

Technical Assistance Document compiled regarding Hearing Aid Dispensing and Dispensing Audiology licensing regulations in Arizona

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Chapter 17 HEARING AID DISPENSERS, AUDIOLOGISTS AND SPEECH-LANGUAGE PATHOLOGISTS

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Arizona Revised Statutes Title 36 Chapter 17

Hearing Aid Dispensers, Audiologists, and Speech-Language Pathologists

Article 1

§ 36-1901. Definitions

In this chapter, unless the context otherwise requires:

1. "Accredited program" means a program leading to the award of a degree in audiology that is accredited by an organization recognized for that purpose by the United States department of education.
2. "Approved training program" means a postsecondary speech-language pathology assistant training program that is approved by the director.
3. "Assistive listening device or system" means an amplification system that is specifically designed to improve the signal-to-noise ratio for the listener who is hearing impaired, reduce interference from noise in the background and enhance hearing levels at a distance by picking up sound from as close to the source as possible and sending it directly to the ear of the listener, excluding hearing aids.
4. "**Audiologist**" means a person who engages in the practice of audiology and who meets the requirements prescribed in this chapter.
5. "**Audiology**" means the nonmedical and nonsurgical application of principles, methods and procedures of measurement, testing, evaluation and prediction that are related to hearing, its disorders and related communication impairments for the purpose of nonmedical diagnosis, prevention, amelioration or modification of these disorders and conditions.
6. "**Clinical interaction**" means a fieldwork practicum in speech-language pathology that is supervised by a licensed speech-language pathologist.
7. "**Department**" means the department of health services.
8. "**Direct supervision**" means the on-site, in-view observation and guidance of a speech-language pathology assistant by a licensed speech-language pathologist while the speech-language pathology assistant performs an assigned clinical activity.
9. "**Director**" means the director of the department.
10. "**Disorders of communication**" means an organic or nonorganic condition that impedes the normal process of human communication and includes disorders of speech, articulation, fluency, voice, verbal and written language, auditory comprehension, cognition and communications and oral, pharyngeal and laryngeal sensorimotor competencies.
11. "**Disorders of hearing**" means an organic or nonorganic condition, whether peripheral or central, that impedes the normal process of human communication and includes disorders of auditory sensitivity, acuity, function or processing.
12. "**Hearing aid**" means any wearable instrument or device designed for or represented as aiding or improving human hearing or as aiding, improving or compensating for defective human hearing, and any parts, attachments or accessories of the instrument or device, including ear molds, but excluding batteries and cords.
13. "**Hearing aid dispenser**" means any person who engages in the practice of fitting and dispensing hearing aids.
14. "**Indirect supervision**" means supervisory activities, other than direct supervision that are performed by a licensed speech-language pathologist and that may include consultation, record review and review and evaluation of audiotaped or videotaped sessions.
15. "**Letter of concern**" means an advisory letter to notify a licensee that, while there is insufficient evidence to support disciplinary action, the director believes the licensee should modify or eliminate certain practices and that continuation of the activities that led to the information being submitted to the director may result in action against the licensee.
16. "**License**" means a license issued by the director under this chapter and includes a temporary license.
17. "**Nonmedical diagnosing**" means the art or act of identifying a communication disorder from its signs and symptoms. Nonmedical diagnosing does not include diagnosing a medical disease.
18. "**Practice of audiology**" means:
 - (a) Rendering or offering to render to a person or persons who have or who are suspected of having disorders of hearing any service in audiology including prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction and research.
 - (b) Participating in hearing conservation, hearing aid and assistive listening device evaluation and hearing aid prescription preparation, fitting, dispensing and orientation.
 - (c) Screening, identifying, assessing, nonmedical diagnosing, preventing and rehabilitating peripheral and central auditory system dysfunctions.
 - (d) Providing and interpreting behavioral and physiological measurements of auditory and vestibular functions.
 - (e) Selecting, fitting and dispensing assistive listening and alerting devices and other systems and providing training in their use.
 - (f) Providing aural rehabilitation and related counseling services to hearing impaired persons and their families.

- (g) Screening speech-language and other factors that affect communication function in order to conduct an audiologic evaluation and an initial identification of persons with other communications disorders and making the appropriate referral.
 - (h) Planning, directing, conducting or supervising services.
19. **"Practice of fitting and dispensing hearing aids"** means the measurement of human hearing by means of an audiometer or by any other means, solely for the purpose of making selections or adaptations of hearing aids, and the fitting, sale and servicing of hearing aids, including assistive listening devices and the making of impressions for ear molds and includes identification, instruction, consultation, rehabilitation and hearing conservation as these relate only to hearing aids and related devices and, at the request of a physician or another licensed health care professional, the making of audiograms for the professional's use in consultation with the hearing impaired. The practice of fitting and dispensing hearing aids does not include formal auditory training programs, lip reading and speech conservation.
20. **"Practice of speech-language pathology"** means:
- (a) Rendering or offering to render to an individual or groups of individuals who have or are suspected of having disorders of communication service in speech-language pathology including prevention, identification, evaluation, consultation, habilitation, rehabilitation, instruction and research.
 - (b) Screening, identifying, assessing, interpreting, nonmedical diagnosing and rehabilitating disorders of speech and language.
 - (c) Screening, identifying, assessing, interpreting, nonmedical diagnosing and rehabilitating disorders of oral-pharyngeal functions and related disorders.
 - (d) Screening, identifying, assessing, interpreting, nonmedical diagnosing and rehabilitating cognitive and communication disorders.
 - (e) Assessing, selecting and developing augmentative and alternative communication systems and providing training in the use of these systems and assistive listening devices.
 - (f) Providing aural rehabilitation and related counseling services to hearing impaired persons and their families.
 - (g) Enhancing speech-language proficiency and communication effectiveness.
 - (h) Screening hearing and other factors for speech-language evaluation and initially identifying persons with other communication disorders and making the appropriate referral.
21. "Regular license" means each type of license issued by the director, except a temporary license.
22. **"Sell" or "sale"** means a transfer of title or of the right to use by lease, bailment or any other contract, but does not include transfers at wholesale to distributors or dealers.
23. **"Speech-language pathology"** means the nonmedical and nonsurgical application of principles, methods and procedures of assessment, testing, evaluation and prediction related to speech and language and its disorders and related communication impairments for the nonmedical diagnosis, prevention, amelioration or modification of these disorders and conditions.
24. **"Speech-language pathology assistant"** means a person who provides services prescribed in section 36-1940.04 and under the direction and supervision of a speech-language pathologist licensed pursuant to this chapter.
25. **"Sponsor"** means a person who is licensed pursuant to this chapter and who agrees to train or directly supervise a temporary licensee in the same field of practice.
26. **"Temporary licensee"** means a person who is licensed under this chapter for a specified period of time under the sponsorship of a person licensed pursuant to this chapter.

27. **"Unprofessional conduct"** means:

- (a) **Obtaining any fee or making any sale by fraud or misrepresentation.**
- (b) **Employing** directly or indirectly any suspended or **unlicensed** person to perform any work covered by this chapter.
- (c) **Using**, or causing or promoting the use of, any advertising **matter**, promotional literature, testimonial, guarantee, warranty, label, brand, insignia or other representation, however disseminated or published, **that is misleading, deceiving, improbable or untruthful.**
- (d) **Advertising for sale a particular model, type or kind of product when purchasers or prospective purchasers responding to the advertisement cannot purchase or are dissuaded from purchasing** the advertised model, type or kind if the purpose of the advertisement is to obtain prospects for the sale of a different model, type or kind than that advertised.
- (e) **Representing** that the professional **services or advice of a physician** will be used or made available in the selling, fitting, adjustment, maintenance or repair of hearing aids **if this is not true, or using the words "doctor", "clinic", "clinical" or like words, abbreviations or symbols while failing to affix the word, term or initials "audiology", "audiologic", "audiologist", "doctor of audiology", "Au.D.", "Ph.D." or "Sc.D."**
- (f) **Defaming competitors by falsely imputing** to them dishonorable conduct, inability to perform contracts or questionable credit standing or by other false representations, or falsely disparaging the products of competitors in any respect, or their business methods, selling prices, values, credit terms, policies or services.

- (g) **Displaying competitive products** in the licensee's show window, shop or advertising in such manner **as to falsely disparage such** products.
- (h) **Representing falsely that competitors are unreliable.**
- (i) **Quoting prices of competitive products without disclosing** that they are not the current prices, or showing, demonstrating or representing competitive models as being current models when they are not current models.
- (j) **Imitating or simulating** the trademarks, trade names, brands or labels of competitors **with the capacity, tendency or effect of misleading or deceiving** purchasers or prospective purchasers.
- (k) **Using** in the licensee's **advertising** the name, model name or trademark of a particular manufacturer of hearing aids in such a manner **as to imply a relationship** with the manufacturer **that does not exist, or otherwise to mislead or deceive** purchasers or prospective purchasers.
- (l) **Using any** trade name, corporate name, trademark or other trade **designation that has the capacity, tendency or effect of misleading or deceiving** purchasers or prospective purchasers as to the name, nature or origin of any product of the industry, or of any material used in the product, or that is false, deceptive or misleading in any other material respect.
- (m) **Obtaining information concerning the business of a competitor by bribery** of an employee or agent of that competitor, **by false or misleading statements or representations, by the impersonation of one in authority, or by any other unfair means.**
- (n) **Giving** directly or indirectly, **offering** to give, or **permitting or causing** to be given money or anything of **value**, except miscellaneous advertising items of nominal value, to any person who advises another **in a professional capacity as an inducement to influence** that person or have that person influence others to purchase or contract to purchase products sold or offered for sale by a hearing aid dispenser, or to influence persons to refrain from dealing in the products of competitors.
- (o) **Sharing any profits** or sharing any percentage of a licensee's income with any person who advises another **in a professional capacity as an inducement to influence** that person or have that person influence others to purchase or contract to purchase products sold or offered for sale by a hearing aid dispenser or to dissuade persons from dealing in products of competitors.
- (p) **Failing to comply with existing federal regulations regarding the fitting and dispensing of a hearing aid.**
- (q) **Conviction of** a felony or a misdemeanor that involves **moral turpitude.**
- (r) **Fraudulently obtaining or attempting to obtain a license** or a temporary license for the applicant, the licensee or another person.
- (s) **Aiding or abetting unlicensed practice.**
- (t) **Wilfully making or filing a false** audiology, speech-language pathology or hearing aid dispenser **evaluation.**
- (u) **The use of** narcotics, alcohol or drugs **to the extent that the performance of professional duties is impaired.**
- (v) **Betraying a professional confidence.**
- (w) **Any conduct, practice or condition that impairs the ability** of the licensee **to safely and competently engage in the practice** of audiology, speech-language pathology or hearing aid dispensing.
- (x) **Providing services or promoting the sale** of devices, appliances or products to a person **who cannot reasonably be expected to benefit** from these services, devices, appliances or products.
- (y) **Being disciplined** by a licensing or disciplinary authority of any state, territory or district of this country **for an act that is grounds for disciplinary action under this chapter.**
- (z) **Violating any provision of this chapter or failing to comply with rules adopted pursuant to this chapter.**
- (aa) **Failing to refer an individual for medical evaluation** if a condition exists that is amenable to surgical or medical intervention prescribed by the advisory committee and consistent with federal regulations.
- (bb) Practicing in a field or area within that licensee's defined scope of practice in which the licensee has not either been tested, taken a course leading to a degree, received supervised training, taken a continuing education course or had adequate prior experience.**
- (cc) **Failing to affix the word, term or initials** "audiology", "audiologic", "audiologist", "doctor of audiology", "Au.D.", "Ph.D." or "Sc.D." in any sign, written communication or advertising media in which the term "doctor" or the abbreviation "Dr." is used in relation to the audiologist holding a doctoral degree.

§ 36-1902. Powers and duties of the director; advisory committee; examining committee

A. The director shall:

1. Appoint an advisory committee to collaborate with and assist the director and to perform duties as prescribed by this chapter. The director shall inform the advisory committee regarding all disciplinary actions.
2. Supervise and administer qualifying examinations to test the knowledge and proficiency of applicants for a hearing aid dispenser's license.
3. Designate the time and place for holding examinations for a hearing aid dispenser's license.

4. License persons who apply for and pass the examination for a license, and possess all other qualifications required for the practice of fitting and dispensing hearing aids, the practice of audiology and the practice of speech-language pathology.
 5. License persons who apply for a license and possess all other qualifications required for licensure as a speech-language pathology assistant.
 6. Authorize all disbursements necessary to carry out this chapter.
 7. Ensure the public's health and safety by adopting and enforcing qualification standards for licensees and applicants for licensure under this chapter.
- B. The director may:
1. Purchase and maintain, or rent, equipment and facilities necessary to carry out the examination of applicants for a license.
 2. Issue and renew a license.
 3. Deny, suspend, revoke or refuse renewal of a license or file a letter of concern, issue a decree of censure, prescribe probation, impose a civil penalty or restrict or limit the practice of a licensee pursuant to this chapter.
 4. Appoint an examining committee to assist in the conduct of the examination of applicants for a hearing aid dispenser's license.
 5. Make and publish rules that are not inconsistent with the laws of this state and that are necessary to carry out this chapter.
 6. Require the periodic inspection of testing equipment and facilities of persons engaging in the practice of fitting and dispensing hearing aids, audiology and speech-language pathology.
 7. Require a licensee to produce customer records of patients involved in complaints on file with the department.
- C. The advisory committee appointed pursuant to subsection A, paragraph 1 consists of the director, two physicians licensed under title 32, chapter 13 or 17, one of whom is a specialist in otolaryngology, two licensed audiologists, one of whom dispenses hearing aids, two licensed speech-language pathologists, two public members, one of whom is hearing impaired, one member of the Arizona commission for the deaf and the hard of hearing who is not licensed pursuant to this chapter and two licensed hearing aid dispensers who are not licensed to practice audiology. Committee members who are licensed under this chapter shall have at least five years' experience immediately preceding the appointment in their field of practice in this state.
- D. The examining committee authorized pursuant to subsection B, paragraph 4 consists of one otolaryngologist, two licensed dispensing audiologists and two licensed hearing aid dispensers. Committee members who are licensed under this chapter shall have at least five years' experience immediately preceding the appointment in their field of practice in this state. The findings of the examining committee shall be advisory to the director.
- E. The director shall verify that the audiology licensee has passed a nationally recognized examination approved by the director.
- F. The director shall verify that the speech-language pathology licensee has passed a nationally recognized examination approved by the director.
- G. The director may recognize a nationally recognized speech-language hearing association or audiology association examination, or both, as an approved examination.
- H. The advisory committee shall provide recommendations to the director in the following areas, on which the director shall act within a reasonable period of time:
1. Issuance and renewal of a license.
 2. Prescribing disciplinary procedures.
 3. Appointment of an examining committee to assist in the conduct of the examination of applicants for a hearing aid dispenser's license.
 4. Adopting rules that are not inconsistent with the laws of this state and that are necessary to carry out this chapter.
 5. Requiring the periodic inspection of testing equipment and facilities of persons engaging in the practice of fitting and dispensing hearing aids, audiology and speech-language pathology.
 6. Requiring a licensee to produce customer records of patients involved in complaints on file with the department of health services.

§ 36-1903. Deposit of monies; hearing and speech professionals fund; exemption

- A. All monies received by the director for any purpose pursuant to this chapter shall be deposited, pursuant to sections 35-146 and 35-147, in a hearing and speech professionals fund established in the state treasury by the director, except monies collected from civil penalties imposed pursuant to this chapter shall be deposited in the state general fund. Monies in the fund shall be administered by the director for the purposes of this chapter.
- B. Monies in the fund are subject to legislative appropriation and are exempt from the provisions of section 35-190 relating to lapsing of appropriations.

§ 36-1904. Issuance of license; renewal of license; continuing education; military members

- A. The director shall issue a regular license to each applicant who meets the requirements of this chapter. A regular license is valid for one year.
- B. A licensee shall renew a regular license annually on payment of the renewal fee prescribed in section 36-1908. There is a thirty day grace period after the expiration of a regular license. During this period the licensee may renew a regular license on payment of a late fee in addition to the renewal fee.
- C. When renewing a regular license as a hearing aid dispenser, the licensee shall provide proof of having completed at least twelve hours of continuing education within the prior twelve months. Courses sponsored by a single manufacturer of hearing aids may not satisfy more than four hours of continuing education within the prior twelve months. Courses on topics that provide a hearing aid dispenser an opportunity to stay current on business or client service practices or trends in the profession or that contribute to the professional or business competence of a hearing aid dispenser may qualify for up to one-third of the annual continuing education requirement.
- D. When renewing a regular license in audiology or in speech-language pathology, the licensee shall provide proof of having completed at least ten hours of continuing education within the prior twelve months. Courses sponsored by a single manufacturer of hearing aids may not satisfy more than four hours of continuing education within the prior twelve months for persons with a license in audiology.
- E. The director by rule shall provide standards for continuing education courses required by this section.
- F. The director may refuse to renew a regular license for any cause provided in section 36-1934.
- G. A person who does not renew a regular license as prescribed by this section shall apply for a new license pursuant to the requirements of this chapter. If an application is received by the director within one year of the expiration date of the license, the applicant is not required to take an examination.
- H. A person who reapplies for a regular license issued pursuant to this chapter must provide proof of completion of the continuing education hours prescribed by subsection C or D of this section within the previous twelve months before the date of reapplication.
- I. A license issued pursuant to this chapter to any member of the Arizona national guard or the United States armed forces reserves shall not expire while the member is serving on federal active duty and shall be extended one hundred eighty days after the member returns from federal active duty, provided that the member, or the legal representative of the member, notifies the director of the federal active duty status of the member. A license issued pursuant to this chapter to any member serving in the regular component of the United States armed forces shall be extended one hundred eighty days from the date of expiration, provided that the member, or the legal representative of the member, notifies the director of the federal active duty status of the member. If the license is renewed during the applicable extended time period after the member returns from federal active duty, the member is responsible only for normal fees and activities relating to renewal of the license and shall not be charged any additional costs such as late fees or delinquency fees. The member, or the legal representative of the member, shall present to the director a copy of the member's official military orders, a redacted military identification card or a written verification from the member's commanding officer before the end of the applicable extended time period in order to qualify for the extension.
- J. A license issued pursuant to this chapter to any member of the Arizona national guard, the United States armed forces reserves or the regular component of the United States armed forces shall not expire and shall be extended one hundred eighty days from the date the military member is able to perform activities necessary under the license if the member both:
 - 1. Is released from active duty service.
 - 2. Suffers an injury as a result of active duty service that temporarily prevents the member from being able to perform activities necessary under the license.

§ 36-1905. Sponsors; duties

- A. A sponsor shall directly train and supervise a temporary licensee. The director shall prescribe by rule a reasonable number of hours of training and supervision required. A sponsor may not sponsor more than two temporary licensees at one time.
- B. A sponsor and the temporary licensee are equally liable for violations of this chapter and rules adopted pursuant to this chapter that are committed by the temporary licensee.
- C. A sponsor who violates this section is subject to disciplinary action as prescribed pursuant to section 36-1934.

§ 36-1906. Registering place of business with director

- A. A person who holds a license shall notify the director in writing of the address of the place or places where the person engages in the practice of fitting and dispensing hearing aids, audiology or speech-language pathology and any change of address.
- B. The director shall keep a record of the places of practice of persons who hold licenses. Any notice required to be given by the director to a person who holds a license may be given by mailing it to that person at the address given by that person to the director.

§ 36-1907. Practicing without a license; prohibition

- A. A person shall not engage in the practice of fitting and dispensing hearing aids, audiology or speech-language pathology or display a sign or in any other way advertise or claim to be a hearing aid dispenser, an audiologist or a speech-language pathologist unless the person holds an active license in good standing issued by the director as provided in this chapter.
- B. A person shall not engage in performing the duties of a speech-language pathology assistant or claim to be a speech-language pathology assistant unless the person holds an active license in good standing issued by the director as provided by this chapter.
- C. A licensee shall conspicuously post a license issued pursuant to this chapter in the licensee's office or place of business.

§ 36-1908. Fees

The director shall prescribe and collect fees from persons who are regulated under this chapter for the following:

- 1. An original application for a regular or temporary license.
- 2. An original issuance of a regular or temporary license.
- 3. An original application for a regular or temporary license if an examination pursuant to section 36-1924 is required.
- 4. A renewal of a regular or temporary license.
- 5. An issuance of a duplicate regular or temporary license.
- 6. A late fee.

§ 36-1909. Bill of sale; requirements

- A. A hearing aid dispenser or dispensing audiologist shall deliver a bill of sale to each person supplied with a hearing aid by the hearing aid dispenser or the dispensing audiologist or at that person's order or direction.
- B. A bill of sale shall contain the hearing aid dispenser's or the dispensing audiologist's signature and shall show the address of that person's regular place of practice and the number of that person's license, a description of the make and model of the hearing aid and the amount charged. The bill of sale shall also state the serial number and the condition of the hearing aid as to whether it is new, used or rebuilt.
- C. A bill of sale shall contain language that verifies that the client has been informed about audio switch technology, including benefits such as increased access to telephones and assistive listening devices. If the hearing device purchased by the client has audio switch technology, the client shall be informed of the proper use of the technology. The client shall be informed that an audio switch is also referred to as a telecoil, t-coil or t-switch.
- D. A bill of sale shall contain language that informs the client about the Arizona telecommunications equipment distribution program established by section 36-1947 that provides assistive telecommunications devices to residents of this state who have hearing loss.

§ 36-1910. Application of chapter to corporations and other organizations; exemptions

- A. Except as provided in subsection B of this section and to the extent practicable, this chapter applies to corporations, partnerships, trusts, associations or like organizations.
- B. Corporations, partnerships, trusts, associations or like organizations that are fitting and dispensing hearing aids are exempt from the qualification and examination requirements of sections 36-1923 and 36-1924, provided they pay the license fee prescribed in section 36-1908 and employ only licensed persons in the over-the-counter or other in-person fitting and dispensing of hearing aids.

Article 2

§ 36-1921. Persons not affected by chapter

This chapter does not:

1. Apply to a person while engaged in the practice of recommending hearing aids if such practice is part of the academic curriculum of an accredited institution of higher education or part of a program conducted by a public or charitable institution, or a nonprofit organization which is primarily supported by voluntary contributions unless they sell hearing aids.
2. Apply to any person engaging in the practice of measuring human hearing for the purpose of selection of hearing aids provided that the person or the organization that employs that person does not sell hearing aids or hearing aid accessories.
3. Prevent a health care professional who is licensed or certified under title 32 from acting within the scope of that person's license or certificate.
4. Apply to a person who is credentialed by this state as a teacher of the deaf from acting within the scope of those credentials.
5. Apply to a student, intern or trainee pursuing a course of study in audiology or speech-language pathology in a nationally or regionally accredited institution of higher education or training institution if all of the following are true:
 - (a) The activities are part of a planned course of study at that institution.
 - (b) The person is designated by a title that clearly indicates the status appropriate to the person's level of education.
 - (c) The person works under the supervision of a person who is licensed in this state as an audiologist or a speech-language pathologist.
 - (d) Before a person receives services from a student or a temporary licensee, the supervising licensee provides written notification of this fact to the patient.
6. Apply to any person certified by the department of health services for the school hearing screening program.

§ 36-1922. Reciprocity

- A. The director may issue a license to a person who is currently licensed in another state or jurisdiction that the director determines meets the minimum licensure requirements of this chapter. The person shall apply for licensure and pay all applicable fees as prescribed by this chapter and shall pass an examination approved by the director in jurisprudence and ethics related to this chapter within six months after initial licensure. The director shall offer the examination at least four times each calendar year.
- B. The applicant shall provide information the director determines is necessary to investigate the status of the applicant's current license.

§ 36-1923. Hearing aid dispensers; licensure; requirements

- A. An applicant for a hearing aid dispenser license shall pay to the director a nonrefundable application fee and shall show to the satisfaction of the director that he:
 1. Is a person of good moral character.
 2. Has an education equivalent to a four-year course in an accredited high school or has continuously engaged in the practice of fitting and dispensing hearing aids during the three years preceding August 11, 1970.
 3. Has not had his license revoked or suspended by a state within the past two years and is presently not ineligible for licensure in any state due to prior revocation or suspension.
- B. An applicant for a hearing aid dispenser license who is notified by the director that he has fulfilled the requirements of subsection A shall appear at a time, place and before persons the director designates, to be examined by written and practical tests in order to demonstrate that he is qualified to practice the fitting and dispensing of hearing aids.
- C. The director shall give at least one and not exceeding four examinations of the type described in this section in each calendar year as the volume of applications may make appropriate. A minimum of three months shall elapse following the last examination before another may be given.

§ 36-1924. Examination for license

- A. The examination provided for in this article shall consist of:
 - 1. A demonstration of minimal knowledge in the techniques of testing hearing and fitting and evaluating hearing aids.
 - 2. A knowledge of the medical and rehabilitation facilities, for children and adults with hearing disorders, in this state.
 - 3. A knowledge of the code of ethics contained in this chapter.
 - 4. Tests of knowledge in the following areas as they pertain to the fitting of hearing aids:
 - (a) Physics.
 - (b) The human hearing mechanism, including its functions and causes of its disorders.
 - (c) The function of hearing aids.
 - 5. Practical tests of proficiency in the techniques of taking ear mold impressions and measurement of hearing by pure tone audiometry, including the air, bone and masking methods, and speech audiometry and other skills as they pertain to the candidacy for, selection of and adaptation of hearing aids.
 - 6. A knowledge of rehabilitation and hearing conservation techniques as they relate only to hearing aids and related devices.
- B. The examination shall not be constructed to require knowledge or abilities inconsistent with the realistic services of a hearing aid dispenser or with the requirements of sound public health practices.
- C. To provide adequate tests of proficiency, the examination requirements provided in this section may be changed when deemed necessary due to technological advances.

§ 36-1926. Temporary license; sponsorship; termination of sponsorship

- A. An applicant who fulfills the requirements of section 36-1923 may apply to the director for a temporary license.
- B. On receiving an application as provided by subsection A of this section, accompanied by an application fee and proof of sponsorship, the director shall issue a temporary license. A temporary license allows the licensee to practice the fitting and dispensing of hearing aids for a period ending on the last day of the month following a scheduled examination.
- C. An applicant shall provide proof to the satisfaction of the director that the applicant is or will be supervised and trained for fitting and dispensing activities by a sponsor licensed pursuant to this chapter.
- D. A sponsor may terminate sponsorship at any time and for any reason. The director shall not review the reasons for the termination. A temporary license terminates on the date that the director receives notice from the sponsor that the sponsor is terminating sponsorship. This notice shall be accompanied by documentation that the sponsor has notified the licensee of the termination. The director shall prescribe by rule how the sponsor shall document this notification of termination. A person whose license is terminated shall apply for a new temporary license as prescribed by this section and shall not practice until granted a license.
- E. A person shall either take the next examination that is given following issuance of a temporary license or renew the temporary license. If the person takes and fails the examination the person may renew the temporary license once. The person shall take the next examination following the issuance of the renewal license. If the person does not take the examination but renews the temporary license, the person shall take the next examination following issuance of renewal of the temporary license.
- F. The director shall not issue a renewal to a person who has renewed a temporary license and failed the examination.
- G. A temporary license expires on the last day of the month following the next scheduled examination.
- H. The director may revoke or suspend a temporary license in the same manner and for the same reasons as prescribed pursuant to section 36-1934.

Article 3

§ 36-1934. Denial, revocation or suspension of license; hearings; alternative sanctions

- A. The director may deny, revoke or suspend a license issued under this chapter for any of the following reasons:
 1. Conviction of a felony or misdemeanor involving moral turpitude. The record of the conviction or a certified copy from the clerk of the court where the conviction occurred or from the judge of that court is sufficient evidence of conviction.
 2. Securing a license under this chapter through fraud or deceit.
 3. Unprofessional conduct, or incompetence in the conduct of his practice.
 4. Using a false name or alias in the practice of his profession.
 5. Violating any of the provisions of this chapter.
 6. Failing to comply with existing federal regulations regarding the fitting and dispensing of a hearing aid.
- B. If the director determines pursuant to a hearing that grounds exist to revoke or suspend a license, the director may do so permanently or for a fixed period of time and may impose conditions as prescribed by rule.
- C. The department may deny a license without holding a hearing. After receiving notification of the denial, the applicant may request a hearing to review the denial.
- D. The department shall conduct any hearing to revoke or suspend a license or impose a civil penalty under section 36-1939 pursuant to title 41, chapter 6, article 10.
- E. Instead of denying, revoking or suspending a license the director may file a letter of concern, issue a decree of censure, prescribe a period of probation or restrict or limit the practice of a licensee.
- F. The director shall promptly notify a licensee's employer if the director initiates a disciplinary action against the licensee.

§ 36-1936. Unlawful acts

A person may not:

1. Sell, barter, or offer to sell or barter, a license.
2. Purchase or procure by barter a license with intent to use it as evidence of the holder's qualification to engage in the practice of fitting and dispensing hearing aids.
3. Alter materially a license with fraudulent intent.
4. Use or attempt to use as a valid license one which has been purchased, fraudulently obtained, counterfeited or materially altered.
5. Wilfully make a false, material statement in an application or related document for a license or for renewal of a license.

§ 36-1937. Injunctive relief

The director may enforce any provision of this chapter by injunction or by any other appropriate proceeding. No such proceeding shall be barred by any proceeding had or pending pursuant to any other provisions of this chapter, or by the imposition of any fine or term of imprisonment pursuant thereto.

§ 36-1938. Violation; classification

Violation of any provision of this chapter is a class 3 misdemeanor.

§ 36-1939. Civil penalties; enforcement

- A. The director may impose a civil penalty of not more than five hundred dollars for a violation of this chapter or a rule adopted pursuant to this chapter.
- B. The attorney general and the county attorney may bring an action in the name of this state to enforce civil penalties imposed pursuant to this section. Actions shall be brought in the superior court in the county where the violation occurs.
- C. The director may impose penalties assessed pursuant to this section in addition to other penalties imposed pursuant to this chapter.
- D. All monies collected from civil penalties collected for violation of this chapter or a rule adopted pursuant to this chapter shall be deposited in the state general fund.

Article 4

§ 36-1940. Audiology; licensure requirements

- A. A person who wishes to be licensed as an audiologist shall:
 1. Submit a nonrefundable application fee as prescribed by section 36-1908.
 2. Submit evidence satisfactory to the director that the applicant has:
 - (a) A doctoral degree with an emphasis in audiology from a nationally or regionally accredited college or university in an accredited program consistent with the standards of this state's universities.
 - (b) Completed supervised clinical rotations in audiology from a nationally or regionally accredited college or university in an accredited program consistent with the standards of this state's universities.
 3. Pass an examination pursuant to section 36-1902, subsection G. The applicant must have completed the examination within three years before the date of application for licensure pursuant to this article.
 4. Be of good moral character.
 5. Not have had a license revoked or suspended by a state within the past two years and not be presently ineligible for licensure in any state because of a prior revocation or suspension.
- B. A person who has a doctoral degree in audiology and who wishes to be licensed as an audiologist to fit and dispense hearing aids shall:
 1. Submit a nonrefundable application fee as prescribed by section 36-1908.
 2. Submit evidence satisfactory to the director that the applicant has:
 - (a) A doctoral degree with an emphasis in audiology from a nationally or regionally accredited college or university in a program consistent with the standards of this state's universities.
 - (b) Completed supervised clinical rotations in audiology from a nationally or regionally accredited college or a university in an accredited program that is consistent with the standards of this state's universities.
 3. Pass an examination pursuant to section 36-1902, subsection G. The applicant must have completed the examination within three years before the date of application for licensure pursuant to this article.
 4. Pass an examination approved by the director in jurisprudence and ethics related to this chapter within six months after initial licensure. The director shall offer the examination at least four times each calendar year.
 5. Be of good moral character.
 6. Not have had a license revoked or suspended by a state within the past two years and not be presently ineligible for licensure in any state because of a prior revocation or suspension.
- C. A person who wishes to be licensed as an audiologist to fit and dispense hearing aids and who was awarded a master's degree in audiology before December 31, 2007 must:
 1. Submit a nonrefundable application fee as prescribed pursuant to section 36-1908.
 2. Submit evidence satisfactory to the director that the applicant meets the requirements prescribed in section 36-1940.02, subsection C for a waiver of the educational and clinical rotation requirements of this article.
 3. Pass an audiology examination pursuant to section 36-1902, subsection E. The applicant must have completed the examination within three years before the date of application for licensure pursuant to this article unless the applicant is currently practicing audiology and meets the audiology examination waiver requirements of section 36-1940.02, subsection D.
 4. Pass the hearing aid dispenser's examination pursuant to section 36-1924.
 5. Be of good moral character.
 6. Not have had a license to practice as an audiologist or hearing aid dispenser revoked or suspended by another state within the past two years and not currently be ineligible for licensure in any state because of a prior revocation or suspension.
- D. The director shall adopt rules prescribing criteria for approved postgraduate professional experience.

§ 36-1940.01. Speech-language pathologist; licensure requirements

- A. A person who wishes to be licensed as a speech-language pathologist shall:
 1. Submit a nonrefundable application fee as prescribed by section 36-1908.
 2. Submit evidence satisfactory to the director that the applicant has:
 - (a) A master's degree in speech-language pathology or the equivalent from a nationally or regionally accredited college or university in a program consistent with the standards of this state's universities.
 - (b) Completed a supervised clinical practicum in speech-language pathology from a nationally or regionally accredited college or university in a program consistent with the standards of this state's universities.
 - (c) Completed postgraduate professional experience in the field of speech-language pathology approved by the director.
 3. Pass an examination pursuant to section 36-1902, subsection G.
 4. Be of good moral character.

5. Not have had a license revoked or suspended by a state within the past two years and not be presently ineligible for licensure in any state because of a prior revocation or suspension.
- B. A person who wishes to be licensed as a speech-language pathologist whose practice is limited to providing services to pupils under the authority of a local education agency or state supported institution shall:
 1. Submit a nonrefundable application fee as provided by section 36-1908.
 2. Submit proof of an employee or contractor relationship with a local education agency or a state supported institution.
 3. Hold a certificate in speech and language therapy awarded by the state board of education.
- C. The director shall adopt rules prescribing criteria for approved postgraduate professional experience.

§ 36-1940.02. Waiver of licensure and examination requirements

- A. The advisory committee appointed under section 36-1902 may recommend to the director a waiver of the educational requirements of sections 36-1940 and 36-1940.01 if an applicant submits proof satisfactory to the department that the applicant received professional education in another country equivalent to the education and practicum requirements of this article.
- B. The department shall waive the examination requirements of section 36-1940.01 under either of the following conditions:
 1. The applicant presents proof satisfactory to the department that the applicant is currently licensed in a state, district or territory of this country that has standards that are at least equivalent to those of this state.
 2. The applicant holds a certificate of clinical competence in speech-language pathology from a nationally recognized speech-language hearing association approved by the department in the field for which the applicant is applying for licensure.
- C. The department shall waive the education and clinical rotation requirements of section 36-1940 if an applicant submits proof satisfactory to the director that the applicant either:
 1. Is currently licensed in a state that has standards that are at least equivalent to those of this state.
 2. Has a master's degree in audiology that was awarded by an accredited program before December 31, 2007 and has completed postgraduate professional experience in audiology as approved by the director.
- D. The department shall waive the audiology examination requirements of section 36-1940 if either:
 1. The applicant presents proof satisfactory to the department that the applicant is currently licensed and practicing audiology in this state or in another state that has standards that are at least equivalent to those of this state.
 2. The applicant presents proof satisfactory to the department that the applicant is currently practicing audiology under the authority and supervision of an agency of the United States government or of another board, agency or department of another state and holds a certificate in audiology from a recognized credentialing body approved by the director.
- E. The department shall waive the hearing aid dispensing examination requirements of section 36-1940 if:
 1. The applicant presents proof satisfactory to the department that the applicant holds a current license that includes dispensing and that is issued by another state that has standards that are at least equivalent to those of this state.
 2. The applicant passes an examination approved by the director in jurisprudence and ethics related to this chapter within six months after initial licensure. The director shall offer the examination at least four times each calendar year.

§ 36-1940.03. Temporary licenses

- A. The department shall issue a temporary license to a person who does not meet the professional experience requirement of section 36-1940.01 if the applicant meets the other requirements of that section and:
 1. Includes with the application a plan for meeting the postgraduate professional experience.
 2. Submits a fee prescribed by section 36-1908.
- B. A person may renew a temporary license only once.
- C. A person issued a temporary license shall practice only under the supervision of a person who is fully licensed by this state.

§ 36-1940.04. Speech-language pathologist assistant; licensure requirements; scope of practice; supervision

- A. A person who wishes to be licensed as a speech-language pathologist assistant shall:
 1. Submit a nonrefundable application fee as prescribed by section 36-1908.
 2. Submit written evidence satisfactory to the director that the applicant has completed:
 - (a) An approved training program for speech-language pathology assistants or the equivalent from a nationally or regionally accredited college or university that consisted of a minimum of sixty semester credit hours of course work with the following curriculum content:
 - (i) Twenty to forty semester credit hours of general education.
 - (ii) Twenty to forty semester credit hours of speech-language pathology technical course work.

- (b) A minimum of one hundred hours of clinical interaction that does not include observation, under the supervision of a licensed master's level speech-language pathologist.
 3. Be of good moral character.
 4. Not have had a license revoked or suspended by a state within the past two years and is not presently ineligible for licensure in any state because of a prior revocation or suspension.
- B. The director shall grant a waiver of the requirements for licensure as provided by subsection A of this section until September 1, 2007 to individuals who have performed the functions of a speech-language pathology assistant if the individual:
 1. Has completed a minimum of forty semester credit hours of speech-language pathology technical course work.
 2. Has satisfactorily completed a minimum of two years of experience as a speech-language pathology assistant under the supervision of a licensed master's level speech-language pathologist.
 3. Is of good moral character.
 4. Has not had a license revoked or suspended by a state within the past two years and is not presently ineligible for licensure in any state because of a prior revocation or suspension.
- C. **A speech-language pathology assistant may do the following under the supervision of the licensed speech-language pathologist:**
 1. Conduct speech and language screenings without interpretation, using screening protocols specified by the supervising speech-language pathologist.
 2. Provide direct treatment assistance, including feeding for nutritional purposes to patients, clients or students except for patients, clients or students with dysphagia, identified by the supervising speech-language pathologist by following written treatment plans, individualized education programs, individual support plans or protocols developed by the supervising speech-language pathologist.
 3. Document patient, client or student progress toward meeting established objectives as stated in the treatment plan, individual support plan or individualized education program without interpretation of the findings, and report this information to the supervising speech-language pathologist.
 4. Assist the speech-language pathologist in the collecting and tallying of data for assessment purposes, without interpretation of the data.
 5. Act as a second-language interpreter during assessments.
 6. Assist with informal documentation during an intervention session by collecting and tallying data as directed by the speech-language pathologist, preparing materials and assisting with other clerical duties as specified by the supervising speech-language pathologist.
 7. Schedule activities and prepare charts, records, graphs or other displays of data.
 8. Perform checks and maintenance of equipment.
 9. Participate with the speech-language pathologist in research projects, in-service training and public relations programs.
 10. Sign and initial treatment notes for review and co-signature by the supervising speech-language pathologist.
- D. **A speech-language pathology assistant shall not:**
 1. Conduct swallowing screening, assessment and intervention protocols, including modified barium swallow studies.
 2. Administer standardized or nonstandardized diagnostic tests, formal or informal evaluations or interpret test results.
 3. Participate in parent conferences, case conferences or any interdisciplinary team meeting without the presence of the supervising speech-language pathologist, except for individualized education program or individual support plan meetings if the licensed speech pathologist has been excused by the individualized education program team or the individual support plan team.
 4. Write, develop or modify a patient's, client's or student's treatment plan, individual support plan or individualized education program in any way.
 5. Provide intervention for patients, clients or students without following the treatment plan, individual support plan or individualized education program prepared by the supervising speech-language pathologist.
 6. Sign any formal documents, including treatment plans, individual support plans, individualized education programs, reimbursement forms or reports.
 7. Select patients, clients or students for services.
 8. Discharge patients, clients or students from services.
 9. Unless required by law, disclose clinical or confidential information orally or in writing to anyone not designated by the speech-language pathologist.
 10. Make a referral for any additional service.
 11. Communicate with the patient, client or student or with family or others regarding any aspect of the patient, client or student status without the specific consent of the supervising speech-language pathologist.
 12. Claim to be a speech-language pathologist.
 13. Write a formal screening, diagnostic, progress or discharge note.
 14. Perform any task without the express knowledge and approval of the supervising speech-language pathologist.

- E. **All services provided by a speech-language pathology assistant shall be performed under the direction and supervision of a speech-language pathologist licensed pursuant to this chapter.**
- F. **A licensed speech-language pathologist who supervises or directs the services provided by a speech-language pathology assistant shall:**
 - 1. Have at least two years of full-time professional experience as a licensed speech-language pathologist.
 - 2. Provide direction and supervision to not more than two full-time or three part-time speech-language pathology assistants at one time.
 - 3. **Ensure that the amount and type of supervision and direction provided to a speech-language pathology assistant is consistent with the individual's skills and experience, the needs of the patient, client or student served, the setting in which services are provided and the tasks assigned and provide:**
 - (a) A minimum of twenty per cent direct supervision and ten per cent indirect supervision of all of the time that a speech-language pathology assistant is providing services during the first ninety days of the person's employment.
 - (b) Subsequent to the first ninety days of a speech-language pathology assistant's employment, a minimum of ten per cent direct supervision and ten per cent indirect supervision of all of the time a speech-language pathologist assistant is providing service.
 - 4. Inform a patient, client or student when the services of a speech-language pathology assistant are being provided.
 - 5. Document all periods of direct and indirect supervision provided to a speech-language pathology assistant.
- G. If more than one speech-language pathologist provides supervision to a speech-language pathology assistant, one of the speech-language pathologists shall be designated as the primary supervisor who is responsible for coordinating any supervision provided by other speech-language pathologists.

Arizona Administrative Code Title 9 Chapter 16

ARTICLE 2. LICENSING AUDIOLOGISTS AND SPEECH-LANGUAGE PATHOLOGISTS

R9-16-201. Definitions

The following definitions apply in this Article, unless otherwise specified:

1. "Accredited" means approved by the:
 - a. New England Association of Schools and Colleges,
 - b. Middle States Association of Colleges and Secondary Schools,
 - c. North Central Association of Colleges and Schools,
 - d. Northwest Association of Schools and Colleges,
 - e. Southern Association of Colleges and Schools, or
 - f. Western Association of Schools and Colleges.
2. "Applicant" means an individual who submits to the Department an initial or a renewal application packet to practice audiology or speech-language pathology in Arizona.
3. "Application packet" means the information, documents, and fees required by the Department for licensure.
4. "Audiology" has the meaning in A.R.S. § 36-1901(2).
5. "ASHA" means the American Speech-Language-Hearing Association, a national scientific and professional organization for audiologists and speech-language pathologists.
6. "CCC" means Certificate of Clinical Competence, an award issued by ASHA to an individual who:
 - a. Completes a degree in audiology or speech-language pathology from an accredited college or university that includes a clinical practicum;
 - b. Passes the ETSNESPA; and
 - c. Completes a clinical fellowship.
7. "CE" means continuing education, the ongoing process of receiving audiology or speech-language pathology-related courses.
8. "Clinical fellow" means an individual engaged in a clinical fellowship.
9. "Clinical fellowship" means an individual's postgraduate professional experience assessing, diagnosing, screening, treating, writing reports, and counseling individuals exhibiting speech, language, hearing, or communication disorders, obtained:
 - a. After completion of graduate level academic course work and a clinical practicum;
 - b. Under the supervision of a clinical fellowship supervisor; and
 - c. While being employed on a full-time or part-time equivalent basis.
10. "Clinical fellowship agreement" means the document submitted to the Department by a clinical fellow to register the initiation of a clinical fellowship.
11. "Clinical fellowship report" means a document completed by a clinical fellowship supervisor containing:
 - a. A summary of a clinical fellow's diagnostic and therapeutic procedures,
 - b. A verification of the clinical fellow's diagnostic and therapeutic procedures by the clinical fellowship supervisor, and
 - c. An evaluation of the clinical fellow's ability to perform the diagnostic and therapeutic procedures.
12. "Clinical fellowship supervisor" means an audiologist or speech-language pathologist who:
 - a. Is a sponsor of a temporary licensee;
 - b. Had a CCC while supervising a clinical fellow before the effective date of this Article; or
 - c. Has a CCC while supervising a clinical fellow in another state.
13. "Clinical practicum" means the experience acquired by an individual who is completing course work in audiology or speech-language pathology, while supervised by a licensed audiologist, a licensed speech-language pathologist, or an individual holding a CCC, by assessing, diagnosing, evaluating, screening, treating, and counseling individuals exhibiting speech, language, hearing, or communication disorders.
14. "Course" means a workshop, seminar, lecture, conference, class, or instruction.
15. "Current CCC" means documentation issued by ASHA verifying that an individual is presently certified by ASHA.
16. "Days" means calendar days.

17. "Diagnostic and therapeutic procedures" means the principles and methods used by an audiologist in the practice of audiology or a speech-language pathologist in the practice of speech-language pathology.
18. "Disciplinary action" means a proceeding that is brought against a licensee by the Department under A.R.S. § 36-1934 or a state licensing agency or board.
19. "ETS/NESPA" means Educational Testing Service National Examination in Speech-Language Pathology and Audiology, the specialty area test of the Praxis Series given by the Education Testing Service, Princeton, N.J.
20. "Full-time" means 30 clock hours or more per week.
21. "Graduate level" means leading to, or creditable towards, a master's or doctoral degree.
22. "License" means the written authorization issued by the Department to practice audiology or speech-language pathology.
23. "Local education agency" means a school district governing board established by A.R.S. §§ 15-301 through 15-396.
24. "Monitoring" means being responsible for and providing direction to a clinical fellow without directly observing diagnostic and therapeutic procedures.
25. "Onsite observations" means the presence of a clinical fellowship supervisor who is watching a clinical fellow perform diagnostic and therapeutic procedures.
26. "Part-time equivalent" means:
 - a. 25-29 clock hours per week for 48 weeks,
 - b. 20-24 clock hours per week for 60 weeks, or
 - c. 15-19 clock hours per week for 72 weeks.
27. "Pupil" means a child attending a school, a charter school, a private school, or an accommodation school, which are defined in A.R.S. § 15-101.
28. "Semester credit hour" means one earned academic unit of study based on completing, at an accredited college or university, a 50 to 60 minute class session per calendar week for 15 to 18 weeks.
29. "Semester credit hour equivalent" means one quarter credit which is equal in value to 2/3 of a semester credit hour.
30. "Speech-language pathology" has the meaning in A.R.S. § 36-1901(17).
31. "State supported institution" means a school receiving funding under A.R.S. §§ 15-901 through 15-1086.
32. "Supervise" means being responsible for and providing direction to:
 - a. A clinical fellow during onsite observation or monitoring of the clinical fellow's diagnostic and therapeutic procedures; or
 - b. An individual completing a clinical practicum.
33. "Supervisory activities" means evaluating and assessing a clinical fellow's diagnostic and therapeutic procedures in assessing diagnosing, evaluating, screening, treating, and counseling individuals exhibiting speech, language, hearing, or communication disorders.
34. "Week" means the period of time beginning at 12:00 a.m. on Sunday and ending at 11:59 p.m. the following Saturday.

R9-16-202. Qualifications for Licensure

An applicant shall meet the requirements in A.R.S. § 36-1940 to qualify for an audiologist's license or A.R.S. § 36-1940.01 to qualify for a speech-language pathologist's license.

1. An applicant shall provide the Department with written documentation of either a current CCC or completion of a minimum of 60 semester credit hours or semester credit hour equivalents in audiology or speech-language pathology from an accredited college or university as evidence of completion of an equivalent to a master's degree in audiology as required in A.R.S. § 36-1940(A)(2)(a), (B)(2)(a) or speech-language pathology as required in A.R.S. § 36-1940.01(A)(2)(a).
 - a. To qualify for an audiologist's license, the 60 semester credit hours shall include a minimum of 21 graduate level semester credit hours in the area of audiology and a minimum of six semester credit hours in the area of speech-language pathology.
 - b. To qualify for a speech-language pathologist's license, the 60 semester credit hours shall include a minimum of 21 graduate level semester credit hours in the area of speech-language pathology and a minimum of six semester credit hours in the area of audiology.
 - c. An applicant is allowed no more than six graduate level semester credit hours for a clinical practicum.
 - d. Thesis or dissertation credit hours may not be used to meet the requirements of this subsection.

2. An applicant shall provide the Department with written documentation of either a current CCC or completion of a minimum of 300 clock hours in a clinical practicum at an accredited college or university as evidence of completion of a clinical practicum in audiology as required in A.R.S. § 36-1940(A)(2)(b), (B)(2)(b) or speech-language pathology as required in A.R.S. § 36-1940.01(A)(2)(b)
 - a. For an individual applying for an audiologist's license, the 300 clock hours shall include at least 20 clock hours in speech-language pathology and 250 clock hours or more in audiology including at least:
 - i. 40 clock hours in the evaluation of hearing in children;
 - ii. 40 clock hours in the evaluation of hearing in adults;
 - iii. 80 clock hours in the selection and use of amplification and assistive devices with a minimum of 10 clock hours with adults and a minimum of 10 clock hours with children; and
 - iv. 20 clock hours in the treatment of hearing disorders in children and adults.
 - b. For an individual applying for a speech-language pathologist's license, the 300 clock hours shall include at least 20 clock hours in audiology and 250 clock hours or more in speech-language pathology including at least 20 clock hours in each of the following categories:
 - i. The evaluation of speech disorders in children;
 - ii. The evaluation of speech disorders in adults;
 - iii. The evaluation of language disorders in children;
 - iv. The evaluation of language disorders in adults;
 - v. The treatment of speech disorders in children;
 - vi. The treatment of speech disorders in adults;
 - vii. The treatment of language disorders in children;
 - viii. The treatment of language disorders in adults.
3. An applicant shall provide the Department with written documentation of either a current CCC or completion of 36 weeks or more of a clinical fellowship as evidence of completion of the postgraduate professional experience required by A.R.S. § 36-1940(A)(2)(c), (B)(2)(c), or A.R.S. § 36-1940.01(A)(2)(c),
 - a. The clinical fellowship shall be completed within seven years from the date the clinical practicum was completed;
 - b. Once initiated, the clinical fellowship shall be completed in no more than 36 consecutive months; and
 - c. A minimum of 80% of the clinical fellowship hours shall be in direct client contact.

R9-16-203. License Application

- A. An applicant for a regular audiology license or a regular speech-language pathology license shall submit to the Department an application packet containing:
 1. An application on a form provided by the Department and signed by the applicant that contains all of the following:
 - a. The applicant's name, social security number, current home address, business address, and home and business telephone numbers;
 - b. If applicable, the name of applicant's employer and the employer's current business address and telephone number;
 - c. A statement of whether the applicant has ever been convicted of a felony or of a misdemeanor involving moral turpitude in this state or any other state;
 - d. A list of all states and countries in which the applicant is or has been licensed as an audiologist or speech-language pathologist;
 - e. A statement of whether any disciplinary action, consent order, or settlement agreement is pending or has been imposed by any state or country upon the applicant's audiology or speech-language pathology license; and
 - f. A statement by the applicant verifying the truthfulness of the information provided by the applicant;
 2. An official transcript issued to the applicant by an accredited college or university after the applicant's completion of a master's degree or 60 semester credit hours or semester credit hour equivalents as provided in R9-16-202(1) or a copy of a current CCC;
 3. Written documentation of the applicant's completion of a clinical practicum as required by R9-16-202(2) or a copy of a current CCC;
 4. A photocopy of the clinical fellowship report signed by the clinical fellowship supervisor as required by R9-16-202(3) or a copy of a current CCC;
 5. Written documentation of a passing grade on the ETSNESPA or a copy of a current CCC; and
 6. An application fee of \$100.
- B. An applicant for a temporary license shall submit to the Department an application packet containing:
 1. An application on a form provided by the Department containing the information in subsections (A)(1), (A)(2), (A)(3), (A)(5), and the fee in (A)(6); and

2. A copy of the clinical fellowship agreement that includes:
 - a. The clinical fellow's name, home address, and telephone number;
 - b. The clinical fellowship supervisor's name, business address, telephone number, and Arizona audiology or speech-language pathology license number;
 - c. The name and address where the clinical fellowship will take place;
 - d. A statement by the clinical fellowship supervisor agreeing to comply with R9-16-205; and
 - e. The signatures of the clinical fellow and the clinical fellowship supervisor.
- C. An applicant for an audiology license to fit and dispense hearing aids shall submit to the Department an application packet containing:
 1. The information, documents, and fee required in subsection (A); and
 2. Written documentation of passing a hearing aid dispenser examination as required by A.R.S. § 36-1940(B)(4).
- D. An applicant for a speech-language pathology license limited to providing services to pupils under the authority of a local education agency or state-supported institution shall submit to the Department an application packet containing:
 1. An application on a form provided by the Department containing the information in subsection (A)(1);
 2. A copy of a temporary or standard certificate in speech-language therapy issued by the State Board of Education;
 3. A copy of an employment contract or an employment contract conditioned upon the applicant's licensure, with a local education agency or state-supported institution that includes:
 - a. The applicant's name and social security number,
 - b. The name of the local education agency or state-supported institution,
 - c. The classification title of the applicant,
 - d. The work dates or projected work dates of the employment contract, and
 - e. Signatures of the applicant and the individual authorized by the governing board to represent the local education agency or state-supported institution, and
 4. An application fee of \$100.

R9-16-204. License Application Time-frames

- A. For any of the license applications in R9-16-203 or R9-16-206, the overall time-frame described in A.R.S. § 41-1072(2) is 60 days.
- B. For any of the license applications in R9-16-203 or R9-16-206, the administrative completeness review time-frame is 30 days and begins on the date the Department receives an application packet.
 1. If an application packet is incomplete, the Department shall send to the applicant a written notice of incompleteness that states each deficiency and the information or documents needed to complete the application packet. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice until the date the Department receives a complete application packet.
 2. When the Department receives a complete application packet, the Department shall send a written notice of administrative completeness to the applicant.
 3. If the applicant does not submit a complete application packet within 90 days from the date the Department sends a written notice of incompleteness to the applicant, the Department shall consider the application withdrawn.
 4. If the Department sends a written notice of approval to the applicant during the time provided to assess administrative completeness, the Department shall not provide a separate written notice of administrative completeness.
- C. For any of the license applications in R9-16-203 or R9-16-206, the substantive review time-frame described in A.R.S. § 41-1072(3) is 30 days and begins on the date the Department sends written notice of administrative completeness to an applicant.
 1. If an applicant does not meet the requirements of A.R.S. §§ 36-1901 through 36-1940.03 and this Article, the Department shall send to the applicant a written comprehensive request for additional information that states each statute and rule upon which the request is based. The substantive review time-frame and the overall time-frame are suspended from the date the written comprehensive request is sent until the date the Department receives the requested information.
 - a. If an applicant does not submit the requested information within 90 days of the date the Department sends the comprehensive written request to the applicant, the Department shall consider the application withdrawn.
 - b. If the information submitted by the applicant does not meet the requirements of A.R.S. §§ 36-1901 through 36-1940.03 and this Article, the Department shall send a written notice of denial to the applicant including a basis for the denial and an explanation of the applicant's right to appeal.
 2. If an applicant meets the requirements of A.R.S. §§ 36-1901 through 36-1940.03 and this Article, the Department shall send written notice of approval to the applicant.

- D. After receiving the written notice of approval in subsection (C)(2), an applicant shall send a \$100 license fee to the Department. If the applicant does not submit the license fee within 30 days after the date the Department sends the written notice of approval to the applicant, the Department shall consider the application withdrawn.

R9-16-205. Clinical Fellowship Supervisors

In addition to complying with the requirements in A.R.S. § 36-1905, a clinical fellowship supervisor shall:

1. Complete a minimum of 36 supervisory activities throughout an individual's clinical fellowship. Of the 36 supervisory activities, the clinical fellowship supervisor shall complete:
 - a. A minimum of 18 onsite observations;
 - b. No more than six onsite observations in 24 hours; and
 - c. A minimum of 18 monitoring activities;
2. Submit a copy of the clinical fellowship report to the Department within 30 days of the completion of the clinical fellowship; and
3. Provide the Department and the clinical fellow with written notice within 72 hours of the decision to stop supervising the clinical fellow if the clinical fellowship supervisor voluntarily stops supervising a clinical fellow before the completion of the clinical fellowship.

R9-16-206. License Renewal

- A. Before the expiration date of a regular license, a licensee shall submit to the Department an application packet containing:
 1. A license renewal fee of \$100;
 2. A completed record of compliance with the CE requirements in R9-16-207; and
 3. A license renewal form provided by the Department that contains:
 - a. The licensee's name, current home address, business address, and home and business telephone numbers;
 - b. If applicable, the name of the licensee's employer and the employer's current business address and telephone number;
 - c. License number and date of expiration; and
 - d. A statement of whether the licensee has been convicted of a felony or a misdemeanor involving moral turpitude since the licensee's previous license application.
- B. A licensee who submits the information and fee in subsection (A)(1) no later than 30 days after the license expiration date shall submit a \$25 late fee in addition to the information and fee required by subsection (A). A licensee who does not submit the information and the fee in subsection (A)(1), within 30 days after the license expiration date, may obtain a license by submitting the application packet required in R9-16-203(A).
- C. When renewing a temporary license, a licensee shall submit a license renewal fee of \$100 and a form provided by the Department containing:
 1. The applicant's name, address, and phone number;
 2. The name of applicant's employer, the employer's current business address, telephone number, and Arizona audiologist or speech-language pathologist license number;
 3. The clinical fellowship supervisor's name, business address, telephone number, and Arizona audiologist or speech-language pathologist license number;
 4. A statement by the clinical fellowship supervisor agreeing to comply with R9-16-205; and
 5. The signature of the clinical fellowship supervisor.

R9-16-207. Continuing Education

- A. Every 12 months from the effective date of a regular license, a licensee shall complete eight credit hours or more of CE approved by the Department. A credit hour consists of a minimum of 50 continuous minutes of instruction.
- B. An individual presenting a CE course or a licensee requesting approval for a CE course shall submit the following to the Department:
 - 1. A brief summary of the course;
 - 2. The name, educational background, and teaching experience of the individual presenting the course;
 - 3. The educational objectives of the course;
 - 4. The name of the organization providing the CE course; and
 - 5. The date, time, and place of presentation of the CE course.
- C. If a licensee submits the information in subsection (B) with a renewal application packet, the Department shall comply with the time-frames in R9-16-204.
- D. For Department approval of a CE course, the overall time-frame described in A.R.S. § 41-1072(2) is 45 days.
- E. For Department approval of a CE course, the administrative completeness review time-frame is 30 days and begins on the date the Department receives a request for CE approval.
 - 1. If a request for CE approval is incomplete, the Department shall send to an individual presenting a CE course or a licensee, a written notice of incompleteness that states each deficiency and the information or documents needed to complete the request. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice until the date the Department receives a complete request for CE approval.
 - 2. When the Department receives a complete request for CE approval, the Department shall send a written notice of administrative completeness to the individual presenting a CE course or the licensee.
 - 3. If the individual presenting a CE course or the licensee does not supply a complete request for CE approval within 60 days from the date the Department receives a request for CE approval, the Department shall consider the request for CE approval withdrawn.
 - 4. If the Department grants approval for a CE course during the time provided to assess administrative completeness, the Department shall not issue a separate written notice of administrative completeness.
- F. For Department approval of a CE course, the substantive review time-frame described in A.R.S. § 41-1072(3) is 15 days and begins on the date the Department sends written notice of administrative completeness to an individual presenting the CE course or a licensee.
 - 1. If a CE course does not meet the requirements in subsection (G), the Department shall send a written notice of denial to the individual presenting the CE course or the licensee including a basis for the denial.
 - 2. If a CE course meets the requirements of subsection (G), the Department shall send written notice of approval to the individual presenting the CE course or the licensee.
- G. The Department shall approve a CE course if the Department determines that the CE course:
 - 1. Is designed to provide current developments, skills, procedures, or treatment in diagnostic and therapeutic procedures in audiology or speech-language pathology;
 - 2. Is developed and presented by individuals knowledgeable and experienced in the subject area; and
 - 3. Contributes directly to the professional competence of a licensee.
- H. A licensee shall maintain a record of each CE course completed by the licensee for 36 months from the date of submitting the record to the Department as required by R9-16-206(A)(2). The record shall contain:
 - 1. The name, address, and license number of the licensee;
 - 2. For each CE course completed by the licensee:
 - a. The name of the organization providing the CE course, and the date and place of presentation;
 - b. The name of the CE course;
 - c. A description of the CE course's content and educational objectives;
 - d. The name and description of the educational background and teaching experience of the individual presenting each course;
 - e. The number of CE credit hours earned for the CE course; and
 - f. A statement, signed by the individual presenting the CE course, verifying the licensee's attendance; and
 - 3. A statement, signed by the licensee, verifying the information contained in the record.
- I. A licensee is not permitted to carry forward CE credit hours from a previous year.

R9-16-208. Disciplinary Actions

In determining the length of license suspension or revocation, or the level of disciplinary action for any violation of A.R.S. §§ 36-1901 through 36-1940.03 or this Article, the Department shall consider:

1. The type of violation,
2. The severity of the violation,
3. The danger to the public health and safety,
4. The number of violations,
5. The degree of harm to the consumer,
6. A pattern of noncompliance, and
7. Any mitigating or aggravating circumstances.

R9-16-209. Equipment; Records; Inspections

- A. A licensee shall maintain equipment used by the licensee in the practice of audiology or the practice of speech-language pathology according to the manufacturer's specifications.
- B. If a licensee uses equipment that requires calibration, the licensee shall ensure that:
 1. The equipment is calibrated a minimum of every 12 months and according to the American National Standard - Specifications for Audiometers, S3.6-1996, Standards Secretariat, c/o Acoustical Society of America, 120 Wall Street, 32nd Floor, New York, New York 10005-3993, January 12, 1996, incorporated by reference and on file with the Department and the Office of the Secretary of State. This incorporation by reference contains no future additions or amendments; and
 2. A written record of the calibration is maintained in the same location as the calibrated equipment for 36 months from the date of the calibration.
- C. **A licensee shall maintain the following records for 36 months from the date the licensee provided a service or dispensed a product while engaged in the practice of audiology, practice of speech-language pathology, or practice of fitting and dispensing hearing aids:**
 1. The name, address, and telephone number of the individual to whom services are provided;
 2. The name or description and the results of each test and procedure used in evaluating speech, language, and hearing disorders or determining the need for dispensing a product or service; and
 3. If a product such as a hearing aid, augmentative communication device, or laryngeal device is dispensed, a record of the following:
 - a. The name of the product dispensed;
 - b. The product's serial number, if any;
 - c. The product's warranty or guarantee, if any;
 - d. The refund policy for the product, if any;
 - e. A statement of whether the product is new or used;
 - f. The total amount charged for the product;
 - g. The name of the licensee; and
 - h. The name of the intended user of the product.
- D. A licensee shall permit the Department to inspect the equipment in subsection (A) and the records listed in subsections (B) and (C).

R9-16-210. Duplicate License Fee

An individual licensed under 9 A.A.C. 16, Article 2, may obtain a duplicate license by submitting to the Department a request for a duplicate license containing the individual's name and address, the number and expiration date of the license to be duplicated, the individual's signature, and a \$25 duplicate license fee.

Arizona Administrative Code Title 9 Chapter 16

ARTICLE 3. LICENSING HEARING AID DISPENSERS

R9-16-301. Definitions

In this Article, unless the context otherwise requires, "CE" means continuing education or the on-going process of receiving in-service education and training that directly relates to the practice of fitting and dispensing hearing aids as defined in A.R.S. § 36-1901(6).

R9-16-302. Appointed Committees

A. Advisory committee

1. The advisory committee members appointed by the Director pursuant to A.R.S. § 36-1902(A)(1) and (C) shall assist the Director by making recommendations to the Department regarding the following:
 - a. Hearing aid dispenser licensing program,
 - b. Resolution of any consumer complaint referred to the committee by the Department involving alleged unethical conduct or incompetence by a dispenser,
 - c. Hearing aid dispenser licensing examination,
 - d. Membership on the examining committee, and
 - e. Membership on the advisory committee.
2. Committee members shall serve a three-year term except for the Department's hearing aid dispenser program manager who shall serve as a permanent member of the committee.

B. Examining committee

The examining committee members appointed by the Director pursuant to A.R.S. § 36-1902(B)(4) and (D) shall assist the Director as follows:

1. Examine applicants for licensure,
2. Score delegated sections of the examination,
3. Provide testimony at administrative hearings related to the examination for licensure, and
4. Evaluate examination materials and procedures and make recommendations for change to the Department.

R9-16-303. Licensing Process

A. For a hearing aid dispenser license by examination:

1. At least 75 days before the date the Department gives a hearing aid dispenser examination, an applicant shall submit to the Department a nonrefundable \$250 application fee and an application on a form provided by the Department that contains:
 - a. The applicant's name, social security number, home address, and home telephone number;
 - b. If applicable, the name of the applicant's employer and the employer's business address and business telephone number;
 - c. Whether the applicant has been convicted in any state of a felony or of a misdemeanor involving moral turpitude and a list that includes each conviction;
 - d. Whether the applicant currently has or had, within the five years before the application date, a condition that impairs the applicant's ability to dispense hearing aids safely;
 - e. A statement that the applicant completed at least a four-year course in an accredited high school or passed the general education development tests and:
 - i. A list of each high school and post-secondary school attended; and
 - ii. A copy of the applicant's high school diploma, general education development diploma, or post-secondary degree;
 - f. A list of each state that has issued the applicant a hearing aid dispenser license;
 - g. Whether:
 - h. Any state has, within the two years before the application date, suspended or revoked a hearing aid dispenser license issued to the applicant; and
 1. ii. The applicant currently is not eligible to apply for a hearing aid dispenser license in any state due to a suspension or revocation; and
 - i. A statement signed by the applicant verifying the truthfulness of the information provided on the application form.
2. The Department shall give one hearing aid dispenser examination in August and may give additional examinations according to A.R.S. § 36-1923(C).

3. According to R9-16-315 and Table 1, the Department shall notify an applicant:
 - a. By certified mail to the applicant's address on the application, that the applicant does not meet the requirements of A.R.S. § 36-1923(A) and subsection (A)(1) and the Department denies a regular hearing aid dispenser license to the applicant; or
 - b. By regular mail to the applicant's address on the application, that the applicant meets the requirements of A.R.S. § 36-1923(A) and subsection (A)(1), and the date, time, and place of the examination.
4. According to R9-16-315 and Table 1, the Department shall notify an applicant whose examination results do not meet the requirements in R9-16-305:
 - a. By certified mail to the applicant's address on the application, unless the applicant provided a different address at the examination;
 - b. Of the applicant's examination results; and
 - c. That the Department denies a regular hearing aid dispenser license to the applicant.
5. According to R9-16-315 and Table 1, the Department shall notify an applicant whose examination results meet the requirements in R9-16-305:
 - a. By regular mail to the applicant's address on the application, unless the applicant provided a different address at the examination;
 - b. Of the applicant's examination results; and
 - c. That the Department approves a regular hearing aid dispenser license for the applicant.
6. The Department shall issue a regular hearing aid dispenser license to an applicant who is notified under subsection (A)(5) and who submits to the Department a nonrefundable \$100 license fee. If the applicant does not submit the license fee within 30 days after the date of the notification in subsection (A)(5), the Department shall consider the application withdrawn. The applicant may reapply by submitting the application fee and information required in subsection (A)(1) at least 75 days before the date the Department gives a hearing aid dispenser examination.
7. If an applicant who was notified under subsection (A)(3)(b) does not take the examination on the date provided in the notification, the Department shall consider the application withdrawn. The applicant may reapply by submitting the application fee and information required in subsection (A)(1) at least 75 days before the date the Department gives a hearing aid dispenser examination.
8. Except for an applicant who fails the hearing aid dispenser examination three times, an applicant who fails an examination may reapply to take the next examination by submitting to the Department the application fee and information required in subsection (A)(1) at least 75 days before the date the Department gives a hearing aid dispenser examination.
9. An applicant who fails the hearing aid dispenser examination three times may reapply by submitting the application fee and information required under subsection (A)(1) no earlier than one year after the date of the third examination failed by the applicant.
10. An applicant who is denied a regular hearing aid dispenser license by examination may appeal the denial according to A.R.S. Title 41, Chapter 6, Article 10.

B. For a hearing aid dispenser license by reciprocity:

1. An applicant shall submit to the Department an application packet that contains:
 - a. A nonrefundable \$100 application fee and a \$100 license fee;
 - b. An application on a form provided by the Department with the information required in subsections (A)(1)(a) through (A)(1)(h) and:
 - i. The name of each state that issued the applicant a current hearing aid dispenser license,
 - ii. The license number of each current hearing aid dispenser license, and
 - iii. The date each current hearing aid dispenser license was issued; and
 - c. For each state named in subsection (B)(1)(b)(i):
 - i. A statement, on the letterhead of the government agency that issued the hearing aid dispenser license and signed by an officer of the government agency, that the applicant holds a current hearing aid dispenser license in good standing;
 - ii. A copy of the state statutes and administrative rules for hearing aid dispensers;
 - iii. A copy of the written and practical portions of a hearing aid dispenser examination taken by the applicant or a detailed description of each portion of the examination;
 - iv. The government agency's statement of the applicant's score on each section of a hearing aid dispenser examination taken by the applicant, of the minimum passing score for each section, and of the minimum passing score for the examination; and
 - v. A copy of the applicant's current license.
2. Based on the information submitted under subsections (B)(1)(b) and (B)(1)(c), the Department shall determine whether:

- a. The content of a hearing aid dispenser examination taken by the applicant is substantially the same as the content of the Department's examination as described in R9-16-306;
 - b. The applicant's scores on the written and practical portions of a hearing aid dispenser examination taken by the applicant meet the requirements in R9-16-305 for passing the Department's hearing aid dispenser examination; and
 - c. The applicant meets the requirements in A.R.S. §§ 36-1922 and 36-1923(A) and subsections (B)(1), (B)(2)(a), and (B)(2)(b) for a regular hearing aid dispenser license by reciprocity.
3. If an applicant meets the requirements in the statutes and rules listed in subsection (B)(2)(c), the Department shall:
 - a. According to R9-16-315 and Table 1, notify the applicant:
 - i. By regular mail to the applicant's address on the application, and
 - ii. That the Department approves a regular hearing aid dispenser license by reciprocity for the applicant; and
 - b. Issue a regular hearing aid dispenser license by reciprocity to the applicant.
 4. If an applicant does not meet a requirement in the statutes and rules listed in subsection (B)(2)(c), the Department shall:
 - a. According to R9-16-315 and Table 1, notify the applicant:
 - i. By certified mail to the applicant's address on the application, and
 - ii. That the Department denies a regular hearing aid dispenser license by reciprocity to the applicant; and
 - b. Return the license fee to the applicant.
 5. An applicant who is denied a regular hearing aid dispenser license by reciprocity may:
 - a. Appeal the denial according to A.R.S. Title 41, Chapter 6, Article 10; and
 - b. Apply for:
 - i. A regular hearing aid dispenser license by examination by submitting the application fee and information required in subsection (A)(1) at least 75 days before the date the Department gives a hearing aid dispenser examination, or
 - ii. A temporary hearing aid dispenser license by submitting the application fee and information required in subsection (D)(1).

C. For an organization hearing aid dispenser license:

1. A corporation, partnership, trust, unincorporated association, or other organization with an Arizona business address shall submit to the Department a nonrefundable \$100 application fee, a \$100 license fee, and an application on a form provided by the Department that contains:
 - a. The name of the organization;
 - b. The organization's Arizona business name, address, and telephone number;
 - c. The name, address, and telephone number of the individual authorized by the organization to receive service of process in Arizona for the organization;
 - d. The name, business telephone number, and Arizona hearing aid dispenser license number of each hearing aid dispenser employed by the organization in Arizona;
 - e. Whether the organization or a hearing aid dispenser working for the organization has had a hearing aid dispenser license suspended or revoked by any state within two years before the application date;
 - f. Whether the organization or a hearing aid dispenser working for the organization currently is not eligible for licensing in any state due to a suspension or revocation; and
 - g. A statement verifying the truthfulness of the information provided on the application form and signed by:
 - h. If the organization is a corporation, two officers;
 1. ii. If the organization is a partnership, two partners;
 2. iii. If the organization is a trust, the trustee, or two trustees if the trust has multiple trustees;
 3. iv. If the organization is an unincorporated association, two officers;
 4. v. If the organization is a limited liability company, the designated manager, or two members if a manager is not designated;
 5. vi. If the organization is a political subdivision or government agency, the political subdivision head or agency head; or
 6. vii. If the organization is a sole proprietorship, the owner.
2. If an organization meets the requirements in A.R.S. § 36-1910 and subsection (C)(1), the Department shall:
 - a. According to R9-16-315 and Table 1, notify the organization:
 - i. By regular mail to the organization's Arizona business address on the application, and
 1. ii. That the Department approves a regular hearing aid dispenser license for the organization; and
 - b. Issue a regular hearing aid dispenser license to the organization.

3. If an organization does not meet the requirements in A.R.S. § 36-1910 and subsection (C)(1), the Department shall:
 - a. According to R9-16-315 and Table 1, notify the organization:
 - j. By certified mail to the organization's Arizona business address on the application, and
 1. ii. That the Department denies a regular hearing aid dispenser license to the organization; and
 - b. Return the license fee to the organization.
4. An organization notified under subsection (C)(3) may appeal the denial according to A.R.S. Title 41, Chapter 6, Article 10.

D. For a temporary hearing aid dispenser license:

1. An applicant shall submit to the Department a nonrefundable \$100 application fee and an application on forms provided by the Department that contain:
 - a. The information required in subsections (A)(1)(a) through (A)(1)(h);
 - b. The sponsor's name, business address, business telephone number, and Arizona hearing aid dispenser license number; and
 - c. A statement signed by the sponsor that the sponsor is a licensed hearing aid dispenser who agrees to train, supervise, and be responsible for the applicant's hearing aid dispenser practice.
2. According to R9-16-315 and Table 1, the Department shall notify:
 - a. An applicant who does not meet the requirements in A.R.S. § 36-1926 and subsection (D)(1):
 - i. By certified mail to the applicant's address on the application, and
 - ii. That the Department denies a temporary hearing aid dispenser license to the applicant; or
 - b. An applicant who meets the requirements in A.R.S. § 36-1926 and subsection (D)(1):
 - i. By regular mail to the applicant's address on the application, and
 - ii. That the Department approves a temporary hearing aid dispenser license for the applicant.
3. The Department shall issue a temporary hearing aid dispenser license to an applicant who is notified under subsection (D)(2)(b) and who submits to the Department a nonrefundable \$100 license fee. If the applicant does not submit the license fee within 30 days after the date of the notification in subsection (D)(2)(b), the Department shall consider the application withdrawn. The applicant may reapply by submitting the application fee and information required in subsection (D)(1).
4. An applicant notified under subsection (D)(2)(a) may appeal the denial according to A.R.S. Title 41, Chapter 6, Article 10.

R9-16-304. Sponsors

A sponsor of a temporary dispenser shall be responsible for the following:

1. Providing a minimum of 64 hours per month of onsite training and supervision. The supervision shall include coordinating, directing, watching, inspecting, and evaluating the fitting and dispensing activities of the temporary dispenser. The training shall directly relate to the type of training and education needed to pass the licensing examination as described in A.R.S. S 36-1924.
2. Maintaining a record, signed by the temporary dispenser, that details the date, time and content of the training and supervision provided to the temporary dispenser by the sponsor during the sponsorship period. The record shall be maintained and available for inspection by the Department for one year following the end of the sponsorship agreement.
3. When terminating a sponsorship agreement, complying with the following:
 - a. Provide a written statement to the temporary dispenser indicating the sponsorship agreement is terminated and that the temporary dispenser shall return the temporary license to the Department, and
 - b. Provide a copy of the written statement of termination and documentation that the temporary dispenser received the termination notice to the Department.
4. Complying with the other requirements in A.R.S. § 36-1926.01.

R9-16-305. Examination for Licensure

- A. An applicant, upon appearing at the examination site, shall present a current driver's license or other government-issued photo identification before the applicant shall be allowed to take the examination.
- B. An applicant who fails to arrive for, or is not allowed to take, the examination pursuant to subsection (A) may reapply for the next scheduled examination by submitting all fees and information required in R9-16-303(A).
- C. An applicant admitted late for the examination shall be limited to the time remaining to complete the examination.
- D. An applicant found cheating shall fail the examination and shall be ineligible to take the examination or renew a hearing aid license for two years.

- E. Each applicant shall bring another person who is not taking the examination to the examination to serve as a test subject along with impression material, cotton or foam dam, syringe, otoscope, and packing box to take an impression of the test subject's ear canal for the purpose of fitting a hearing aid. The applicant may bring additional equipment and materials to accomplish this task.
- F. Each applicant shall bring to the examination an otoscope, a listening tube, and a screwdriver to evaluate different types and models of hearing aids and to identify the major problem that renders the hearing aid inoperable. The applicant may bring additional equipment to accomplish this task.
- G. The successful applicant shall pass a practical and written examination with a combined average score of 75% or above for the two parts of the examination; however, no more than one section of either the practical or the written examination shall have a score under 75%. A rounding procedure shall not be used in determining any score.

R9-16-306. Structure of the Examination

- A. The written and practical part of the examination shall be administered on the same day. The practical part shall include the following subjects:
 - 1. Identification of medical aspects or conditions relating to abnormal middle ear problems,
 - 2. Oral exam on pure tone audiometry,
 - 3. Oral exam on speech audiometry,
 - 4. Obtaining air and bone conduction thresholds using simulators,
 - 5. Hearing aid maintenance and service,
 - 6. Selecting a particular hearing aid based on an audiogram review,
 - 7. Determining the effects of different earmold modifications, and
 - 8. Taking an earmold impression.
- B. The written part of the examination shall contain the following:
 - 1. Examination booklet provided by the International Hearing Society;
 - 2. Questions on the Arizona Revised Statutes, and Arizona and federal rules; and
 - 3. Questions on the evaluation and rehabilitation services for the hearing impaired in Arizona.

R9-16-307. License Renewal

- A. **This subsection applies to renewal of a hearing aid dispenser license initially issued under R9-16-303(A) or R9-16-303(B).**
 - 1. A hearing aid dispenser shall submit to the Department, before the license expiration date:
 - a. A nonrefundable \$100 license renewal fee,
 - b. Confirmation of CE hours according to R9-16-308(C) and R9-16-308(D), and
 - c. A license renewal application on a form provided by the Department that contains:
 - i. The hearing aid dispenser's name, home address, and home telephone number;
 - ii. If applicable, the name of the hearing aid dispenser's employer and the employer's business address and business telephone number;
 - iii. The hearing aid dispenser's license number and expiration date;
 - iv. Whether the hearing aid dispenser has been convicted of a felony or of a misdemeanor involving moral turpitude since the hearing aid dispenser's previous license application;
 - v. Whether the hearing aid dispenser has had, within two years before the renewal application date, a hearing aid dispenser license suspended or revoked by any state;
 - vi. Whether the hearing aid dispenser currently is under investigation by any state or government agency, has a disciplinary action pending in any state, or has an agreement with any state or government agency that resolves a violation by the hearing aid dispenser; and
 - vii. A statement signed by the hearing aid dispenser verifying the truthfulness of the information on the application form.
 - 2. According to A.R.S. § 36-1904(B), the Department shall allow a hearing aid dispenser to renew the license within 30 days after the expiration date of the license by submitting to the Department the information and renewal fee required in subsection (A)(1) and a \$25 late fee.
 - 3. If a hearing aid dispenser does not meet the requirements in A.R.S. § 36-1904 and subsections (A)(1) and (A)(2), the Department shall notify the hearing aid dispenser:
 - a. According to R9-16-315 and Table 1,
 - b. By certified mail to the hearing aid dispenser's address on the renewal application, and
 - c. That the Department denies a renewal license to the hearing aid dispenser.

4. If a hearing aid dispenser meets the requirements in A.R.S. § 36-1904 and subsections (A)(1) and (A)(2), the Department shall
 - a. Notify the hearing aid dispenser:
 - i. According to R9-16-315 and Table 1,
 - ii. By regular mail to the hearing aid dispenser's address on the renewal application, and
 - iii. That the Department approves a renewal license for the hearing aid dispenser; and
 - b. Issue a renewal license, valid for one year after the expiration date of the previous license, to the hearing aid dispenser.
5. An individual notified under subsection (A)(3) may appeal the denial of a renewal license according to A.R.S. Title 41, Chapter 6, Article 10.
6. If a hearing aid dispenser does not submit to the Department, within 30 days after the expiration date of the previous license, the renewal fee and information required in subsection (A)(1) and the late fee required in subsection (A)(2), the license is nonrenewable. The individual may apply for a new license under subsection (A)(7) or subsection (A)(8).
7. An individual whose hearing aid dispenser license is nonrenewable under subsection (A)(6) may apply for a new license by submitting to the Department, within one year after the expiration date of the nonrenewable license:
 - a. A nonrefundable \$100 application fee,
 - b. A \$100 license fee,
 - c. The information required in R9-16-303(A)(1)(a) through R9-16-303(A)(1)(h), and
 - d. Confirmation of CE hours according to R9-16-308(C) and R9-16-308(D).
8. An individual who applies for a new license more than one year after the expiration date of a license that is nonrenewable under subsection (A)(6) shall follow the licensing process in R9-16-303(A).

B. This subsection applies to renewal of a hearing aid dispenser license initially issued under R9-16-303(C).

1. An organization renewing a hearing aid dispenser license shall submit to the Department the information required in R9-16-303(C)(1)(a) through R9-16-303(C)(1)(g) and a nonrefundable \$100 renewal fee. According to A.R.S. § 36-1904(B), the Department shall assess a \$25 late fee for a renewal application submitted within 30 days after the expiration of the previous license.
2. If an organization meets the requirements in A.R.S. § 36-1910 and subsection (B)(1), the Department shall:
 - a. Notify the organization:
 - i. According to R9-16-315 and Table 1,
 - ii. By regular mail to the organization's address on the application, and
 - iii. That the Department approves a renewal license for the organization; and
 - b. Issue a renewal license to the organization.
3. If an organization does not meet the requirements in A.R.S. § 1910 and subsection (B)(1), the Department shall notify the organization:
 - a. According to R9-16-315 and Table 1,
 - b. By certified mail to the organization's address on the application, and
 - c. That the Department denies a renewal license to the organization.
4. An organization notified under subsection (B)(3) may appeal the denial of a renewal license according to A.R.S. Title 41, Chapter 6, Article 10.
5. If an organization does not submit to the Department, within 30 days after the expiration of the previous license, the renewal fee and information required in subsection (B)(1) and the \$25 late fee, the license is nonrenewable. The organization may apply for a new organization hearing aid dispenser license according to subsection R9-16-303(C)(1).

C. This subsection applies to renewal of an initial temporary hearing aid dispenser license issued under R9-16-303(D).

1. An individual whose temporary hearing aid dispenser license expires according to A.R.S. §§ 36-1926(B) or 36-1926(G) may renew the license according to subsection (C)(2) without taking the next hearing aid dispenser examination.
2. According to A.R.S. §§ 36-1926(E) and 36-1926(F), the Department shall allow one renewal of a temporary hearing aid dispenser license by submitting to the Department, by the expiration date of the initial temporary hearing aid dispenser license, a nonrefundable \$100 renewal fee and the following:
 - a. The individual's name, home address, and home telephone number;
 - b. The name of the individual's employer and the employer's business address and business telephone number; and
 - c. The information required in R9-16-303(D)(1)(a) through R9-16-303(D)(1)(c).
3. If an individual meets the requirements in A.R.S. § 36-1926 and subsection (C)(2), the Department shall:
 - a. Notify the individual:

- i. According to R9-16-315 and Table 1,
 - ii. By regular mail to the individual's address on the renewal application, and
 - iii. That the Department approves a renewal license for the individual; and
 - b. Issue a renewal license to the individual.
4. If an individual does not meet the requirements in A.R.S. § 36-1926 and subsection (C)(2), the Department shall and notify the individual:
 - a. According to R9-16-315 and Table 1,
 - b. By certified mail to the individual's address on the renewal application, and
 - c. That the Department denies a renewal license to the individual.
5. An individual notified under subsection (C)(4) may appeal the denial of a renewal license according to A.R.S. Title 41, Chapter 6, Article 10.
6. If an individual does not submit the renewal fee and information required in subsection (C)(2) by the expiration date of the initial temporary hearing aid dispenser license, the license is nonrenewable. The individual may apply for a new temporary hearing aid dispenser license by submitting the application fee and information required in R9-16-303(D)(1).
7. An individual whose initial temporary hearing aid dispenser license terminates according to A.R.S. § 36-1926(D) may apply for a new temporary hearing aid dispenser license by submitting the application fee and information required in subsection R9-16-303(D)(1).

R9-16-308. Continuing Education Licensure Requirements

- A. Each dispenser shall complete eight hours of continuing education approved under R9-16-309 within 12 months of the effective date of the regular license.
- B. A CE hour shall contain 60 minutes of actual course work instruction.
- C. If the CE course work complies with the preapproved provisions of R9-16-309 (B) or (C), the dispenser shall complete a CE form provided by the Department that contains the information required in subsections (D)(1), (2), (3), (7), (8) and (9).
- D. A dispenser submitting confirmation of CE hours earned which do not comply with the preapproved provisions of R9-16-309(B) or (C) shall complete the CE form that contains the following information:
 1. Name, business address, and license number of the dispenser;
 2. Name of the organization providing the course work, date, and location;
 3. Specific courses attended;
 4. Detailed description of each course's content;
 5. Description of each course's educational objectives;
 6. Description of each instructor's education, training and experience background;
 7. Number of CE hours earned for each course;
 8. Statement indicating if the course work was preapproved in accordance with R9-16-309; and
 9. Signed statement under penalty of perjury that the dispenser attended the CE course and that all information on the CE form is complete and accurate.
- E. The Director shall approve course work that meets the course requirements outlined in R9-16-309(A). The Director shall notify the dispenser stating whether or not the CE hours have been approved.
- F. The Director shall not give a dispenser credit for CE course work which is substantially the same in content to courses utilized to meet the CE requirements within the preceding year.
- G. A dispenser who does not complete eight hours of approved CE may be issued a renewal license if the dispenser applies for and obtains a waiver issued by the Director in accordance with R9-16-310.
- H. The dispenser shall maintain, for a period of three years, CE receipts, canceled checks, certificates, attendance sheets, or other documentation which establishes completion of the CE requirement. The Department may randomly audit the dispenser's compliance with the CE requirements.

R9-16-309. Continuing Education Course Requirements

- A. For course work to be eligible for preapproval for CE hours, the course content shall directly relate to the practice of fitting and dispensing hearing aids and the educational objectives shall exceed an introductory level of knowledge as it relates to fitting and dispensing hearing aids. The course work shall include advances, within the last five years, in the field as follows:
 - 1. Procedures in the selection and fitting of hearing aids,
 - 2. Pre- and post-fitting management of clients,
 - 3. Instrument circuitry and acoustic performance data,
 - 4. Earmold design and modification contributing to improved client performance,
 - 5. Audiometric equipment or testing techniques which demonstrate an improved ability to identify and evaluate hearing loss,
 - 6. Auditory rehabilitation,
 - 7. Ethics,
 - 8. Federal and state statutes or rules, or
 - 9. Assistive listening devices
- B. Course work that meets the requirements of subsection (A) and is endorsed or sponsored by the following organizations shall be deemed preapproved for CE hours:
 - 1. Arizona Hearing Aid Society,
 - 2. Arizona Speech-Language-Hearing Association,
 - 3. American Speech-Language-Hearing Association,
 - 4. International Hearing Society,
 - 5. National Institute of Hearing Instrument Studies,
 - 6. National Society of Hearing Professionals,
 - 7. American Academy of Audiology,
 - 8. Academy of Dispensing Audiologists,
 - 9. Arizona Society of Otolaryngology-Head and Neck Surgery, or
 - 10. American Academy of Otolaryngology-Head and Neck Surgery.
- C. The Director shall preapprove other CE course work that complies with subsection (A) upon the following:
 - 1. The organization providing the course work shall submit the following information 45 days before the course is offered:
 - a. Name, date, and location of the CE course work;
 - b. Detailed description of the course content;
 - c. Description of the educational objectives;
 - d. Description of each instructor's education, training, and experience background; and
 - e. CE hours offered for completing the course.
 - 2. The provider shall report any change in the course content or instructor to the Department before the course begins.
- D. The Director shall withdraw the approval of any CE provider for failure to comply with the provisions of this Section.

R9-16-311. Dispenser Operating Guidelines

- A. A dispenser shall conduct audiometric tests, before selecting a hearing aid for a prospective user, that provide detailed information about the client's hearing loss as follows:
 - 1. Type, degree, and configuration of hearing loss;
 - 2. Ability, as measured by the percentage of words the client is able to repeat correctly, to discriminate speech; and
 - 3. Client's most comfortable and uncomfortable loudness levels in decibels.
- B. Audiometric testing may be excluded prior to selling a client a hearing aid if the client presents to the dispenser the information outlined in subsection (A) which was obtained within the last 12 months for an adult or within the last six months for a person under the age of 18.
- C. Audiometric tests listed in subsection (A) that cannot be performed due to the young age or mental or physical disability of the client may be excluded; however, documentation shall be maintained by the dispenser for three years that supports the exclusion of the specific audiometric tests.
- D. Prior to any hearing aid sale, the dispenser shall evaluate the performance characteristics of the hearing aid for the purpose of assessing the degree of benefit to the client.
- E. Prior to any hearing aid sale, the dispenser shall follow the requirements contained in 21 CFR 801.420 and 801.421, April 1, 1989, and no further amendments, incorporated herein by reference and on file with the Office of the Secretary of State.
- F. In addition to complying with the requirements in A.R.S. § 36- 1932, the bill of sale, signed by the client, shall include the following:
 - 1. Detailed description of warranty information,
 - 2. Year hearing aid was manufactured, and
 - 3. Full disclosure of the conditions of any offer of a trial period with a money back guarantee or partial refund. A trial period shall not include any time that the hearing aid is in the possession of the dispenser or the manufacturer.
- G. A dispenser shall notify the Director in writing of any change in business address within 30 days of the change.

R9-16-312. Inspection Requirements

- A. A dispenser's place of business shall have available for inspection by the Department the following:
 - 1. Audiometer that performs the audiometric tests as outlined in R9-16-311(A);
 - 2. Documentation which provides evidence of annual calibration of the audiometer in accordance with the American National Institute Standards, S3.6-1989, Standards Secretariat, c/o Acoustical Society of America, 335 East 45th Street, New York, New York 10017-3483, May 23, 1989, and no further amendments, incorporated herein by reference and on file with the Office of the Secretary of State;
 - 3. Customer record for each client which shall include the following:
 - a. Written statement from a licensed physician that the customer has medical clearance to use hearing aids or a medical waiver signed by the customer 18 years of age or older,
 - b. Copy of the bill of sale,
 - c. Audiometric test results by date performed and signed by the person performing the tests, and
 - d. Contracts, agreements, warranties, trial periods, or other documents involving the client.
- B. The records referenced in subsection (A) shall be retained for 36 months from date of sale.

R9-16-313. Complaint Procedure

- A. All complaints filed against a dispenser relating to the practice of fitting and dispensing hearing aids shall be submitted in writing to the Department. The complainant shall submit a statement of the facts and provide copies of all documentation which may support the alleged violation of state statutes or rules.
- B. The Department shall send a certified letter to the dispenser describing each complaint. The dispenser shall provide to the Department, within 15 days of receipt of the certified letter, a written response addressing each allegation.
- C. The Department shall review each complaint and the corresponding response by the dispenser. A certified letter shall be sent to both the complainant and the dispenser notifying them of any action to be taken by the Department.
- D. A dispenser may appeal an action taken by the Department in accordance with 9 A.A.C. 1, Article 1, Rules of Practice and Procedures.

R9-16-314. Enforcement Actions

- A. In accordance with A.R.S. § 36-1934, the following factors shall be considered in determining the length of suspension or revocation, or conditions thereof, or the level of disciplinary action for any violation of A.R.S., Title 36, Chapter 17 or this Article:
 - 1. Severity of the offense;
 - 2. Danger to the public;
 - 3. Number of specified offenses;
 - 4. Degree of damage, physical or otherwise, to the consumer;
 - 5. Number and nature of prior offenses;
 - 6. Degree of cooperation displayed in resolving past or recent complaints and violations;
 - 7. Degree of negligence pertaining to any violation; and
 - 8. Other mitigating or aggravating circumstances.
- B. Upon consideration of the factors outlined in subsection (A), the Director may revoke or suspend a license permanently or for a fixed period and may impose the following:
 - 1. Suspend all or certain areas of the dispenser's practice where the dispenser has shown unethical conduct or incompetence in the conduct of the practice;
 - 2. Restrict the practice of a dispenser to only those activities that are directly supervised by a licensed dispenser; and
 - 3. Prescribe a period of probation in which the dispenser shall obtain a specified number of CE hours in areas where the dispenser has shown negligence, unethical behavior, or incompetence in the conduct of the practice.

R9-16-315. Time-frames

- A. For purposes of this Section, "application packet" means the information, documents, and fees required by the Department for:
 - 1. Approval to take an examination,
 - 2. An initial regular license or renewal of a regular license,
 - 3. An initial temporary license or renewal of a temporary license, or
 - 4. Approval of a continuing education course that is requested separately from an application for renewal of a license.
- B. The overall time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is specified in Table 1. The applicant and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.
- C. The administrative completeness review time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Article is specified in Table 1.
 - 1. The administrative completeness review time-frame begins:
 - a. For approval to take an examination, on the date the Department receives an application packet;
 - b. For approval of a regular license by examination, when the applicant takes the examination; and
 - c. For approval of a regular license by reciprocity, a regular license for a business, an initial temporary license, a renewal of a regular license, a renewal of a temporary license, or approval of a continuing education course that is requested separately from an application for renewal of a license, on the date the Department receives an application packet.
 - 2. When an application packet is complete, or when an applicant for approval of a regular license by examination submits an examination for scoring, the Department shall provide a written notice of administrative completeness to the applicant.
 - 3. If the Department grants an approval during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.
 - 4. If an application packet is incomplete, the Department shall provide to the applicant a written notice of deficiencies specifying the missing documents or incomplete information. The administrative completeness review time-frame and the overall time-frame are suspended from the date of the notice until the date the Department receives a complete application packet from the applicant.
 - 5. If the applicant fails to submit to the Department all of the items and information listed in the notice of deficiencies within 90 days from the date of the notice of deficiencies, the Department shall consider the application withdrawn.

- D. The substantive review time-frame described in A.R.S. § 41-1072 is specified in Table 1 and begins on the date of the notice of administrative completeness.
1. During the substantive review time-frame, the Department may make one comprehensive written request for additional documents or information, or a supplemental request for additional documents or information by mutual written agreement with the applicant.
 2. If the Department provides to the applicant a comprehensive written request or a supplemental request for additional documents or information, the substantive review time-frame and the overall time-frame are suspended from the date of the request until the date the Department receives all of the documents or information requested.
 3. If the applicant fails to submit to the Department the documents or information requested by the Department in a comprehensive written request or supplemental request for additional documents or information within 90 days from the date of the request, the Department shall consider the application withdrawn.

Table 1. Time-frames (in calendar days)

Type of Approval	Statutory Authority	Overall Time-frame	Administrative Completeness Review Time-frame	Substantive Review Time-frame
Approval to take an examination (R9-16-303(A)(1) and (A)(2))	A.R.S. §§ 36-1904, 36-1923	60	30	30
Regular License by Examination (R9-16-303(A)(3), (A)(4), and (A)(5))	A.R.S. §§ 36-1904, 36-1923	60	30	30
Regular License by Reciprocity (R9-16-303(B))	A.R.S. §§ 36-1904, 36-1922	60	30	30
Regular License for a Business (R9-16-303(C))	A.R.S. §§ 36-1904, 36-1910	60	30	30
Initial Temporary License (R9-16-303(D))	A.R.S. § 36-1926	60	30	30
Renewal of a Temporary License (R9-16-303(D))	A.R.S. § 36-1926	60	30	30
Renewal of a Regular License (R9-16-303(C) and R9-16-307)	A.R.S. §§ 36-1904, 36-1904, 36-1910	60	30	30
Approval of a continuing education course that is requested separately from an application for renewal of a license (R9-16-308 and R9-16-309)	A.R.S. § 36-1904(C)	60	30	30

R9-16-316. Duplicate License Fee

- A. An individual licensed under 9 A.A.C. 16, Article 3, may obtain a duplicate license by submitting to the Department a request for a duplicate license containing the individual's name and address, the number and expiration date of the license to be duplicated, the individual's signature, and a nonrefundable \$25 duplicate license fee.
- B. An organization licensed under 9 A.A.C. 16, Article 3, may obtain a duplicate license by submitting to the Department a request for a duplicate license containing the organization's name and address, the number and expiration date of the license to be duplicated, the titles and signatures of the individuals specified in R9-16-303(C)(1)(g) for the type of organization requesting the duplicate license, and a nonrefundable \$25 duplicate license fee.

21CFR801.420

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)
PART 801--LABELING--Table of Contents
Subpart H--Special Requirements for Specific Devices

Sec. 801.420 Hearing aid devices; professional and patient labeling.

(a) Definitions for the purposes of this section and Sec. 801.421.

(a-1) Hearing aid means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(a-2) Ear specialist means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(a-3) Dispenser means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(a-4) Audiologist means any person qualified by training and experience to **specialize in the evaluation and rehabilitation** of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(a-5) Sale or purchase includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(a-6) Used hearing aid means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) Label requirements for hearing aids. Hearing aids shall be clearly and permanently marked with:

(b-1) The **name of the manufacturer** or distributor, the **model name** or number, the **serial number**, and the **year of manufacture**.

(b-2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) Labeling requirements for hearing aids—

(c-1) General. All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be **developed** by the manufacturer or distributor, shall **accompany** the hearing aid, and shall be **provided** to the prospective user by the dispenser of the hearing aid in accordance with Sec. 801.421(c).

The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

- (i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.
- (ii) Information on the function of all controls intended for user adjustment.
- (iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.
- (iv) Specific instructions for:
 - (a) Use of the hearing aid.
 - (b) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.
 - (c) Replacing or recharging the batteries, including a generic designation of replacement batteries.
- (v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

- (vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.
- (vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).
- (viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.
- (ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.
- (x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.
- (xi) The warning statement required by paragraph (c)(2) of this section.
- (xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section.
- (xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device.

(c-2) Warning statement. The User Instructional Brochure shall contain the following warning statement:

Warning to Hearing Aid Dispensers

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

- (i) Visible congenital or traumatic deformity of the ear.
- (ii) History of active drainage from the ear within the previous 90 days.
- (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
- (iv) Acute or chronic dizziness.
- (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- (viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(c-3) Notice for prospective hearing aid users. The User Instructional Brochure shall contain the following notice:

Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit 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.

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

Children with hearing loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth

of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(c-4) Technical data.

Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-1996 (ASA 70-1996) (Revision of ANSI S3.22-1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993, or are available for inspection at the Regulations Staff, CDRH (HFZ-215), FDA, 1350 Piccard Dr., rm. 240, Rockville, MD 20850, and at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF-Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (ACG aids only).
- (xii) Attack and release times (ACG aids only).

(c-5) Statement if hearing aid is used or rebuilt. If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(c-6) Statements in User Instructional Brochure other than those required. A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

- (i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and
- (ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) Submission of all labeling for each type of hearing aid.

Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK-116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

21CFR801.421

TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
(CONTINUED)
PART 801--LABELING--Table of Contents
Subpart H--Special Requirements for Specific Devices

Sec. 801.421 Hearing aid devices; conditions for sale.

(a) Medical evaluation requirements--

- (a-1) General. Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser **shall not sell a hearing aid unless** the prospective user has presented to the hearing aid dispenser a **written statement signed by a licensed physician** that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical **evaluation must have taken place within the preceding 6 months.**
- (a-2) Waiver to the medical evaluation requirements. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an **opportunity to waive the medical evaluation requirement** of paragraph(a)(1) of this section **provided that the hearing aid dispenser:**
- (a-2-i) **Informs** the prospective user that the exercise of the waiver is **not in the user's best health interest;**
 - (a-2-ii) **Does not in any way actively encourage** the prospective user **to waive** such a medical evaluation; and
 - (a-2-iii) Affords the prospective user the **opportunity to sign** the following statement:

I have been advised by ----- (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) Opportunity to review User Instructional Brochure. Before signing any statement under paragraph (a)(2)(iii) of this section **and before the sale** of a hearing aid to a prospective user, the hearing aid dispenser shall:

- (b-1) **Provide the prospective user** a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;
- (b-2) **Review the content of the User Instructional Brochure** with the prospective user orally, or in the predominate method of communication used during the sale;
- (b-3) **Afford the prospective user an opportunity to read** the User Instructional Brochure.

(c) Availability of User Instructional Brochure.

- (c-1) **Upon request** by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, **provide a copy of the User Instructional Brochure for the hearing aid** or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.
- (c-2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:
- (c-2-i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;
 - (c-2-ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) **Recordkeeping.** The dispenser shall **retain for 3 years after the dispensing** of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) **Exemption for group auditory trainers.** Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

Arizona Revised Statutes

[Title 32 – Professions and Occupations](#)

Chapter 32	HEALTH PROFESSIONALS
Article 1	General Provisions
32-3201	Definitions
32-3211	Medical records; protocol; unprofessional conduct; corrective action; exemptions

32-3201. [Definitions](#)

In this chapter, unless the context otherwise requires:

1. "Health profession regulatory board" means any board that regulates one or more health professionals in this state.
2. **"Health professional" means a person who is certified or licensed pursuant to** chapter 7, 8, 11, 13, 14, 15, 15.1, 16, 17, 18, 19, 19.1, 21, 25, 28, 29, 33, 34, 35, 39, 41 or 42 of this title, title 36, chapter 4, article 6, title 36, chapter 6, article 7 or **title 36, chapter 17.**
3. **"Medical record" has the same meaning prescribed in section 12-2291** but does not include prescription orders.

32-3211. [Medical records; protocol; unprofessional conduct; corrective action; exemptions](#)

A. A health professional must prepare a written protocol for the secure storage, transfer and access of the medical records of the health professional's patients. At a minimum the protocol **must specify:**

1. If the health professional terminates or sells the health professional's practice and the patient's medical records will not remain in the same physical location, the procedure by which the health professional shall notify each patient in a timely manner before the health professional terminates or sells the health professional's practice in order to inform the patient regarding the future location of the patient's medical records and how the patient can access those records.
2. The procedure by which the health professional may dispose of unclaimed medical records after a specified period of time and after the health professional has made good faith efforts to contact the patient.
3. How the health professional shall timely respond to requests from patients for copies of their medical records or to access their medical records.

B. The protocol prescribed in subsection A of this section **must comply with the relevant requirements of title 12, chapter 13, article 7.1 regarding medical records.**

C. A health professional shall indicate compliance with the requirements of this section on the health professional's application for relicensure in a manner prescribed by the health professional's regulatory board.

D. A health professional who does not comply with this section commits an act of unprofessional conduct.

E. In addition to taking disciplinary action against a health professional who does not comply with this section, the health professional's regulatory board may take corrective action regarding the proper storage, transfer and access of the medical records of the health professional's patients. For the purposes of this subsection, corrective action does not include taking possession or management of the medical records.

F. For the purposes of this section, health professional does not include a veterinarian.

G. This section does not apply to a health professional who is employed by a health care institution as defined in [section ARS §36-401](#)ⁱ that is responsible for the maintenance of the medical records.

Arizona Revised Statutes Title 12 – Courts and Civil Proceedings

Chapter 13 EVIDENCE

Article 7.1 Medical Records

12-2291	Definitions
12-2292	Confidentiality of medical records and payment records
12-2293	Release of medical records and payment records to patients and health care decision makers; definition
12-2294	Release of medical records and payment records to third parties
12-2294.01	Release of medical records or payment records to third parties pursuant to subpoena
12-2295	Charges
12-2296	Immunity
12-2297	Retention of records

12-2291. Definitions

In this article, unless the context otherwise requires:

1. "Contractor" means an agency or service that duplicates medical records on behalf of health care providers.
2. "Department" means the department of health services.
3. "Health care decision maker" means an individual who is authorized to make health care treatment decisions for the patient, including a parent of a minor or an individual who is authorized pursuant to section 8-514.05, title 14, chapter 5, article 2 or 3 or section 36-3221, 36-3231 or 36-3281.
4. "Health care provider" means:
 - (a) A person who is licensed pursuant to title 32 and who maintains medical records.
 - (b) A health care institution as defined in section 36-401.
 - (c) An ambulance service as defined in section 36-2201.
 - (d) A health care services organization licensed pursuant to title 20, chapter 4, article 9.
5. "Medical records" means all communications related to a patient's physical or mental health or condition that are recorded in any form or medium and that are maintained for purposes of patient diagnosis or treatment, including medical records that are prepared by a health care provider or by other providers. Medical records do not include materials that are prepared in connection with utilization review, peer review or quality assurance activities, including records that a health care provider prepares pursuant to section 36-441, 36-445, 36-2402 or 36-2917. Medical records do not include recorded telephone and radio calls to and from a publicly operated emergency dispatch office relating to requests for emergency services or reports of suspected criminal activity, but shall include communications that are recorded in any form or medium between emergency medical personnel and medical personnel concerning the diagnosis or treatment of a person.
6. "Payment records" means all communications related to payment for a patient's health care that contain individually identifiable information.
7. "Source data" means information that is summarized, interpreted or reported in the medical record, including x-rays and other diagnostic images.

12-2292. Confidentiality of medical records and payment records

- A. Unless otherwise provided by law, all medical records and payment records, and the information contained in medical records and payment records, are privileged and confidential. A health care provider may only disclose that part or all of a patient's medical records and payment records as authorized by state or federal law or written authorization signed by the patient or the patient's health care decision maker.
- B. This article does not limit the effect of any other federal or state law governing the confidentiality of medical records and payment records.

12-2293. Release of medical records and payment records to patients and health care decision makers; definition

- A. Except as provided in subsections B and C of this section, on the written request of a patient or the patient's health care decision maker for access to or copies of the patient's medical records and payment records, the health care provider in possession of the record shall provide access to or copies of the records to the patient or the patient's health care decision maker.
- B. A health care provider may deny a request for access to or copies of medical records or payment records if a health professional determines that either:
 1. Access by the patient or the patient's health care decision maker is reasonably likely to endanger the life or physical safety of the patient or another person.

2. The records make reference to a person other than a health professional and access by the patient or the patient's health care decision maker is reasonably likely to cause substantial harm to that other person.
3. Access by the patient's health care decision maker is reasonably likely to cause substantial harm to the patient or another person.
4. Access by the patient or the patient's health care decision maker would reveal information obtained under a promise of confidentiality with someone other than a health professional and access would be reasonably likely to reveal the source of the information.

C. A health care provider may deny a request for access to or copies of medical records or payment records if the health care provider determines that either:

1. The information was created or obtained in the course of clinical research and the patient or the patient's health care decision maker agreed to the denial of access when consenting to participate in the research and was informed that the right of access will be reinstated on completion of the research.
2. A health care provider is a correctional institution or is acting under the direction of a correctional institution and access by a patient who is an inmate in the correctional institution would jeopardize the health, safety, security, custody or rehabilitation of the patient or other inmates or the safety of any officer, employee or other person at the correctional institution or of a person who is responsible for transporting the inmate.

D. If the health care provider denies a request for access to or copies of the medical records or payment records, the health care provider must note this determination in the patient's records and provide to the patient or the patient's health care decision maker a written explanation of the reason for the denial of access. The health care provider must release the medical records or payment records information for which there is not a basis to deny access under subsection B of this section.

E. For the purposes of this section, "health professional" has the same meaning prescribed in section 32-3201.

12-2294. Release of medical records and payment records to third parties

A. A health care provider shall disclose medical records or payment records, or the information contained in medical records or payment records, without the patient's written authorization as otherwise required by law or when ordered by a court or tribunal of competent jurisdiction.

B. A health care provider may disclose medical records or payment records, or the information contained in medical records or payment records, pursuant to written authorization signed by the patient or the patient's health care decision maker.

C. A health care provider may disclose medical records or payment records or the information contained in medical records or payment records without the written authorization of the patient or the patient's health care decision maker as otherwise authorized by state or federal law, including the health insurance portability and accountability act privacy standards (45 Code of Federal Regulations part 160 and part 164, subpart E), or as follows:

1. To health care providers who are currently providing health care to the patient for the purpose of diagnosis or treatment of the patient.
2. To health care providers who have previously provided treatment to the patient, to the extent that the records pertain to the provided treatment.
3. To ambulance attendants as defined in section 36-2201 for the purpose of providing care to or transferring the patient whose records are requested.
4. To a private agency that accredits health care providers and with whom the health care provider has an agreement requiring the agency to protect the confidentiality of patient information.
5. To a health profession regulatory board as defined in section 32-3201.
6. To health care providers for the purpose of conducting utilization review, peer review and quality assurance pursuant to section 36-441, 36-445, 36-2402 or 36-2917.
7. To a person or entity that provides billing, claims management, medical data processing, utilization review or other administrative services to the patient's health care providers and with whom the health care provider has an agreement requiring the person or entity to protect the confidentiality of patient information.
8. To the legal representative of a health care provider in possession of the medical records or payment records for the purpose of securing legal advice.
9. To the patient's third party payor or the payor's contractor.
10. To the industrial commission of Arizona or parties to an industrial commission claim pursuant to title 23, chapter 6.

D. A health care provider may disclose a deceased patient's medical records or payment records or the information contained in medical records or payment records to the patient's health care decision maker at the time of the patient's death. A health care provider also may disclose a deceased patient's medical records or payment records or the information contained in medical records or payment records to the personal representative or administrator of the estate of a deceased patient, or if a personal representative or administrator has not been appointed, to the following persons in the following order of priority, unless the

deceased patient during the deceased patient's lifetime or a person in a higher order of priority has notified the health care provider in writing that the deceased patient opposed the release of the medical records or payment records:

1. The deceased patient's spouse, unless the patient and the patient's spouse were legally separated at the time of the patient's death.
2. The acting trustee of a trust created by the deceased patient either alone or with the deceased patient's spouse if the trust was a revocable inter vivos trust during the deceased patient's lifetime and the deceased patient was a beneficiary of the trust during the deceased patient's lifetime.
3. An adult child of the deceased patient.
4. A parent of the deceased patient.
5. An adult brother or sister of the deceased patient.
6. A guardian or conservator of the deceased patient at the time of the patient's death.

E. A person who receives medical records or payment records pursuant to this section shall not disclose those records without the written authorization of the patient or the patient's health care decision maker, unless otherwise authorized by law.

F. If a health care provider releases a patient's medical records or payment records to a contractor for the purpose of duplicating or disclosing the records on behalf of the health care provider, the contractor shall not disclose any part or all of a patient's medical records or payment records in its custody except as provided in this article. After duplicating or disclosing a patient's medical records or payment records on behalf of a health care provider, a contractor must return the records to the health care provider who released the medical records or payment records to the contractor.

12-2294.01. Release of medical records or payment records to third parties pursuant to subpoena

A. A subpoena seeking medical records or payment records shall be served on the health care provider and any party to the proceedings at least ten days before the production date on the subpoena.

B. A subpoena that seeks medical records or payments records must meet one of the following requirements:

1. The subpoena is accompanied by a written authorization signed by the patient or the patient's health care decision maker.
2. The subpoena is accompanied by a court or tribunal order that requires the release of the records to the party seeking the records or that meets the requirements for a qualified protective order under the health insurance portability and accountability act privacy standards (42 Code of Federal Regulations section 164.512(e)).
3. The subpoena is a grand jury subpoena issued in a criminal investigation.
4. The subpoena is issued by a health profession regulatory board as defined in section 32-3201.
5. The health care provider is required by another law to release the records to the party seeking the records.

C. If a subpoena does not meet one of the requirements of subsection B of this section, a health care provider shall not produce the medical records or payment records to the party seeking the records, but may either file the records under seal pursuant to subsection D of this section, object to production under subsection E of this section or file a motion to quash or modify the subpoena under rule 45 of the Arizona rules of civil procedure.

D. It is sufficient compliance with a subpoena issued in a court or tribunal proceeding if a health care provider delivers the medical records or payment records under seal as follows:

1. The health care provider may deliver by certified mail or in person a copy of all the records described in the subpoena by the production date to the clerk of the court or tribunal or if there is no clerk then to the court or tribunal, together with the affidavit described in paragraph 4 of this subsection.
2. The health care provider shall separately enclose and seal a copy of the records in an inner envelope or wrapper, with the title and number of the action, name of the health care provider and date of the subpoena clearly inscribed on the copy of the records. The health care provider shall enclose the sealed envelope or wrapper in an outer envelope or wrapper that is sealed and directed to the clerk of the court or tribunal or if there is no clerk then to the court or tribunal.
3. The copy of the records shall remain sealed and shall be opened only on order of the court or tribunal conducting the proceeding.
4. The records shall be accompanied by the affidavit of the custodian or other qualified witness, stating in substance each of the following:
 - (a) That the affiant is the duly authorized custodian of the records and has authority to certify the records.
 - (b) That the copy is a true complete copy of the records described in the subpoena.
 - (c) If applicable, that the health care provider is subject to the confidentiality requirements in 42 United States Code sections 290dd-3 and 290ee-3 and applicable regulations and that those confidentiality requirements may apply to the requested records. The affidavit shall request that the court make a determination, if required under applicable federal law and regulations, as to the confidentiality of the records submitted.
 - (d) If applicable, that the health care provider has none of the records described or only part of the records described in the subpoena.

5. The copy of the records is admissible in evidence as provided under rule 902(11), Arizona rules of evidence. The affidavit is admissible as evidence of the matters stated in the affidavit and the matters stated are presumed true. If more than one person has knowledge of the facts, more than one affidavit may be made. The presumption established by this paragraph is a presumption affecting the burden of producing evidence.

E. If a subpoena does not meet one of the requirements of subsection B of this section or if grounds for objection exist under rule 45 of the Arizona rules of civil procedure, a health care provider may file with the court or tribunal an objection to the inspection or copying of any or all of the records as follows:

1. On filing an objection, the health care provider shall send a copy of the objection to the patient at the patient's last known address, to the patient's attorney if known and to the party seeking the records, unless after reasonable inquiry the health care provider cannot determine the last known address of the patient.
2. On filing the objection, the health care provider has no further obligation to assert a state or federal privilege pertaining to the records or to appear or respond to a motion to compel production of records, and may produce the records if ordered by a court or tribunal. If an objection is filed, the patient or the patient's attorney is responsible for asserting or waiving any state or federal privilege that pertains to the records.
3. If an objection is filed, the party seeking production may request an order compelling production of the records. If the court or tribunal issues an order compelling production, a copy of the order shall be provided to the health care provider. On receipt of the order, the health care provider shall produce the records.
4. If applicable, an objection shall state that the health care provider is subject to the confidentiality requirements in 42 United States Code sections 290dd-3 and 290ee-3, shall state that the records may be subject to those confidentiality requirements and shall request that the court make a determination, if required under applicable federal law and regulations, on whether the submitted records are subject to discovery.

F. If a party seeking medical records or payment records wishes to examine the original records maintained by a health care provider, the health care provider may permit the party to examine the original records if the subpoena meets one of the requirements of subsection B of this section. The party seeking the records also may petition a court or tribunal for an order directing the health care provider to allow the party to examine the original records or to file the original records under seal with the court or tribunal under subsection D of this section.

12-2295. Charges

A. Except as otherwise provided by law, a health care provider or contractor may charge a person who requests copies of medical records or payment records a reasonable fee for the production of the records. Except as necessary for continuity of care, a health care provider or contractor may require the payment of any fees in advance.

B. A health care provider or contractor shall not charge for the pertinent information contained in medical records provided to:

1. Another health care provider for the purpose of providing continuing care to the patient to whom the medical record pertains.
2. The patient to whom the medical record pertains for the demonstrated purpose of obtaining health care.
3. The health care decision maker of the patient to whom the medical record pertains for the demonstrated purpose of obtaining health care for the patient.
4. The Arizona medical board, the board of osteopathic examiners in medicine and surgery or an officer of the department of health services or the local health department requesting records pursuant to section 36-662.

12-2296. Immunity

A health care provider or contractor that acts in good faith under this article is not liable for damages in any civil action for the disclosure of medical records or payment records or information contained in medical records or payment records that is made pursuant to this article or as otherwise provided by law. The health care provider or contractor is presumed to have acted in good faith. The presumption may be rebutted by clear and convincing evidence.

12-2297. Retention of records

A. Unless otherwise required by statute or by federal law, a health care provider shall retain the original or copies of a patient's medical records as follows:

1. If the patient is an adult, for at least six years after the last date the adult patient received medical or health care services from that provider.
2. If the patient is a child, either for at least three years after the child's eighteenth birthday or for at least six years after the last date the child received medical or health care services from that provider, whichever date occurs later.

3. Source data may be maintained separately from the medical record and must be retained for six years from the date of collection of the source data.

B. When a health care provider retires or sells the provider's practice the provider shall take reasonable measures to ensure that the provider's records are retained pursuant to this section.

C. A person who is licensed pursuant to title 32 as an employee of a health care provider is not responsible for storing or retaining medical records but shall compile and record the records in the customary manner.

D. A nursing care institution as defined in section 36-401 shall retain patient records for six years after the date of the patient's discharge. For a minor, the nursing care institution shall retain the records for three years after the patient reaches eighteen years of age or for six years after the date of the patient's discharge, whichever date occurs last.

ⁱ 36-401. Definitions; adult foster care

A. In this chapter, unless the context otherwise requires:

1. "Accredited health care institution" means a health care institution, other than a hospital, that is currently accredited by a nationally recognized accreditation organization.
2. "Accredited hospital" means a hospital that is currently accredited by a nationally recognized organization on hospital accreditation.
3. "Adult day health care facility" means a facility that provides adult day health services during a portion of a continuous twenty-four hour period for compensation on a regular basis for five or more adults not related to the proprietor.
4. "Adult day health services" means a program that provides planned care supervision and activities, personal care, personal living skills training, meals and health monitoring in a group setting during a portion of a continuous twenty-four hour period. Adult day health services may also include preventive, therapeutic and restorative health-related services that do not include behavioral health services.
5. "Adult foster care home" means a residential setting that provides room and board and adult foster care services for at least one and no more than four adults who are participants in the Arizona long-term care system pursuant to chapter 29, article 2 of this title and in which the sponsor or the manager resides with the residents and integrates the residents who are receiving adult foster care into that person's family.
6. "Adult foster care services" means supervision, assistance with eating, bathing, toileting, dressing, self-medication and other routines of daily living or services authorized by section 36-2939, subsection C and rules adopted pursuant to that section.
7. "Assisted living center" means an assisted living facility that provides resident rooms or residential units to eleven or more residents.
8. "Assisted living facility" means a residential care institution, including an adult foster care home, that provides or contracts to provide supervisory care services, personal care services or directed care services on a continuous basis.
9. "Assisted living home" means an assisted living facility that provides resident rooms to ten or fewer residents.
10. "Construction" means the building, erection, fabrication or installation of a health care institution.
11. "Continuous" means available at all times without cessation, break or interruption.
12. "Controlling person" means a person who:
 - (a) Through ownership, has the power to vote at least ten per cent of the outstanding voting securities.
 - (b) If the applicant or licensee is a partnership, is the general partner or a limited partner who holds at least ten per cent of the voting rights of the partnership.
 - (c) If the applicant or licensee is a corporation, an association or a limited liability company, is the president, the chief executive officer, the incorporator or any person who owns or controls at least ten per cent of the voting securities. For the purposes of this subdivision, corporation does not include nonprofit corporations.
 - (d) Holds a beneficial interest in ten per cent or more of the liabilities of the applicant or the licensee.
13. "Department" means the department of health services.
14. "Directed care services" means programs and services, including supervisory and personal care services, that are provided to persons who are incapable of recognizing danger, summoning assistance, expressing need or making basic care decisions.
15. "Direction" means authoritative policy or procedural guidance for the accomplishment of a function or activity.
16. "Director" means the director of the department of health services.
17. "Facilities" means buildings that are used by a health care institution for providing any of the types of services as defined in this chapter.
18. "Freestanding urgent care center":
 - (a) Means an outpatient treatment center that, regardless of its posted or advertised name, meets any of the following requirements:
 - (i) Is open twenty-four hours a day, excluding at its option weekends or certain holidays, but is not licensed as a hospital.
 - (ii) Claims to provide unscheduled medical services not otherwise routinely available in primary care physician offices.
 - (iii) By its posted or advertised name, gives the impression to the public that it provides medical care for urgent, immediate or emergency conditions.
 - (iv) Routinely provides ongoing unscheduled medical services for more than eight consecutive hours for an individual patient.
 - (b) Does not include the following:
 - (i) A medical facility that is licensed under a hospital's license and that uses the hospital's medical provider number.
 - (ii) A qualifying community health center pursuant to section 36-2907.06.
 - (iii) Any other health care institution licensed pursuant to this chapter.
 - (iv) A physician's office that offers extended hours or same day appointments to existing and new patients and that does not meet the requirements of subdivision (a), item (i), (iii) or (iv). For the purposes of this item, "physician" means a person licensed pursuant to title 32, chapter 13 or 17.
19. "Governing authority" means the individual, agency, group or corporation, appointed, elected or otherwise designated, in which the ultimate responsibility and authority for the conduct of the health care institution are vested.

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20. "Health care institution" means every place, institution, building or agency, whether organized for profit or not, that provides facilities with medical services, nursing services, health screening services, other health-related services, supervisory care services, personal care services or directed care services and includes home health agencies as defined in section 36-151, outdoor behavioral health care programs and hospice service agencies.
21. "Health-related services" means services, other than medical, that pertain to general supervision, protective, preventive and personal care services, supervisory care services or directed care services.
22. "Health screening services" means the acquisition, analysis and delivery of health-related data of individuals to aid in the determination of the need for medical services.
23. "Hospice" means a hospice service agency or the provision of hospice services in an inpatient facility.
24. "Hospice service" means a program of palliative and supportive care for terminally ill persons and their families or caregivers.
25. "Hospice service agency" means an agency or organization, or a subdivision of that agency or organization, that is engaged in providing hospice services at the place of residence of its clients.
26. "Inpatient beds" or "resident beds" means accommodations with supporting services, such as food, laundry and housekeeping, for patients or residents who generally stay in excess of twenty-four hours.
27. "Licensed capacity" means the total number of persons for whom the health care institution is authorized by the department to provide services as required pursuant to this chapter if the person is expected to stay in the health care institution for more than twenty-four hours. For a hospital, licensed capacity means only those beds specified on the hospital license.
28. "Medical services" means the services that pertain to medical care and that are performed at the direction of a physician on behalf of patients by physicians, dentists, nurses and other professional and technical personnel.
29. "Modification" means the substantial improvement, enlargement, reduction or alteration of or other change in a health care institution.
30. "Nonproprietary institution" means any health care institution that is organized and operated exclusively for charitable purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual, or that is operated by the state or any political subdivision of the state.
31. "Nursing care institution" means a health care institution that provides inpatient beds or resident beds and nursing services to persons who need continuous nursing services but who do not require hospital care or direct daily care from a physician.
32. "Nursing services" means those services that pertain to the curative, restorative and preventive aspects of nursing care and that are performed at the direction of a physician by or under the supervision of a registered nurse licensed in this state.
33. "Organized medical staff" means a formal organization of physicians, and dentists where appropriate, with the delegated authority and responsibility to maintain proper standards of medical care and to plan for continued betterment of that care.
34. "Outdoor behavioral health care program" means an agency that provides behavioral health services in an outdoor environment as an alternative to behavioral health services that are provided in a health care institution with facilities. Outdoor behavioral health care programs do not include:
- (a) Programs, facilities or activities that are operated by a government entity or that are licensed by the department as a child care program pursuant to chapter 7.1 of this title.
 - (b) Outdoor activities for youth that are designated to be primarily recreational and that are organized by church groups, scouting organizations or similar groups.
 - (c) Outdoor youth programs licensed by the department of economic security.
35. "Personal care services" means assistance with activities of daily living that can be performed by persons without professional skills or professional training and includes the coordination or provision of intermittent nursing services and the administration of medications and treatments by a nurse who is licensed pursuant to title 32, chapter 15 or as otherwise provided by law.
36. "Physician" means any person who is licensed pursuant to title 32, chapter 13 or 17.
37. "Residential care institution" means a health care institution other than a hospital or a nursing care institution that provides resident beds or residential units, supervisory care services, personal care services, directed care services or health-related services for persons who do not need continuous nursing services.
38. "Residential unit" means a private apartment, unless otherwise requested by a resident, that includes a living and sleeping space, kitchen area, private bathroom and storage area.
39. "Respite care services" means services that are provided by a licensed health care institution to persons otherwise cared for in foster homes and in private homes to provide an interval of rest or relief of not more than thirty days to operators of foster homes or to family members.
40. "Substantial compliance" means that the nature or number of violations revealed by any type of inspection or investigation of a health care institution does not pose a direct risk to the life, health or safety of patients or residents.
41. "Supervision" means direct overseeing and inspection of the act of accomplishing a function or activity.
42. "Supervisory care services" means general supervision, including daily awareness of resident functioning and continuing needs, the ability to intervene in a crisis and assistance in the self-administration of prescribed medications.
43. "Temporary license" means a license issued by the department to operate a class or subclass of a health care institution at a specific location that is valid until an initial licensing inspection.
44. "Unscheduled medical services" means medically necessary periodic health care services that are unanticipated or cannot reasonably be anticipated and that require medical evaluation or treatment before the next business day.
- B.** If there are fewer than four Arizona long-term care system participants receiving adult foster care in an adult foster care home, nonparticipating adults may receive other types of services that are authorized by law to be provided in the adult foster care home as long as the number of adults served, including the Arizona long-term care system participants, does not exceed four.
- C.** Nursing care services may be provided by the adult foster care licensee if the licensee is a nurse who is licensed pursuant to title 32, chapter 15 and the services are limited to those allowed pursuant to law. The licensee shall keep a record of nursing services rendered.