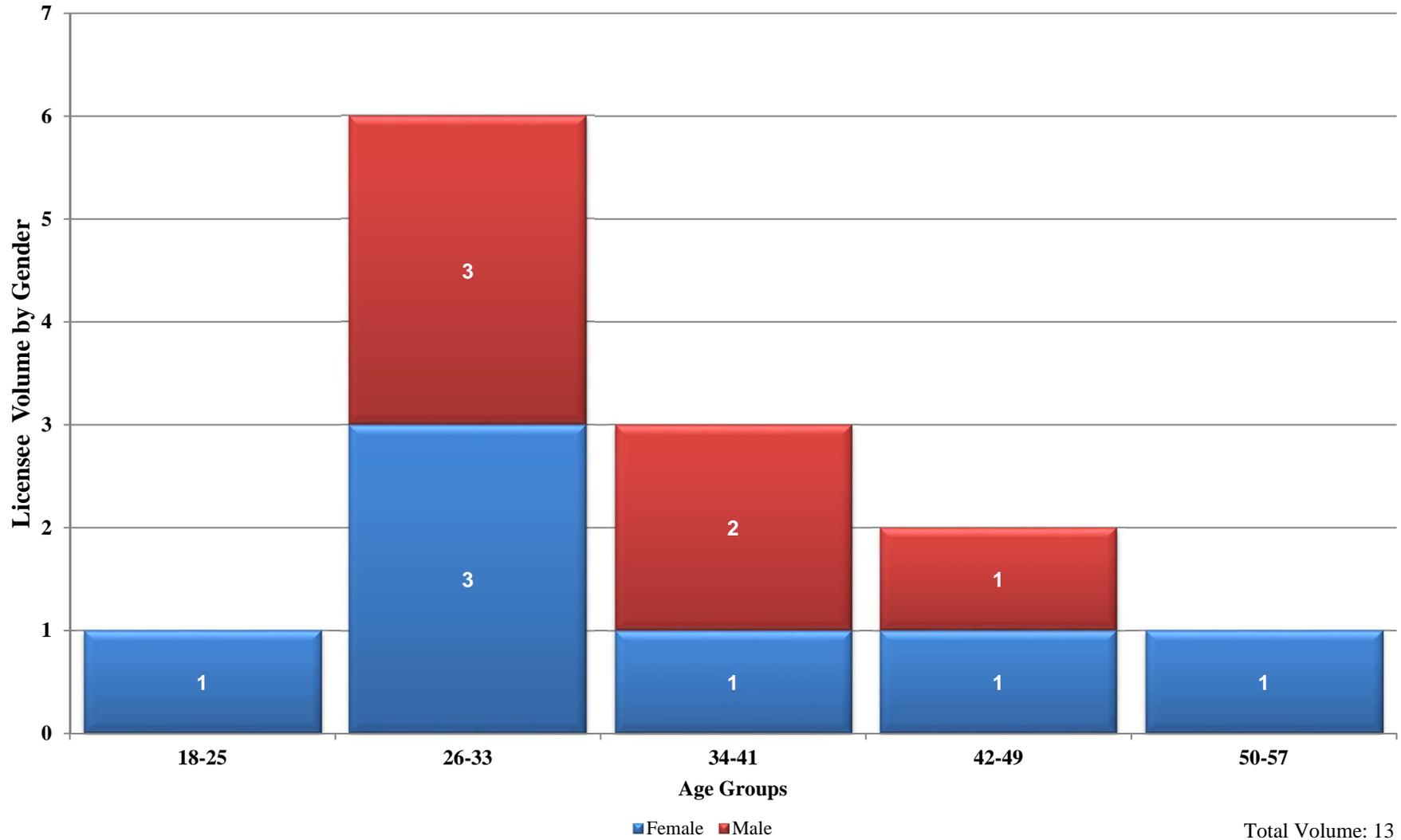
160.0% change in growth over 1 year  
-67.5% change in growth over 5 years



# Advisory Council on Hearing Aids

## Active Temporary Licensee Volume

Statistics grouped by Gender and Age Group as of March 14, 2016  
2015 - 2017 Biennium

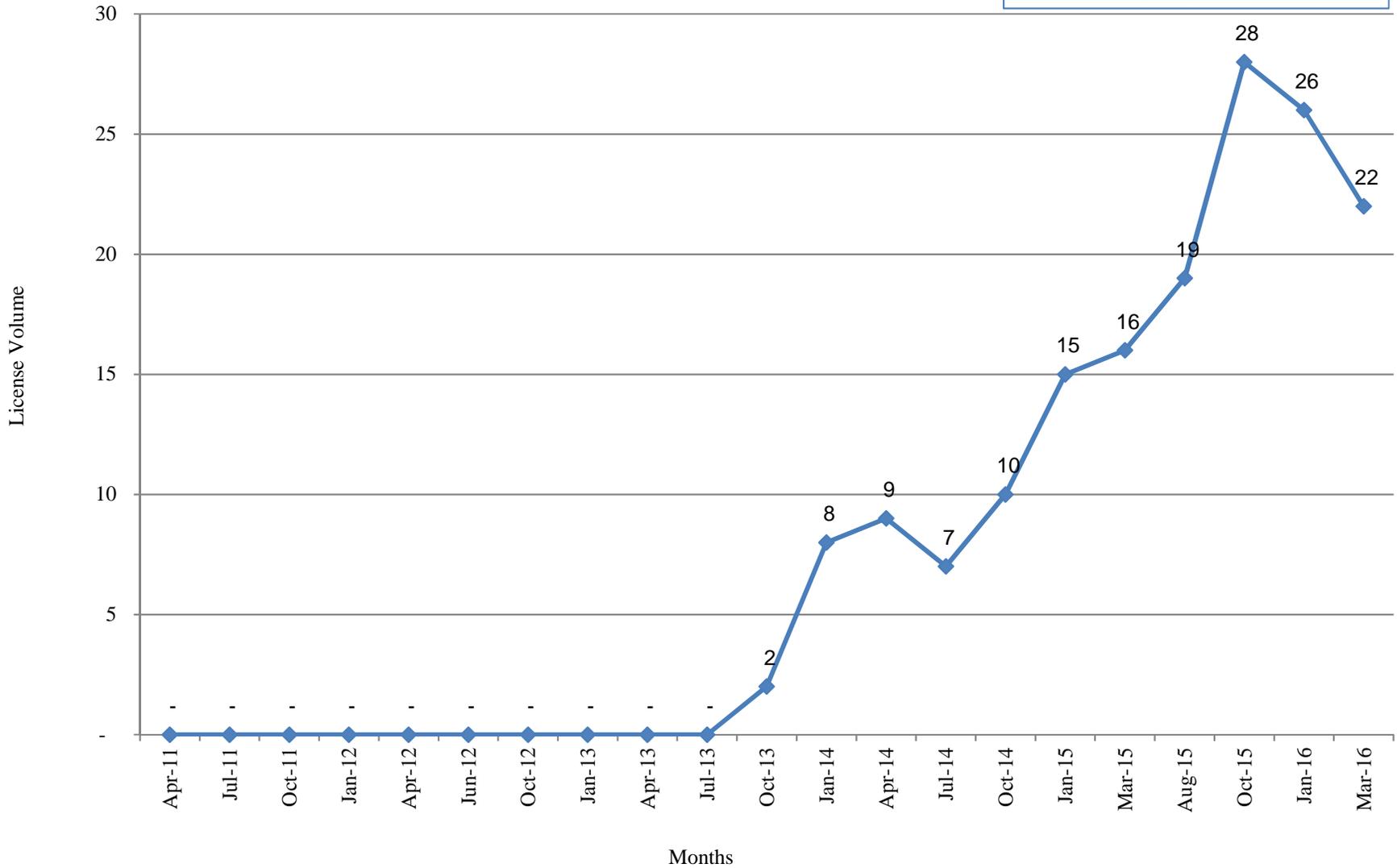


# Advisory Council on Hearing Aids

## Active Trainee Registration Trend

April 2011 - March 2016

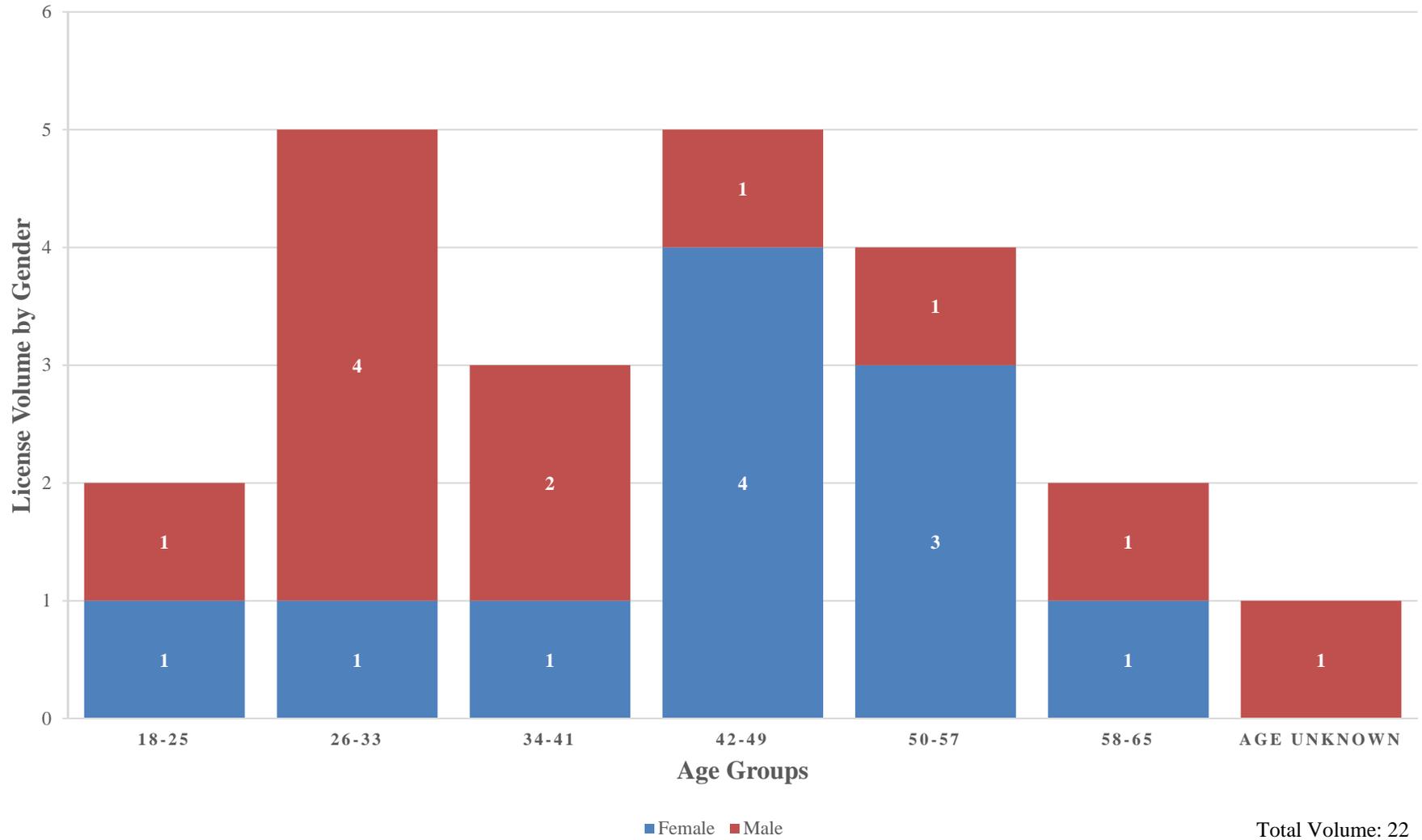
37.5% change in growth over 1 year



# Advisory Council on Hearing Aids

## Active Trainee Licensee Volume

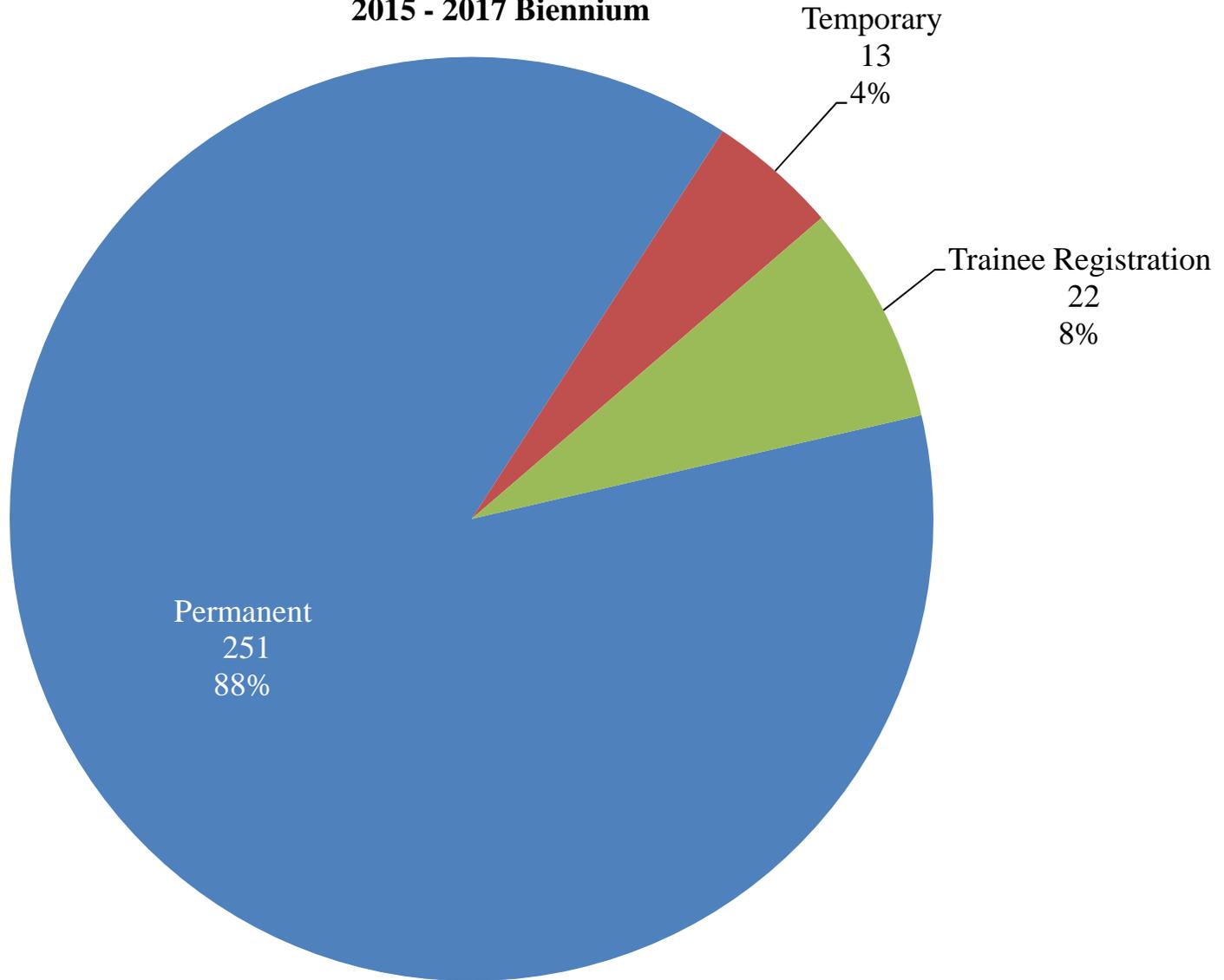
Statistics grouped by Gender and Age Group as of March 14, 2016  
2015 - 2017 Biennium



# Advisory Council on Hearing Aids

License Volume as of March 14, 2016

2015 - 2017 Biennium



<b>HEALTH LICENSING OFFICE</b> <b>Fund 3620 - HEARING AID SPECIALIST</b> <b>STATEMENT OF CASH FLOW</b> <b>FOR THE PERIOD 07/01/15 - 03/14/16</b>	
CURRENT	
<b>15-17' Beginning Cash Balance</b>	\$ 189,960.00
Revenues	\$ 32,035.00
Expenditures	\$ 24,955.99
Less: Accrued Expenditures	
Less: Total Expenditures	\$ (24,955.99)
Subtotal: Resources Available	\$ 197,039.01
Change in (Current Assets)/Liabilities	\$ -
<b>Ending Cash Balance (Actual)</b>	<b>\$ 197,039.01</b>
Indirect Charges are calculated using the following rates:	
* Based on average Licensee Volume	
Shared Assessment %	0.40%
Examination %	1.16%
Small Board Qualification %	4.78%
Inspection %	0.00%

<b>HEALTH LICENSING OFFICE</b> <b>Fund 3620 - HEARING AID SPECIALIST</b> <b>STATEMENT OF CASH FLOW</b> <b>FOR THE PERIOD 07/01/15- 06/30/17</b>	
PROJECTED	
<b>15-17' Beginning Cash Balance</b>	\$ 189,960.00
Revenues	\$ 97,645.49
Expenditures	\$ 76,992.33
Less: Accrued Expenditures	\$ -
Less: Total Expenditures	\$ (76,992.33)
Subtotal: Resources Available	\$ 210,613.16
Change in (Current Assets)/Liabilities	\$ -
<b>Ending Cash Balance (Projection)</b>	<b>\$ 210,613.16</b>
Indirect Charges are calculated using the following rates:	
* Based on average Licensee Volume	
Shared Assessment %	0.40%
Examination %	1.16%
Small Board Qualification %	4.78%
Inspection %	0.00%

# **Regulatory Report**

# Health Licensing Office



700 Summer St. NE, Suite 320  
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E-mail: [hlo.info@state.or.us](mailto:hlo.info@state.or.us)

## ***Advisory Council on Hearing Aids***

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*March 25, 2016*

### ***2013 – 2015 Biennium***

Between July 1, 2013 and June 30, 2015, 30 complaints were received by the Office. Total open 17. Total closed 13.

<b>ANONYMOUS</b>	<b>CLIENT</b>	<b>OTHER</b>
2	15	13

### ***2015 – 2017 Biennium***

Between July 1, 2015 and February 29, 2016, 5 complaints were received by the Office. Total open 4. Total closed 1

<b>ANONYMOUS</b>	<b>CLIENT</b>	<b>OTHER</b>
0	3	2

Other: Internal  
General Public  
Licensees  
Other Agencies

# **Policy Report**

Date	Action	Time
March 25, 2016	Council meeting to approve rulemaking schedule	1 p.m.
May 5, 2016	Rules advisory committee meeting	9 a.m. to noon
June 1, 2016	Council meeting to approve proposed rules	9 a.m.
June 15, 2016	Deadline for notice in Oregon Bulletin	
July 1, 2016	Public comment period for proposed rules opens	
Aug. 1, 2016	Public comment period closes; and public hearing from 10 a.m. to noon	10 a.m. to noon
Aug. 26, 2016	Council meeting; review public comment and vote on permanent rules	1 p.m.
Sept. 1, 2016	Administrative rules go into effect	

Please send all public comment or questions to:

Anne Thompson, Policy Analyst

700 Summer St NE, Suite 320, Salem, OR 97301-1287

[anne.p.thompson@state.or.us](mailto:anne.p.thompson@state.or.us) . Work: (503) 373-1904

All meetings are held at the Health Licensing Office, Rhoades Conference Room, 700 Summer St, Suite 320, Salem, OR 97301, unless otherwise specified. Members of the public are invited and encouraged to attend all board and committee meetings. However, audience members will not be allowed to participate.

Invited technical experts may be invited to participate in meetings regarding their knowledge and expertise in specific areas.

For current information regarding administrative rules or the rulemaking process visit the Web at [http://www.oregon.gov/OHLA/HAS/Pages/HASlaws\\_rules.aspx](http://www.oregon.gov/OHLA/HAS/Pages/HASlaws_rules.aspx)

HEALTH LICENSING OFFICE  
Advisory Council on Hearing Aids

**Issue**

The Advisory Council on Hearing Aids' administrative rules need to be brought up to date with new practice standards and advances in the profession.

**Recommendation**

Approve the rulemaking schedule to begin the rulemaking process.

# **Items for Board Action II**

# **Public/Interested Parties' Feedback**

December 21, 2015

Dr. Garry Harris, MD, Chair  
Oregon Advisory Council on Hearing Aids  
C/O Health Licensing Office  
700 Summer Street, NE., Suite 320  
Salem, OR 97301-1287

Dear Chairman Harris and Members of the Council:

I am writing in regards to the “Hearing Aid Specialists – Tinnitus FAQ” published on July 2, 2015, by the Health Licensing Office (HLO) and available on the Advisory Council on Hearing Aids website. I would like to share the perspective of the International Hearing Society on this topic, clear up some misconceptions that exist on this issue, and ask that the HLO either retract or revise the FAQs accordingly.

While hearing aid specialists do not “treat” tinnitus, many hearing aid specialists do play a role in managing their patients’ tinnitus through the use of amplification. Their involvement has been well-documented in articles and periodicals over the years. Appropriately-fitted hearing aids provide residual inhibition, environmental masking, auditory re-attention, and stress relief. These are documented in the literature as benefits of amplification for many tinnitus sufferers. IHS takes no issue with the state’s assertion that hearing aid specialists may not diagnose or treat tinnitus. Diagnosis and treatment are considered the practice of medicine and should therefore only be performed by MD- and DO-physicians. It is critical, however, that in dealing with patients with tinnitus, hearing aid specialists are fully informed of and adhere to standards that define when a referral to a physician or audiologist is needed, and whether amplification is appropriate for that individual.

IHS is concerned, however, that the FAQs 1) disregard hearing aid specialists’ role in managing tinnitus, 2) that they were based at least in part on false information, and 3) that they could and are being misconstrued as restricting hearing aid specialists’ ability and legal authority to help patients who present with a primary complaint of hearing loss to gain the full benefit of their hearing aids. Further, hearing aid specialists who have obtained additional training in tinnitus management and therapies under current law are able to perform services for which they are qualified to provide in accordance with federal and state law.

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. The information in the email contains several inaccuracies.

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.” This is simply not true.

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 contradict 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.** (*Emphasis added*) 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, 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 instruments. 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.<sup>1</sup> 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.<sup>2</sup> 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 masking circuits; no manufacturer ever told them they had done this...”

Further, the classification of the device - Class I versus Class II - is a moot point. The FDA has affirmed that it “has no restrictions on who can fit medical devices based on the class of the device.” Wireless air-conduction hearing aids, master hearing aids, and audiometers, for example, are Class II medical devices. Hearing aid specialists have been using these devices since their entry into the marketplace.

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<sup>1</sup> [http://www.accessdata.fda.gov/cdrh\\_docs/pdf13/K133308.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf13/K133308.pdf)

<sup>2</sup> [http://www.accessdata.fda.gov/cdrh\\_docs/pdf11/K110973.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf11/K110973.pdf)

The FDA also affirmed that its regulations do not address the issue of “appropriate training.” The FDA leaves this decision-making to the manufacturer, professional societies, and/or state licensing agencies. According to Mr. Nandkumar, “Delineating or ruling on the specific qualifications is not within the scope of the FDA’s interest or statutory authority. While there are certain devices for which the manufacturer is held responsible for ensuring providers are specifically trained, such as some surgical ENT devices, this does not apply to tinnitus maskers or tinnitus management devices.”

Therefore it is left up to the states to regulate the professions, set training standards, and determine which professions are authorized to dispense devices. In the experience of our organization, tinnitus management is within the routine scope of practice of hearing aid specialists and is not prohibited under Oregon law. The FAQ document is correct that “tinnitus” is not specifically included in the statutes governing the hearing aid specialist profession (Chapter 694 – Hearing Aid Specialists of the Oregon Revised Statutes). Equally important, however, is that “tinnitus” is also not specifically included in the statutes governing audiologists (Chapter 681 – Hearing and Speech Professionals of the Oregon Revised Statutes) or any other covered profession to the best of our knowledge. Oregon statutes are silent on the management of tinnitus, neither positively delineating it as a part of any profession’s scope of practice nor restricting any profession from the management of tinnitus.

As stated in the FAQ document, Chapter 694 of the Oregon Revised Statutes, ORS 694.015 (2) “Dealing in Hearing Aids” means: “the sale, lease or rental or attempted sale, lease or rental of hearing aids in conjunction with the evaluation or measurement of the powers or range of human hearing and the **recommendation, selection or adaptation of hearing aids.**” (Emphasis added). ORS 694.015(3) defines a hearing aid as “**any prosthetic instrument or device designed** for or represented as aiding, improving, or correcting defective human hearing and **any parts, attachments, or accessories** of such an instrument or device.” (*Emphasis added*)

The masker is a feature of the hearing aid that can provide improved hearing to the end user regardless of whether they have the secondary symptom of tinnitus. Hearing aids that include a tinnitus masker clearly fall within the Oregon Revised Statutes’ definition of “any prosthetic instrument or device...for improving, or correcting defective human hearing.” Furthermore, as the statute makes clear, hearing aid specialists are permitted to provide “recommendation, selection, or adaptation” of these hearing aids. Using a tinnitus masker that is fully integrated into the device clearly is an allowable “adaptation” of the device.

For the purpose of reference and comparison, Chapter 681 – Hearing and Speech Professionals of the Oregon Revised Statutes, ORS 681.205 (4) “Practice of Audiology means: (a) “To apply the principles, methods and procedures of measurement, prediction, evaluation, testing, counseling, consultation and instruction that relate to the development and disorders of hearing, vestibular functions and related language and speech disorders to prevent or modify the disorders or to assist individuals in auditory and related skills for communication. (b) To fit and sell hearing aids.” As is clear, the statutory text does not specifically address tinnitus and does not include detailed language regarding the selection or modifications or hearing instruments, including the use of tinnitus maskers. Instead, it is presumably in the interpretation of an audiologist’s ability to “measure,” “counsel” and “consult” that provides the authority of an audiologist to manage a patient’s tinnitus. Applying the same interpretation to the text of the hearing aid specialist statute, specifically the authority to “evaluate,” “measure,” and “recommend” and “adapt” devices, allows for a hearing aid specialist to use the tinnitus masking feature of hearing instruments.

IHS is aware that the FAQs are being misinterpreted as restricting licensed dispensers from using tinnitus features in hearing aids in all circumstances, regardless of advertising. For example, in a November 2015 email, Mr. Frink stated, “[D]ispensers are prohibited from utilizing tinnitus features in hearing aids. Patients requesting such features should be referred to an audiologist or ENT to work with these features. Dispensers are also likewise [prohibited] from advertising that they have tinnitus solutions. This is per the Advisory Council's ruling, which was simply based on the FDA guidelines.” This instructive misinterpretation not only relies on hearsay from the aforementioned audiology forum and serves to benefit no one but the audiology community, but, most importantly, it is inconsistent with the FAQs that were released by the OPH that relate only to diagnosing, treating, or advertising the treatment of tinnitus.

Finally, I would like to draw your attention to the fourth question and response of the FAQs, which in our read infers that audiologists diagnose and treat tinnitus. As previously stated, the definition of the practice of audiology does not include the functions of diagnosing or treating. According to the ORS §677.085:

*A person is practicing medicine if the person does one or more of the following:*

*(1) Advertise, hold out to the public or represent in any manner that the person is authorized to practice medicine in this state.*

*(2) For compensation directly or indirectly received or to be received, offer or undertake to prescribe, give or administer any drug or medicine for the use of any other person.*

*(3) Offer or undertake to perform any surgical operation upon any person.*

*(4) Offer or undertake to diagnose, cure or treat in any manner, or by any means, methods, devices or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of any person.*

While IHS takes no issue with the agency’s direction that hearing aid specialists do not practice medicine or audiology, in the context of the FAQs, including audiology in this answer may cause confusion for individuals with tinnitus about which healthcare providers are authorized to diagnose and treat tinnitus.

For these reasons, IHS encourages the Advisory Council to work with the Health Licensing Office to reconsider the FAQ document. IHS looks forward to working with the Council to make sure that the oversight of hearing aid specialists is thorough and appropriate without exceeding the statutory authority of the Council and creating limits to care where none need exist.

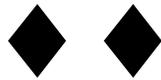
Thank you very much for your time and attention and for all of the work that you do on behalf of the hearing impaired people of Oregon. With questions or to discuss this issue further, you may reach me at 734.522.7200 or [aparady@ihsinfo.org](mailto:aparady@ihsinfo.org).

Sincerely,



Alissa Parady  
IHS Government Affairs Director

# **Executive Session**



ORS 192.660(2)(f) for the purpose of considering  
information or records exempt from public inspection.

# **Other Board Business**



Health Licensing Office  
Advisory Council on Hearing Aids  
March 25, 2016

**\*\*PLEASE PRINT\*\***

Name (First, Last)	Representing	Request to Comment (yes/no)
Mitchell Tudorache	Crystal Clear Audio Medical	
Paula Proctor		
Paradise Sinclair	Salmon Audio Logic Clinic	As Needed
S. Scott Fink		
Cheryl Greenleaf		