2006 SUNSET REVIEW

Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform

Audiologists and Hearing Aid Provider Regulation

October 12, 2006

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
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Bill Owens
Governor

October 12, 2006

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed the evaluation of Colorado's registration of audiologists and hearing aid providers. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2007 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

> The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...
>
> The department of regulatory agencies shall submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination….

The report discusses the question of whether there is a need for the regulation provided under Article 5.5 of Title 12, C.R.S. The report also discusses the effectiveness of the program and staff in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Tambor Williams

Tambor Williams
Executive Director

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Quick Facts

What is Regulated? Individual audiologists and hearing aid providers.

Who is Regulated? In fiscal year 05-06, there were a total of 420 program registrants, with 314 active audiologists, and 106 active hearing aid providers.

How is it Regulated? The Colorado Audiologists and Hearing Aid Provider Registration Office is located in the Division of Registrations of the Department of Regulatory Agencies. In practice, the Office registers audiologists, hearing aid providers and trainees of both occupations. This involves processing and evaluating applications from prospective registrants, enforcing minimum standards of practice and sales as defined by law, and disciplining those in violation of the law.

What Does it Cost? The fiscal year 04-05 expenditure to oversee this program was $35,397 and there were 0.3 FTE associated with this program.

In 2006, registration costs were:	New	Renewal
Audiologists	$50	$35
Hearing Aid Providers	$50	$85

What Disciplinary Activity is There? During the six-year period of fiscal year 00-01 to fiscal year 05-06, the program's disciplinary proceedings consisted of:

	AUD	HAP
Revocations	0	4
Retirement/Surrender	1	1
Letters of Admonition	0	7
Cease and Desist	2	8
Probation	1	11
Dismissed	27	50
Total Disciplinary Actions	4	31

Where Do I Get the Full Report? The full sunset review can be found on the internet at: http://www.dora.state.co.us/opr/oprpublications.htm

Key Recommendations

Continue the registration of audiologists and hearing aid providers until 2012.
The registration of audiologists and hearing aid providers benefits the people of Colorado by providing a basic assurance that substandard service and potential harm to consumers is reduced by means of education, experience, and examination or certification requirements. The Office performs effectively to register, discipline, and provide guidance relating to the sales of hearing instruments. Consequently, as an essential component of the existing regulatory scheme, the Office should be continued until 2012.

Define the Practice of Audiology.
Inherent to the appropriate regulation of any profession is a general definition of what the practice or profession entails. Audiology is evolving and progressing along with its supporting technology. By adopting a definition or scope of practice, state regulatory agencies, practitioners, and the public will have a better understanding of what the profession or practice entails.

Relocate the relevant sections of the Consumer Protection Act to Title 12 to be administered by the Audiology and Hearing Aid Provider Registration Office.
The Consumer Protection Act (CPA) defines deceptive trade practices uniquely related to the dispensing of hearing aids. Incorporating these provisions of the CPA into the current regulatory program will enable the agency that is responsible for the registration of hearing aid providers to enforce all aspects of the hearing aid sales process and procedure.

Major Contacts Made In Researching the 2006 Sunset Review of the Program

American Academy of Audiology
American Auditory Society
Academy of Dispensing Audiologists
Colorado Department of Health and Environment
National Board for Certification Hearing Instrument Sciences
Marion Downs Hearing Center – University of Colorado Hospital
Colorado Hearing Society
Division of Registrations staff

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with the public interest. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the rights of businesses to exist and thrive in a highly competitive market, free from unfair, costly or unnecessary regulation.

Sunset Reviews are Prepared By:
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Background

The Sunset Process

The regulatory functions of the Colorado Audiology and Hearing Aid Provider Registration Office (Office), in accordance with Article 5.5 of Title 12, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2007, unless continued by the General Assembly. During the year prior to this date, it is the duty of the Department of Regulatory Agencies (DORA) to conduct an analysis and evaluation of the Office pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the registration of audiologists and hearing aid providers should be continued for the protection of the public and to evaluate the performance of the Office and staff of the Division of Registrations (Division). During this review, the Director of the Division (Director) must demonstrate that there is still a need for regulation and that the regulation is the least restrictive regulation consistent with the public interest. DORA's findings and recommendations are submitted via this report to the legislative committee of reference of the Colorado General Assembly. Statutory criteria used in sunset reviews may be found in Appendix A on page 33.

Methodology

As part of this review, DORA staff attended meetings with members of both occupations; interviewed Office staff; reviewed Office records, including complaint and disciplinary actions; interviewed officials with state and national professional associations; interviewed health care providers; reviewed Colorado statutes and program rules; and reviewed the laws of other states.

Profile of the Profession

Audiologists

Hearing loss is the third most common health problem in the United States.[1] In excess of 31 million Americans suffer from hearing problems. Typically, hearing problems are associated with the aging process. However, more than one-half of all hearing impaired individuals are under the age of 65.[2]

[1] American Academy of Audiology, "Consumer Education," www.audiology.org/aboutaudiology/consumered/, accessed September 27, 2006.
[2] Ibid.

The following is based on the U.S. Department of Labor's *Occupational Outlook Handbook*, 2005-2006 edition.

Audiologists generally work with individual patients who experience hearing, balance, and medically related ear problems. They examine individuals of all ages and identify those with the symptoms of hearing loss and other auditory, balance, and related sensory and neural problems. Audiologists evaluate and assess the nature and extent of these and related problems and attempt to help individual patients manage them. Using audiometers, computers, and other modern testing devices, audiologists measure the volume at which a person begins to hear sounds, the ability to distinguish between sounds, and the impact of hearing loss on an individual's life. In addition, audiologists use computer equipment to evaluate and diagnose balance disorders. Audiologists are trained to interpret these results and may coordinate them with medical, educational, and psychological information to make a diagnosis and determine the best course of treatment.

Hearing disorders can result from a variety of causes including trauma at birth, viral infections, genetic disorders, exposure to loud noise, certain medications, or aging. Treatment may include examining and cleaning the ear canal, fitting and dispensing hearing aids, and fitting and programming cochlear implants. Audiological treatment may also include counseling on adjusting to hearing loss, training on the use of hearing instruments, and teaching communication strategies for use in a variety of situations and environments. For example, audiologists may provide information and instruction in listening strategies. Audiologists also may recommend, fit, and dispense personal or large area amplification systems and alerting devices.

In audiology facilities and clinics, audiologists independently develop and carry out treatment programs. They keep records on the initial evaluation, progress, and discharge of patients. Audiologists may work with other health and education providers as part of a team in planning and implementing services for children and adults. Audiologists who diagnose and treat balance disorders often work in collaboration with physicians, and physical and occupational therapists.

Some audiologists specialize in work with the elderly, children, or hearing-impaired individuals who need special treatment programs. Others develop and implement ways to protect workers' hearing from on-the-job injuries. They may measure noise levels in workplaces and conduct hearing protection programs in factories, as well as in schools and communities.

Some audiologists conduct research on types of (and treatment for) hearing, balance, and related disorders. Other audiologists may be involved in the design and development of equipment or techniques for diagnosing and treating these disorders.

The U.S. Department of Labor anticipates that the audiologist's profession will grow about as fast as the average for all occupations through the year 2014. This expectation takes into consideration that hearing loss is generally associated with the aging process, and that the anticipated rapid growth in the population age 55 and over will cause the number of persons with impaired hearing to increase substantially.

Audiologists are currently regulated in all 50 states (Colorado registers audiologists), and most, including Colorado, require that individual applicants have at least a master's degree in audiology. However, it is anticipated that over the next couple of years, a clinical doctoral requirement will become the new educational standard. Approximately 107 colleges and universities nationwide offer graduate programs in audiology, and 39 of these offer a Doctor of Audiology (Au.D.) degree. In Colorado, the University of Colorado and the University of Northern Colorado offer clinical doctoral programs.

Hearing Aid Providers

Hearing aid providers are individuals who are engaged in the practice of dispensing, fitting, selling, or otherwise dealing in hearing aids. As of June 30, 2006, there were 106 registered hearing aid providers in Colorado. Colorado requires that all hearing aid providers acquire state registration. To qualify for registration as a hearing aid provider, an applicant must be certified by the National Board for Certification for Hearing Instrument Sciences (NBC-HIS).

An individual may remain in trainee or associate status for no longer than three years from date of issuance of the first temporary registration or 60 days after successful completion of the NBC-HIS examination, whichever comes first.

Pursuant to the Director's rules and regulations, written disclosures to patients or purchasers must include the following information:

- The seller's name, registration type and number, address and telephone number; and
- A statement that informs the buyer that complaints may be filed against the seller with the Office.

History of Regulation

The Colorado General Assembly originally established regulation for hearing aid providers in 1975 through the creation of the Hearing Aid Dealer Board (Board) in the Division of Registrations (Division) in the Department of Regulatory Agencies (DORA). Subsequently, the Board was the subject of Colorado's sunset review process, and the 1985 review found that although the Board received numerous complaints, no hearing aid dealer's license had been denied, suspended, or revoked in a disciplinary setting. The report concluded, and the General Assembly agreed, that the Board was ineffective in protecting the health, welfare and safety of the public.

Consequently, the General Assembly sunset the Board and placed general consumer protection provisions in the Colorado Consumer Protection Act (CPA) contained in section 6-1-105.5, *et seq*., Colorado Revised Statutes (C.R.S.), and in 1999 added industry-specific provisions located in section 6-1-701, C.R.S. These provisions required hearing aid providers to comply with standards specific to this occupation, such as return and refund procedures, the content of the sales contract, and referrals to licensed physicians in certain circumstances. This is in addition to the general provisions of the CPA governing deceptive trade and sales practices. From 1986 through 1995, the CPA governed the regulation of hearing aid sales in Colorado.

In 1994, the Colorado Hearing Aid Society (CHAS) and the Colorado Academy of Audiology (CAA) filed a sunrise application for the regulation of audiologists and hearing aid providers. The sunrise review found sufficient evidence of harm to the public to recommend a regulatory program for hearing aid providers. The General Assembly agreed with the conclusions of the sunrise report and subsequent legislation (HB 95-1011) was introduced and passed during the 1995 legislative session to create a registration program in the Division. The legislation required registration for all individuals selling or dispensing hearing aids.

The 1994 sunrise report did not find actual harm to the public by the unregulated practice of audiology. However, advocates for licensure presented arguments in the sunrise hearing that the unregulated practice of audiology presented significant potential harm to the public. Based on this information, the General Assembly included registration of audiologists in HB 95-1011. An individual practicing the profession of audiology was required to demonstrate minimum qualifications for registration as an audiologist by July 1, 1997.

The regulation of audiologists and hearing aid providers was the subject of a sunset review in 1999. The 1999 report recommended that it was unnecessary for Colorado to regulate audiologists, but recommended increasing the bond requirement for hearing aid providers from $5,000 to $10,000 in the event that the General Assembly continued regulation. The General Assembly raised the bond to $10,000 and continued the regulation of audiologists.

Pursuant to the general provisions of Title 6, C.R.S., enforcement of the CPA is within the concurrent jurisdiction of both the Colorado Attorney General and the state's district attorneys. As noted in the 1999 sunset review, both the Attorney General and local district attorneys reported increases in complaints and enforcement actions for violations of the CPA by hearing aid providers during the late 1980s and early 1990s, when the profession was not regulated in Colorado. In 1990 alone, the Attorney General's office investigated 100 complaints. Local district attorneys reported 123 complaint investigations generally related to hearing aid sales from 1989 through 1993.

The majority of the complaints investigated by both the Attorney General and district attorneys involved failure of hearing aid providers to comply with the refund provisions of the CPA. There were also complaints of failure to deliver hearing devices after the order was placed, and complaints about poor service. Elderly persons were particularly susceptible to fraudulent practices by hearing aid providers governed by the CPA. However, the Attorney General and the Denver metro area district attorney's currently indicate that they have not brought a single enforcement action over the past five years related to violations of the CPA by hearing aid providers.

House Bill 97-1095 (Infant Hearing Act) created the Colorado Infant Hearing Advisory Committee (CIHAC) in 1997. The CIHAC was required to have at least seven members appointed by the Executive Director of the Colorado Department of Public Health and Environment with training, experience, or interests in the area of hearing conditions in children.

The General Assembly found that hearing loss in newborn infants occurred more frequently than other health conditions for which newborn screenings were required. The Infant Hearing Act required the CIHAC to collect data on which hospitals were voluntarily administering newborn screenings and to prepare a report to the General Assembly by December 1, 1998, detailing information about the number of hospitals screening infants, the number of infants screened and the pass rate of screened infants.

The report found that the level of voluntary screenings being conducted at that time was over the 85 percent minimum required by the Infant Hearing Act. Therefore, no regulations requiring screenings were promulgated under the provision contained in section 25-4-1004.7(4), C.R.S.

Legal Framework

The Colorado statutory authority for the regulation of audiologists and hearing aid providers is contained in Article 5.5 of Title 12 of the Colorado Revised Statutes (C.R.S.), (Act). The Act is divided into two parts. Part 1 contains the requirements for the regulation of audiologists. Part 2 contains the requirements for hearing aid providers. The Director of the Division of Registrations (Director) in the Department of Regulatory Agencies (DORA) is authorized to promulgate regulations to administer the Act.

Audiologist Statutes and Rules

Other than delineating the qualifications to become a registered audiologist in Colorado, the Act does not define the audiologists' scope of practice.

Section 12-5.5-101, C.R.S., which applies to audiologists, contains a provision for the registration of audiologists practicing on or before July 1, 1995. This provision is no longer relevant since the statute requires standard requirements for the practice of audiology effective July 1, 1997. To renew a registration, or apply for initial registration after July 1, 1997, audiologists must comply with the remaining provisions of the Act. Applicants for registration must submit:

- A complete application on a form provided by the Director;[3]
- A non-refundable registration fee;[4]
- Proof of a master's or doctoral degree in audiology or other degree determined by the Director to be equivalent;[5]
- A certificate of competency in audiology from a nationally recognized certification agency, such as the American Speech-Language-Hearing Association or Board Certification in Audiology from the American Board of Audiology. An exception exists for those audiologists that hold a license from the Colorado Department of Education pursuant to section 12-60-104(1), C.R.S.;[6] and
- Proof of malpractice insurance in an amount determined to be appropriate by the Director, and valid through the expiration date of the registration or renewal. Pursuant to the Director's rules, the amount is set at $1 million per incident and $3 million aggregate per year.[7]

[3] §§ 12-5.5-102(2) and (3), C.R.S.
[4] § 12-5.5-102(2), C.R.S.
[5] § 12-5.5-101(1)(a), C.R.S.
[6] § 12-5.5-101(1)(b), C.R.S.
[7] § 12-5.5-102(3)(e), C.R.S., and Program Rule 2.

Registered audiologists must notify the Director within 30 days of any changes in the registration information.[8] The Director is required to grant a temporary registration to applicants with the required education who are engaged in a year of clinical fellowship. Pursuant to section 12-5.5-102.5, C.R.S., temporary registrations are valid for no more than 12 months.

Section 12-5.5-105(1)(b), C.R.S., contains the grounds for discipline. The Director, after conducting an investigation and providing the opportunity for a hearing, in accordance with the State Administrative Procedure Act (APA), may impose disciplinary action for violation of the statute or regulations. The Director, pursuant to section 12-5.5-105(1)(a), C.R.S., has several options for disciplinary actions including:

- Letter of Admonition;
- Probation, including supervised practice;
- Suspension;
- Revocation;
- Denial or refusal to renew; and
- Administrative fines not to exceed $2,500 for each offense.

In addition, the Director has the authority, pursuant to section 12-5.5-107(1)(a), C.R.S., to issue a letter directing a registrant or unregistered individual to cease and desist an activity that constitutes unregistered activity, or that poses an imminent threat to the health and safety of the public. The recipient of such cease and desist order may request a hearing on the facts alleged in the letter within 10 days of its receipt.[9]

After reviewing a complaint, the Director, pursuant to section 12-5.5-105(1)(a)(V), C.R.S., may also issue a confidential letter of concern (LOC). The Director generally issues a LOC in situations where the allegations of the complaint are considered relatively minor in nature, and therefore do not warrant formal action. A LOC is a dismissal of the complaint, often coupled with a statement that the alleged conduct could lead to serious consequences if not corrected or reoccurs.

[8] § 12-5.5-102(2), C.R.S.
[9] § 12-5.5-107(1)(b), C.R.S.

The Director may conduct investigations and inspections pursuant to section 12-5.5-106(1), C.R.S., to ensure compliance with the statute and regulations. The Director may apply to a court for injunctive relief to prevent violations of statutory provisions in accordance with section 12-5.5-106(2), C.R.S., including failure of a practitioner to register with the Director. Pursuant to section 12-5.5-106(3)(a), C.R.S., the Director may conduct disciplinary hearings or delegate hearings to an administrative law judge under the provisions of the APA. The Director is authorized to promulgate regulations to administer the Act, as authorized by section 12- 5.5-106(5), C.R.S.

Temporary registrations for clinical fellows are valid for no more than 12 months. To qualify for a temporary registration, applicants must obtain a master's or doctoral degree in audiology, as set forth in section 12-5.5-102.5, C.R.S.

Audiologists must include their registration number on all contracts and receipts.[10]

Grounds for discipline of an audiologist's registration are contained in section 12-5.5-105(1)(b), C.R.S. They consist of the following:

- Using false or misleading advertising or making false or misleading statements or omissions in an application for registration;
- Conviction or pleading guilty or *nolo contendere*, or receipt of a deferred sentence to a crime involving fraud, deception, false pretence, theft, misrepresentation, false advertising, or dishonest dealing;
- Failure to comply with a stipulation or agreement with the Director;
- Violation of any provision of the Act, or any rule promulgated by the Director under Part 1 of the Act;
- Violating the Colorado Consumer Protection Act (CPA);
- Employing a sales agent or employee who violates any provision of the Act;
- Failing to notify the Director of any change in information filed pursuant to the Act;
- Causing physical harm to a customer;
- Failing to practice according to commonly accepted professional standards; and
- Failing to adequately supervise a registered hearing aid provider trainee or associate.

[10] § 12-5.5-102(1), C.R.S.

Hearing Aid Provider Statutes and Rules

The first section of the hearing aid provider statutory directives contains a provision for the registration of hearing aid providers practicing on or before July 1, 1995. This provision allowed hearing aid providers two years to obtain the qualifications currently required.

Similar to the audiologist program, oversight of the regulation of hearing aid dealers is vested in the Director. Hearing aid providers are statutorily defined as individuals engaged in the practice of dispensing, fitting, or dealing in hearing aids, and who have passed an examination conducted under the auspices of the National Board for Certification in Hearing Instrument Sciences (NBC-HIS) or an equivalent examination as determined by the Director.[11] Persons registered as audiologists under Part 1 of the Act are not required to register as hearing aid providers if engaged in both occupations.[12] Hearing aid providers who are not registered as audiologists must register with the Director.

The statute establishes registration requirements and the cash fund for the program.[13]

To renew a registration, or apply for initial registration, hearing aid providers must comply with the remaining provisions of the statutes. These requirements include submission of:

- A complete application on a form provided by the Director;[14]
- A non-refundable registration fee;[15]
- Location information for each business office from which sales of hearing devices are intended to be made;[16]
- A statement indicating whether an applicant was issued a hearing aid provider license, certificate, or registration by any local, state, or national health care agency, the status of said license, certificate or registration, whether charges or complaints against such license, certificate or registration are pending, and whether disciplinary actions were taken against such license, certificate, or registration.[17]

[11] § 12-5.5-201(3), C.R.S.
[12] § 12-5.5-202(1), C.R.S.
[13] § 12-5.5-204, C.R.S.
[14] § 12-5.5-202(2)(a), C.R.S.
[15] § 12-5.5-202(2)(a), C.R.S.
[16] § 12-5.5-202(2)(b)(II), C.R.S.
[17] § 12-5.5-202(2)(b)(IV), C.R.S.

- Proof of a surety bond or approved alternative in the amount of $10,000;[18] and
- Proof of a passing score on the examination administered by the NBC-HIS, or an equivalent examination approved by the Director.[19]

Hearing aid providers must include their registration number on all contracts and receipts. In addition, hearing aid providers must inform all clients in writing that the Director regulates hearing aid providers, and provide the address and telephone number of the Director.

Pursuant to section 6-1-701(2)(e)(I), C.R.S., the buyer of a hearing aid has the right to return and cancel the purchase of a hearing aid for any reason within 30 days of said purchase by giving written notice of such intent, and returning the hearing instrument. This 30-day rescission period is tolled for any period of time during which a registered hearing aid provider takes control or possession of the device after its original date of delivery. Upon cancellation, the buyer is entitled to receive a full refund pursuant to the CPA, section 6-1-701(2)(e)(II), C.R.S. However, this statute also allows the seller to retain an itemized amount of money (not to exceed five percent of the total cost for the hearing aid) paid by the consumer to cover the "minimum costs of materials used" by a registrant, and a manufacturer's return fee. The CPA requires that this information about refunds be included in the contract for purchase.

As a condition of registration, hearing aid providers must maintain a surety bond in the amount of $10,000, pursuant to section 12-5.5-202(2)(b)(III), C.R.S. The purpose of this surety bond is to provide financial relief for a consumer in the event that a hearing aid provider is unable or unwilling to grant a consumer a refund pursuant to the CPA.

Section 12-5.5-202.5, C.R.S., requires the registration of hearing aid provider trainees and associates. The Act requires a trainee to inform consumers of his/her status as a trainee, and prohibits a trainee from selling hearing aids independently of the supervising hearing aid provider or audiologist.[20] The Director has promulgated regulations regarding training and registration time period requirements for trainees.

Hearing aid provider trainees are issued temporary registrations. A registrant may not be classified as a trainee for more than three years.[21]

[18] § 12-5.5-202(2)(b)(III), C.R.S.
[19] § 12-5.5-201(3), C.R.S. (The National Board for Certification in Hearing Instrument Sciences (NBC-HIS) is the only organization currently approved by the Director for certifying hearing aid providers).
[20] § 12-5.5-202.5(3), C.R.S.
[21] Program Rule 3(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.[22]

A "hearing aid provider associate" is defined by Colorado statutes 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 Director by a registered audiologist or hearing aid provider who directly supervised the associate.[23]

Pursuant to the Director's rules, 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 areas:[24]

- Taking and reviewing case histories;
- Otoscopy (physical examination of the ear canal);
- Testing of hearing, including air conduction and bone conduction with proper masking when needed;
- Testing of speech, including discrimination with proper masking when needed;
- Interpreting hearing tests and the making of medical referrals as necessary;
- Taking of standard and in-the-canal ear impressions;
- 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;
- Checking for proper fit and making needed adjustments; and
- 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 physical ear measurements, word discrimination, aided verses unaided, or other forms of aided measurements as may be standard in the industry.

A hearing aid provider trainee must be supervised at all times while learning and performing the tasks identified above. A hearing aid provider trainee may not perform any of these activities without the on-site, direct supervision of a registered audiologist or hearing aid provider.[25]

[22] Program Rule 3(A).
[23] Program Rule 3(B).
[24] Program Rule 3(C).
[25] Program Rule 3(D).

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 NBC-HIS. Until such completion of the examination, a hearing aid provider associate may independently engage in the activities described above. However, a registered audiologist or hearing aid provider must review all hearing aid sales, and the registered audiologist or hearing aid provider must sign all contracts.[26]

No applicant may practice as a trainee or associate prior to being issued a temporary registration number by the Director. Any work-related time spent prior to the issuance of a temporary registration will not apply as training hours towards the associate status.[27]

An individual may remain in trainee or associate status for no longer than three years from date of issuance of the first temporary registration or 60 days after successful completion of the NBC-HIS examination, whichever comes first.[28]

The statute details the grounds for disciplinary action in section 12-5.5-205(1)(b), C.R.S. Disciplinary actions are set forth in section 12-5.5-205(1)(a), C.R.S., and include:

- Letter of Admonition;
- Probation, including supervised practice;
- Suspension;
- Revocation;
- Denial or refusal to renew;
- Administrative fines not to exceed $2,500 for each offense; and
- Letter of Concern.

As with the regulation of audiologists, the Director may issue cease and desist orders in appropriate situations.[29] The Director may conduct investigations and inspections to ensure compliance with the statute and regulations;[30] apply to a court for injunctive relief to prevent violations of statutory provisions, including failure of a practitioner to register with the Director;[31] and conduct disciplinary hearings or delegate hearings to an administrative law judge under the provisions of the APA.[32]

[26] Program Rule 3(E).
[27] Program Rule 3(F).
[28] Program Rule 3(G).
[29] § 12-5.5-205.5, C.R.S.
[30] § 12-5.5-206(1), C.R.S.
[31] § 12-5.5-206(2), C.R.S.
[32] § 12-5.5-206(3)(a), C.R.S.

In addition to the regulation of hearing aid providers set forth in section 12-5.5 201, *et seq.,* the CPA, in section 6-1-701, C.R.S., specifically prohibits deceptive trade practices by hearing aid providers. Noteworthy examples of the deceptive trade practices include:[33]

- Selling a used hearing aid without disclosure of such fact;
- Failure to notify a consumer that any representation made by a hearing aid provider is not medical advice;
- Failure to include the factory warranty with the sales receipt;
- Selling a hearing aid to a child under the age of 18, without determining that the patient has seen a medical doctor within a six-month period;
- Failure to inform the consumer of the right to rescind and cancel the transaction;
- Making false or misleading statements concerning goods or services, or the consumer's right to cancel; and
- Charging or collecting any fee for goods or services that has been represented by the registered hearing aid provider as free.

Federal Regulation

Hearing aids are considered medical devices, and as such, are subject to regulation by the U.S. Food and Drug Administration (FDA). The FDA has promulgated regulations regarding the manufacture and labeling of hearing aids. The FDA also has regulations requiring an examination by a physician before a hearing aid can be sold, although consumers have the right to waive that examination. The FDA regulations are incorporated into Colorado law in section 6-1-701(2)(d), C.R.S., and require hearing aid providers to refer patients with the following conditions to a physician before dispensing a hearing device:

- Visible congenital or traumatic deformity of the ear;
- History of active drainage from the ear within the previous 90 days;
- Acute or chronic dizziness;
- Unilateral hearing loss of sudden or recent onset within the previous 90 days;

[33] § 6-1-701(2), C.R.S.

- Audiometric air-bone gap equal to or greater than 15 decibles at 500 Hertz, 1,000 Hertz, 2,000 Hertz;
- Visible evidence of cerumen (ear wax) or a foreign body in the ear canal; or
- Pain or discomfort in the ear.

Program Description and Administration

Agency Overview

For the purpose of administering the Audiologist and Hearing Aid Provider Practice Act (Act), the Director of the Division of Registrations (Director), has created the Audiology and Hearing Aid Provider Registration Office (Office). The Office is located within the Division of Registrations (Division), Department of Regulatory Agencies (DORA), and is administered by the Division Director (Director).

The Director is responsible for registering qualified applicants, investigating complaints, initiating disciplinary actions when appropriate, enjoining the unlicensed practice, and adopting rules and regulations. The Director has appointed a Program Director to head the Office and oversee the day-to-day operations of the Office. Legally, however, all actions taken by the Office or Program Director are done so in the name of the Director.

Audiologists are required to register with the Director before providing services in Colorado. The Office is cash funded and the Director annually adjusts the fees to cover the direct and indirect costs of the Office. Registration requirements do not apply to persons employed by or under contract to public schools while in the performance of duties related to the employment or contract, provided the individual meets the licensing and certification requirements for the State Board of Education.[34]

Policymaking

During the last five years, the Director has amended the rules and regulations pursuant to the statutory directives enacted by the Colorado General Assembly. The Director has also created a sample purchase agreement (Appendix B on page 34) to conform to the requirements in the Colorado Consumer Protection Act.

[34] § 12-5.5-101(1)(b), C.R.S.

The total full-time equivalent (FTE) employees allocated to the Office is 0.3, and includes a Program Director (General Professional VI) and an Administrative Assistant III. The Program Director and Administrative Assistant also staff six other programs within the Division. The FTE allocated to the Office was reduced from 0.65 to 0.3 when the Division underwent reorganization in fiscal year 02-03.

The Program Director handles the day-to-day administration of the Office, which includes complaint processing and monitoring, budget, personnel matters, licensure, and making recommendations to the Director. The Administrative Assistant is responsible for the clerical functions involved with complaint processing and post-disciplinary monitoring.

Chart 1
Office Expenditures and FTE

Fiscal Year	Total Office Expenditure	FTE
00-01	$65,841	0.65
01-02	$65,613	0.65
02-03	$58,399	0.3
03-04	$46,906	0.3
04-05	$35,397	0.3
05-06	$33,078	0.3

Compiled by the Audiologist and Hearing Aid Provider Registration Office.

The total Office expenditures have declined over the last five years for two reasons. First, the reduction in FTE lowered the expenses for personal services from $37,145 to the current level of $24,654. The second factor was a reduction in the use of legal services. In fiscal year 00-01 and fiscal year 01-02, the Office averaged $15,000 in legal services. When the new Program Director took over in fiscal year 02-03 and implemented an expedited settlement program, the use of legal services decreased dramatically, as evidenced by Chart 2 below.

Chart 2
Legal Services Expenditures

Fiscal Year	Legal Services Expenditures
00-01	$14,582.11
01-02	$17,747.24
02-03	$294.26
03-04	$12.83
04-05	$83.37
05-06	$571.96

Compiled by the Audiologist and Hearing Aid Provider Registration Office.

Registration Information

Audiologists and hearing aid providers are issued registrations, not licenses. All applicants seeking registration in Colorado must acquire the appropriate certification regardless of whether the applicant was previously licensed/registered in another state. Renewals occurred on an annual basis until June 30, 2006, after which renewals are on a biennual basis, with all registrations expiring on March 31. Chart 3 sets forth the number of registrations issued by the Director over the past five fiscal years.

Chart 3
Number of Registrations

Fiscal Year	Audiologists		Hearing Aid Providers	
	New Registrants	Active Registrants	New Registrants	Active Registrants
01-02	47	268	28	95
02-03	38	295	35	104
03-04	39	325	33	122
04-05	30	326	35	121
05-06	41	314	58	106

Compiled by the Audiologist and Hearing Aid Provider Registration Office.

The Office does not administer any examinations. Instead, applicants must be certified prior to application. The certification process includes an examination component. Audiologists need to obtain a certificate of competency in audiology from a nationally recognized certification agency. Currently, two certificates are recognized. Audiology applicants need to have either a Certificate of Clinical Competence from the American Speech-Language-Hearing Association, or a Board Certification in Audiology from the American Board of Audiology.

Hearing aid providers must pass an examination administered by the National Board for Certification in Hearing Instrument Sciences. Since these exams and certifications are completed prior to application, the Office does not maintain examination information.

Hearing aid providers must maintain a $10,000-surety bond as a requirement of registration. The surety companies are required by section 12-5.5-202(2)(b)(III), Colorado Revised Statutes (C.R.S.), to notify the Office when a claim is made on a bond, or when a bond is cancelled. The Office has indicated that no bonds have been the subject of a claim during the past five years.

Complaint and Disciplinary Information

After the Office receives a complaint, it is initially reviewed by the Program Director. The Program Director then makes a decision on how to proceed, which could include sending a letter to the respondent, asking for more information related to the complaint, sending a subpoena for records or other items, or referring the complaint to the Division's Office of Investigations. Depending on the nature of the complaint, an audiologist or hearing aid provider may be consulted for professional advice and guidance.

Once all the necessary information is obtained, a memorandum is prepared and sent to the Director for final action. The memo generally recites the relevant facts and makes an outcome recommendation. The Director makes the final decision as to the case outcome, i.e., whether it is dismissed, or referred to the Attorney General for disciplinary or other action. Chart 4 below breaks down the general categories and numbers of complaints received by the Office.

Chart 4
Nature of Complaints

Nature of Complaints	FY00-01		FY01-02		FY02-03		FY03-04		FY04-05		FY05-06	
	AUD	HAP	AUD	HAP	AUD	HAP	AUD	HAP	AUD	HAP	AUD	HAP
Refund Dispute	2	4	2	5	2	3	3	4	1	2	1	2
CPA Contract Violation	0	4	0	5	1	2	1	0	0	1	0	2
CPA Advertising Violation	0	2	2	0	0	3	0	5	1	4	2	2
Fraud/Misrepresentation	0	2	0	2	0	2	0	4	0	1	2	0
Improper Supervision	0	2	0	1	0	0	0	1	0	0	0	1
Employing Unregistered Person	0	0	0	0	0	0	1	1	1	0	0	2
Unregistered Practice	0	2	0	2	2	0	1	3	1	1	0	1
Substandard Care	0	2	0	5	0	4	2	1	2	0	1	2
Violation of Patient Confidentiality	0	0	0	0	0	0	0	1	0	0	0	0
Practice Beyond the Scope	0	0	0	0	0	0	0	1	0	1	0	3
Violation of Stipulation/Final Agency Order	0	1	0	2	0	1	0	0	0	1	0	1
No Bond/Malpractice Insurance	0	1	0	0	0	0	0	0	0	0	0	6
TOTAL	2	20	4	22	5	15	8	21	6	11	6	22

Compiled by the Audiologist and Hearing Aid Provider Registration Office.

CPA - Colorado Consumer Protection Act, § 6-1-701, *et seq*., C.R.S., and pertains to the contractual obligations required of audiologists and hearing aid providers.
AUD - Audiologists
HAP - Hearing Aid Providers

A review of a sample of the complaints against audiologists from the last five years revealed that most of the complaints relate to the dispensing of hearing aids, such as false advertising, failure to provide refunds, and improper or missing sales contract provisions. A review of hearing aid provider complaints revealed a broad spectrum of alleged violations of the practice Act and CPA, with the majority of complaints relating to the actual fitting and sale of hearing aids.

Complaints against audiologists not related to the dispensing of hearing aids involved such allegations as theft of employer funds, practicing with an expired license, rude treatment, and holding out as a licensed physician. None of the complaints involved an allegation relating to the substandard practice of audiology.

Since fiscal year 00-01, the Office reports that there have been 29 complaints lodged against audiologists, and 111 complaints against hearing aid providers. However, during these six fiscal years, audiologists have outnumbered hearing aid providers by almost three to one (see chart 3, page 17). Many factors could account for this disparity including education, training, and type or scope of practice.

Disciplinary Actions

The Director initiates disciplinary action pursuant to sections 12-5.5-105 and -205, C.R.S. The Director's disciplinary policy takes into consideration the nature of the case. The stated goal is to tailor a sanction that will prevent future violations. For example, if a registrant has a contract violation, then the appropriate sanction could be proof of utilization of a conforming contract. Whereas, an audiologist or hearing aid provider engaging in deceptive trade practices might merit a suspension or revocation.

Chart 5 below, sets forth the final agency actions taken by the Director over the past five fiscal years. It is broken down by fiscal year, occupation, and penalty or sanction ordered.

Chart 5
Final Agency Actions

Type of Action	FY00-01		FY01-02		FY02-03		FY03-04		FY04-05		FY05-06	
	AUD	HAP	AUD	HAP	AUD	HAP	AUD	HAP	AUD	HAP	AUD	HAP
Revocation	0	1	0	3	0	0	0	0	0	0	0	0
Surrender of License / Retirement	0	0	0	0	0	0	0	1	1	0	0	0
Suspension with Probation	0	1	0	0	0	0	0	0	0	0	0	0
Probation / Practice Limitation	0	2	0	5	1	1	0	1	0	1	0	0
Letter of Admonition	0	0	0	4	0	2	0	0	0	0	0	1
License Granted with Probation / Practice Limitations	0	0	0	0	0	0	0	0	0	0	0	0
License Denied after Hearing	0	0	0	0	0	0	0	0	0	0	0	0
Injunction	0	0	0	0	0	0	0	0	0	0	0	0
Fine	0	0	0	0	0	0	0	0	0	0	0	0
Stipulated Agreement	0	0	0	0	0	0	0	0	0	0	0	0
Suspension without Probation	0	0	0	0	0	0	0	0	0	0	0	0
Dismiss	2	6	3	6	4	4	8	5	5	13	5	16
Cease and Desist Order	0	2	1	0	0	2	0	1	0	2	1	1
TOTAL	2	12	4	18	5	9	8	8	6	16	6	18

Compiled by the Audiologist and Hearing Aid Provider Registration Office.

AUD – Audiologists
HAP - Hearing Aid Providers

In all cases referred by the Director for disciplinary action, the matter is sent through the expedited settlement process prior to referring it to the Office of the Attorney General. If the respondent chooses to accept the settlement terms offered by the Director, the case is resolved internally and expeditiously. If the respondent does not accept the settlement proposal, the case is then referred to the Office of the Attorney General.

Although the Director has the authority to issue fines, no fines have been imposed as a result of disciplinary actions.

Registration Fees and Revenue

The following chart highlights the initial registration and renewal fees for audiologists and hearing aid providers.

Chart 6
Registration Fees

Fiscal Year	Audiologists		Hearing Aid Providers	
	Initial Registration Fee	Renewal Fee	Initial Registration Fee	Renewal Fee
01-02	$125	$145	$125	$145
02-03	$125	$145	$125	$195
03-04	$125	$145	$125	$195
04-05	$125	$145	$125	$195
05-06	$50	$35	$50	$85

In fiscal year 02-03, the renewal fee for hearing aid providers was increased due to the fact that the majority of the complaints received, and disciplinary actions initiated, involved hearing aid providers.

Analysis and Recommendations

Recommendation 1 – Continue the registration of audiologists and hearing aid providers for five years, until 2012.

The regulatory functions of the Director of the Division of Registrations (Director), with respect to audiologists and hearing aid providers, as provided by Article 5.5 of Title 12, Colorado Revised Statutes (C.R.S.)(Act), are scheduled to expire on July 1, 2007, unless affirmatively extended by the General Assembly. The Department of Regulatory Agencies (DORA) recommends that the General Assembly extend such regulation for five years, until 2012.

The first sunset criterion asks whether regulation is necessary to protect the public health, safety or welfare. DORA finds that such regulation of audiologists and hearing aid providers is necessary to protect the citizens of Colorado. Generally, the average consumer finds it difficult to determine whether he or she receives quality services by these two regulated occupations. The level of skill and safety with which those services are rendered is equally difficult to evaluate. The Audiology and Hearing Aid Provider Registration Office (Office) ensures a minimum level of knowledge, skill and experience by establishing minimum educational and training requirements that provide reasonable assurance that persons registered by the Office are qualified practitioners. Active investigation of complaints, coupled with the disciplinary sanctions of revocation and suspension, also provide assurance that registrants perform in a competent manner.

The unregulated practice of hearing aid sales has been previously demonstrated to present harm to the public. In the past, consumers have had difficulty compelling dealers to comply with the provisions of the Consumer Protection Act (CPA). Indeed, as Chart 4 on page 18 shows, Colorado consumers continue to be harmed by and complain about hearing aid providers, thereby demonstrating the need for continued regulation.

However, Chart 4 is somewhat misleading with respect to audiologists. Although the Office has received relatively few complaints against audiologists, there is other evidence of harm. As part of this sunset review, DORA looked to other sources for evidence of harm.

The following complaints were submitted by the University of Colorado Hospital Audiology Clinic.

Case 1. (11/2004): This child was sedated for testing after the family expressed concerns about lack of speech and language development and responses to sound (child was 15 months old). Behavioral testing in sound field only indicated inconsistent responses. The child was then sedated for testing and received click Audiometric Brain-Stem Response (ABR) testing. Family was informed that the child had no response on the testing, indicating a severe to profound hearing loss bilaterally. Family was also informed that there was a lot of electrical noise during testing. Review of data indicated the child actually had a cochlear microphonic and was subsequently diagnosed as having auditory neuropathy/dys-synchrony. The inaccurate diagnosis made by an audiologist at a Denver hospital resulted in potential harm because powerful hearing aids were recommended which could have caused damage to the inner ear hair cells. Fortunately, this family received a second opinion at the University of Colorado Hospital Audiology Clinic.

Case 2. (4/2002): This child failed a hearing screening four times in the newborn nursery and was seen in follow-up by an audiologist at a Denver hospital for ABR click test only. No frequency-specific results were obtained as recommended in the state guidelines. The waveforms were interpreted as normal for both ears, however, waveforms quality was poor. The child was then referred at one year of age for follow up testing, which was incomplete and interpreted as normal. Due to lack of speech and language development at age 21 months, the child was seen again at a facility where pediatric patients are not often evaluated. Due to elevated behavioral responses, the child was referred to the University of Colorado Hospital Audiology Clinic for additional testing and hearing aid fitting. The child was then diagnosed with a moderately severe to profound hearing loss bilaterally and fit with hearing aids. This child experienced a significant speech delay at that time and required intervention and private speech therapy. Parents had been concerned about possible hearing loss for over a year and were alarmed that the loss appeared to go undetected for so long. This child experienced significant delay in communication skills due to the late identification of the hearing loss.

Case 3. (9/2001): This child failed newborn hearing screening in the left ear. ABR testing with clicks only (no frequency-specific testing was completed as recommended in the state guidelines) indicated moderate hearing loss in the left ear and normal hearing in the right ear. Subsequent behavioral tests were always done in sound field and therefore provided no information about the function of each ear. Even though the results were never within normal limits, the assessing audiologist made no recommendation for hearing aids or early intervention. At age 21 months, the child had significant speech and language delay. Frequency and ear specific testing was completed at the University of Colorado Hospital Audiology Clinic and indicated a moderate sensorineural hearing loss rising to normal hearing in the right ear and a flat moderate sensorineural hearing loss in the left ear. The child was then fit with hearing aids in both ears and began intervention services. This child experienced significant delay in communication skills due to the late diagnosis.

Case 4. (7/2006): This child failed a newborn hearing screening in left ear and was seen for follow-up testing. The parents were told that the results of the ABR assessment were consistent with normal hearing. The ABR assessment was completed by an audiologist in a Denver area hospital and included only click responses. This assessment does not meet the accepted standard of complete testing recommended pursuant to state guidelines. The misdiagnosis resulted in harm to the child who has been in speech therapy for four years and now at age five has had a complete evaluation indicating normal hearing sloping to a severe sensorineural hearing loss in the left ear. She has now been fit with a hearing aid. This child experienced significant delay in communication skills due to the late diagnosis.

Case 5. (6/2002): This child was referred for left ear hearing screening four times, and was subsequently referred for diagnostic testing. Follow-up testing of the left ear was completed by an audiologist at a Denver area hospital and indicated a moderate hearing loss (using clicks and tone bursts). The other ear was not assessed as it was assumed it was hearing normally. Second opinion testing was completed at the University of Colorado Hospital Audiology Clinic, which indicated the presence of a moderate hearing loss in both ears using ABR clicks, and tone bursts. The child was fit binaurally with hearing aids and began intervention services. The incomplete testing by the original audiologist resulted in the potential harm of a misdiagnosed hearing loss resulting in inappropriate recommendations.

Case 6. (7/2003): This child was seen for a second opinion at six months of age. The results of an incomplete ABR assessment (clicks only) resulted in a diagnosis of severe hearing loss in the right ear and a moderate hearing loss in the left ear. The child was fit with linear hearing aids and directional microphones. This amplification technology would not be considered within the standard of care as defined in the Colorado Amplification Guidelines. The child received a second opinion at the University of Colorado Hospital Audiology Clinic where additional testing was completed. It was determined that the child's hearing loss was in the mild-moderate range and that the original hearing aids were too powerful. This child's subsequent hearing tests have confirmed the diagnosis of the mild-moderate hearing loss. The potential harm of the original misdiagnosis of this child includes possible additional hearing loss caused by the excessive power from the inappropriately provided hearing aids

Additionally, DORA contacted the Colorado Department of Public Health and Environment (CDPHE), and requested a review of all complaints filed over the past five years relating to audiologists and hearing aid providers. The following three cases were received by DORA from CDPHE.

Case 7. In 2003-2004, an infant failed a hearing screen given at birth in the left ear only. The infant was sent to a clinic in Grand Junction for follow up with a Colorado-registered audiologist. The child had three ABR tests over a one-year period, which tests all indicated profound loss in the left ear. The child was never fitted with a hearing aid, tested behaviorally, nor were any of the other infant assessment guidelines followed. The ABR was air conduction only, no bone or tone bursts. The audiologist missed the 1-3-6 (months) assessment guidelines for age, and the child then had to be sent to a Denver area hospital for a sedated ABR to complete follow up and begin the appropriate early intervention. When asked about the long delays in intervention and proper testing protocols the audiologist said he didn't think his equipment was working.

Case 8. An audiologist that works for a Greeley physician (ear, nose and throat specialist) has been prescribing medications, ordering Magnetic Resonance Imaging tests, and performing other duties that should be handled by the physician. It was reported that the patients were required to see the audiologist first, then the physician.

Case 9. An audiologist has two children on her caseload that were late identified (20-24 months of age versus the national and state recommendation of identification by three months of age), and the audiologist did not follow the guidelines for appropriate assessment.

The nine complaints reported above have not been reviewed by the Office, or any other professional review group to determine if the alleged conduct violated section 12-5.5-105(1)(b)(IX), C.R.S., which defines grounds for discipline as failing to practice according to commonly accepted professional standards. However, these complaints involve the quality of care provided to patients as opposed to complaints relating to the sale or fitting of hearing aids. Several Colorado-registered audiologists, who read these complaint summaries, felt that some of them would amount to a violation of section 12-5.5-105(1)(b)(IX), C.R.S.

The sunrise review considered by the General Assembly in 1995 did not find justification to recommend regulation of audiologists. Members of the profession, then and now, maintain there is significant potential for harm to the public. Over the past five years, documentation of harm (as opposed to potential harm) has not been extensive, and is highly subjective and largely anecdotal.

Nevertheless, this review concludes that the current registration requirements are not overly burdensome. This review did not find any indication that the registration program improperly excluded anyone with the proper qualifications from registering as an audiologist, or establishing a hearing aid dealer practice.

The Office performs an important mission: to regulate the audiological profession and hearing aid provider occupation and ensure that safe practices exist. The Office plays a vital role in protecting the public by ensuring that only qualified individuals practice in Colorado, and by sanctioning those practitioners who violate the law.

Recommendation 2 – Define the practice of audiology.

Inherent to the appropriate regulation of any profession is a general legal definition of what the practice of the profession entails. The American Academy of Audiology has developed such a definition, based upon the educational programs and common practices of audiologists throughout the country.[35] That definition reads:

> The "practice of audiology" means:
>
> (a) The application of principles, methods, and procedures related to the development and disorders of the human auditory-vestibular system, which disorders shall include any and all conditions whether of organic or functional origin, including, but not limited to, disorders of hearing, balance, tinnitus, auditory processing and other neural functions, as those principles, methods, and procedures are taught in doctoral programs in audiology in accredited programs.
>
> (b) Such principles, methods, or procedures include, without limitation, those of diagnosis, assessment, measurement, testing, appraisal, evaluation, rehabilitation, treatment, prevention, conservation, identification, consultation, counseling, intervention, management, interpretation, instruction or research related to hearing, vestibular function, balance and fall prevention, and associated neural systems, or any abnormal condition related to tinnitus, auditory sensitivity, acuity, function or processing, speech, language or other aberrant behavior resulting from hearing loss, for the purpose of diagnosing, designing, and implementing audiological management and treatment or other programs for the amelioration of such disorders and conditions. Management and treatment shall include but not be limited to the activities described in paragraph (c) of this subsection.
>
> (c) Engaging in the practice of prescribing, selecting, specifying, evaluating, assisting in the adjustment to, and dispensing of prosthetic devices for hearing loss, including but not limited to hearing aids and hearing assistive devices by means of specialized audiometric equipment or by any other means accepted by the Director.

[35] American Academy of Dispensing Audiologists, Model Licensure Statute, Chapter 1, page 1, Section 2.5, February 9, 2005. Accessed from www.audiologist.org/professionals/AcademyDocs/index.cfm on September 28, 2006.

Numerous audiologists registered in Colorado, as well as the Colorado Academy of Audiology and the University of Colorado Audiology Clinic, have endorsed the adoption of this definition. Audiology is evolving and progressing along with the technology that supports this profession. As many medically related professions and occupations experience, there is some overlap of responsibilities and duties that confuse practitioners and the public alike. By adopting a definition or scope of practice, state regulatory agencies, the profession's practitioners, and the public have the same general understanding of what the profession or practice entails.

Recommendation 3 – Delete outdated and obsolete language in Article 5.5 of Title 12, C.R.S.

Sections 12-5.5-101(1) and 12-5.5-201(3), C.R.S., refer to audiologists and hearing aid providers who were in practice prior to 1995, with requirements to demonstrate compliance with these sections by 1997. These two provisions no longer have any effect on the current registrants, as any and all requirements in these sections expired over nine years ago. Deleting them will have no effect on the current registration program.

Section 12-5.5-202(1), C.R.S., states that, "a registered hearing aid provider shall register before selling… any hearing aid device," and section 12-5.5-202(2)(a), C.R.S., states that, "A registered hearing aid provider desiring to register pursuant to this section…" However, a hearing aid provider is not a "registered" hearing aid provider until such time as the individual actually registers with the Director. Consequently, the first use of the word "registered" in both sections should be deleted to accurately reflect the correct status of hearing aid provider applicants.

Recommendation 4 – Revise section 12-5.5-206(4)(b), C.R.S., to exclude minor accessories from the hearing aid provider record keeping requirement.

Section 12-5.5-206(4)(b), C.R.S., requires the Director to promulgate rules:

> That supervising registrants or registrants designated by such registrants' employers maintain for at least seven years records identifying customers by name, the goods and services provided to each customer, and the date and price of each transaction.

The specific recommendation here is to insert the terminology, "except batteries and minor accessories", after the words "goods and services."

This would eliminate the requirement that registrants keep records of sales of batteries, cords, and minor accessories for seven years, which is unnecessary to protect the public's health, safety, or welfare, and is unduly burdensome.

Recommendation 5 - Modify section 6-1-701(2)(d)(VII), C.R.S., by adding terminology that would require cerumen accumulation to be significant prior to requiring a hearing aid provider to provide written recommendation for a consulation with a physician.

Section 6-1-701(2)(d)(VII), C.R.S., lists the conditions in which a hearing aid provider should recommend to the patient that the patient consult with a licensed physician. One of those conditions, listed in subparagraph (VII), is simply the visible presence of cerumen. It is recommended that the word "significant" be added to this section, which would then read as follows:

> (d)(VII) - Visible evidence of A SIGNIFICANT cerumen accumulation on or a foreign body in the ear canal.

Cerumen is most commonly known as earwax. Most patients have at least a small amount of cerumen in their ears; consequently, adding the word "significant" would be a more relevant standard that would not require a physician referral unnecessarily. This modification may also save a consumer time and financial resources.

Recommendation 6 – Modify sections 6-1-701(2)(e)(I), (II), and (III), C.R.S., to clarify the regulation governing refunds, in the event of loss or damage.

The current statutory provisions governing refunding the purchase price of hearing aids does not address the problem of the buyer losing or damaging the hearing aid prior to its return to the seller. This section does not indicate that a purchaser of hearing aids must physically return the device prior to receiving a refund. Therefore, section 6-1-701(2)(e)(I), C.R.S., should be modified to read:

> The buyer shall have the right to cancel the purchase for any reason before the expiration of the rescission period by giving or mailing written notice of cancellation to the seller, **and presenting the hearing aid to the dealer**, **unless the hearing aid has been lost or significantly damaged beyond repair while in the buyer's possession and control.** The thirty-day rescission period shall be tolled for any period during which a registered hearing aid provider takes possession or control of a hearing aid after its original delivery.

This modification provides a reasonable and fair balance to the transaction between the consumer and the hearing aid provider when the hearing aid has been lost or significantly damaged by the consumer. It places the burden of loss on the party that was responsible for said loss.

Section 6-1-701(2)(e)(II), C.R.S., provides for the actual, physical return of a hearing aid by a purchaser prior to a refund being issued by the seller. However, the statute does not address the issue of a hearing aid being damaged beyond repair by the buyer. Therefore, the first sentence of section 6-1-701(2)(e)(II), C.R.S., should be modified to read:

> The buyer, upon cancellation, is entitled to receive a full refund of any payment made for the hearing aid within thirty days of return of the hearing aid to the seller, **unless the hearing aid was significantly damaged beyond repair while the hearing aid was in the buyer's possession and control;** except that, if the hearing aid…

Section 6-1-701(2)(e)(III)(A), C.R.S., requires that the sales contract for hearing aids contain a specific refund statement in capital, bold-faced letters. This statement provides for the actual, physical return of a hearing aid by a purchaser prior to a refund being issued by the seller. However, it does not address the issue of a hearing aid being damaged beyond repair by the buyer. Therefore, section 6-1-701(2)(e)(III)(A), C.R.S., should be modified to read:

> "THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO 12 MIDNIGHT OF THE 30TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID BY GIVING OR MAILING THE SELLER WRITTEN NOTICE OF CANCELLATION AND BY RETURNING THE HEARING AID, **UNLESS THE HEARING AID HAS BEEN SIGNIFICANTLY DAMAGED BEYOND REPAIR WHILE THE HEARING AID WAS IN THE BUYER'S CONTROL.** BY LAW, THE SELLER IS ALLOWED TO RETAIN AN ITEMIZED AMOUNT, NOT TO EXCEED FIVE PERCENT OF THE TOTAL CHARGE FOR THE HEARING AID, TO COVER THE COSTS OF A MANUFACTURER'S RETURN FEE AND THE MINIMUM COSTS OF MATERIALS USED BY THE REGISTERED HEARING AID PROVIDER, UNLESS THE HEARING AID IS RETURNED BECAUSE IT IS DEFECTIVE**."**

Recommendation 7 – Move the substantive provisions of section 6-1-701, C.R.S., of the Consumer Protection Act, as amended by Recommendations 5 and 6 of this report, to Part 2, Article 5.5 of Title 12, C.R.S.

Section 6-1-701, C.R.S., of the Consumer Protection Act (CPA), is entitled, "Registered hearing aid providers – deceptive trade practices." This section defines deceptive trade practices uniquely related to the dispensing of hearing aids. Section 6-1-701, C.R.S., also contains specific language to be utilized in the hearing aid sales contract, and specifies the conditions for sales cancellation and refunds.

This recommendation is to relocate and incorporate the substantive provisions of the CPA, relating to hearing aid dispensers, into Part 2, Article 5.5 of Title 12, C.R.S. This Part 2 provides for the current regulatory body that registers and disciplines hearing aid providers in Colorado. Colorado's hearing aid providers are subject to disciplinary action by this registration program for any violation of the terms set forth in the CPA.[36]

When this recommendation is implemented, complaints against hearing aid providers will be made with the same agency responsible for the registration and discipline of hearing aid providers. The complaint review process would receive the perspective of regulatory professionals who are attuned to the unique issues and circumstances inherent in the sales of hearing aids. Importantly, this recommendation will result in no substantive changes. The only changes will pertain to which government agency enforces these provisions.

Currently, hearing aid provider registrants must consider two entirely different sections of Colorado statutes, the CPA and Title 12, C.R.S., to determine the laws and regulations under which they practice. This regulatory scheme is potentially confusing and could very well lead to a registrant's inadvertent violation of the law. More importantly, consolidating the enforcement of the CPA provisions into the current regulatory scheme would benefit consumers. By moving section 6-1-701, C.R.S., into Title 12, C.R.S., the consumer will not have to determine the appropriate agency or organization with which to file a complaint. After consolidation, all complaints would be filed with DORA, and processed by the Director.

[36] Section 12-5.5-205(1)(b)(IV), C.R.S.

The Colorado Attorney General (AG) and the state's district attorney's (DAs) are statutorily mandated with the enforcement of criminal and civil violations of specific state laws and regulations. Interviews with the AG's Consumer Protection unit, and selected Colorado district attorney offices indicate that there has been no enforcement of section 6-1-701, C.R.S., during the past five years. The lack of CPA-generated prosecutions or actions by the AG and DAs, and the complaints and disciplinary actions taken by the Director, substantiate that consumer complaints are now being filed with the Director. Consequently, the AG and DAs enforcement of this provision of the CPA is minimal to nonexistent, duplicative and unnecessary.

Appendix A – Sunset Statutory Evaluation Criteria

(I) Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;

(II) If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;

(III) Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;

(IV) Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;

(V) Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;

(VI) The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;

(VII) Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;

(VIII) Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

(IX) Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

Appendix B – Uniform Sales Contract

PURCHASE AGREEMENT

	[NAME OF BUSINESS]	[LOGO]
[TELEPHONE & FAX NUMBER]		[BUSINESS ADDRESS] [EMAIL OR WEB SITE ADDRESS]

I ("Buyer") hereby purchase from [name of business] ("Seller") the hearing system and equipment described below, agree to pay the purchase price written, and honor the following terms and conditions:

MANUFACTURER OF AID	MODEL	LEFT SERIAL NO.	RIGHT SERIAL NO.	CONDITION
				New _____ Used _____ Reconditioned _____
PURCHASE PRICE				$
Professional Services – Testing, Fitting, and Follow-up				$
Warranty - Loss, Damage, & Repair				$
Other – Sales Tax, Etc.				$
TOTAL				$
Less Payment With Order				$( )
Balance Due Upon Delivery				$

WARRANTY: The manufacturer guarantees Buyer's hearing aid to be free from all defects of workmanship and materials for a period ____ year(s) from date of purchase and agrees to make all necessary repairs, replacements, and check-ups with promptness and without charge to Buyer during the guarantee period.

ADVISEMENTS: Buyer has been advised that any examination or representation made by Seller in connection with the practice of dispensing, fitting, or dealing in hearing aids is not an examination, diagnosis, or prescription by a person licensed to practice medicine in this state and therefore, must not be regarded as a medical opinion or advice.

Buyer has been advised that the Buyer's best interests would be served by consulting a licensed physician specializing in diseases of the ear, or, any licensed physician, if any of the following conditions exists: visible congenital or traumatic deformity of the ear; history of or active drainage of the ear within the previous ninety days; history of sudden or rapidly progressive hearing loss; acute or chronic dizziness; unilateral hearing loss of sudden onset within the previous ninety days; audiometric air-bone gap equal to or greater than fifteen decibels at 500 hertz ("Hz"), 1,000 Hz, and 2,000 Hz; visible evidence of cerumen accumulation on or a foreign body in the ear canal; and pain or discomfort in the ear.

Buyer has been advised that Buyer's best interest would be served by consulting and receiving a written prescription or recommendation from a licensed physician prior to dispensing, fitting, or dealing in a hearing aid that specifies Buyer is in fact in need of a hearing aid. Based on religious or personal beliefs, Buyer hereby waives such requirement. _____ Buyer's Initials

Buyer has been advised that this sale is void and unenforceable if the hearing aid being purchased is not delivered to Buyer within thirty days after the date the written contract is signed or the receipt is issued, whichever occurs later. Seller shall promptly refund all moneys paid for the purchase of a hearing aid if it is not delivered to Buyer within such thirty-day period.

Buyer has been advised that upon cancellation, Buyer is entitled to receive a full refund of any payment made for the hearing aid within 30 days of return of the hearing aid to Seller; except that, if the hearing aid is returned for any reason other than a defect in such hearing aid, the Seller may retain an itemized amount to cover the minimum costs of materials used by the Seller and a manufacturer's return fee, but such amount may not be greater than five percent of the total charge for the hearing aid.

Buyer has been advised that consumer complaints which cannot be resolved with Seller may be filed initially with the Office of the District Attorney at [include address and telephone number for the district attorney in the county where sold] or with the Office of the Attorney General, 1525 Sherman Street, 7th Floor, Denver, Colorado, 80203, (303) 866-4500. Complaints against Seller may also be filed with the Colorado Hearing Aid Providers Registration, 1560 Broadway, Suite 1545, Denver, Colorado, 80202, (303) 894-2440.

THE BUYER HAS THE RIGHT TO CANCEL THIS PURCHASE FOR ANY REASON AT ANY TIME PRIOR TO 12 MIDNIGHT OF THE 30TH CALENDAR DAY AFTER RECEIPT OF THE HEARING AID BY GIVING OR MAILING THE SELLER WRITTEN NOTICE OF CANCELLATION AND BY RETURNING THE HEARING AID. BY LAW, THE SELLER IS ALLOWED TO RETAIN AN ITEMIZED AMOUNT, NOT TO EXCEED FIVE PERCENT OF THE TOTAL CHARGE FOR THE HEARING AID, TO COVER THE COSTS OF A MANUFACTURER'S RETURN FEE AND THE MINIMUM COSTS OF MATERIALS USED BY THE REGISTERED HEARING AID PROVIDER, UNLESS THE HEARING AID IS RETURNED BECAUSE IT IS DEFECTIVE.

Seller's Signature	Buyer's Signature
Seller's Printed Name	Buyer's Printed Name
Seller's Hearing Aid Provider Registration No. _____	Street Address
	City, State, & Zip Code
Executed this _____ day of _____, _____.	Telephone Number

REFUND REQUEST - THIS FORM MUST BE POSTMARKED BY _____ (DATE TO BE FILLED IN), NO REFUND WILL BE GIVEN UNTIL THE HEARING AID OR HEARING AIDS ARE RETURNED TO THE SELLER.

Buyer's Name: _____ Date: _____

Buyer's Address:

_____

Buyer's Telephone Number: _____ Signature: _____

THIS REFUND REQUEST FORM MUST BE RETURNED TO:

[Name, Address, and Phone Number of Seller]

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