

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 266. HEARING AID DEALERS AND FITTERS REGULATIONS**

**RULEMAKING ACTION:**

Notice of proposed PERMANENT rulemaking.

**PROPOSED RULES:**

Chapter 266. Hearing Aid Dealers and Fitters Regulations [NEW]

**SUMMARY:**

The Department's rules for hearing aid dealers and fitters have been rewritten and reorganized for increased clarity and ease of understanding. This includes: adding definitions of terms used in the Chapter; updating the education and supervision requirements for trainees; clarifying the fee schedule; and adding an exclusion from the licensing requirements for sales of over-the-counter hearing aids.

**AUTHORITY:**

Commissioner of Health, Titles 63 O.S. § 1-104, 63 O.S. § 1-1750 *et seq.* and 15 O.S. § 764.1.

**COMMENT PERIOD:**

January 17, 2023 through the close of the Department's normal business hours, 5 PM, on February 17, 2023. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through the close of the Department's normal business hours, 5 PM, on February 17, 2023 submit written comments to the contact person identified below, or may, at the hearing, ask to present written or oral views.

**PUBLIC HEARING:**

Pursuant to 75 O.S. § 303(A), the public hearing for the proposed rulemaking in this chapter shall be on February 17, 2023 at the Oklahoma State Department of Health Auditorium, 123 Robert S. Kerr Avenue, Oklahoma City, Oklahoma 73102 from 9:30 AM to 12:30 PM. The meeting may adjourn earlier if all attendees who signed up to comment have completed giving their comments. The alternate date and time in the event of an office closure due to inclement weather is February 21, 2023 in the Auditorium, from 9:30 AM to 12:30 PM. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice. Validated parking will be provided for the parking lot located at the east corner of Broadway and Robert S. Kerr Avenue, subject to availability.

**REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:**

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through February 17, 2023, to the contact person identified below.

**COPIES OF PROPOSED RULES:**

The proposed rules may be obtained for review from the contact person identified below or via the agency website at [www.ok.gov/health](http://www.ok.gov/health).

**RULE IMPACT STATEMENT:**

Pursuant to 75 O.S., § 303(D), a rule impact statement is available through the contact person identified below or via the agency website at [www.ok.gov/health](http://www.ok.gov/health).

**CONTACT PERSON:**

Audrey C. Talley, Agency Rule Liaison, Oklahoma State Department of Health, 123 Robert S. Kerr Avenue, Oklahoma City, OK 73102, phone (405) 426-8563, e-mail [AudreyT@health.ok.gov](mailto:AudreyT@health.ok.gov).

**INITIAL RULE IMPACT STATEMENT**

**(This document may be revised based on comment received during the public comment period.)**

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 266. HEARING AID DEALERS AND FITTERS REGULATIONS [NEW]**

**1. DESCRIPTION:**

The Department's rules for hearing aid dealers and fitters have been rewritten and reorganized for increased clarity and ease of understanding. This includes: adding definitions of terms used in the Chapter; updating the education and supervision requirements for trainees; clarifying the fee schedule; and adding an exclusion from the licensing requirements for sales of over-the-counter hearing aids.

**2. DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE:**

The persons affected will be hearing aid dealers and fitters and consumers. Dealers and fitters may incur nominal expenses in tailoring supervision of trainees. Consumers should not experience any cost impact and the Department will not experience any increased expenses as a result of the proposals.

**3. DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**

Consumers will benefit from the availability of well-trained dealers and fitters and clarity as to the ability to purchase over-the-counter hearing aids. The industry will benefit from regulations that are straightforward and easier to understand.

**4. ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**

There are no fee changes. The Department does not anticipate a significant economic impact or significant increase in the cost of compliance for the industry.

**5. COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**

There are no costs associated with implementation.

**6. IMPACT ON POLITICAL SUBDIVISIONS:**

There will be no impact on political subdivisions and it will not require their cooperation in implementing or enforcing the proposed amendment.

**7. ADVERSE EFFECT ON SMALL BUSINESS:**

There is no known adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act.

**8. EFFORTS TO MINIMIZE COSTS OF RULE:**

There are no less costly means currently identified.

**9. EFFECT ON PUBLIC HEALTH AND SAFETY:**

The new Chapter 266 should have a positive effect on public health and safety as a result of clearer rules on licensing and training of hearing aid dealers and fitters.

**10. DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**

The new Chapter 266 is expected to remove any confusion caused by the organization of, and requirements in, the current chapter.

**11. PREPARATION AND MODIFICATION DATES:**

This rule impact statement was prepared on November 4, 2022.

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 266. HEARING AID DEALERS AND FITTERS REGULATIONS**

**SUBCHAPTER 1. GENERAL PROVISIONS**

**310:266-1-1. Purpose**

The rules in this Chapter implement the Hearing Aid Dealers and Fitters Act, 63 O.S. § 1-1750 *et seq.* and 15 O.S. § 764.1. Hearing Aid Providers – Contracts – Rescission Period.

**310:266-1-2. Definitions**

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

**"Act"** means those statutes relating to Hearing Aid Dealers and Fitters codified at 63 O.S. §§ 1-1750 through 1-1754 and 15 O.S. § 764.1.

**"Air-conduction hearing aid"** means *a hearing aid that conducts sound to the ear through the air.* [Title 21 CFR Part 800, § 800.30]

**"Commissioner"** means the State Commissioner of Health or his/her authorized representative.

**"Department"** means the Oklahoma State Department of Health.

**"Direct on-site supervision"** means a licensed hearing aid dealer and fitter shall accompany a temporary permit holder anytime the permit holder is performing the practice of fitting and dealing in hearing aids.

**"Hearing aid"** means any wearable instrument or device designed for or offered for the purpose of aiding or compensating for impaired human hearing. It includes both air conduction and bone conduction devices.

**"Hearing aid provider "** means *a hearing aid dealer or fitter licensed pursuant to Section 1-1750 et seq. of Title 63 of the Oklahoma Statutes.* [Title 15 O.S. § 764.1]

**"Hearing Screening"** means a binary pure tone screening at a preset intensity level for the purpose of determining if an individual screened needs further testing prior to the selection or sale of a hearing aid.

**"Indirect supervision"** means that the supervising licensed hearing aid dealer and fitter is not required to be present in the same facility as is the person being supervised, but is available for voice to voice contact by telephone, radio, or other means at the initiation of the person being supervised. It means specific supervisory activities, other than direct supervision, that are performed by a licensed hearing aid dealer and fitter and that may include consultation, record review, consulting, and evaluation of audiotaped or videotaped sessions, at a minimum on a weekly basis.

**"Involvement of a licensed person"** means *the supervision, prescription, or other order, involvement, or intervention of a licensed person.* [Title 21 CFR Part 800, § 800.30]

**"License"** means a license issued by the Commissioner to hearing aid dealers and fitters.

**"Over-the-counter hearing aid"** means *an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device 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, provided that the device satisfies the requirements in Title 21 CFR Part 800, § 800.30(b).*

**"Poses a reasonable threat"** means *the nature of criminal conduct for which the person was convicted involved an act or threat of harm against another and has a bearing on the fitness or ability to serve the public or work with others in the occupation.* [63 O.S. Section 1-1454(E)(2)]

**"Practice of fitting and dealing in hearing aids"** means those practices used for the purpose of selection, adaptation and sale of hearing aids including direct observation of the ear together with the counseling and instruction pertaining thereto, the testing of human hearing for these purposes and the making of impressions for earmolds.

**"Rescission period"** means *thirty (30) calendar days from the day the hearing aid is placed in the possession of the purchaser.* [15 O.S. § 764.1 (A) (3)]

**"Sell" or "sale"** means any transfer of title or of the right to use by lease, bailment, or any other contract, excluding wholesale transactions with distributors or dealers.

**"Sponsor"** means a person who is licensed and in good standing pursuant to this Chapter to fit and dispense hearing aids and who agrees to train and supervise a temporary permit holder.

**"Substantially relates"** means *the nature of criminal conduct for which the person was convicted has a direct bearing on the fitness of ability to perform one or more of the duties or responsibilities necessarily related to the occupation.* [63 O.S. 1-1454 (E)(1)]

**"Temporary permit"** means a permit issued while the applicant is training to become a licensed hearing aid dealer or fitter.

### **SUBCHAPTER 3. QUALIFICATIONS**

#### **310:266-3-1. General qualifications**

**(a) Applicants for a hearing aid dealer or fitter temporary permit or license must, at a minimum, meet the following criteria:**

- (1) At least eighteen (18) years of age;**
- (2) Has a GED or high school diploma; and**
- (3) Has submitted to a background check.**

**(b) A criminal record shall not itself bar an applicant from licensing, but evidence of such record may be considered along with other information in determining whether to issue a license.**

#### **310:266-3-2. Reciprocity**

**(a) Whenever the Department determines another state or jurisdiction has requirements equivalent to or higher than those in effect pursuant to these regulations, and that such state or jurisdiction has a program equivalent to or stricter than the program for determining whether applicants pursuant to these regulations are qualified to dispense and fit hearing aids, the Department may issue an Oklahoma license to applicants who hold current, unsuspended and unrevoked certificates or licenses to fit and sell hearing aids in such other state or jurisdiction.**

**(b) Applicants must submit an application for reciprocity on forms as designated by the Department.**

**(c) Applicants must submit an Out-of-State Licensure Verification form filled out by the other licensing state.**

**(d) Applicants must register with the Department.**

**(e) Active duty military personnel and their spouses seeking a reciprocal license are not subject to the fees established for the first period of issuance of a license.**

### **SUBCHAPTER 5. TEMPORARY PERMITS, EXAMINATIONS AND LICENSURE**

#### **310:266-5-1. Temporary permits**

**(a) An applicant who is at least 18 years of age and has a GED or high school diploma shall be entitled to a temporary hearing aid dealer or fitter permit upon application to the Commissioner if minimum qualifications are met.**

**(b) Once a complete application is received and eligibility confirmed, the Department will issue a temporary permit entitling the applicant to engage in the fitting and sale of hearing aids for a period up to twelve (12) months until the temporary permit holder becomes fully licensed.**

(c) The temporary permit holder shall complete training under the direct on-site supervision of a Sponsor who holds a valid Oklahoma Hearing Aid Dealers' and Fitters' License. The Sponsor shall be responsible for direct on-site supervision and training of a temporary permit holder until they have passed every portion of the practical exam.

(d) The temporary permit holder must continue to receive indirect supervision from their Sponsor until they are fully licensed as a hearing aid dealer and fitter.

(e) If full licensure is not achieved in the twelve (12) month period, an additional temporary permit may be issued one (1) time by the Department within the subsequent twelve (12) months upon request for a payment of the Fifteen Dollar (\$15.00) fee.

(f) A maximum of three (3) people with temporary permits may work under the direct on-site supervision of a Sponsor holding a valid Oklahoma Hearing Aid Dealers' and Fitters' License at one time.

### **310:266-5-2. License or permit required**

(a) No person shall engage in the sale or practice of fitting hearing aids or display a sign or in any other way advertise or represent themselves as a person who practices the fitting and sale of hearing aids without first obtaining a license or permit in accordance with these rules from the Department. The license shall be conspicuously posted in every physical place of business where the licensee practices. Duplicate licenses may be issued by the Department to valid license holders operating more than one office, without additional payment.

(b) A corporation, partnership, trust, association or other like organization may engage in the business of selling or offering for sale hearing aids at retail, provided it employs only properly licensed persons in the direct sale and fitting of such products. Such corporations, partnerships, trust, associations or other like organizations shall make available to the Department information related to licensed dealers upon request.

### **310:266-5-3. Examinations**

(a) A Sponsor shall attest to the temporary permit holder's readiness to take the practical examination.

(b) An applicant must wait a minimum of seven (7) days before applying to retake any failed section of the practical examination. A temporary permit holder is not required to retake any previously passed section of the practical exam, provided they pass all sections of the practical exam within the allowable timeframe.

(c) Upon submission of the application to take the practical examination, a temporary permit holder is eligible to take the International Licensing Examination for Hearing Healthcare Professionals written exam or other written exam approved by the Department.

(d) Temporary permit holders must pass the practical and written examinations to be eligible for a full license.

(e) Any temporary permit holder who fails a section of the practical examination or the written examination three (3) times will have their temporary permit revoked and will be required to wait a minimum of one (1) year from their last failed testing date to reapply for a new temporary permit.

### **310:266-5-4. Contents of examinations**

(a) The practical examination shall consist of tests pertaining to the sale and fitting of hearing aids as follows:

(1) Technique

(A) Pure tone audiometry

(B) Recorded speech audiometry

(2) Masking;

(3) Earmold impressions; and

(4) Detecting damage and defects.

(b) A temporary permit holder must pass all sections of the practical exam and the International Licensing Examination for Hearing Healthcare Professionals written examination or other Department approved written examination to be eligible for a full license.

### **310:266-5-5. Initial licensure**

An applicant must meet the General Qualifications as required in OAC 310:266-3-1, file a complete application with the Department, pay the required fee in full, and pass all required examinations in order to be licensed.

### **310:266-5-6. Renewal of license**

(a) Each person who engages in the fitting and sale of hearing aids shall pay to the Department the annual renewal fee, submit required documentation, and keep licensure certificate conspicuously posted in every place of business at all times. A license expired for a length of time greater than five years will require the holder of an expired license to follow the initial licensure process.

(b) At the time of renewal, the licensee must provide the following:

- (1) Documentation of required continuing education hours from an approved source;
- (2) Updated address(es) if applicable;
- (3) Copy of a current receipt or contract template;
- (4) Copy of a patient file template;
- (5) Verification all instruments meet the American National Standard Specifications for Audiometers according to factory standards, dated within the last three years;
- (6) The percentage of clients tested under an exception; and
- (7) Sponsor information to include the name and permit number of all temporary permit holders sponsored in the licensure year. Information shall include the start and end dates for each instance of direct on-site supervision.

### **310:266-5-7. Continuing education requirements**

Each applicant for renewal of a hearing aid dealer or fitter license must submit written evidence showing completion of ten (10) clock hours of continuing education, completed during the previous year pertaining to the hearing sciences. The continuing education hours must be approved by the International Hearing Society or the Oklahoma Hearing Aid Dispenser's Association.

## **SUBCHAPTER 7. FEES**

### **310:266-7-1. Fees**

(a) Fees for license applications, permits and examinations shall be as follows:

- (1) Temporary Permit Application Fee - \$15.00;
- (2) Temporary Permit Extension Fee - \$15.00;
- (3) Examination Fee – payable directly to the Department approved examination administrator;
- (4) Reexamination Fee – payable to the Department approved examination administrator;
- (5) Initial License Application Fee - \$50.00;
- (6) Renewal License Fee - \$50.00;
- (7) Renewal of License (within thirty-day grace period) - \$75.00; and
- (8) Renewal of License (after thirty-day grace period) - \$100.00.

(b) Application fees are non-refundable.

## **SUBCHAPTER 9. INSTRUMENTS AND TESTING**

### **310:266-9-1. Procedures and instrumentation in fitting of hearing aids**

(a) All instruments used to measure thresholds shall be certified to meet American National Standard Specifications for Audiometer, S3.6-1969 or a standard which supersedes it. In addition, some form of live voice or recorded voice testing must be made to obtain at least a subjective evaluation of the individual's ability to discriminate. In the case of live voice testing, the tests should be run without visual cue. A hearing aid of similar characteristics can be refitted to an individual without a hearing test if this is done within six (6) months of the original fitting and original hearing test.

(b) Hearing testing for the purpose of fitting hearing aids shall not be conducted where ambient noise levels exceed 45 dB measured on a slow weighted dB (a) scale. If the testing environment exceeds 45 dB, the testing shall be considered a Hearing Screening and individuals informed that further testing should be done to determine auditory thresholds for the selection of a hearing aid.

### **310:266-9-2. Exceptions**

(a) If a patient is incapable of presenting at a testing center, the licensed hearing aid dealer and fitter must maintain information in the patient file detailing the physical address where the testing occurred and why the testing was not done in a testing center.

(b) When utilizing an exception, the licensed hearing aid dealer and fitter must provide documentation to the patient signed by both the licensed hearing aid dealer and fitter and the patient, the patient's guardian, parent or their power of attorney. The documentation shall include:

(1) Testing environment specification requirements as outlined in this chapter;

(2) A description of the alternate testing environment;

(3) The physical address of the alternate testing location;

(4) The reason for testing at the alternate location;

(5) A list of any testing environment requirements that may not be met at the alternate location; and

(6) Notification that the test may not be as accurate when conducted outside a testing center.

(c) Testing exceptions will not be granted for the purposes of mass gatherings and are only intended for patients who cannot be physically present at a testing center.

## **SUBCHAPTER 11. REGULATORY ENFORCEMENT**

### **310:266-11-1. Revocation or suspension of license**

(a) The Commissioner shall have the power and duty to deny, suspend, or revoke the license of any person registered under this act, after a hearing, based upon a substantiated finding that the licensee has not operated in compliance with applicable laws, rules, and standards. Any action taken relative to denial, suspension or revocation of a license shall be initiated in compliance with the Oklahoma Administrative Procedures Act.

(b) The Commissioner shall have the power and duty to request administrative penalties pursuant to 63 O.S. §1-1701 et seq.

### **310:266-11-2. Prohibited acts**

No person shall:

(1) Buy, sell, or fraudulently obtain a license;

(2) Alter a license with fraudulent intent;

(3) Use or attempt to use the valid license of another;

(4) Willfully make a false or misleading statement in an application for a license or application for renewal;

(5) Violate the temporary permit supervision requirements stated in 310:266-5-1;

(6) Sell a hearing instrument to a minor without receiving documentation from a licensed physician within six (6) months prior to fitting;

(7) Represent in any manner that a hearing aid dealer and fitter is a licensed physician or audiologist or performs diagnostic procedures to determine the cause of a hearing impairment;



- (8) Use false or misleading advertisement;
- (9) Receive a criminal conviction for any crime that substantially relates to the practice of hearing aid dealing and fitting and poses a reasonable threat to public safety;
- (10) Obtain any fee or make any sale by fraud or misrepresentation;
- (11) Directly or indirectly giving or offering to give money or anything of value to any person who advises another in a professional capacity as an inducement to influence the person or have the person influence others to purchase or contract to purchase products sold or offered for sale by a licensee or influencing person to refrain from dealing in the products of competitors;
- (12) Commit gross incompetence or negligence in the fitting and selling of hearing aids; or
- (13) Fail to respond to a written request by the Department within thirty (30) days.

**SUBCHAPTER 13. REQUIRED DOCUMENTS AND COMPLAINT PROCEDURES**

**310:266-13-1. Contracts and return policies**

(a) A receipt or contract shall be provided to each person supplied with a hearing aid. It shall contain the licensee's signature, physical business address, state license number, make and model specifications of the hearing aid purchased, and full terms of the sale clearly stated. If applicable, the receipt shall be clearly marked as "used" or "reconditioned", with any terms of guarantee.

(b) The receipt or contract for a hearing aid shall include an original signature of a licensed hearing aid dealer and fitter. The holder of a temporary license may not issue a receipt unless the original signature of the direct supervisor also appears on the receipt or contract. The receipt shall have the state license number of both the licensed hearing aid dealer and fitter and the temporary licensed person.

(c) A hearing aid provider shall provide a thirty-day rescission period on a hearing aid purchase consistent with the following terms:

(1) The purchaser shall have the right to cancel for any reason if the hearing aid is returned to the hearing aid provider in the same condition as when purchased, ordinary wear and tear excepted, within thirty (30) days of the date of receipt of the hearing aid. The thirty-day recession period shall be tolled for any period during which the hearing aid provider takes possession or control of a hearing aid after its original delivery.

(2) The purchaser is entitled to receive a full refund of the purchase price, provided the hearing aid provider may be entitled to a cancellation fee no greater than ten percent (10%) of the total purchase price for the hearing aid or One Hundred Fifty Dollars (\$150.00) per hearing aid, whichever is less.

(3) The hearing receipt or contract shall include, in immediate proximity to the space reserved for the signature of the purchaser, the specific statement in all bold-faced type capital letters no smaller than the largest print used in the written receipt or contract:

**OKLAHOMA STATE LAW GIVES THE PURCHASER THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON BY RETURNING THE HEARING AID TO THE HEARING AID PROVIDER AT ANY TIME PRIOR TO MIDNIGHT OF THE THIRTIETH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID.**

**BY LAW, THE HEARING AID PROVIDER MAY BE ENTITLED TO A CANCELLATION FEE NOT TO EXCEED TEN PERCENT (10%) OF THE TOTAL PURCHASE PRICE FOR THE HEARING AID OR ONE HUNDRED FIFTY DOLLARS (\$150.00) PER HEARING AID, WHICHEVER IS LESS, TO COVER THE COSTS INCURRED BY THE HEARING AID PROVIDER.**

**IF THE PURCHASER RETURNS THE HEARING AID WITHIN THE THIRTY-DAY PERIOD, THE PURCHASER WILL RECEIVE A REFUND OF \$ \_\_\_\_ .00 (HEARING AID PROVIDER MUST INSERT THE DOLLAR AMOUNT OF THE REFUND).**

**IF THE HEARING AID PROVIDER FAILS TO COMPLY WITH THIS PROVISIONS, COMPLAINTS SHOULD BE FORWARDED TO:**

**OKLAHOMA STATE DEPARTMENT OF HEALTH  
OCCUPATIONAL LICENSING DIVISION  
123 ROBERT S. KERR AVENUE**

**310:266-13-2. Patient File**

The following information and measurements shall be included in each customer/patient file or permanent record, and documented for the client:

- (1) A description, including location of any visible, congenital or deformity of the ear;
- (2) Whether the client has active, or a history of, drainage from the ear within the last 90 days.
- (3) Whether the client has acute or chronic dizziness;
- (4) Whether the client has unilateral hearing loss of a sudden or recent onset within the previous 90 days;
- (5) Whether the client has a history of sudden or rapidly progressive hearing loss within the previous 90 days;
- (6) Whether the client has an Audiometric Air Bone Gap equal to or greater than 15 decibels at 500 Hertz, 1000 Hertz and 2000 Hertz;
- (7) Whether the client has visible evidence of significant cerumen accumulation or a foreign body in the ear canal; and
- (8) All documentation required in instances where exceptions have occurred.

**310:266-13-3. Address of place of business**

When a hearing aid dealer and fitter changes business addresses, the licensee shall notify the Department, in writing, within thirty (30) days of the address change. The address provided must be a physical address. A post office box number by itself does not fulfill this requirement.

**310:266-13-4. Complaint procedures**

Any person who believes a hearing aid dealer and fitter is operating contrary to the Act or these rules may file a complaint with the Department. The Department shall receive complaints verbally or in writing. Investigations will be completed and a written report of findings provided to the hearing aid dealer and fitter and to the complainant via email if a copy is requested. The identity of the complainant shall not be disclosed by the Department.

**SUBCHAPTER 15. OVER-THE-COUNTER HEARING AIDS**

**310:266-15-1. Over-the-counter hearing aid sales**

(a) Over-the-counter (OTC) hearing aids that satisfy the conditions in Title 21 CFR Part 800, § 800.30 may be available for sale 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. The term "sale" includes leases or rentals.

(b) OTC hearing aids are required to satisfy the conditions imposed by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 9 § 301 *et seq.* and the U.S. Food and Drug Administration rules in Title 21 CFR Part 800 including without limitation:

- (1) Labeling;
- (2) Output limits;
- (3) Electroacoustic performance limits;
- (4) Design requirements; and
- (5) Conditions for sale of an OTC hearing aid – consumer age minimum of 18 years old with perceived mild to moderate hearing impairment.

(c) A license issued under this Chapter is not required for the sale of OTC hearing aids. Persons licensed under this Chapter may sell OTC hearing aids.