Rule 1 - Minimum Practice Standards for the Sale of Hearing Aids

The purpose of this rule is to list some of the commonly accepted professional standards in the practice of audiology and as a hearing aid provider as required by § 12-5.5-105(1)(b)(IX) and § 12-5.5-205(1)(b)(X), C.R.S. Commonly accepted professional standards include, but are not limited to the following:

A. A hearing aid shall not be sold unless, within 6 months of the sale, an examination of the client/purchaser is conducted using pure tone air conduction, bone conduction, speech audiometry, and other tests utilizing appropriate established procedures and instrumentation in the fitting of hearing aids, except in cases of selling replacement hearing aids within one year after the date of the original purchase. Such tests shall be performed by a registered audiologist or registered hearing aid provider. An audiologist trainee or associate and a hearing aid provider trainee or associate may perform the examination when there is appropriate supervision.

B. The fitter of a hearing aid shall at a minimum attempt to:

1. Perform air conduction tests for hearing thresholds at frequencies of 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz with masking where necessary;
2. Perform bone conduction tests for hearing thresholds at frequencies of 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz with masking where necessary;
3. Perform a speech reception or speech awareness threshold test;
4. Perform a word discrimination/ recognition test;
5. Perform an otoscopic examination of the ear or ears; and
6. Obtain a medical history.

C. Any child under the age of 18 must have a medical evaluation by a licensed physician in the state of Colorado, preferably a physician who specializes in diseases of the ear, before purchasing a hearing aid. Any child who is to be fitted with a hearing aid must be referred to an audiologist for an evaluation and rehabilitation before a hearing aid is fitted, since hearing loss may cause problems in language development and educational and social growth of the child.

D. All test instruments shall be calibrated at least once a year, or more often if necessary, to meet current standards established by the American National Standards Institute. Calibration of all test instruments must be performed by a qualified individual. A signed certificate indicating the most recent date of calibration shall be maintained and available for inspection.

E. All customer records must be maintained by a registered audiologist or hearing aid provider. If a hearing aid business is not owned by a registered audiologist or hearing aid provider, then such records must be maintained by the supervising registered audiologist or hearing aid provider or the registered audiologist or hearing aid provider designated by the owner. Customer records are the property of the business but must remain under the control of a registered audiologist or hearing aid provider at all times.
F. Any extension of the 30-day refund period must be in writing and submitted to the client.

Rule 2 - Malpractice Insurance for Audiologists

The purpose of the following rule is to establish the amount of malpractice coverage that must be obtained by an audiologist who provides services to patients as required by § 12-5.5-106(4), and § 12-5.5-102(3)(e), C.R.S.:

An audiologist shall maintain malpractice coverage of at least of $1,000,000 per incident and $3,000,000 aggregate per year.

Rule 3 - Hearing Aid Provider Trainees and Associates

The purpose of this rule is to establish the time period during which a trainee and associate registration certificate shall be valid, and to specify the components of the training required to be completed by trainees and associates pursuant to § 12-5.5-202.5(4), C.R.S.

A. A “hearing aid provider trainee” is defined as an individual who has not completed 300 documented hours of training with a registered hearing aid provider or registered audiologist in the state of Colorado.

B. A “hearing aid provider associate” is defined as an individual who has completed a minimum of 300 hours of on-site supervised practice with a registered hearing aid provider or audiologist in the state of Colorado and is reported as being competent to the Audiologists and Hearing Aid Providers Registration by a registered audiologist or hearing aid provider who directly supervised the associate.

C. Before a hearing aid provider trainee can become a hearing aid provider associate, the hearing aid provider trainee must complete 300 hours of supervised training in the following:

1. taking a case history and review;
2. otoscopy;
3. testing of hearing including air conduction and bone conduction with proper masking when needed;
4. testing of speech including SRT, MCL, UCL and Discrimination with proper masking when needed;
5. interpreting hearing tests and the making of medical referrals as necessary;
6. taking of standard and in the canal ear impressions;
7. fitting and post-fitting counseling including the delivery of the hearing aid, insertion and removal of the hearing aid, instruction on changing the batteries, and education to the user and family as to expectations and performance;
8. checking for proper fit and making needed adjustments; and
9. verifying the hearing aid performance to determine if the hearing aid is correcting and conforming to the hearing loss as expected. This includes but is not limited to the use of real ear measurement, word discrimination, aided vs. unaided, or other forms of aided measurements as may be standard in the industry.
D. A hearing aid provider trainee must be supervised at all times while learning and performing the tasks identified in paragraph C above. At no time shall a hearing aid provider trainee perform any of the activities in paragraph C without the on-site, direct supervision of a registered audiologist or hearing aid provider.

E. A hearing aid provider associate can only become a registered hearing aid provider upon successful completion and passage of the National Competency Examination of the National Board for Certification in Hearing Instrument Sciences. Until such completion of the examination, a hearing aid provider associate may independently engage in the activities described in paragraph C above. However, all hearing aid sales must be reviewed by a registered audiologist or hearing aid provider and all contracts need to be signed by the registered audiologist or hearing aid provider.

F. No person may practice as a trainee or associate prior to being issued a temporary registration number by the Audiologist and Hearing Aid Providers Registration. Any work prior to the issuance of a temporary registration will not apply as training hours towards the associate status.

G. An individual may remain in trainee or associate status for no longer than three (3) years from date of issuance of the first temporary registration or 60 days after successful completion of the National Board for Certification-Hearing Instrument Science examination, whichever comes first.

Rule 4 - Written Disclosures to Purchasers

The purpose of this rule is specify the type of written disclosures to be provided to purchasers of hearing aids pursuant to § 12-5.5-206(4)(a), C.R.S., that will protect such purchasers.

A. Sellers of hearing aids shall identify themselves by listing their name, registration type (i.e., audiologist or hearing aid provider), and registration number on every contract or purchase agreement.

B. Sellers of hearing aids shall include a statement on all contracts and purchase agreements that complaints can be filed against the seller with the Audiologists and Hearing Aid Providers Registration, and shall include the Registration's address and telephone number.

C. The following written disclosures must be made in order for a seller of hearing aids to retain any money upon a buyer's cancellation and request for a full refund:

1. Section 6-1-701(2)(e)(II) of the Colorado Consumer Protection Act allows a seller of hearing aids to retain an itemized amount to cover the "minimum costs of materials used" by a registrant and a manufacturer's return fee, but such amount may not be greater than five percent of the total charge for the hearing aid.

2. Professional services that are itemized in the purchaser's contract are not considered "minimum costs of materials used" subject to the five percent limit referenced in § 6-1-701(2)(e)(II), C.R.S., and include the following actual costs:
   a. Ear molds, but not impressions;
   b. Fitting and consultation fees; and
   c. Rehabilitation services.

3. All professional services listed in subsection 2 above must clearly be listed and identified as non-refundable, and the exact charge for each non-refundable item and service must be included in the contract at the time of sale. Otherwise, a seller of hearing aids may not retain any monies upon a buyer's cancellation.
4. Minimum costs subject to the five percent ceiling must also be clearly listed as a non-refundable fee with the exact dollar amount included on the contract at the time of sale, but does not require an itemization of the items and services that constitute the minimum cost. Without such disclosure of the minimum cost at the time of the sale, a seller of hearing aids may not retain any monies upon a buyer's cancellation.

Rule 5 - Declaratory Orders

The purpose of this rule is to establish procedures for the handling of requests for declaratory orders filed pursuant to the Colorado Administrative Procedures Act at § 24-4-105(11), C.R.S.

A. Any person or entity may petition the Director for a declaratory order to terminate controversies or remove uncertainties as to the applicability of any statutory provision or of any rule or order of the Director.

B. The Director will determine, at her discretion and without notice to petitioner, whether to rule upon any such petition. If the Director determines that she will not rule upon such a petition, the Director shall promptly notify the petitioner of her action and state the reasons for such decision.

C. In determining whether to rule upon a petition filed pursuant to this rule, the Director will consider the following matters, among others:
   1. Whether a ruling on the petition will terminate a controversy or remove uncertainties as to the applicability to petitioner of any statutory provisions or rule or order of the Director.
   2. Whether the petition involves any subject, question or issue that is the subject of a formal or informal matter or investigation currently pending before the Director or a court involving one or more petitioners.
   3. Whether the petition involves any subject, question or issue that is the subject of a formal or informal matter or investigation currently pending before the Director or a court but not involving any petitioner.
   4. Whether the petition seeks a ruling on a moot or hypothetical question or will result in an advisory ruling or opinion.
   5. Whether the petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to CRCP 57, which will terminate the controversy or remove any uncertainty as to the applicability to the petitioner of the statute, rule or order in question.

D. Any petition filed pursuant to this rule shall set forth the following:
   1. The name and address of the petitioner and whether the petitioner is registered pursuant to Title 12, Article 5.5.
   2. The statute, rule or order to which the petition relates.
   3. A concise statement of all of the facts necessary to show the nature of the controversy or uncertainty and the manner in which the statute, rule, or order in question applies or potentially applies to the petitioner.

E. If the Director determines that she will rule on the petition, the following procedures shall apply:
   1. The Director may rule upon the petition based solely upon the facts presented in the petition.
In such a case:

a. Any ruling of the Director will apply only to the extent of the facts presented in the petition and any amendment to the petition.

b. The Director may order the petitioner to file a written brief, memorandum or statement of position.

c. The Director may set the petition, upon due notice to petitioner, for a non-evidentiary hearing.

d. The Director may dispose of the petition on the sole basis of the matters set forth in the petition.

e. The Director may request the petitioner to submit additional facts in writing. In such event, such additional facts will be considered as an amendment to the petition.

f. The Director may take administrative notice of facts pursuant to the Administrative Procedure Act at § 24-4-105(8), C.R.S., and may utilize her experience, technical competence, and specialized knowledge in the disposition of the petition.

2. If the Director rules upon the petition without a hearing, she shall promptly notify the petitioner of her decision.

3. The Director may, at her discretion, set the petition for hearing, upon due notice to petitioner, for the purpose of obtaining additional facts or information or to determine the truth of any facts set forth in the petition or to hear oral argument on the petition. The notice to the petitioner shall set forth, to the extent known, the factual or other matters into which the Director intends to inquire.

For the purpose of such a hearing, to the extent necessary, the petitioner shall have the burden of proving all the facts stated in the petition; all of the facts necessary to show the nature of the controversy or uncertainty; and the manner in which the statute, rule, or order in question applies or potentially applies to the petitioner and any other facts the petitioner desires the Director to consider.

F. The parties to any proceeding pursuant to this rule shall be the Director and the petitioner. Any other person may seek leave of the Director to intervene in such a proceeding, and leave to intervene will be granted at the sole discretion of the Director. A petition to intervene shall set forth the same matters as are required by Section D of this Rule. Any reference to a “petitioner” in this Rule also refers to any person who has been granted leave to intervene by the Director.

G. Any declaratory order or other order disposing of a petition pursuant to this Rule shall constitute agency action subject to judicial review pursuant to the Colorado Administrative Procedures Act at § 24-4-106, C.R.S.