STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
SPEECH-LANGUAGE PATHOLOGY & AUDIOLOGY & HEARING AID DISPENSERS BOARD
1601 Response Road, Suite 260, Sacramento, CA 95815
P (916) 287-7915 | www.speechandhearing.ca.gov

TELECONFERENCE BOARD MEETING NOTICE AND AGENDA

The Speech-Language Pathology & Audiology & Hearing Aid Dispensers Board (Board) will hold a Board Meeting via WebEx Events on

Thursday, January 13, 2022 beginning 2:00 p.m.

NOTE: Pursuant to the provisions of Government Code section 11133, neither Board member locations nor a public meeting location are provided. Public participation may be through teleconferencing as provided below. If you have trouble getting on the WebEx event to listen or participate, please call 916-287-7915.

Important Notice to the Public:

The Board will hold this public meeting via WebEx Events. Instructions to connect to this meeting can be found at the end of this agenda. To participate in the WebEx Events meeting, please log on to the following website the day of the meeting:

Thursday, January 13, 2022 WebEx Link:
https://dca-meetings.webex.com/dca-meetings/j.php?MTID=m631dffbc812e42ab0bd3ee442172414a

Due to potential technical difficulties, please consider submitting written comments by 5:00 pm, January 11, 2022, to speechandhearing@dca.ca.gov for consideration.

Action may be taken on any agenda item.

Board Members
Marcia Raggio, Dispensing Audiologist, Board Chair
Holly Kaiser, Speech-Language Pathologist, Vice Chair
Tod Borges, Hearing Aid Dispenser
Karen Chang, Public Member
Gilda Dominguez, Speech-Language Pathologist
Debbie Snow, Public Member
Tulio Valdez, Otolaryngologist, Public Member
Amy White, Dispensing Audiologist
VACANT, Hearing Aid Dispenser

Thursday, January 13, 2022

Full Board Meeting Agenda

OPEN SESSION

1. Call to Order / Roll Call / Establishment of Quorum

2. Public Comment for Items not on the Agenda *(The Board may not discuss or take any action on any item raised during this public comment section, except to decide whether to place the matter on the agenda of a future meeting (Government Code Sections 11125, 11125.7(a))*

3. Swearing In New Board Members

4. Discussion and Possible Action on Filing of Public Comment Regarding U.S. Food and Drug Administration Proposed Rule on Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids

5. Future Agenda Items

CLOSED SESSION

6. Pursuant to Government Code Section 11126(c)(3), the Board will Meet in Closed Session to Discuss Disciplinary Matters Including Proposed Decisions, Stipulated Decisions, Defaults, Petitions for Reductions in Penalty, Petitions for Reconsideration, and Remands.

OPEN SESSION

7. Adjournment

Agendas and materials can be found on the Board's website at www.speechandhearing.ca.gov.

Action may be taken on any item on the Agenda. The time and order of agenda items are subject to change at the discretion of the Board Chair and may be taken out of order. In accordance with the Bagley-Keene Open Meeting Act, all meetings of the Board are open to the public. In the event a quorum of the board is unable to attend the meeting, or the board is unable to maintain a quorum once the meeting is called to order, the members present may, at the Chair's discretion, continue to discuss items from the agenda and make recommendations to the full board at a future meeting. Adjournment, if it is the only item that occurs after a closed session, may not be webcast.

The meeting facility is accessible to persons with a disability. Any person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting the Board office at (916) 287-7915 or making a written request to Cherise Burns, Assistant Executive Officer, 1601 Response Road, Suite 260, Sacramento, California 95815. Providing your request at least five (5) business days before the meeting will help ensure availability of the requested accommodation.

WEBEX FEATURES FOR PARTICIPANTS

Note: The following features and functions reflect only those relative to participant end user interface and functionality. For programs who desire to moderate/co-moderate their own meetings, SOLID can provide training and materials to reflect features and functions associated with these roles.

Joining a Webex Event

Navigate to the WebEx event using the link provided by the DCA entity via an internet browser. Webex will, in some instances, auto-populate name fields upon sign-in. As a result, some individuals may be automatically logged into the meeting with a Webex generated name (examples below).

Note: It is important for individuals to update the name fields when logging in to correctly reflect their identity to assist the moderator in identifying meeting participants. While we do not require the public to identify themselves, this is particularly important for staff, members, and presenters.

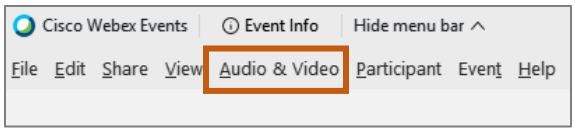
The event password will be entered automatically. If you alter the password by accident, close the browser and click the event link provided again. Click on "Join Now" (do not click "Join by browser").

Audio

You can select to use either your computer speaker/microphone, a headset, or your phone for audio.

To utilize your phone:

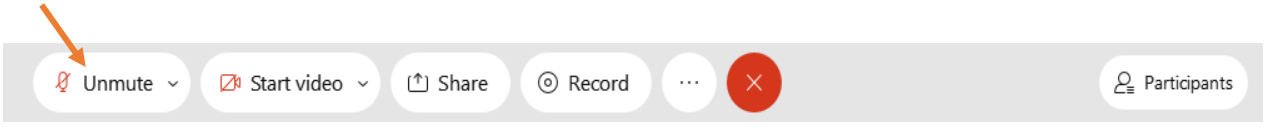
- Click on "Audio & Video" from the menu bar
- Select "Switch Audio"
- Select the "Call In" option and follow the directions



Note: If you connected your audio through your phone, your mute and unmute button should be controlled from your computer or tablet. If you are having trouble unmuting yourself, you may be muted through your phone.

Microphone Indicators

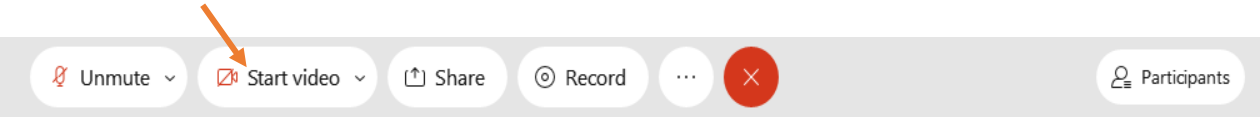
Click on the microphone icon to mute and unmute yourself. You can also mute and unmute yourself using microphone icon next to your name from the participant panel.



The green microphone indicates your microphone is open and meeting participants can hear you. If your microphone is red, you are muted.

Camera Indicators

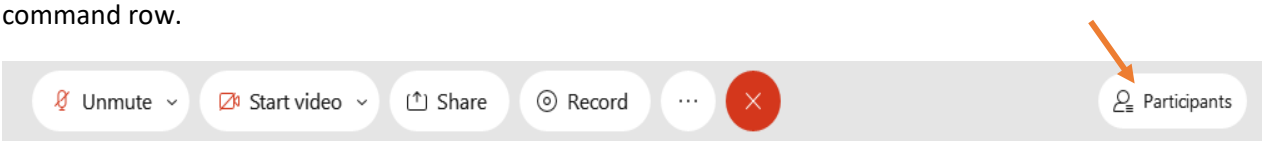
Click on the video icon to turn your camera on and off.



The green camera indicates your camera is on and meeting participants can see you. If your camera is red, your camera is off, and you cannot be seen.

Meeting Participants

To see who is in the meeting, you can access the participant list by clicking on the participant icon on the command row.

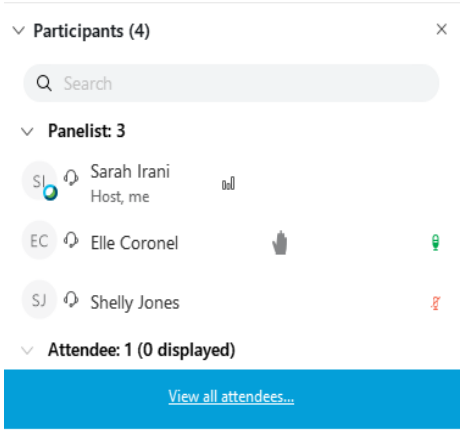


By clicking on this icon, it should display the participant list on the right side of your screen.

This is an example of a participant list that will display on the right side of your screen.

Icons will appear next to individual names to indicate if they are muted, speaking or background noise, or have their hand raised.

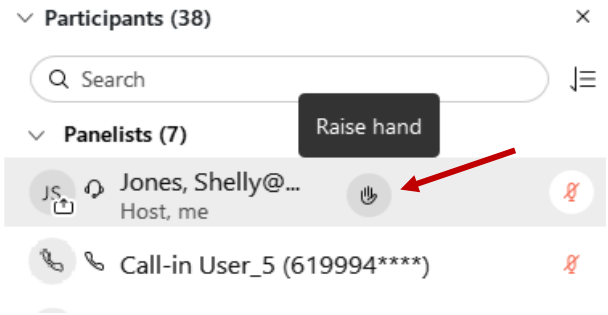
This is helpful to distinguish who is speaking or who is trying to contribute to the conversation. In addition, it is helpful if you state your name before speaking.



The panelist list has a “sort” feature, which can be located to the right of the search field in the participant panel. Clicking on the sort icon allows the list of panelists to be sorted by either name or raised hands. This feature can be particularly useful for programs who utilize the hand raise feature for discussion.

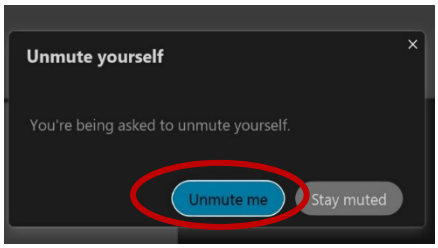
Hand Raise Feature

The hand raise feature is now located next to each participant's name in Webex, both for panelists and attendees. Participants can click the hand icon next to their name to raise and lower their hand.



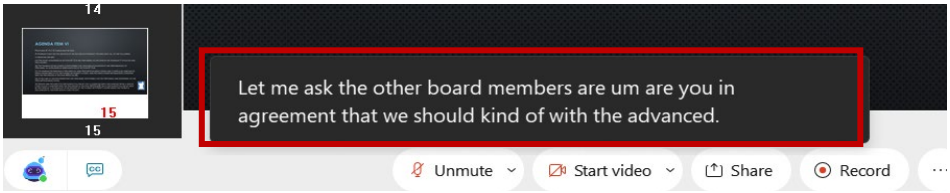
Unmuting Microphones

When the moderator unmutes a participant's microphone, Webex will prompt the participant to unmute themselves. The participant must click the displayed "Unmute me" button to unmute their microphone.

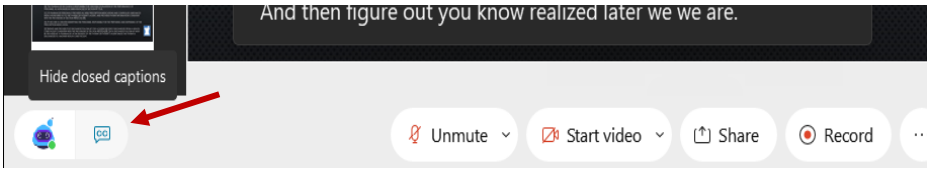


Closed Captioning

Webex provides real-time closed captioning that are displayed in a dialog box within the Webex screen. Participants can click on the dialog box and drag it to any location on the Webex screen.

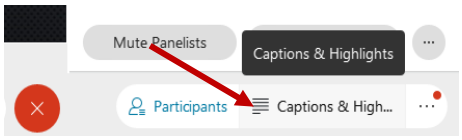


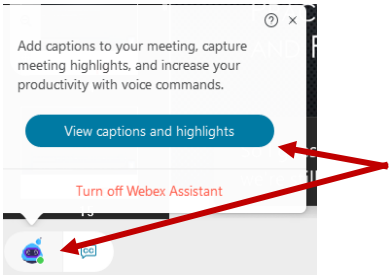
The closed captioning can be hidden from view by clicking on the closed captioning icon. You can repeat this action to unhide the dialog box.



Closed captioning can be viewed in a transcript style that displays the captions by speaker. You can enable and disable this feature through either the participant panel or the Webex Assistant.

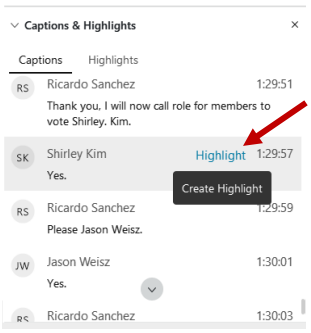
- To access this feature via that participant panel, click on the 3 dots at the bottom of the participant panel and select Captions and Highlights
- To use the Webex Assistant, hover over the robot icon on your screen and select either View or Hide captions and highlights.





"Highlighting" is a feature of Webex closed captioning that provides a valuable tool for program staff by allowing quick and easy access to important information, such as motions, votes, action items, or any other caption that contains pertinent information that the program may need to revisit or reference.

To highlight a caption, hover over the caption and click Highlight.



You can also undo a highlight by hovering over a previously highlighted caption and clicking Unhighlight.

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MEMORANDUM

DATE	January 6, 2022
TO	Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board
FROM	Paul Sanchez, Executive Officer
SUBJECT	Agenda Item 4: Discussion and Possible Action on Filing of Public Comment Regarding U.S. Food and Drug Administration Proposed Rule on Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids

Background

The U.S. Food and Drug Administration (FDA) Reauthorization Act of 2017 established a category of over-the-counter (OTC) hearing aids and required the FDA to promulgate the regulatory requirements that will apply to them. To establish the OTC category and realign other regulations for hearing aids to reflect the new category, the FDA published proposed regulations for public comment and will eventually publish final regulations, taking public comments into account.

According to the FDA, hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention. The FDA identified several barriers that impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price).

The FDA is proposing rules to address some of these concerns. Specifically, the FDA proposes to:

- Define OTC hearing aids and establish applicable requirements;
- Amend existing rules for consistency with a new OTC category;
- Provide that state and local government laws that restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids are preempted (superceded) by federal law;
- Repeal the conditions for sale applicable to hearing aids;
- Amend the existing labeling requirements for hearing aids; and

- Update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements.

According to the FDA, this action, if finalized, would clearly define prescription hearing aids; and not change the classification of existing device types. In creating a regulatory category for OTC hearing aids and amending existing rules, the FDA intends to provide a reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

Board staff and DCA Legal Counsel reviewed the proposed regulations and believe that the proposed regulations do not impede the Board's regulation of its licensees or the enforcement of the Board's Practice Act in relation to its licensees. Specifically, the proposed regulations:

- Do not create an exemption from the Practice Act's requirements for a person identifying as a "licensed dispenser" in relation to the sale of OTC hearing aids. (Prop. 21 CFR 800.30(h)(1)(B)).
- Do not exempt a licensed hearing aid dispenser or dispensing audiologist from being subject to the requirements of the Practice Act even if the licensee "undertakes commercial or professional activities only in relation to OTC hearing aids." (Prop. 21 CFR 800.30(h)(1)(C)).

Board staff and DCA Legal Counsel do note that individuals would not need a Board license to sell, dispense, distribute, or provide customer support for OTC hearing aids.

Board staff and DCA Legal Counsel have identified concerns for potential inclusion in the Board's letter of public comment and have provided comparison charts on labeling and warranty information in Attachments B and C to help facilitate discussion of these provisions. The concerns regarding the proposed regulations are as follows:

- In the proposed 21 Code of Federal Regulations (CFR) Part 801, Section 801.422(b) it would define "Dispenser" as "A dispenser is any person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act, engaged in the sale of prescription hearing aids to any member of the consuming public or any employee, agent, salesperson, and/or representative of such a person." Therefore, the use of "dispenser" in the Over-the-Counter Hearing Aid Controls sections in 21 CFR Part 800, Section 800.30, subdivisions (b) and (h)(2)(C) seems inappropriate and would likely create confusion for consumers that the dispenser is licensed.

  In 21 CFR Part 800, Section 800.30(b), it proposes that "A person that represents as a marketer, seller, **dispenser**, distributor, or customer service support representative (or an equivalent description) is not a "licensed person" solely by making such representations." (Emphasis added). Similarly, in 21

CFR Part 800, Section 800.30(h)(2)(C) it proposes that “Representations may create professional obligations. A person shall not incur specialized obligations by representing as a servicer, marketer, seller, **dispenser**, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.” (Emphasis added).

Under the proposed regulations, while those selling OTC hearing aids may be allowed to dispense OTC hearing aids under the Federal Food, Drug, and Cosmetic Act, allowing these individuals to represent themselves as “dispensers” connotates a higher level of knowledge and skill to assist consumers and may create confusion as to who is allowed under federal law to sell prescription hearing aids without a state license. According to the FDA’s proposed regulations, the use of the word “dispenser” alone would not imply licensure, which may impact the Board’s ability to issue citations to unlicensed individuals relating to the use of the title “Hearing Aid Dispenser” if they, in fact, are only dispensing OTC hearing aids.

The Board may wish to comment on the use of “dispener” in the OTC sections of the regulations and suggest the removal of the word “dispenser” as it relates to OTC hearing aids.

- The proposed OTC regulations would provide that state and local government laws that restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids are preempted (superceded) by federal law. The regulations would also establish that a preemption waiver is not available relative to OTC hearing aids, including those regarding outside package labeling and programming software that could be locked or proprietary. Due to the fact that the most likely consumer of OTC hearing aids would be elderly individuals with low incomes, federal regulations should engender protections for these vulnerable consumers so that the outside package labeling most likely to be read prior to purchase of the device is legible and understandable. It should also have protections so that consumers do not purchase OTC hearing aids that say they are programmable, but in reality are locked and only programable by specified authorized retailers.

  The Board may wish to comment on the device requirements and/or labeling requirements, specifically the outside package labeling, such as unclear proposed language and establishing a minimum font size, and ensuring OTC hearing aids do not contain locked programming software.

- In 21 CFR Part 800, Section 800.30(h)(3), the proposed OTC hearing aid regulations would not “modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability,

tort, warranty, contract, or consumer protection law." However, this does not specifically require that OTC hearing aids have a minimum federally consistent return policy. While many well established retailers may offer a return policy, if online sellers and small store front sellers do not offer a return policy, the consumer will have to use private civil remedies to ensure they can return the OTC hearing aid and be refunded their money as the Board would not have jurisdiction if the seller of the OTC hearing aid is not licensed by the Board. For vulnerable consumers, suing the seller to get a few hundred dollars back may not be a viable option and thus the consumer is ultimately harmed.

The Board may wish to comment on the lack of consumer protection that exists when there is not a minimal standard of return policy in the regulations governing OTC hearing aids.

Board staff also recommends that the Board discuss the output limits, electroacoustic performance limits, and design requirements, or lack thereof, for OTC hearing aids and whether these provide adequate consumer protection or merit comments to improve the consumer protections for OTC hearing aids. The the output limits, electroacoustic performance limits, and design requirements for OTC hearing aids can be found in 21 CFR Part 800, Section 800.30(d-f).

Action Requested

Staff recommends the Board review and discuss the provided materials. The Board may wish to determine whether or not to take action and file a public comment on these proposed regulations by the end of the public comment period on Tuesday, January 18, 2022.

If the Board would like to submit public comment, the Board can make a motion to delegate to the Board Chair and Executive Officer the responsibility of combining and submitting the Board's comments regarding the FDA's proposed regulations for OTC Hearing Aids prior to the end of the public comment period.

Attachment A: Proposed Federal Rules - OTC Hearing Aids
Attachment B: OTC Vs. Prescription Labeling Comparison
Attachment C: Song-Beverly Consumer Warranty Act for Hearing Aids

Agenda Item 4 – Attachment A

Attachment A is the October 20, 2021 Federal Register Notice of Proposed Rule by the Federal Food and Drug Administration on ***"Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids"***.

This document is available online at https://www.govinfo.gov/content/pkg/FR-2021-10-20/pdf/2021-22473.pdf.

Proposed OTC vs. Prescription Hearing Aids Labeling Comparison

§ 800.30(c)(1) Over-the-Counter Hearing Aid Controls. Outside package labeling.

(A) *Warning against use in people younger than 18.--*

WARNING: If you are younger than 18, do not use this.

You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) *Symptoms suggesting perceived mild to moderate hearing loss.--*

This hearing aid is designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss:

- Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking
- Difficulty hearing while using a telephone
- Fatigue due to greater listening effort
- Needing to turn up the volume of television, radio, or music louder than normal or loud enough for others to complain

(C) *Advice of availability of professional services.--*

Important Information: You can seek assistance from a hearing healthcare professional.

This device may not be useful for more significant hearing loss or complicated hearing needs. If you cannot hear conversations in a quiet environment, or you have trouble hearing loud sounds—for example, loud music, motor vehicles, power tools, noisy appliances—this device may not help you hear better. If you try this device and continue to struggle with or remain concerned about your hearing, you should seek a consultation with a hearing healthcare professional.

(D) *"Red flag" conditions.--*

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(E) *Notice of weblink and telephone number for information.--*

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] to request a paper copy of this information and other labeling.

(F) *Notice of manufacturer's return policy.--*

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

§ 801.422(c)(1) Prescription hearing aid labeling. Outside package labeling.

(A) *Warning against use in people younger than 18 without prior medical evaluation.--*

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *"Red flag" conditions.--*

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(A) *Note about device trial options.--*

Note: Ask about trial-rental or purchase-option programs.

If you are unsure about your ability to adapt to using a hearing aid, you should ask about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers offer programs that allow you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Proposed OTC vs. Prescription Hearing Aids Labeling Comparison

§ 800.30(c) (2) Over-the-Counter Hearing Aid Controls. Labeling, inside the package.

(A) *Warning against use in people younger than 18.--*

WARNING: If you are younger than 18, do not use this. You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 and older.

This over-the-counter hearing aid is for users age 18 and older to compensate for perceived mild-to-moderate hearing impairment. A younger person with hearing loss should see a licensed physician, preferably an ear specialist, for diagnosis of potential associated medical conditions. Furthermore, children should receive a formal hearing evaluation and rehabilitation since hearing loss may cause problems in language development and educational and social growth of a child.

(B) *"Red flag" conditions.--*

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(C) *Warning about pain from device placement.--*

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when inserting or placing it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. You may also report this to FDA as an adverse event according to the instructions that appear later.

(A) *Caution about hearing protection.--*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.--*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) *Advice to seek professional services.--*

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

§ 801.422(c)(2) Prescription hearing aid labeling. Labeling, inside the package.

(A) *Warning against use in people younger than 18 without prior medical evaluation.--*

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *"Red flag" conditions, addressed to dispensers.--*

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a licensed physician, preferably an ear specialist, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodic vertigo or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

(C) *Warning to dispensers about very high-output devices.--*

WARNING to Hearing Aid Dispensers, Outputs in excess of 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

(A) *Caution about hearing protection.--*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.--*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

Proposed OTC vs. Prescription Hearing Aids Labeling Comparison

§ 800.30(c) (2) Over-the-Counter Hearing Aid Controls. Labeling, inside the package. (cont.)

(D) *Note about user expectations.*--

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.*--

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088.

§ 801.422(c)(2) Prescription hearing aid labeling. Labeling, inside the package. (cont.)

(C) *Note about user expectations.*--

Note: Expectations about what a hearing aid can do

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Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088.

(E) *Note about hearing loss in people younger than 18 and fitting devices.*--

Note: Hearing loss in people younger than 18

- If you're younger than 18, you should see a doctor first, preferably an ear specialist.
- The doctor will identify and treat medical conditions when appropriate.
- The doctor may refer you to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the right hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a licensed physician, preferably an ear specialist, before the purchase of a hearing aid. Licensed physicians who specialize in the ear are often called otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation is to identify and treat all medical conditions that may affect hearing before the hearing aid is purchased for the person.

Following the medical evaluation and if appropriate, the physician will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The physician may refer you to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the hearing aid candidate's ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist to select and fit a hearing aid to the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

SPEECH-LANGUAGE PATHOLOGY AND AUDIOLOGY AND HEARING AID DISPENSERS BOARD

Attachment C: Song-Beverly Consumer Warranty Act Provisions for Hearing Aids

Civil Code (CIV) Section 1793.02.

(a) (1) Except as provided in paragraph (2), all new and used assistive devices sold at retail in this state shall be accompanied by the retail seller's written warranty which shall contain the following language: "This assistive device is warranted to be specifically fit for the particular needs of you, the buyer. If the device is not specifically fit for your particular needs, it may be returned to the seller within 30 days of the date of actual receipt by you or completion of fitting by the seller, whichever occurs later. If you return the device, the seller will either adjust or replace the device or promptly refund the total amount paid. This warranty does not affect the protections and remedies you have under other laws." In lieu of the words "30 days" the retail seller may specify any longer period.

(2) (A) All new and used hearing aids sold in this state shall be accompanied by the retail seller's written warranty and shall contain the following language: "This hearing aid is warranted to be specifically fit for the particular needs of you, the buyer. If the hearing aid is not initially fit for your particular needs, it may be returned to the seller within 45 days of the initial date of delivery to you. If you return the hearing aid, the seller will either adjust or replace the hearing aid or promptly refund the total amount paid. This warranty does not affect the protections and remedies you have under other laws."

(B) In lieu of the words "45 days" the retail seller may specify any longer period.

(C) On the initial date of delivery, the retail seller shall revise the written warranty to include the initial date of delivery to the buyer of the hearing aid and expiration date of the warranty.

(b) The language prescribed in subdivision (a) shall appear on the first page of the warranty in at least 10-point bold type. The warranty shall be delivered to the buyer at the time of the sale of the device.

(c) If the buyer returns the device within the period specified in the written warranty, the seller shall, without charge and within a reasonable time, adjust the device or, if appropriate, replace it with a device that is specifically fit for the particular needs of the buyer. If the seller does not adjust or replace the device so that it is specifically fit for the particular needs of the buyer, the seller shall promptly refund to the buyer the total amount paid, the transaction shall be deemed rescinded, and the seller shall promptly return to the buyer all payments and any assistive device or other consideration exchanged as part of the transaction and shall promptly cancel or cause to be canceled all contracts, instruments, and security agreements executed by the buyer in connection with the sale. When a sale is rescinded under this section, no charge, penalty, or other fee may be imposed in connection with the purchase, fitting, financing, or return of the device.

(d) With respect to the retail sale of an assistive device to an individual, organization, or agency known by the seller to be purchasing for the ultimate user of the device, this section and subdivision (b) of Section 1792.2 shall be construed to require that the device be specifically fit for the particular needs of the ultimate user.

(e) This section and subdivision (b) of Section 1792.2 shall not apply to any of the following sales of assistive devices:
(1) A catalog or similar sale, as defined in subdivision (q) of Section 1791, except a sale of a hearing aid.
(2) A sale which involves a retail sale price of less than fifteen dollars ($15).
(3) A surgical implant performed by a physician and surgeon, or a restoration or dental prosthesis provided by a dentist.

(f) The rights and remedies of the buyer under this section and subdivision (b) of Section 1792.2 are not subject to waiver under Section 1792.3. The rights and remedies of the buyer under this section and subdivision (b) of Section 1792.2 are cumulative, and shall not be construed to affect the obligations of the retail seller or any other party or to supplant the rights or remedies of the buyer under any other section of this chapter or under any other law or instrument.

(g) Section 1795.5 shall not apply to a sale of used assistive devices, and for the purposes of the Song-Beverly Consumer Warranty Act the buyer of a used assistive device shall have the same rights and remedies as the buyer of a new assistive device.

(h) The language in subdivision (a) shall not constitute an express warranty for purposes of Sections 1793.2 and 1793.3.

CIV Section 1795.6.
(a) (1) Except as provided in paragraph (2) warranty period relating to an implied or express warranty accompanying a sale or consignment for sale of consumer goods selling for fifty dollars ($50) or more shall automatically be tolled for the period from the date upon which the buyer either (1) delivers nonconforming goods to the manufacturer or seller for warranty repairs or service or (2), pursuant to subdivision (c) of Section 1793.2 or Section 1793.22, notifies the manufacturer or seller of the nonconformity of the goods up to, and including, the date upon which (1) the repaired or serviced goods are delivered to the buyer, (2) the buyer is notified the goods are repaired or serviced and are available for the buyer's possession or (3) the buyer is notified that repairs or service is completed, if repairs or service is made at the buyer's residence.
(2) With respect to hearing aids, the warranty period shall resume on the date upon which (1) the repaired or serviced hearing aid is delivered to the buyer or (2) five days after the buyer is notified the hearing aid is repaired or serviced and is available for the buyer's possession, whichever is earlier.

(b) Notwithstanding the date or conditions set for the expiration of the warranty period, such warranty period shall not be deemed expired if either or both of the following situations occur:
(1) after the buyer has satisfied the requirements of subdivision (a), the warranty repairs or service has not been performed due to delays caused by circumstances beyond the control of the buyer or (2) the warranty repairs or service performed upon the nonconforming goods did not remedy the nonconformity for which such repairs or service was performed and the buyer notified the manufacturer or seller of this failure within 60 days after the repairs or service was

completed. When the warranty repairs or service has been performed so as to remedy the nonconformity, the warranty period shall expire in accordance with its terms, including any extension to the warranty period for warranty repairs or service.

(c) For purposes of this section only, “manufacturer” includes the manufacturer’s service or repair facility.

(d) (1) Except as provided in paragraph (2), every manufacturer or seller of consumer goods selling for fifty dollars ($50) or more shall provide a receipt to the buyer showing the date of purchase. Every manufacturer or seller performing warranty repairs or service on the goods shall provide to the buyer a work order or receipt with the date of return and either the date the buyer was notified that the goods were repaired or serviced or, where applicable, the date the goods were shipped or delivered to the buyer.
(2) With respect to hearing aids, the seller, after receiving the hearing aid for warranty repairs or service, shall also provide at the time of delivery to the buyer a work order or receipt with the following: (1) the date the warranty period resumes and (2) the revised expiration date of the warranty, as adjusted to reflect the suspension of the warranty period provided under this section.

CIV Section 1795.7.
Whenever a warranty, express or implied, is tolled pursuant to Section 1795.6 as a result of repairs or service performed by any retail seller, the warranty shall be extended with regard to the liability of the manufacturer to a retail seller pursuant to law. In such event, the manufacturer shall be liable in accordance with the provisions of Section 1793.5 for the period that an express warranty has been extended by virtue of Section 1795.6 to every retail seller who incurs obligations in giving effect to such express warranty. The manufacturer shall also be liable to every retail seller for the period that an implied warranty has been extended by virtue of Section 1795.6, in the same manner as he would be liable under Section 1793.5 for an express warranty. If a manufacturer provides for warranty repairs and service through its own service and repair facilities and through independent repair facilities in the state, its exclusive liability pursuant to this section shall be to such facilities.