Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	2002 JUN 24 PM 4:30 IRRC Number: 2278
(2) I.D. Number (Governors Office Use) DOH Reg. No. 10-165	

(3) Short Title

Hearing Aid Sales and Registration Regulations

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers 717-783-8078
28 Pa. Code Chapter 25	Primary Contact: Jan Staloski, Director Chief, Division of Home Health 132 Kline Plaza, Suite A Harrisburg, PA 17104 (717) 783-1379 Secondary Contact: Theresa Ritchie, Program Spec. Drug Program Specialist 132 Kline Plaza, Suite A Harrisburg, PA 17104 (717) 787-4779

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
x Proposed Rulemaking	x No
Final Order Adopting Regulation	Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The regulation governs the sale of hearing aids and the activities of hearing fitters and dealers. The proposed regulations are intended to incorporate changes made to Act 262 of 1976 by Act 153 of 1998, including increased registration fees, requirements for continuing education, and the requirement of providing written disclosure agreements and money-back guarantees to customers.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Act 262 of 1976, as amended by Act 153 of 1998

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Section 205(b) of Pennsylvania Act 153-1998.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

Statutory amendments have been made to the Hearing Aid Sales Registration Law; the amendments to the regulations will incorporate these. The statute requires regulations to be promulgated to administer the continuing education requirements and the requirement that each customer be given a written money-back guarantee. The additional sections provide additional clarification of changes made by the statute, including the requirement that a written disclosure statement be provided to prospective customers.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

Regulations will not be a helpful source of information for the regulated community if they do not reflect all current requirements.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

All hearing challenged consumers, approximately 1.5 million Pennsylvanians, will benefit from this regulation.
The regulation also will benefit approximately 1,400 fitters and dealersby aiding in the development of clearer standards of practice.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

These regulations will not adversely affect anyone.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All fitters or sellers/dealers of hearing aids in Commonwealth of Pennsylvania. The number is approximately 1,400

All persons or entities who offer continuing education courses to hearing aid fitters. Currently 10 professional associations and manufacturers are approved CEU providers. However, the number is expected to increase to approximately 30-40.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

A meeting of the Hearing Aid Advisory Council was held on June 18, 1999. Council members and stakeholders who attended the meeting offered comments on the draft regulations. This included members from the Pennsylvania Hearing Association Alliance. On August 20, 1999, the Department made a draft regulation available to stakeholders and asked for written comments to be submitted by September 30, 1999. Four sets of comments were received and reviewed. A meeting also took place with the Department of State, Board of Speech-Language and Hearing in December 1999, to address their comments and concerns.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

a. Registration and renewal fees were increased by the 1998 statute.
Dealer registration from $100.00 to $200.00
Apprentice registration from $25.00 to $50.00
Exam fee from $75.00 to $150.00
Delinquency $25.00 to $50.00
The Department estimates 1,400 fitters/dealers will have to pay the $100 increase in registration fees, 40 apprentices will pay $25 increase in registration fees, and 60 candidates will pay the $75 increase in the exam fee. An estimated 10% of all fitters/dealers will pay the $25 increase in the delinquency fee. The statute therefore increased the costs to the regulated community by $149,000.

$$(1{,}400 \times \$100) + (40 \times \$25) + (60 \times \$75) + (140 \times \$25) = \$149{,}000.$$

b. Continuing education courses. Approximately $100-400 the first year (with the first year to be the most expensive). Costs in subsequent years are expected to decrease as more options, including more home study and local courses, become available. Estimating education courses for 1,400 dealers @ $200 = $280,000 for the first year. This cost is estimated to be decreased by half for the out years.

c. One-time (almost insignificant) cost of revising forms and documentation used in the sale of hearing aids to comply with the new requirement of written disclosure agreements and money-back guarantees.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

These regulations have no fiscal impact on local governments.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including and legal, accounting, or consulting procedures which may be required.

Additional costs may be incurred to ensure and verify compliance with the new requirements (i.e. Continuing education credits, proper disclosure agreements, etc.) These costs may include additional time and effort by existing program staff as well as legal staff. This may also include on-site inspections and audits to further ensure compliance.

However, many possible costs of increased enforcement efforts would be offset by the increased fees. These fees generated an approximate increase of $149,000 to the general fund in the first year.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
	$	$	$	$	$	$
SAVINGS:						
Regulated Community	$ 0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$ 0	0	0	0	0	0
Total Savings						
COSTS:						
Regulated Community	$280,000	140,000	140,000	140,000	140,000	140,000
Local Government	$ 0	0	0	0	0	0
State Government	$ 0	0	0	0	0	0
Total Costs	$280,000	140,000	140,000	140,000	140,000	140,000
REVENUE LOSSES:						
Regulated Community	$ 0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$ 0	0	0	0	0	0
Total Revenue Losses						

(20a) Explain how the cost estimates listed above were derived.

Estimates for the impact on the regulated community are explained in section 17(a). The first year $70,000 amount represents initial registration certificates issued during the second half of the registered years as per Section 25.207 (b).

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY - 3	FY - 2	FY - 1	Current FY
Planning	$			$65,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

The Act requires fee increases and will generate new revenue.
The regulations would benefit the hearing challenged and the regulated community (as reviewed in sections 11 and 12).

(22) Describe the non-regulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

Act 1998-153 has mandated that the Department promulgate regulations to enforce and administer changes made to the Hearing Aid Sales Registration Law by that Act.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

The requirements of Act 1998-153 are clear, and there is an existing regulatory framework for the administration of the Program. For these reasons, no schemes very unlike the final product were considered.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

Certain provisions of the Hearing Aid Sales Registration Law as it existed prior to Act 1998-153 contain standards more stringent than those contained in regulations later promulgated by the FDA; those standards that were not preempted still stand. Specifically, the Pennsylvania statute provides that a hearing aid may not be prescribed for children 18 and under unless a physician specialist, as opposed to a generalist, has first been consulted. Other Pennsylvania standards were preempted by the Federal regulations; some of the proposed changes cause the regulations to be less stringent in order to reflect the Federal standards.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

Several states currently require continuing education for hearing aid fitters/specialists.

No competitive disadvantage.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No regulations will be affected.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

Purpose/dates/locations/times TBA subsequent to publication in the *Pennsylvania Bulletin.*

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

Yes.

a. Government will need to keep records and verification of continuing education as completed by individual fitters.
b. Fitters and dealers will need to implement written disclosure agreements and money-back guarantees, and keep those on file for 7 years.
c. Fitters will also need to maintain their own records of participation in any continuing education courses for two years and report annually to the State.
d. Individuals and entities who intend to offer continuing education courses must apply to the Department for approval of those courses. Additionally, reporting and record keeping requirements will apply.

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

N/A

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

Based on Act 153 of 1998, the disclosure agreement and fees were effective 60 days after the law was signed on December 21, 1998. The continuing education requirements were effective beginning December 21, 2000.

(31) Provide the schedule for continual review of the regulation.

Annual.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2278

2002 JUN 24 PM 4:30

DO NOT WRITE IN THIS SPACE

REVIEW COMMISSION

Copy below is hereby approved as to form and legality. Attorney General BY _____ DEPUTY ATTORNEY GENERAL MAY 28 2002 DATE OF APPROVAL Check if applicable. Copy not approved. Objections attached.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by: DEPARTMENT OF HEALTH (AGENCY) DOCUMENT/FISCAL NOTE NO. 10-165 DATE OF ADOPTION: _____ BY: _____ Robert S. Zimmerman, Jr. TITLE: Secretary of Health	Copy below is hereby approved as to form and legality. Executive or Independent Agency. BY _____ 4/24/02 DATE OF APPROVAL (Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title) Check if applicable. No Attorney General approval or objection within 30 days after submission.

PROPOSED RULEMAKING
DEPARTMENT OF HEALTH
TITLE 28. HEALTH AND SAFETY
PART III. PREVENTION OF DISEASES
[28 Pa. Code Ch. 25]
Hearing Aid Sales and Registration

CONTINUATION SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to the Commonwealth Documents Law).

Notice is hereby given that the Department of Health (Department) proposes to amend Part III of Title 28 (relating to prevention of diseases) by amending Chapter 25 (relating to controlled substances, drugs, devices, and cosmetics). The proposed amendments are set forth in Annex A.

A. Purpose and Procedure

The proposed amendments are intended to facilitate implementation of amendments made to the Hearing Aid Sales Registration Law (Act) (P.L. 1182, No. 262) (35 P.S. §§6700-101 -- 6700-802) by Act 1998-153, and to otherwise bring up to date the regulations promulgated under the Act. The Act governs the sale of hearing aids and regulates the related activities of hearing aid dealers and fitters. It imposes duties upon, and prohibits certain acts by, hearing aid dealers and fitters, and provides for penalties that may include denial, suspension, or revocation of a dealer's or fitter's registration. The changes made by Act 1998-153 included imposing continuing education requirements upon hearing aid fitters and making failure to comply with those requirements a cause for denial, suspension, or revocation of a registration certificate. Act 1998-153 also raised the fees for registration certificates, and required disclosure agreements and money-back-guarantees to be provided to purchasers and prospective purchasers of hearing aids.

The proposed amendments are also responsive to Federal preemption of certain portions of the Act due to regulations promulgated by the Federal Food and Drug Administration (FDA) pursuant to the Federal Food Drug and Cosmetic Act (21 U.S.C §§ 301 et seq., specifically 21 U.S.C. §360k). The Federal regulations regarding hearing aids are published at 21 CFR 801.420 and 801.421. A few Pennsylvania requirements that conflict with the Federal regulations were

conditionally exempted from preemption pursuant to the final rule issued by the FDA in Docket No. 77N-0333, dated October 10, 1980 (45 FR 67321) (Final Rule). These will be discussed. Other amendments are proposed for the sake of clarity or correctness, to fix typographical errors, or to bring the regulations into compliance with the Pennsylvania Code and Bulletin Style Manual. Proposed grammatical changes will not be discussed. A number of amendments have been proposed to ensure that terms are used consistently, including the use of "registrant" to refer to dealers and fitters, and "prospective hearing aid user" to refer to one who is being evaluated but who has not purchased a hearing aid. Additionally, the term "authorized representative" would be defined and used to clarify that one who fits the definition of "authorized representative" may act for a prospective hearing aid user. Also proposed is the addition of a "Subchapter B" heading for 28 Pa. Code §§25.201—25.221, entitled "Hearing Aid Sales and Registration," to differentiate the hearing aid regulations from regulations in proposed new "Subchapter A," entitled "Controlled Substances, Drugs, Devices and Cosmetics."

Following the passage of Act 1998-153, stakeholders began contacting the Department with suggestions and ideas for the revised regulations, and draft proposed regulations were formulated. In drafting the proposed changes to the regulations, the Department has taken into account the recommendations of the Hearing Aid Advisory Council, as well as the written and oral comments that have been made in response to the draft proposed regulations by stakeholders, primarily members of the regulated community. Changes made in response to this input include the proposed updating or removal of archaic technical requirements, and proposed changes to more accurately reflect the procedures followed by the Department in administering examinations to hearing aid fitters and in registering both dealers and fitters.

In addition to enforcement responsibilities this Act confers upon the Department, the Act also confers enforcement responsibilities upon the Office of Attorney General and district attorneys offices. In developing the proposed amendments, the Department consulted with the Office of Attorney General, in particular, its Bureau of Consumer Protection.

B. Summary of the proposed amendments.

It is proposed that the Chapter be divided into Subchapters A and B to separate the hearing aid regulations from the other regulations in the Chapter. Proposed Subchapter B would include regulations adopted under the Act, while proposed Subchapter A would include regulations adopted under the Controlled Substance, Drug, Device and Cosmetic Act (P.L. 233, No. 64) (35 P.S. §§780-101-780-144).

Section 25.201. Application.

This section sets out the scope of the regulations that would comprise Subchapter B and the Department's authority to adopt these regulations. The proposed changes are made to enhance clarity and to substitute a reference to Subchapter B for the present reference to the span of regulations that would comprise that subchapter. Removal of the term "surgeon" is proposed in this section and throughout the regulations, as that term is encompassed by the term "physician." This change was suggested by a stakeholder during the drafting process.

Section 25.202. Definitions.

This section defines the relevant terms used in the regulations that would comprise Subchapter B. The Department proposes several amendments to this section. The Department seeks to clarify that information or documentation required to be provided to a prospective hearing aid user must also be provided to a person authorized to act on behalf of the prospective user. The Department, therefore, proposes to include the term "authorized representative," and

to define that term as being a person who is authorized by law to make a decision for a hearing aid user or prospective user. Defining the term "physician," as proposed, will provide consistency with regulations in other chapters of the Department's regulations, and clarify that the term refers to a medical or osteopathic medical doctor who has a currently registered license to practice in Pennsylvania.

The definition of "advertise and any of its variants" would be revised to include the use of the internet for advertising purposes. This change is certainly a necessary one, given the ubiquity and ease of internet marketing and advertising.

The proposed addition of the term "used hearing aid" is made pursuant to an FDA requirement. Federal regulations require that a statement identifying a used or rebuilt hearing aid must appear on the package and on a tag attached to the hearing aid, and may also appear in the "User Instructional Brochure." (21 CFR 801.420(c)(5)). Pennsylvania's requirement that the receipts provided to hearing aid purchasers must also identify used or reconditioned hearing aids as such could, therefore, have been preempted. However, the FDA decided to exempt Pennsylvania's requirement from preemption contingent on Pennsylvania applying the Federal definition of "used hearing aid." To comply with this directive, the proposed definition of "used hearing aid" is included. It is substantially the same as the Federal definition.

The definition of "continuing education program" is included to label a program that the Department will recognize towards satisfaction of the continuing education requirements effected by Act 1998-153. Hearing aid fitters are now required to secure continuing education credits to renew their registrations. Finally, a new definition of the term "audiologist" is proposed to more accurately reflect the regulatory scheme governing that profession.

Section 25.203. Advisory Council.

This section sets out the requirements for the Council, established under section 201 of the Act (35 P.S. §6700-201). It is proposed that subsection (c)(2), which pertains to Council meetings, be removed. The requirements of the paragraph are too rigid and relate to internal Department matters that do not need to be addressed by regulation. The Department will, of course, coordinate with Council members to schedule Council meetings and make every effort to give Council members timely notice of meetings far in advance. The few remaining proposed changes are to improve clarity and consistency of language.

Section 25.204. Application for and renewal of registration.

This section sets out the process of applying for or renewing a registration, as required by sections 301 and 312 of the Act (35 P.S. §§6700-301 and 6700-312). The proposed change in the title of the section simply gives the reader notice that the requirements of the section apply to both registration and renewal of registration.

A proposed change to subsection (b) would clarify that the $50 registration fee for an apprentice hearing aid fitter is separate from the initial $150 fee to take the fitter's examination, and that the amounts may be paid separately. As specified in proposed §25.207(g) (relating to categories of registrations; fee schedule), an apprentice hearing aid fitter, or the holder of a temporary fitter's registration, who has failed the fitter's examination need only pay an additional examination fee of $50 to take the examination again. The applicant does not have to pay an additional $150 each time the exam is taken. Additional proposed changes to subsections (b) and (c) allow for the Department to approve payment methods other than check or money order to pay registration fees and other amounts that may be due.

The proposed requirement in subsection (b) that a completed application for registration examination applies when an apprentice fitter failed the examination the first time and must reregister as an apprentice. The 30-day requirement does not apply to an apprentice fitter who is applying for a registration certificate for the first time. An apprentice is required to serve in an apprenticeship for at least four months prior to taking the exam for the first time. An apprentice cannot even begin the apprenticeship prior to being registered. Therefore, the apprentice fitter who has never been registered previously would already have applied for registration more than four months prior to taking the fitter's examination, far in excess of the required 30 days. The 30-day requirement does ensure that an apprentice fitter who is retaking the fitter's examination will reapply for a registration certificate at least 30 days prior to retaking the examination.

Some registrants apply for renewals of registration certificates only a few days before their certificates are due to expire. This creates an unreasonable administrative burden for the Department to process these applications within a few days to prevent the registrations from lapsing. The addition of the proposed requirement in subsection (d) that a renewal must be applied for at least 30 days prior to the expiration of a registration certificate, and the proposed addition of subsection (g), which states that a renewal applied for after that time may not be approved before the certificate expires, are intended to ensure that the Department has a reasonable period of time to process renewal requests. This is especially reasonable in view of the fact that all registration certificates expire on the same date – April 15 of each year. The remaining changes the Department proposes in this section would revise fees to be consistent with changes made by Act 1998-153, and relate that certain registrants must meet continuing education requirements to renew their registrations, which requirements are also imposed by Act 1998-153.

Section 25.205. Additional registration requirements.

This section sets out the requirements for registration as a dealer, fitter, or apprentice in addition to those set forth in §25.204 (relating to application for and renewal of registration), as well as the requirements for reciprocal or temporary registration. The proposed addition of subsection (c)(3) is intended to address a practical problem. While the regulation allows for registration certificates by endorsement (by the Secretary) to be issued to persons licensed as dealers or fitters by states that maintain reciprocal practice privileges with Pennsylvania, there are no states that actually have such arrangements with the Commonwealth at this time. Therefore, there are no persons currently eligible for registration by endorsement. Proposed subsection (c) informs persons who believe they may be potential registrants by endorsement how they may register, given that registration by endorsement is not an option at this time.

The proposed additions to subsection (d)(2)(ii) are also intended to address a practical problem. The Hearing Aid Program staff receive frequent telephone calls from registrants who are preparing to sponsor an apprentice, asking what should be included in a training program, so that they may prepare the required outline. Section 302 of the statute (35 P.S. §6700-302) states that applicants shall demonstrate thorough knowledge of certain subject areas, which areas will be included on the examination. These subject areas are repeated in the proposed regulatory language. This should provide sufficient guidance for those registrants who are sponsoring apprentices to develop an effective training program.

The remaining changes to this section are proposed by the Department to promote clarity and consistency of language.

Section 25.206. Examinations.

This section deals with the qualifying examination for hearing aid fitters. It addresses matters such as the frequency with which the examination is given, obtaining examination dates, and the determination of passing grades. The changes to this section are proposed by the Department to promote clarity and consistency of language.

Section 25.207. Categories of registrations; fee schedule.

This section sets out application and registration fees for dealers, fitters, and apprentices, and other fees provided for by the Act. The Department is proposing changes to this section to incorporate the increased registration fees adopted by Act 1998-153. Other changes proposed by the Department include changes to subsections (b) and (c) to clarify that, if an initial registration certificate is issued during the second half of the registered year, only half of the registration fee will be charged. Because all registrations expire on April 15 (pursuant to section 311 of the Act (35 P.S. §6700-311)), initial dealer registrations issued between October 15 and April 14 are prorated so that the initial fee is $100, rather than the full $200. However, because initial fitter registrations are always preceded by an exam, and $150 of the initial fee is associated with the exam, initial fees for fitter's registration certificates are not prorated. After an initial registration certificate is issued, all renewals are for a full year. Both dealer and fitter renewals will carry a fee of $100.

Changes to subsection (e) have been proposed to clarify that the part of the registration fee which is charged to the applicant holder of a temporary fitter's registration certificate to take the hearing aid fitter's examination for the first time, which is currently $150, will be refunded if the applicant is ineligible to take the exam. Because a considerable period of time may legitimately elapse between the issuance of a temporary fitter's registration certificate and the

registrant taking the fitter's examination, subsection (e) would allow the examination fee to be paid separately from and later than the registration fee for the temporary fitter's certificate (as subsection (f) already explicitly allows apprentice fitters to do).

The proposed changes to subsection (g) serve to illustrate the difference between duplicate certificates, which are issued to replace an original certificate that has been lost or destroyed or so that a registrant has an official copy of the certificate for display in more than one location, and replacement certificates, which are issued upon a name change by the holder of the certificate.

Subsection (i) would state that a $50 delinquency fee applies when an applicant applies for the renewal of a registration certificate more than 30 days after the registration certificate has expired. The Act states that such a delinquency fee applies if the registration certificate is renewed more than 30 days after expiration (35 P.S. §6700-312); the proposed language is intended simply to ensure that registrants are aware of that fact. Act 1998-153 increases the delinquency fee from $25 to $50, and increases the fee for renewal of a suspended registration certificate from $50 to $100.

Section 25.208. Display of registration certificates; offices.

This section contains requirements for display and inspection of registration certificates. It also includes various requirements regarding a registrant's place or places of business.

The proposed rewrite of subsection (b) would make explicit the requirement that registrants display a duplicate certificate of registration in each branch office. The registrant would apply for and obtain the duplicate from the Department. In addition to the information contained on the original certificate, the address of the correct branch office would appear on a certificate issued for that office. The change would ensure that the certificate on display shows

that the location has been brought to the attention of the Department, as required by the Act. An additional proposed change is to address the subject matter currently addressed in subsections (b) and (c), in subsections (c) and (d), respectively, due to the proposed repeal of the current text of subsection (d).

The proposed change to current subsection (b) (proposed subsection (c)) specifies that a registrant shall identify a fixed place of business in an application for registration. This protects the public both by preventing registrants from operating without any fixed place of business, and by ensuring that the Department and hearing aid purchasers can locate and contact registrants. The proposed requirement that a registrant operating out of a residence use a space that is set aside for office purposes protects the public health and safety by ensuring that there is a proper space for testing and for the comfort of the prospective hearing aid user. The deletion of the current text of subsection (d) is proposed because the Department no longer issues the cards bearing the expiration date of registration certificates that are the subject matter of subsection (d). The remaining changes to subsections (c) through (e) are proposed for greater clarity.

Section 25.209. Facilities, procedures and instrumentation.

This section identifies the facilities registrants must provide, the procedures that must be followed in fitting and selling a hearing aid, and the standards with which instruments must be in compliance. The proposed addition of the word "documented" in subsection (a)(1) serves to reinforce the requirement, stated in §25.214(1)(i) (relating to recordkeeping), that records of the ambient noise levels of the test area must be maintained for 7 years as part of the registrant's records.

Several changes are proposed in subsection (b). A number of these are technical changes brought to the attention of the Department by stakeholders, and are intended to more closely

reflect current technical standards for testing. They include the addition, in subsection (b)(2)(i), of 8000 Hz to the frequencies at which air conduction tests for hearing level thresholds can be performed, as 8000 Hz is a commonly tested frequency. The frequency of 250 Hz would be removed as an acceptable one for testing hearing level thresholds, as 250 Hz is not really a speech frequency, and is an unreliable test frequency that tends to indicate a greater hearing loss than actually exists. Suggested changes to subsection (b)(2)(iv) and (v) would allow additional methods to be used to determine how well an individual can hear speech. Other proposed changes include references to the use of both head and insert earphones in testing, and the inclusion of speech intelligibility as an area of hearing function that may be improved by the use of hearing aids.

An addition to subsection (b)(1) is proposed to supplement the present prohibition against registrants selling a hearing aid unless the prospective user has had specified hearing tests within the previous six months. The section currently exempts sales of identical replacement hearing aids from this requirement, thus enabling identical hearing aids to be sold indefinitely without the hearing aid user being retested. Because the needs of hearing aid users change periodically, it is reasonable to ensure that hearing aid users who wish to purchase an identical hearing aid are retested at least every twelve months.

Section 25.210. Receipt, disclosure agreement and money back guarantee to purchaser – purchaser protection.

This section sets out requirements for written receipts, disclosure agreements, and money back guarantees. The Department proposes to divide this section into subsections to deal with additional subject matter. The existing regulation would be incorporated in subsection (a). A minor change to subsection (a) would address stakeholder queries as to whether the Act requires

receipts to be on a single sheet of paper. The proposed change clarifies that they are not required to be on a single sheet of paper.

The Department further proposes an addition to subsection (a)(2), which currently requires the serial number of the hearing aid to be on the receipt. The change, which allows another identification number to be used if a serial number is not available, addresses the sale of new disposable hearing aids, which do not have serial numbers.

Proposed subsections (b) and (c) are new. They are proposed in response to Act 1998-153 requirements that fitters provide a written disclosure agreement and a written 30-day money back guarantee to hearing aid purchasers to allow them to return the hearing aids for a refund. In keeping with Act 1998-153, the Department's proposed form is written in conformance with the Plain Language Consumer Contract Act (P.L. 128, No. 29) (73 P.S. §§2201-2212). Proposed subsection (b) would require the disclosure agreement/money back guarantee to be printed in ten-point or larger type. It would further require the registrant to provide the disclosure agreement/money back guarantee prior to the provision of any service relating to the possible sale of a hearing aid, and to explain it in detail, as required by the statute.

The Department proposes to require registrants to use a form disclosure agreement that includes the money back guarantee as part of the same document. The use of a single document is proposed because the money back guarantee is closely related to the fees that are a main part of the subject matter of the disclosure agreement. The Department is aware that there has been some confusion on the part of both registrants and hearing aid purchasers as to what fees may be retained by registrants when a hearing aid is returned, and how the cancellation fee is to be calculated. In fact, improper cancellation fees or disclosure agreements are among the leading causes of consumer complaints received by the Department in the last few years.

The Department's believes that a very small number of registrants deliberately take advantage of a customer population that, due to the nature of the services offered, includes a large percentage of elderly persons, who are particularly vulnerable to bad practices. However, while some improper disclosure and cancellation practices may be deliberately utilized, there also seems to be genuine misunderstanding by some hearing aid dealers and fitters as to how the law in these areas is to be applied. The Department is therefore proposing that registrants be required to use the form disclosure agreement/money back guarantee the Department is proposing as part of the regulation. This would reduce confusion and protect vulnerable consumers by ensuring insofar as is possible that they receive a full explanation of what they must pay for services and goods and what part of that money may be refunded. This also would clarify the Department's interpretation of the Act for the regulated parties and the public at large.

The primary problem that has arisen with regard to the money back guarantee is that, in practice, registrants often charge, in addition to the charge for a hearing aid, fees for services associated with the fitting procedure, such as hearing testing, hearing evaluation, and fitting a hearing aid, and retain those fees in addition to the statutorily permitted cancellation fee when a hearing aid is returned. As a result, registrants sometimes retain several hundred dollars in addition to the statutorily permitted cancellation fee, whereas the purchasers returning the hearing aid believe that they would receive a refund of all money paid except for a maximum cancellation fee of $150 per hearing aid. The Department interprets Act 1998-153 to permit registrants to charge fees for services separately from the price of a hearing aid. The cancellation fee permitted by statute deals solely with, and is calculated based solely upon, the price of the hearing aid and accessories. In other words, the cancellation fee pertains solely to the goods sold, and registrants may properly charge additional fees for services. Those fees are separate

from the price of the hearing aid. Because they are attributable to services that have already been rendered, they are not required to be refunded upon the return of a hearing aid.

Although the practice of charging separate fees for services is not necessarily illegal or improper, it has become evident that in many cases registrants have not been making clear to customers that charges for services may be retained or collected by them when a hearing aid is returned, in addition to the cancellation fee, which is calculated based upon the price of a hearing aid and accessories. Indeed, some registrants do not appear to grasp this distinction themselves, and incorrectly represent charges for services as being part of the price of the hearing aid. This misunderstanding on the part of registrants is evident in confusing practices such as stating a single price for a hearing aid on the receipt, which price in fact includes service fees that the registrant intends to retain if the hearing aid is returned. In such cases, even if the service fees are properly itemized on the disclosure agreement, consumers get mixed messages. This problem is compounded when registrants fail to fully explain the disclosure agreement, which no doubt occurs at times. In some cases, registrants add the amounts attributable to fees for services to the price of the hearing aid, and then calculate the cancellation fee based on that amount. The registrants then retain both that cancellation fee and the fees for the services. This is not in keeping with the statute in several respects. First, the cancellation fee is inflated by including amounts not attributable to the actual price of the hearing aid when calculating it. Second, although the statute requires registrants to explain disclosure agreements in detail, in some instances registrants are not giving consumers clear explanations of what amounts paid are attributable to fees for services and what the actual price is for the hearing aid.

Because the statute requires fees, including the cancellation fee, to be itemized and disclosed on the disclosure agreement, and because the frequent confusion as discussed above

implicates both the disclosure agreement and the money back guarantee provisions of the statute, the Department's proposed form addresses both matters. To address the lack of clarity which has been noted in the failure on the part of some registrants to distinguish the difference between fees for services and the price of hearing aids, the proposed form disclosure agreement/money back guarantee is divided into Parts A and B. Part A requires the registrant to list and describe the services offered in the first column, as the statute requires. Part A provides space for the registrant to state the fee for each service, and to clearly identify which amounts are refundable if a hearing aid is returned, and which are not. Further, Part A requires registrants to state, along with the fee, whether the fee will be waived if a hearing aid is purchased. This is included because some registrants follow this practice, and stating it as such serves to clarify that the fees for services are not part of the price of the hearing aid.

Part B of the proposed disclosure agreement/ money back guarantee form is devoted to stating the price of each hearing aid and the associated accessories. The only amounts that should be identified as being "not refundable" are the cancellation fees for the hearing aids and associated accessories, the combined amount of which is restricted by statute.

The proposed form has three separate places for the potential hearing aid purchaser to sign. Two of these must include the date and time of the signature. The signature required directly under Part B is intended to ensure that the registrant explained the disclosure agreement/money back guarantee, particularly the service fees that will be incurred and the cancellation fees that might be incurred, to the potential purchaser prior to the provision of any service, as required by the statute. Of course, Part B cannot be fully completed prior to providing some service, since the registrant cannot know what hearing aid may be necessary, let alone its price. However, it can and must be preliminarily explained. In any case, the

customer's signature on the second signature line, indicating that a sale has been made, must be obtained following the sale. The registrant should be sure that the cancellation fees and money back guarantee are fully understood by the purchaser prior to the second signature being obtained. The customer should be provided with a completed copy of the disclosure agreement before leaving.

The customer should not be asked to sign or initial the box identifying the date of delivery until the customer picks up the hearing aid. At that time, as proposed, the date of delivery must be noted, the customer's initials or signature must be obtained in the block, and the registrant must provide another copy of the form to the purchaser with all purchaser signatures and initials. The Department is proposing to require this additional protection because consumers are often unsure as to when the 30-day return period will end, resulting in disputes between consumers and registrants as to whether a hearing aid was returned within the period allowed. The statute provides that the 30-day return period runs from the date of delivery of the hearing aid, not the date the sale was made. It is hoped that by bringing the date of delivery to the attention of both the registrant and consumer, these disputes will occur less often, as both parties should be clear as to the date by which the hearing aid must be returned to trigger a refund. Again, the registrant is expected to explain these matters clearly to the consumer.

Registrants should expand the form if necessary to fill in the proper information in the blanks provided. The form may also comprise more than one page if necessary; however, it should be clearly identified as being a single document.

The form should not be interpreted to require a charge for services. There are many registrants who charge no fee for fitting services. These registrants need only indicate that the price is zero. If registrants choose to give full refunds if a hearing aid is returned rather than

retaining a cancellation fee, they may simply state the entire price of the hearing aids in the "refundable" column of Part B. As stated in subsection (c)(3), registrants are certainly permitted to extend the money back guarantee period beyond the statutorily required minimum 30 days. The return period may not, of course, be made shorter than 30 days in contravention of Act 1998-153.

The form disclosure agreement/money back guarantee provides that, if a purchaser cancels an order prior to taking delivery of the hearing aid, the purchaser is entitled to a full refund of the purchase price of hearing aids, and a refund of money paid for services not yet rendered. This rule is dictated by the Act, which permits a registrant to charge a cancellation fee for the return of a hearing aid and accessories. If delivery never takes place, the hearing aid and accessories are not returned, so a cancellation fee is not applicable and may not be charged. Registrants do not suffer much, if any, financial impact due to giving full refunds in such circumstances, as hearing aid manufacturers generally give full credit to registrants when hearing aids are returned to the manufacturer prior to a customer having taken delivery. Inclusion of the statement on the disclosure agreement/money back guarantee telling the purchaser that orders cancelled prior to delivery are entitled to full refunds is intended to prevent registrants from representing to purchasers who attempt to cancel orders prior to taking delivery that the purchasers are not allowed to do so. The Department does not believe that this is a widespread practice, but it has occurred, most egregiously in cases where the intended user died shortly after purchase and prior to delivery.

Section 25.211. Medical recommendations; waiver forms.

This section addresses when a medical recommendation made by a physician is required prior to the sale of a hearing aid, and sets out a waiver form for use when a written waiver of

such an exam is permitted. The title of the section was changed to clarify that the section discusses both medical recommendations, and the right of a prospective hearing aid user to waive a medical exam. The proposed change to subsection (a), specifying that only prospective hearing aid users over the age of 18 may waive a medical examination, is not a substantive change; that requirement would be moved from the current subsection (b). Proposed subsection (a) also clarifies that the medical waiver must be signed before the sale of a hearing aid occurs. Note that proposed subsection (a) contains the waiver language mandated by the Act as opposed to the Federal waiver language. Because Pennsylvania's waiver language was found by the FDA to be "substantially similar" to the Federal one, it was specifically exempted from preemption by the FDA.

The text of subsections (b) and (c) would be deleted; replacement language for both has been proposed. These proposed changes are made largely in response to the Federal preemption of certain portions of the Act. Specifically, section 402 of the Act (35 P.S. §6700-402) was preempted to the extent it purports to prohibit registrants from fitting or selling a hearing aid to any person who exhibits certain enumerated physical symptoms without first having a written recommendation from a licensed physician stating that a hearing aid may be beneficial to the person. The FDA declared that contrary to the language of the Act, Pennsylvania cannot restrict the right of persons over 18 to waive an exam based on whether they have certain physical symptoms. The current subsection (b) is invalid because it states that a waiver may not be used for persons having the conditions enumerated in section 402 of the Act. The current subsection (c) states that subsection (b) cannot be enforced unless the FDA exempted it from preemption. As stated above, the FDA did not grant such exemption.

Proposed subsections (a) and (b) require a registrant either to obtain a medical recommendation prior to selling a hearing aid, or to ensure that a prospective user or authorized representative signs a waiver form indicating that the individual wishes to waive the medical examination. Proposed subsection (a) goes on to state when and in what form a waiver of a medical exam is required when dealing with prospective users over 18 years of age. A written waiver form which appears exactly as set out in subsection (a) is required if the prospective hearing aid user elects to waive a medical examination, unless the registrant is selling an identical replacement for a worn out or damaged hearing aid. In the latter event, the Federal waiver form is prescribed by Federal regulation, but use of the Pennsylvania form is permitted.

Technically, the Federal waiver form (the language of which is somewhat different than Pennsylvania's, although substantially the same) applies when a registrant is selling a replacement hearing aid. Although Pennsylvania's waiver form was deemed by the FDA to be acceptable for the purposes for which its use is prescribed by the Act, Pennsylvania's Act provides that neither an examination by a physician nor a waiver are necessary if a registrant is selling replacement parts or accessories, or replacing a worn out or damaged hearing aid. This exception in the Act is not mirrored in the Federal regulations. Therefore, although Pennsylvania does not require either a medical exam or waiver when selling replacements, the Federal requirement for a medical evaluation or waiver does apply when the registrant is replacing a worn out or damaged hearing aid. Since the requirement of a medical exam or waiver in those cases is Federal, the Federal waiver form technically would apply. However, because the FDA has stated that Pennsylvania's waiver form is acceptable, the Department encourages its use. It will generate less confusion to substitute Pennsylvania's waiver form for the Federal one when

dealing with replacements, than to use the Pennsylvania form in some cases and the Federal form in other cases.

Stakeholder input regarding the use of the Federal form indicated that there was some belief that including the full text of the Federal form in the regulations and stating that it could be used when selling a replacement for a worn-out or damaged hearing aid, would be very confusing for registrants. The Department agrees and has not reproduced it. However, the Department has no statutory authority to *require* registrants to use the Pennsylvania form in all circumstances, even though it is acceptable in all circumstances. Therefore, subsection (b), rather than stating that either the Federal or State waiver form may be used, would state that a "legally proper" waiver form should be used. Again, it is hoped that registrants will use the Pennsylvania waiver form in all circumstances; this is certainly easier for them than trying to remember when the Federal waiver is appropriate and when it is not.

Like proposed subsection (b), proposed subsection (c) clarifies current requirements given the interaction of Federal requirements with Pennsylvania law - in this case, when dealing with prospective hearing aid users that are 18 years of age or younger. The FDA exempted from preemption Pennsylvania's requirement that, for a registrant to sell a hearing aid to an individual 18 years of age or younger, a recommendation for a hearing aid must have been made within the previous six months by a physician specializing in otology or otolaryngology. This requirement was not preempted even though it is more stringent than the Federal requirement, which permits the recommendation to be made by any physician. However, Pennsylvania's Law does not require any medical examination and recommendation for a person 18 or younger (or any other person) where a hearing aid is being sold to replace an identical hearing aid within six months of the purchase of the original one. Conversely, the Federal regulations require a person under the

age of 18 to be examined by a licensed physician within six months prior to the sale, regardless of whether the hearing aid is an identical replacement aid or not. Because Pennsylvania law is, therefore, less stringent where identical replacement hearing aids are concerned, the Federal requirement that a person under the age of 18 must have a medical recommendation for a hearing aid from a licensed physician (as opposed to a specialist) applies where the hearing aid in question is an identical replacement being sold within six months.

Note that in no case may a medical examination be waived for a person under 18 years of age– a physician's (usually a specialist's) recommendation is always required in advance of a sale of a hearing aid for such a person. Note also that the requirement for examination by a specialist found in Pennsylvania's Law applies to children up to **and including** 18-year-olds, while the Federal regulations permit prospective hearing aid users who are 18 and older to waive a medical examination. Eighteen-year-olds who are buying new hearing aids are therefore subject to Pennsylvania's requirement for examination by a specialist, but an 18-year-old buying an identical replacement hearing aid may waive a medical examination entirely. This explains the necessity for the potentially confusing (but accurate) use in subsection (a) of the phrase, "older than 18 years of age," while subsection (c) uses both "18 years of age or younger," and "younger than 18 years of age."

The requirement of section 402 that registrants must inform prospective users in writing that it would be in their best interest to consult a physician specializing in diseases of the ear if any of the enumerated conditions are present, survives, as the FDA granted a waiver of that requirement. Proposed subsection (d), therefore, requires registrants to advise prospective purchasers in writing that it would be in their best interest to consult a physician if they exhibit the enumerated conditions. Note that proposed subsection (d)(7) does not repeat the statutory

language, which is "Significant air-bone gap, when *generally accepted standards have been applied*" (emphasis added), but instead specifically identifies the current "generally accepted standards" in Hz.

Section 25.212. Medical recommendations by examining physicians.

This section provides a statement that is to appear in an equivalent or more detailed form in any medical recommendation for a hearing aid, and requires a birthdate to appear in any recommendation made for an individual 18 years of age or younger. It is proposed that subsection (a) be changed to clarify that a medical recommendation must be signed by an examining physician within 180 days prior to the sale of a hearing aid. Subsection (c) would be deleted as being redundant due to this clarification of subsection (a). The proposed changes to subsection (b) are also made for the purpose of clarity, and do not affect the substantive requirements of the section.

Section 25.213. Consumer review.

This section sets out those documents that a registrant must provide and explain to a prospective hearing aid user or to that individual's authorized representative, and covers additional rules that apply to sales made in a purchaser's residence. The proposed changes to this section promote clarity and consistency of language.

Section 25.214. Recordkeeping.

This section describes the records and information that must be kept and maintained by registrants for 7 years following the sale of a hearing aid. These requirements were not preempted. They were specifically given a waiver by the FDA even though they are more stringent than Federal requirements. The proposed change to paragraph (1)(i) ensures that records will be kept of the ambient noise level of the test area. This will enable the Department

to better enforce the related regulatory requirement that registrants provide an appropriate test area, the ambient noise level of which shall not exceed 55dB on the A scale of a sound level meter. The changes to paragraph (1)(v) are proposed to incorporate up-to-date technical testing requirements. The proposed changes to paragraph (2) are made in response to the statutory requirements of Act 1998-153, that registrants are to provide purchasers with a disclosure agreement and a written money-back guarantee. These documents must also be retained as part of a registrant's records.

Section 25.215. Denial, revocation, or suspension of a registrant's certificate.

This section specifies a number of causes for which the Secretary may deny, suspend, revoke or impose conditions upon registration certificates. The proposed change to paragraph (6) is made to clarify that a registrant's certificate is jeopardized if the registrant employs to perform fitter functions any person unauthorized by law to perform within a fitter's scope of practice. Paragraph (9) includes a proposed change clarifying that an audiologist or physician may legitimately function under a registrant's registration number. The Department proposes to add the phrase "and fees associated with those services or adjustments" to paragraph (13)(ii), to explicitly include misrepresentations having to do with fees for services among those offenses that may result in action being taken against a registrant's certificate.

Paragraph (23)(i) would prohibit registrants from making representations that a hearing aid is "new" when that is not the case, as when a hearing aid has been rebuilt, and would require registrants to identify used hearing aids as such. As stated previously in discussing the definition of "used hearing aid," the FDA required Pennsylvania to utilize the Federal definition of "used hearing aid" in order to avoid preemption of the Act's requirement that used hearing aids be identified as such on sales receipts. Subsequently, Act 1998-153 was adopted. Section 504.1 of

the Act (35 P.S. §6700-504.1) appears to permit hearing aids that have been refinished or reconditioned by the hearing aid manufacturer or its agent to be identified as new rather than used, if the hearing aids are subject to all of the warranties and guarantees that would normally accompany a new hearing aid. This interpretation, however, does not comport with the requirement that Pennsylvania abide by the Federal definition of "used hearing aid," and must therefore be understood to be limited to making such hearing aids subject to the money back guarantee that is the subject matter of Section 504.1. Those hearing aids must still be identified as required in paragraph (23)(i).

Proposed paragraph 24(iv) would prohibit a registrant from making a false, misleading or deceptive representation about another registrant or manufacturer, which representation enhances or is likely to enhance the registrant's own hearing aid related business. Paragraph 27 is proposed in response to the addition of continuing education requirements by Act 1998-153, and clarifies that failing to furnish evidence of having fulfilled those requirements or providing false information regarding continuing education obtained may result in denial, revocation, or suspension of a registrant's certificate.

Section 25.216. Continuing education requirements.

This section, as well as §§25.217 – 25.220, is proposed to facilitate implementation of the continuing education requirements imposed by Act 1998-153.

This proposed section implements the continuing education requirements of Act 1998-153, which provides that the continuing education requirement for renewal of a fitter's registration certificate is 20 hours of credit over the preceding two years. Proposed subsection (a) explains that requirements for applicants who have had a certificate for less than two years will be calculated by prorating the required credits over the number of months during which the

applicant has held a certificate, counting only those months during which the applicant held the certificate for at least 15 days. Proposed subsection (b) states that an expired certificate can be renewed within five years of the expiration if 20 hours of continuing education credits have been obtained within the two years preceding the request for renewal. Proposed subsection (c) would require a fitter who has a suspended certificate to satisfy the continuing education requirement during the period of suspension such that the general requirements for number of credits are met.

Proposed subsection (d) clarifies that the first full two-year period for which credits are required begins running as of April 15, 2003. Demonstrating the high standards to which they hold their profession, hearing aid fitters have already been voluntarily complying with the continuing education requirements of the statute. The Program gratefully acknowledges their response, and anticipates that voluntary compliance will continue through the implementation period of the regulations.

Proposed subsection (e) states that acceptable subject matter for a continuing education program includes any subject that contributes directly to the competence, skills and education of a fitter. It further provides that at least one-half of all credits must be obtained in the listed "core subject" areas.

Section 25.217. Approval of continuing education programs.

This proposed section states how Department approval of continuing education programs may be obtained, the length of time for which that approval is valid, and how to renew it.

Section 25.218. Credit for continuing education.

This proposed section states how continuing education credits will be obtained and reported, and what credits will be accepted by the Department, including continuing education credits through endorsement, and for self-study, practical courses, and instruction.

Section 25.219. Responsibilities of persons offering continuing education programs.

This proposed section would impose requirements for persons offering continuing education programs, including reporting, course evaluation, record retention, and monitoring requirements.

Section 25.220. Right to enter, inspect, and obtain records.

This proposed section would require persons who offer continuing education programs to produce documents and other items for copying and inspection upon the request of the Department.

Section 25.221. Exceptions.

This proposed section would allow the Department to grant exceptions to any of the requirements in Subchapter B for good cause shown, except for statutory requirements repeated in the subchapter. This is intended to allow the Department and the regulated public some flexibility in dealing with each other and the requirements of Subchapter B.

C. Statutory authority

The Department's general authority to promulgate regulations is established by section 2102(g) of the Administrative Code of 1929 (71 P.S. §532(g)). The Department is given specific authority to promulgate rules and regulations to enforce the Act in section 205 of the Act (35 P.S. §6700-205), which section was amended by Act 1998-153 to include the authority to promulgate regulations to effect the new requirements of Act 1998-153.

D. Who is affected by the proposed amendments

The proposed changes would affect hearing aid users and prospective users. Hearing aid dealers and fitters are already required by Act 1998-153 to comply with that statute's new requirements, including requirements that they provide disclosure agreements and money-back

guarantees to hearing aid purchasers, and pay increased fees for registration certificates. Hearing aid fitters must also comply with the Act's continuing education requirements. Amending the regulations ensures that all requirements affecting the regulated parties will be in one place, and also provides some clarification and updates to requirements that pre-existed Act 1998-153.

E. Cost and paperwork estimates

The proposed amendments repeat the increased registration fees for hearing aid dealers and fitters imposed by Act 1998-153. Additionally, hearing aid fitters will incur costs to obtain the continuing education credits required by Act 1998-153. Because the fees set forth in the regulations merely repeat the fees imposed by statute, and because the amount of continuing education required is also imposed by statute, virtually all costs directly attributable to the proposed regulations are costs that will be incurred by persons who need to meet regulatory requirements to offer continuing education courses. However, persons offering continuing education credits are permitted to charge persons who attend those courses, and may recoup their costs through enrollment fees. One cost that is directly attributable to the regulations will be the cost incurred due to having to make a change to using the Department's proposed disclosure agreement/money back guarantee form. Registrants may also incur some costs due to the establishment, in Act 1998-153, of a 30-day money-back guarantee to purchasers, which may enable purchasers to return hearing aids where registrants otherwise might not have permitted them to do so. However, Act 1998-153 does allow registrants to retain the lesser of $150 or 10% of the purchase price of the items, so it is unlikely that registrants will suffer actual financial loss due to the new requirement.

The proposed amendments will result in some additional paperwork for the Commonwealth in that the Department will be responsible for ensuring that hearing aid fitters

have met their continuing education requirements. Hearing aid fitters will also need to retain records enabling them to establish that these requirements are met. Registrants will need to provide to each customer the disclosure agreement and money-back guarantee required by Act 1998-153, and will also be required to retain copies of those documents in their records. Persons who offer continuing education courses will need to satisfy paperwork requirements.

F. Effective/sunset dates

The proposed regulations will become effective upon final publication in the Pennsylvania Bulletin. No sunset date is established. The Department will monitor the effectiveness of the regulations on a continuing basis and make changes as needed.

G. Regulatory review

Under section 5(a) of the Regulatory Review Act (71 P.S. §§745.1-745-15), the Department submitted a copy of these proposed regulations on June 24, 2002 to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department by September 4, 2002. The notification shall specify the regulatory review criteria that have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review of objections raised, prior to final publication of the regulation by the Department, the General Assembly and the Governor.

H. Contact person

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulations to Theresa A. Ritchie, R.Ph., Director, Hearing Aid Program, Department of Health, P.O. Box 90, Harrisburg, PA 17108, Ph.: (717) 783-1379, within 30 days of publication of this notice in the Pennsylvania Bulletin. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulations may do so by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800-654-5984[TT]). Persons who require an alternative format of this document may contact Ms. Ritchie so that necessary arrangements may be made.

Annex A

Title 28. Health and Safety

Part III. Prevention of Diseases

Chapter 25. Controlled Substances, Drugs, Devices and Cosmetics.

Subchapter A. Controlled Substances, Drugs, Devices and Cosmetics

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Subchapter B. Hearing Aid Sales and Registration

§ 25.201. Application.

(a) *Scope.* [These §§25.201-25.215] This subchapter (relating to hearing aid sales and registration) [apply] applies to all persons engaged in the business of selling or fitting hearing aids in this Commonwealth; [provided however] except that physicians[, surgeons] and audiologists are exempted from all provisions regarding hearing aid fitters.

(b) *Authority.* [These §§25.201–25.215 (relating to hearing aid sales and registration) are issued] This subchapter is adopted pursuant to the act [262].

§ 25.202. Definitions.

The following words and terms[,] when used in [these §§25.201–25.215] this subchapter shall have the following meaning, unless the context clearly indicates otherwise:

Act [262] - The Hearing Aid Sales Registration Law (35 P. S. §§6700-101-6700-802).

Advertise and any of its variants - The use of a newspaper, magazine or other publication, book, notice, circular, pamphlet, letter, handbill, poster, sign, placard, label, tag, window display, store sign, radio, television announcement, internet, or any other means or methods [now or hereafter] employed to bring to the attention of the public the practice of selling or fitting hearing aids.

Audiologist - A person [holding the Certificate of Clinical Competence in Audiology awarded by the American Speech and Hearing Association or any person who can provide evidence to the Secretary of having successfully completed equivalent academic training and clinical experience.] who holds a current license as an audiologist issued by the State Board of Examiners in Speech-Language and Hearing, or a person who is permitted to practice audiology pursuant to an exemption to the audiologist

licensure requirement under section 6(b) of the Speech-Language and Hearing Licensure Act (63 P.S. §1706(b)).

Authorized representative - A person who is authorized by law to make a decision, required pursuant to this subchapter, for a hearing aid user or prospective hearing aid user.

Business of selling hearing aids - Selling, leasing, or offering for sale or lease new, used, or reconditioned hearing aids exclusive of parts, attachments, or accessories, at retail, either as exact replacements for damaged or worn out units or pursuant to written specifications provided by an audiologist, otologist, or otolaryngologist; but not including fitting or the practice of fitting and selling [of] hearing aids.

Continuing education program - A program approved by the Department for credit towards the continuing education requirements for the renewal of the registration certificate of a hearing aid fitter.

Conviction - A plea or verdict of guilty, or a conviction following a plea of *nolo contendere* [made] to a charge of a crime involving moral turpitude.

Department - The Department of Health of the Commonwealth.

Fitting - Includes the physical acts of adjusting the hearing aid to the individual, taking audiograms, making ear molds, advising the individual with respect to hearing aids, making audiogram [interpretation] interpretations, and assisting in the selection of a suitable hearing aid [for the sole purpose of the sale of] to sell a hearing aid.

Hearing aid – [Any] A wearable instrument or device designed or offered [for the purpose of aiding or compensating] to aid or compensate for impaired human hearing together with any parts, attachments, or accessories for such device, including ear molds but excluding batteries and cords.

Hearing aid dealer - [Any] A person engaged in the business of selling hearing aids.

Hearing aid fitter – [Any] An individual engaged in the practice of fitting and selling hearing aids.

Physician - An individual who has a currently registered license to practice medicine or osteopathic medicine in this Commonwealth.

Practice of fitting and selling hearing aids – Those practices used solely for making selections, adaptations, and sales of hearing aids.

Registrant – A hearing aid dealer or fitter holding a current certificate of registration.

Secretary – The Secretary of Health of the Commonwealth.

Sponsor – [A] An individual registered in this Commonwealth as a hearing aid fitter who agrees to supervise an apprentice hearing aid fitter.

Used hearing aid - A hearing aid that has been worn for any period of time by a user. A hearing aid is not a used hearing aid if it has been worn only by a prospective user as part of a bona fide hearing aid evaluation conducted in the presence of the registrant or an individual selected by the registrant and authorized by law to assist the prospective user in making such an evaluation.

§ 25.203. Advisory Council.

(a) The Advisory Council will be composed as provided for under section 201 of the act [262] (35 P.S. §6700-201).

(b) It will be the duty of the Advisory Council to advise the Secretary, to the best of its ability, on the administration of [Act 262] the act.

(c) [Meetings of the Advisory Council will be as follows:

(1)]The Council will hold at least one annual meeting at [the] a time and place designated by the Secretary for the purpose of providing information and advice to the Department.

[(2) Each Council member will be notified of scheduled meetings at least four weeks in advance; however, special or emergency meetings may be scheduled on shorter notice.]

(d) [No] A Council member [shall] may convey the impression, either publicly or privately, that [such] the member is acting officially for the [council without] Council only with prior authorization from the [council] Council.

§ 25.204. Application for and renewal of registration.

(a) *Application.* [Application] An application for registration or renewal of registration as a hearing aid dealer, [as a] hearing aid fitter, [as an] apprentice hearing aid fitter, or [as a] temporary hearing aid fitter can be obtained from the Division of [Drugs, Devices and Cosmetics,] Home Health, Pennsylvania Department of Health, [P.O.Box 90,] 132 Kline Plaza, Suite A, Harrisburg, Pennsylvania [17120] 17104.

(b) *[Hearing] Apprentice hearing aid fitter.* [Completed applications] A completed application for registration as [a] an apprentice hearing aid fitter shall be filed with the Department at least 30 days [prior to] before the [schedule] fitter's examination [date] that the applicant intends to take, together with a check [or], money order, or other approved method of payment as the Department publishes in a notice in the *Pennsylvania Bulletin,* in the amount of [the required application fee] $50. An additional $150 shall be paid before taking the fitter's examination. The application fee is not refundable [except to applicants], but the $150 fee for the examination will be refunded to

an applicant who [are] is found to be ineligible to take the examination [, in which case a $75 refund will be made].

(c) *All other registrations.* [Completed applications] A completed application for any registration certificate, other than a registration certificate as an apprentice hearing aid fitter, may be filed at any time, together with a check [or], money order, or other approved method of payment as the Department publishes in a notice in the *Pennsylvania Bulletin,* in the amount of the appropriate application fee.

(d) *Renewal of current certificate.* [Prior to] At least 30 days before the expiration of [any] a registration certificate, a registrant may apply to renew that certificate by submitting a completed renewal [applications] application, available from the Department, along with the renewal fee of [$50] $100. To renew a hearing aid fitter's registration certificate the applicant shall also demonstrate satisfaction of the continuing education requirements under §25.216 (relating to continuing education requirements).

(e) *Renewal of expired certificate.* An expired registration certificate may be renewed [at any time] within 5 years after its expiration date by filing an application for renewal, with payment of the renewal fee, and payment of the delinquency fee if the application is received more than 30 days after the expiration date. To renew an expired hearing aid fitter's registration certificate the applicant shall also demonstrate satisfaction of the continuing education requirements under §25.216.

(f) *Renewal of fitter's temporary registration [certificates] certificate and apprentice [certificates] certificate.* Upon application, the Secretary may renew a temporary certificate or apprentice certificate for a period which shall expire 30 days after the next available fitter's qualifying examination has been given. The Secretary will not issue more than two renewals of these certificates, except upon petition of an applicant for good and sufficient cause shown.

(g) *Late application for renewal.* A person who files for renewal of a registration certificate less than 30 days before the expiration of the registration certificate may not receive the renewal before the registration certificate expires.

§ 25.205. [Special application] Additional registration requirements.

(a) *Hearing aid dealers.* No [additional requirements need be met] requirement is imposed in addition to those imposed under §25.204(c) (relating to application for and renewal of registration).

(b) *Hearing aid fitters.* [Hearing] A hearing aid [fitters] fitter shall pass the qualifying examination as provided by [Act 262] the act.

(c) *Reciprocal registration - certificate [of] by endorsement.*

(1) [Applicants] An applicant for registration to practice as a hearing aid dealer or as a hearing aid fitter who [are] is licensed or registered in any other state, which has requirements equal to or [higher] greater than [Pennsylvania] those in this Commonwealth for registration as a hearing aid dealer or fitter and which maintains reciprocal practice privileges with Pennsylvania, may be granted a registration certificate [of] by endorsement by the Secretary [which]. Being qualified to apply for a hearing aid fitter's registration certificate by endorsement relieves the applicant from having to take the qualifying examination otherwise required under [Act 262] the act.

(2) In all other respects, the applicant for a registration certificate [of] by endorsement shall be registered in the same manner and meet the same requirements as other registrants.

(3) If Pennsylvania does not maintain reciprocal practice privileges with a state in which a person is registered or otherwise authorized to function as a hearing aid fitter or dealer, the person may apply for a temporary registration certificate pursuant to subsection (e).

(d) *Apprentice registration.* Apprentice registration shall conform [with] to the following:

(1) [Applicants] An applicant for registration as an apprentice hearing aid fitter shall have a sponsor responsible for the training and supervision of the [apprentice trainee] applicant.

(2) [Applications] An application shall be accompanied by a statement of the sponsor:

(i) Setting forth the type of supervision which shall be given the [trainee] applicant.

(ii) Providing an outline of the training program to be followed in preparing the [trainee] applicant for examination. The training program shall include education and training in at least the following areas:

(A) The anatomy and physiology of the ear.

(B) The function of hearing aids.

(C) The grounds for revocation or suspension of a certificate of registration, or probation of a registrant, under the act.

(D) The violations and penalties under the act.

(E) The procedures and use of equipment established by the Department for the fitting and selling of hearing aids.

(F) The taking of ear mold impressions.

(G) The medical and rehabilitation facilities for children and adults that are available in the areas served.

(H) The criteria for medical referral when found to exist either from observation by the registrant or on the basis of information furnished by the prospective hearing aid user, to include those criteria listed in §25.211(d) (relating to medical recommendations; waiver forms).

(iii) Providing the registration number of the [employer who shall be licensed as a hearing aid fitter in this Commonwealth] sponsor.

(3) [A trainee] An apprentice hearing aid fitter desiring to change sponsors shall furnish the Department a sworn or affirmed request giving reasons for the change and a sworn or affirmed statement from the new sponsor setting forth the information required by paragraph (2), and accompanied by the [trainee's apprentice] apprentice's certificate of registration.

(4) A sponsor desiring to terminate responsibilities with regard to an apprentice shall give the apprentice 10 days written notice [giving] of the reasons for the action and shall notify the Department at the same time by certified mail.

(e) *Temporary registration.* Temporary registration shall conform [with] to the following:

(1) [An] A temporary fitter's registration certificate will be issued to an applicant who [proves to the satisfaction of the Department that he has] satisfactorily demonstrates having been engaged in the fitting and selling of hearing aids at an established place of business in a state other than Pennsylvania for a period of 2 years within a 5-year period immediately [prior to his] before making application and who otherwise fulfills the requirements of [Act 262] the act and [these §§25.201–25.215 will be issued a temporary fitter's registration certificate] this subchapter.

(2) The temporary registrant [must] shall take the hearing aid fitter's examination to qualify for a regular hearing aid fitter's registration certificate.

(3) The temporary registration certificate shall expire [no later than] 30 days after the administration of the qualifying examination [given not earlier than 90 days after the issuance of the certificate but not later than one year from the date of issue, whichever comes sooner] that the temporary registrant takes. The temporary registrant shall take the qualifying examination no earlier than 90 days after the date the temporary registration certificate was issued, and no later than one year after the date the temporary registration certificate was issued .

§ 25.206. Examinations.

(a) [Examinations for] An examination to obtain registration as a hearing aid [fitters' registration certificates] fitter shall be held at least twice each year, at a time and place to be fixed by the Secretary[,] at least 45 days [in advance of] before the examination date.

(b) The date of [the examinations] an examination may be obtained by writing to the Department.

(c) The passing grade on [the] an examination will be determined by the Secretary.

§ 25.207. Categories of registrations; fee schedule.

(a) [Regular] A registration [certificates] certificate, other than a temporary or apprentice registration certificate, shall expire at midnight of April 15 of each year, if not renewed.

(b) For a hearing aid [dealers] dealer, the initial registration fee shall be [$100. From October 15 through April 14, the fee shall be $50] $200 if the Department issues the registration certificate between April 15 and October 14, and $100 if the Department issues the registration certificate between October 15 and April 14. The annual renewal fee shall be [$50] $100 for both dealers and fitters.

(c) For a hearing aid [fitters] fitter's registration certificate, the initial registration fee shall be [$100, $75] $200, $150 of which will be refunded if the applicant is [found to be] ineligible to take the qualifying fitters' examination. [From October 15 through April 14, the fee shall be $50.] The annual renewal fee shall be [$50] $100.

(d) For a registration [by reciprocity] certificate [of] by endorsement the fees shall be the same as in [subsections (a) and] subsection (b)[, as applicable].

(e) For a temporary hearing aid fitter's registration certificate, the initial registration fee shall be [$100, $75] $200, $150 of which is for the examination. [will be refunded] A refund of the $150 will be made if the applicant is [found to be] ineligible to take the qualifying examination for a fitter's registration certificate. Instead of paying the full $200 when making the application, the applicant may pay $50 when making the initial application, and $150 before taking the examination for the first time. The renewal fee shall be [$50] $100.

(f) For an apprentice fitter's registration certificate, the fee shall be [$25] $50 plus an additional [$75 prior to taking the qualifying] $150 before the apprentice takes the fitter's examination. The renewal fee shall be [$50] $100.

(g) For a duplicate or replacement registration certificate, the fee shall be [$5.00] $10. [A] The registrant shall obtain a duplicate certificate [shall be issued] upon the loss of an original certificate[,] or for a branch office[, or]. The registrant shall obtain a replacement registration certificate upon a name change by the person holding a certificate.

(h) The fee to retake the fitter's examination for [applicants] an applicant for a fitter's registration certificate who [have] has failed a previous examination shall be [$25] $50 for each succeeding examination.

(i) A delinquency fee will be assessed if an applicant applies for renewal of a registration certificate more than 30 days after the registration certificate has expired. The delinquency fee shall be [$25] $50.

(j) For renewal of a suspended registration certificate, the fee shall be [$50] $100 plus the delinquency fee if one has otherwise accrued.

§ 25.208. Display of registration certificates; offices.

(a) [Each hearing aid dealer or fitter] A registrant shall display [his] the dealer's or fitter's registration certificate at the place of business listed in the registrant's application.

(b) [Offices which are part of a building normally used as a residence shall be in a space set aside for office purposes only.] If a registrant maintains more than one place of business within the Commonwealth, the registrant shall apply for a duplicate registration certificate for each branch office. The registrant shall display the appropriate duplicate registration certificate in each office.

(c) [Whenever a registrant desires to move his place of business, notice of the change shall be filed with the Department within 10 working days of such a change.] The place of business identified

in a registrant's application shall be an office at a fixed location. An office which is part of a building normally used as a residence shall be in a space set aside for office purposes only.

(d) [When a hearing aid fitter's or temporary hearing aid fitter's registration certificate is issued and on each renewal thereof, the Department will issue a card bearing the expiration date to the registrant, who shall keep it in his possession at all times during the performance of duties.] A registrant shall file notice of a change in the registrant's place of business with the Department at least 10 work days before the change.

(e) [The] A registrant shall make the registration certificate [or card, or both, shall be] available for inspection on request of any client, prospective client, Department employe, or [peace officer] law enforcement official.

§ 25.209. Facilities, procedures and instrumentation.

(a) *Facilities.* [No] A registrant shall engage in the practice of fitting or selling a hearing aid [unless he] only if the registrant provides:

(1) An appropriate test area, the ambient noise level of which [must] shall have a documented readout of 55 dB or lower on the A scale of a sound level [matter] meter.

(2) A selection of hearing aid models, supplies, and accessories to provide for the immediate needs of [clients] hearing aid users or prospective hearing aid users.

(b) *Procedures.* [Procedures] A registrant shall [conform with] satisfy the following:

(1) [A] The registrant shall sell a hearing aid [shall not be sold unless] only if within 6 months [of] before the sale an examination of the [client] prospective hearing aid user was conducted using pure tone air conduction, bone conduction, and speech audiometry tests [has been conducted, or], except this requirement does not apply when the registrant is replacing a hearing aid with another of the same make, model, and response. The registrant shall sell a hearing aid replacing another of the same make, model, and response only if within 12 months before the sale an examination of the prospective hearing aid user was conducted using pure tone air conduction, bone conduction, and speech audiometry tests. [Such] The registrant shall verify that the tests [shall be] were performed by [a physician, surgeon, audiologist, or registered fitter or by an individual supervised by any of the aforementioned persons] an individual authorized by law to do so.

(2) The [fitter] registrant shall[, as a minimum]:

(i) Perform air [conductor] conduction tests for hearing level thresholds at frequencies of 250 Hz, 500 Hz, 1,000 Hz, 2,000 Hz, 4,000 Hz, and 6,000 Hz or 8,000 Hz, with masking [where] if necessary.

(ii) Perform bone conduction tests for hearing level thresholds at frequencies of [250 Hz,] 500 Hz, 1,000 Hz, 2,000 Hz, and 4,000 Hz, with masking [where] if necessary.

(iii) Maintain records of the test results for each ear for a period of 7 years.

(iv) Perform a speech reception or speech awareness threshold test using an electronic speech audiometer [under] with head or insert ear phones[; additional testing may be performed with other sound pressure instruments as needed].

(v) Perform a word discrimination or other speech intelligibility test for conversational level speech using an electronic speech audiometer [under] with head or insert ear phones.

(3) [No registered hearing aid fitter] The registrant shall [fit and] sell a hearing aid [to any individual unless the instrument] only if the hearing aid is fitted to the wearer [so as] to [insure] ensure physical and operational comfort and [unless documented] improvement in hearing function is demonstrated and documented in [one or more] at least one of the following areas[;]: speech detection, speech awareness levels, [sensitivity] speech intelligibility, orientation or [SRT] speech reception threshhold [changes].

(c) *Instrumentation.* [Instrumentation shall conform with] A registrant shall satisfy the following:

(1) All test instruments shall be calibrated [at least] once each year or more often if necessary to meet current American National Standards Institute standards for pure tone and speech audiometry as identified by A.N.S.I. S3.6-1969 or as identified in [revised forms] succeeding A.N.S.I. standards.

(2) Instruments transported to test sites shall be calibrated to the standard set forth in paragraph (1) [at least] every 6 months, or more frequently as needed.

(3) Calibration [will be] shall be performed by a qualified individual other than the owner.

(4) A signed certificate [indicating] identifying the most recent date of calibration shall be maintained for inspection by the Department.

§ 25.210. Receipt, disclosure agreement and money back guarantee to purchaser - purchaser protection.

(a) *Receipt.* Upon the sale of [any] a hearing aid, the registrant shall provide the purchaser a

signed receipt [containing]. The receipt may be made out on more than one sheet of paper and shall contain the following:

(1) The date of sale.

(2) The make, model, and serial number or, if no serial number is applicable, an identification number of the hearing aid.

(3) The address of the principal place of business of the registrant.

(4) If the hearing aid is used or reconditioned, a statement which [indicates that fact] provides that information and which meets the requirements of §25.215(23) (relating to denial, revocation, or suspension of registrant's certificate).

(5) The registrant's registration certificate number.

(6) The terms of any guarantee or express warranty made to the purchaser with respect to the hearing aid.

(7) A copy of the written forms as required by §25.211 (relating to medical recommendations; waiver forms).

(8) A statement on or attached to the receipt, in no smaller than 10 point type, as follows: "The purchaser has been advised at the outset of his relationship with the hearing aid dealer that any examination or representation made by a registered hearing aid dealer and fitter in [conjunction] connection with the practice of fitting and selling of this hearing aid, is not an examination, diagnosis, or prescription by a person licensed to practice medicine in this Commonwealth and therefore must not be regarded as medical opinion."

(9) A statement on the face of the receipt, in no smaller than 10 point bold type, as follows: "If your rights are violated, you may contact the State Bureau of Consumer Protection [or], the Pennsylvania Department of Health in Harrisburg, or your local district attorney."

(b) *Disclosure agreement and money back written guarantee.* Before the provision of any service incidental to or connected with the potential sale of a hearing aid, the registrant shall provide a disclosure agreement and money back written guarantee to the prospective hearing aid user or authorized representative. This shall be in 10 point type or larger, and may be made out on more than one sheet of paper, but shall employ the following format:

****The following form would be new. Underlines are included only where intended on the form.****

HEARING AID DISCLOSURE AGREEMENT/MONEY BACK GUARANTEE

(Business Name)_____(Business Address)_____
Telephone No. ( ) _____

PART A.

Description of services included in fitting procedure or process, and sale and delivery of hearing aid.	**FEE** (State whether fee is waived if hearing aid purchased)	**REFUNDABLE** (Upon return of hearing aids)	**NOT REFUNDABLE**

PART B.

HEARING AIDS & ACCESSORIES		**DESCRIPTION of GOODS** – include make, model, serial number(s)	**PRICE**	**REFUNDABLE** (upon return of hearing aid)	**NOT REFUNDABLE** (Cancellation Fee)
Hearing Aid(s)	**Right**				
	Left				
Accessories (Describe, if applicable)					
TOTAL					

Total maximum Cancellation Fee is lesser of 10% or $150 per hearing aid <u>including</u> accessories.

I RECEIVED THIS DISCLOSURE AGREEMENT, AND IT WAS EXPLAINED TO ME, INCLUDING PART A, FEES FOR SERVICES THAT ARE NOT PART OF THE PRICE OF THE HEARING AID, AND PART B, CANCELLATION FEES THAT WILL BE INCURRED IF I RETURN A HEARING AID FOR A REFUND UNDER THE 30 DAY MONEY BACK GUARANTEE BELOW, AT _____(time) ON _____(date), BEFORE ANY SERVICES WERE PROVIDED.

_____
Customer's Signature

30 Day Money Back Guarantee: If a hearing aid is returned within 30 days of <u>date of delivery</u> in the same condition, ordinary wear and tear excluded, you are entitled to a refund of the portion of the purchase price of the hearing aid and accessories as itemized on the receipt and above, less the cancellation fee stated above. If a cancellation fee is imposed the nonrefundable amount for each aid and accessories cannot exceed 10% of the purchase price of the hearing aid and accessories <u>or</u> $150.00 per aid and accessories, whichever is less. You will, however, be responsible for all nonrefundable service fees listed in Part A. If you cancel your order <u>prior to delivery</u>, you are entitled to full refund of the purchase price of the aid and accessories, and a full refund for services not yet rendered.

_____ _____
Customer's Signature Date and time of Sale

_____ _____
Registrant's Signature Registration No.

_____
DATE of DELIVERY

_____
Customer's Signature or Initials

(c) *Additional responsibilities of registrant with respect to the disclosure agreement/money back guarantee.*

(1) The registrant shall fill in the appropriate spaces on the disclosure agreement/money back guarantee. The registrant shall include in Part A a complete description of what the fitting procedure or process includes, and shall itemize and disclose fees associated with the fitting procedure or process and the sale and delivery of the hearing aid. For each service provided, the registrant shall identify by dollar amount the portion of the fee that is refundable and the portion that is not refundable. If a fee will be waived if a hearing aid is purchased, that shall be stated. If the registrant charges no fees for services, Part A may be left blank.

(2) The registrant shall itemize in Part B any cancellation fee associated with the sale and delivery of a hearing aid and its accessories, by designating that amount as "not refundable."

(3) The registrant may revise the relevant portion of the disclosure agreement/money back guarantee form to disclose the registrant's policy of offering a money back guarantee return period longer than 30 days. The money back guarantee shall be for at least 30 days.

(4) The registrant shall explain in detail the entire disclosure agreement/money back guarantee to the prospective hearing aid user or authorized representative, before securing the signature of the purchaser.

(5) The registrant shall ensure that the prospective hearing aid user or authorized representative signs the disclosure agreement/money back guarantee under Part B, before the registrant provides any service incidental to the possible sale of a hearing aid to the prospective hearing aid user.

(6) The registrant shall ensure that the purchaser signs the bottom portion of the disclosure agreement/money back guarantee, directly under the money back guarantee provision, and inserts the date and time of sale on the appropriate line, after the decision to purchase a hearing aid is made.

(7) At the time the hearing aid is delivered to the hearing aid user or authorized representative, the registrant shall ensure that the signature or initials of the user or authorized representative is obtained and the date of delivery is inserted in the block provided for that purpose on the disclosure agreement/money back guarantee. After the block is completed with the initials or signature and date, the registrant shall provide a copy of the completed disclosure agreement/money back guarantee to the purchaser.

§ 25.211. **[Waiver] Medical recommendations; waiver forms.**

(a) [Where a client wishes to waive a medical examination,] Except when selling a replacement of a worn out or damaged hearing aid, when selling a hearing aid for he use of a prospective hearing aid user who is older than 18 years of age a registrant shall either obtain for the prospective user a medical recommendation that complies with the requirements of §25.212 (relating to medical recommendations by examining physicians), or ensure that the prospective user or authorized representative signs a waiver form as provided under section 403 of the act [262] (35 P. S. §6700-403) [a]. The waiver form [must] shall be prepared and used as follows:

(1) The waiver form [must] shall be in 10 point type or larger.

(2) The waiver [must] shall be read to the [client] prospective hearing aid user or authorized representative and explained in a manner such that the [client] individual is not encouraged to waive a medical examination and so that the [client] individual will be thoroughly aware that signing the waiver will not be in [his] the prospective hearing aid user's best interest.

(3) The waiver form shall read as follows:

I have been advised that my best [interest] interests would be served if I had a medical examination by an otologist or otolaryngologist or any licensed physician before my purchase of a hearing aid.

_____ (Registrant's Name) has fully and clearly informed me of the value of such medical examination. After such explanation, I voluntarily sign[ed] this waiver[,]. I choose not to seek a medical examination [for] before the purchase of the hearing aid.

_____ (Signature of [registrant] Registrant)

_____ (Address of [registrant] Registrant)

_____ (Signature of Purchaser)

_____ (Date of Signature)

(b) [The waiver set forth in subsection (a)(3) may not be used for any person 18 years of age or younger or for individuals having any of the following conditions.

(1) Visible congenital or traumatic deformity of the ear.

(2) Active drainage from the ear within the previous 90 days of history of this symptom.

(3) Sudden or rapidly progressive hearing loss within the previous 90 days of history of this symptom.

(4) Acute or chronic dizziness.

(5) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(6) Visible evidence of cerumen accumulation or a foreign body in the ear canal.

(7) Significant air-borne gap, when generally acceptable standards have been established.

(8) Pain in the ear within the previous 90 days.]

When selling a replacement of a worn out or damaged hearing aid for the use of a prospective hearing aid user who is 18 years of age or older, a registrant shall either obtain for the prospective user a medical recommendation that complies with the requirements of §25. 212, or ensure that the prospective user or authorized representative signs a legally proper waiver of the medical examination.

(c) [Subsection (b) shall not be enforced until such time as the Food and Drug Administration of the United States Department of Health, Education, and Welfare acts upon the Department of Health's application for exemption from pre-emption of less stringent Federal requirements on the same subject. The FDA has proposed to grant that exemption in a notice of proposed rule making found at 43 Fed. Reg. 33,180 (1970).] Except when a registrant is selling a hearing aid to replace an identical hearing aid, the registrant may sell a hearing aid for the use of a prospective user 18 years of age or younger only if the registrant obtains a medical recommendation that complies with the requirements of §25.212 and is signed by a physician specializing in otolaryngology or otology. When selling an identical replacement hearing aid for the use of an individual younger than18 years of age, the registrant shall obtain a medical recommendation that complies with the requirements of §25.212.

(d) Before the sale of a hearing aid a registrant shall inform the prospective hearing aid user or authorized representative, in writing, that it would be in the best interest of the

prospective hearing aid user to consult a physician specializing in or qualified to deal with diseases of the ear if the prospective hearing aid user has any of the following conditions:

(1) Visible congenital or traumatic deformity of the ear.

(2) Active drainage from the ear within the previous 90 days or a history of this symptom.

(3) Sudden or rapidly progressive hearing loss within the previous 90 days or a history of this symptom.

(4) Acute or chronic dizziness.

(5) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(6) Visible evidence of cerumen accumulation or a foreign body in the ear canal.

(7) Significant air-bone gap of 15dB or greater at 500 Hz, 1000 Hz, and 2000 Hz.

(8) Pain in the ear within the previous 90 days.

§ 25.212. Medical recommendations by examining physicians.

(a) Whenever a medical examination is performed pursuant to the act [262] or Federal requirements, before fitting and selling a hearing aid the registrant shall ensure that a medical recommendation [shall be] has been signed by the examining physician, within 180 days before the sale, on a form which includes the following statement or its equivalent:

I have medically evaluated the hearing ability of

_____

([patient's name] Patient's Name)

and a hearing aid may be beneficial to this person.

_____

(Signature of [physician] Physician)

_____

(Date of evaluation)

(b) [Where] If the [client] prospective hearing aid user is 18 years of age or younger, the registrant shall ensure that the [patient's] prospective user's date of birth [shall be] has been included on the medical recommendation form.

[(c) Such form will be valid for up to 6 months from the date of signature.]

§ 25.213. **Consumer review.**

(a) Before signing [any statement] a waiver form under §25.211 (relating to medical recommendations; waiver forms) and before the sale of [any] a hearing aid to or for the use of a prospective hearing aid user, the [hearing aid fitter or dealer] registrant shall:

(1) Provide the prospective hearing aid user or authorized representative with a copy of the User Instructional Brochure for the hearing aid that has been or may be selected for the prospective user.

(2) Review the content of the User Instructional Brochure with the prospective hearing aid user or authorized representative orally or in the predominant method of communication used during the sale.

(3) Give the prospective hearing aid user or authorized representative an opportunity to read the User Instructional Brochure.

(b) [Where] If goods or services having a sale price of $25 or more are sold or contracted to be sold to a [buyer] purchaser as a result of or in connection with a contact with or call on the [buyer] purchaser at [his] the purchaser's residence, the [consumer] purchaser may avoid the contract or sale by notifying[, in writing,] the [seller] registrant of that decision, in writing, within 3 full business days following the day on which the contract or sale was made and by returning or holding available for return to the [seller] registrant, in its original condition, any merchandise received under the contract or sale. [Such] The notice of rescission [shall be] is effective [upon depositing the same] when deposited in the United States mail or [upon other] when service is made in another manner which gives the [seller] registrant notice of rescission.

(c) Additional provisions relating to the sale of goods in the [buyer's] purchaser's home, including specific items[,] which [must] shall be included on the receipt, are hereby made a part of this section[,] by [Incorporation] incorporation of section 7 of the Unfair Trade Practices and Consumer Protection Law (73 P. S. §201.7).

§ 25.214. **Recordkeeping.**

A registrant shall, upon the consummation of a sale of a hearing aid, keep and maintain records in [his] the registrant's office or place of business at all times. These records shall be kept for 7

years and shall include the following [information]:

(1) Results of all testing conducted pursuant to §25.209 (relating to facilities, procedures and instrumentation). The minimum acceptable test records shall be records of:

(i) Pure tone tests including air and bone conduction with masking where appropriate, and the ambient noise level of the test area.

(ii) Speech reception threshold expressed in decibels of hearing level.

(iii) Most comfortable level expressed in decibels.

(iv) Uncomfortable (tolerance) level expressed in decibels.

(v) Word discrimination test results expressed in percentage indicating the test words used, presentation level, masking level (where applicable), and signal to noise ratio (where applicable).

(2) A copy of the written receipt, disclosure agreement and money back guarantee required by §25.210 (relating to receipt, disclosure agreement and money back guarantee to purchaser–purchaser protection).

(3) The written physician's recommendation required by §25.212 (relating to medical recommendations by examining physicians) or the waiver form required by §25.211 (relating to medical recommendations; waiver forms).

§ 25.215. Denial, revocation, or suspension of registrant's certificate.

The Secretary may deny, suspend, or revoke [any] a registration certificate provided under the act [262] or [he] the Secretary may impose conditions of probation upon a registrant for any of the following causes:

(1) Gross incompetency which includes, but is not limited to, the improper or unnecessary fitting of a hearing aid.

(2) Conviction of [any] a felony or misdemeanor involving moral turpitude.

(3) Obtaining a registration certificate by fraud or deceit.

(4) Using the term "doctor" or "physician" or "clinic" or "audiologist" or any derivation thereof as part of the firm name under which the registrant fits and sells hearing aids, unless authorized by law.

(5) Fraud or misrepresentation in the repair, fitting or selling of a hearing aid.

(6) Employing [any persons whose registration certificate has been suspended or who do not possess a valid registration certificate issued under act 262 to perform any function covered by the provisions of act 262] a person to perform a function within the scope of practice of a hearing aid fitter who is not authorized by law to perform the function.

(7) Habitual intemperance.

(8) Gross immorality.

(9) Permitting another person to use the registration certificate for any purpose, except permitting an audiologist or physician employed by the registrant to sell hearing aids for the registrant.

(10) Violating or, with notice or knowledge permitting [,with notice or knowledge of its commission, the violation by any registered employee of any provision of] an employee to violate, the act [262] or [these §§25.201–25.215] this subchapter.

(11) [Any] A cause which would be [grounds] a ground for denial of an application for a registration certificate.

(12) Having been enjoined from violating [any provisions] a provision of the Unfair Trade Practices and Consumer Protection Law (73 P. S. §§201-1--209-6) or being subject to a final order of the Federal Trade Commission, the Department, or the Food and Drug Administration of the United States Department of Health, Education and Welfare, concerning the sale or offering for sale of an unsafe, unhealthful, or worthless hearing [devices] device or for engaging in conduct which has the tendency to mislead or deceive.

(13) Using, causing, or promoting the use of any advertising matter, promotional literature, testimonial, guarantee, warranty, label, brand, insignia, or any other representation, however disseminated or published, that is misleading, deceiving, improbable, or untruthful[. Included among the foregoing acts are misrepresentations], such as a misrepresentation relating to:

(i) The grade, quality, quantity, origin, novelty, price, dealer cost, terms of sale, use, construction, size, composition, dimensions, type, design, development, visibility, durability, performance, fit, appearance, efficacy, benefits, cost of operation, resistance to climatic conditions, or physiological benefits of [any] a hearing aid or the psychological well-being induced by a hearing aid; or

(ii) [Any] A service or adjustment offered, promised, or supplied to [purchasers] a purchaser of [any] a hearing aid, or the fee

associated with the service or adjustment.

(14) Making [representations in advertising or otherwise] a representation that a hearing aid is "guaranteed," without clear and conspicuous disclosure of:

(i) The nature and extent of the guarantee[;].

(ii) [Any] A material [conditions or limitations in] condition or limitation of the guarantee which [are] is imposed by the guarantor[;].

(iii) The manner in which the guarantor will perform thereunder[;].

(iv) The identity of the guarantor, with disclosure, where applicable, that any guarantee made by the [dealer] registrant which is not backed up by the manufacturer is offered by the [dealer] registrant only.

(v) The meaning of "life" or "lifetime" to clarify whether it refers to the life of the purchaser, the product, or otherwise, whenever representations are made that a hearing aid is "guaranteed for life" or has a "lifetime guarantee."

(15) Making [guarantees, warranties, or any promises] a guarantee, warranty, or promise which, under normal conditions, [are] is impractical of fulfillment or which [are] is for [such] a period of time or [are otherwise of such] of a nature [as may have the tendency to mislead purchasers into the belief] that may cause a purchaser to believe that the hearing aid has a greater degree of service ability, durability, or performance capability in actual use than is [in fact] true.

(16) Making [misrepresentations] a misrepresentation as to the character of the business conducted by the registrant. Unless it is true, a [hearing aid dealer] registrant shall not represent directly or indirectly through the use of any word or term, in [his] the corporate or trade name, in [his] advertising, or otherwise, that [he] the registrant owns or maintains a laboratory devoted to hearing [and] aid research, testing, experimentation, or development; nor shall a [dealer] registrant misrepresent in any other material respect the character, extent, or type of [his] business conducted by the registrant.

(17) Causing deception that services or advice of a physician were used in the design or [manufacturer] manufacture of hearing aids. Unless it is true, a [hearing aid dealer] registrant shall not represent, directly or by implication, that the services or advice of a physician have been used in the designing or manufacturing of hearing aids. The prohibitions of this paragraph are applicable to the use of the terms "doctor," "physician," "otologist," or "otolaryngologist"; to the use of any

abbreviations, variations or derivatives of such terms; and to the use of any symbol, depiction, or representation having a medical connotation.

(18) Making a deceptive [representations] representation as to the visibility or the construction of a hearing aid. A [hearing aid dealer] registrant shall not do any of the following:

(i) Represent, directly or by implication, through the use of such words or expressions as "invisible," "hidden," "hidden hearing," "completely out of sight," "conceal your deafness," "hear in secret," "unnoticed even by your closest friends," "no one will know you are hard of hearing," "your hearing loss is your secret," "no one need know you are wearing a hearing-aid," "hidden out of sight when inserted in the ear canal" or by any other words or expressions of similar import, that any hearing aid, device, or part is hidden or cannot be seen unless such is a fact.

(ii) [Use in advertising, the words or expressions "no cord," "cordless," "100% cordless," "no unsightly cord dangling from your ear," "no tell-tale wires," or other words or expressions of similar import unless such representations are true and unless, in close connection therewith and with equal prominence, a clear and adequate disclosure is made that a plastic tube or similar device runs from the instrument to the ear if such is the fact.

(iii) Use in advertising the words or expressions "no button," "no ear button," "no buttons or receivers in either ear" or other words or expressions of similar import unless such representations are true and unless, in close connection therewith and with equal prominence, a clear and adequate disclosure is made that an ear mold or plastic tip is inserted in the ear if such is the fact.

(iv)] Represent directly or by implication that a hearing aid utilizing bone conduction has a [certain] specified [features] feature such as the absence of anything in the ear or leading to the ear, or the like, without disclosing clearly and conspicuously that the instrument operates on the bone-conduction principle and that, in many cases of hearing loss, this type of instrument may not be suitable.

(19) Making [advertisements] an advertisement or other [representations] representation which may have the tendency or effect of misleading or deceiving [purchasers] a purchaser or prospective [purchasers into the belief] purchaser to believe that [any] a hearing aid or device or part or accessory thereof is a new invention or involves a new mechanical or scientific principle, when [such] that is not [a fact] true. Representations of the following or similar types, when not fully

justified by the facts, are among those prohibited by this paragraph: "amazing new discovery," "revolutionary new invention," "radically new and different," "sensational new laboratory development," "remarkable new electronic device," "brand new invention," "marvelous new hearing invention," "new scientific aid," and "miracle."

(20) Misrepresenting the commercial nature of the registrant's business. A [hearing aid dealer] registrant shall not represent, directly or by implication, that a commercial hearing aid establishment is a governmental or public one or is a nonprofit medical, educational, or research institution, through the use of [terms] a term having a medical, professional, or scientific connotation, such as "Hearing Center," "Hearing Institute," "Hearing Bureau," "Hearing Clinic," "State's Hearing Clinic," or "State's Speech and Hearing Center." Nothing in this paragraph [is meant to preclude] precludes a [hearing aid dealer] registrant from representing, if [such be the fact] true, that [he] the registrant owns, operates, or controls a "Hearing Aid Center" or from using other words or expressions which clearly and nondeceptively identify the [dealer's] registrant's establishment as a commercial hearing aid enterprise.

(21) Making a deceptive [advertisements] advertisement of a hearing aid [parts] part, [accessories] accessory, or [components] component. A [hearing aid dealer] registrant shall not use or cause to be used any type of advertising or promotional literature depicting or describing only a single part, accessory, or component of [any] a hearing aid or device, such as a battery on the finger or a transistor held in the hand, in [such] a manner [as] that may have the tendency to mislead or deceive [purchasers] a purchaser or prospective [purchasers into the erroneous belief] purchaser to believe that [such] the part, accessory, or component is all that [needs to] must be worn or carried.

(22) Making a deceptive [endorsements, testimonials, and so forth] testimonial or other endorsement. A [hearing aid dealer] registrant shall not advertise or otherwise represent:

(i) That a particular individual, organization, or institution endorses, uses, or recommends [such dealer's] the registrant's hearing aids or devices when [such] that is not [a fact] true; or

(ii) That a particular individual wears [such dealer's] the registrant's hearing aids or devices when [such] that is not [a fact] true.

(23) Making [representations] a representation either directly or indirectly that [any] a hearing aid or part thereof is new, unused, or rebuilt when [such] that is not [a fact. The term "new" shall mean a hearing aid which has not been previously sold at retail or used as a clinic demonstrator] true.

(i) In the marketing of a used hearing aid [which has been used] or a hearing aid which contains used parts, a [hearing aid dealer] registrant shall make full and nondeceptive disclosure of the fact in advertising and promotional literature relating to the product on the container, box or package in which the product is packed or enclosed. The required disclosure may be made by use of [the] words such as "Used," "Second-hand," "Repaired," or "Rebuilt," whichever is applicable to the product involved, and it shall appear on a tag physically attached to a hearing aid.

(ii) A [hearing aid dealer] registrant may not misrepresent the identity of the rebuilder of a hearing aid. If the rebuilding of a hearing aid was done by other than the original manufacturer, a [hearing aid dealer may not fail to] registrant shall disclose the fact wherever the original manufacturer is identified.

(24) Doing any of the following:

(i) Representing or using [seals, emblems, shields] a seal, emblem, shield or other insignia which [represent] represents, directly or by implication that a hearing aid or device has been tested, accepted or approved by an individual, concern, organization, group or association unless it is [a] true [fact] and unless the hearing aid or device has been [so] used in a manner as will reasonably [insure] ensure the quality and performance of the instrument in relation to its intended use and the fulfillment of a material [claims] claim made, implied or intended to be supported by the representation or insignia.

(ii) Representing that a hearing aid or device tested, accepted or approved by an individual, concern, organization, group or association has been subjected to [tests] a test based on a more severe [standards] standard of performance, workmanship and quality than is [in fact] true.

(iii) Making any other false, misleading or deceptive representation respecting the testing, acceptance or approval of a hearing aid device by an individual, concern, organization, group or association. It is not necessary for an individual hearing aid or device to be tested [where] if the method employed is a sample testing and full and nondeceptive disclosure of this fact is given in advertising and otherwise.

(iv) Making a false, misleading or deceptive representation regarding the practice of another registrant or the quality of a hearing aid

product made by a hearing aid manufacturer, which enhances or is likely to enhance the registrant's business as a repairer, fitter or seller of hearing aids.

(25) Doing any of the following:

(i) [Imitate] Imitating or [simulate] simulating the [trademarks] trademark, [trade names] trade name, [brands] brand or [labels] label of [competitors] a competitor which may have the tendency or effect of misleading or deceiving [purchasers] a purchaser or prospective [purchasers] purchaser.

(ii) [Use] Using in advertising the name, model name or trademark of a particular manufacturer of hearing aids in a manner [as to imply] that implies a relationship with the manufacturer that does not exist or which otherwise may mislead or deceive [purchasers] a purchaser or prospective [purchasers] purchaser.

(iii) [Use] Using a trade name, corporate name, trademark or other designation which may have the tendency or effect of misleading or deceiving [purchasers] a purchaser or prospective [purchasers] purchaser as to the name, nature or origin of a hearing aid or of a material used therein or which is false, deceptive or misleading in another material respect.

(26) Advertising a particular model, type or kind of hearing aid for sale when [purchasers] a purchaser or prospective [purchasers] purchaser responding to the advertisement cannot purchase or [are] is dissuaded from purchasing the advertised model, type or kind, [where] if it is established that the purpose of the advertisement is to obtain prospects for the sale of a different model, type or kind than that advertised.

(i) In determining whether there has been a violation of this paragraph, consideration will be given to acts or practices indicating that the offer was not made in good faith for the purpose of selling the advertised product but was made for the purpose of contacting prospective purchasers and selling them a product or products other than that offered. Among acts or practices which will be considered in making that determination are the following:

(A) The creation, through the initial offer or advertisement, of a false impression of the product offered in a material respect.

(B) The refusal to show, demonstrate or sell the product offered

in accordance with the terms of the offer.

(C) The disparagement, by acts or words, of the product offered or the disparagement of the guarantee; credit terms; or availability of service, repairs or parts or the disparagement in another respect, in connection with it.

(D) The showing, demonstrating and in the event of sale, delivery of a product which is unusable or impractical for the purpose represented or implied in the offer.

(E) The refusal, in the event of sale of the product offered, to deliver the product to the [buyer] purchaser within a reasonable time thereafter.

(F) The failure to have available a quantity of the advertised product at the advertised price sufficient to meet reasonably anticipated demands.

(ii) It is not necessary that each act or practice set forth in subparagraph (i) be present in order to establish that a particular offer violates this paragraph; any one will be sufficient.

(27) Failing to furnish evidence of the required continuing education or truthful information regarding the continuing education secured when applying for renewal of a registration certificate as a hearing aid fitter.

§ 25.216. Continuing education requirements.

(a) *General requirements.* Except as provided in subsection (d), the continuing education requirement for renewal of a hearing aid fitter's registration certificate is 20 hours of continuing education credit in the two years immediately preceding the expiration of the current registration certificate. If the applicant for renewal has had a registration certificate for less than two years, the required number of continuing education hours shall be calculated by prorating the number of credit hours required over a two-year period by the number of months in which the applicant for renewal had the registration certificate which is about to expire. Only months in which the applicant had the registration certificate for at least 15 days shall be considered in the calculations.

(b) *Requirements for renewal of an expired registration certificate.* Except as provided in subsection (d), the continuing education requirement for renewal of a hearing aid fitter's registration certificate that has expired is 20 hours of continuing education credit in the two years immediately preceding the filing of the application for renewal, provided that the application for renewal is filed within five years after expiration of the previous

registration certificate. If more than five years have passed since the registration certificate expired, the registration certificate may not be renewed. Instead, the individual would need to repeat the hearing aid fitter's certification examination and satisfy other requirements then in effect for an original hearing aid fitter's registration certificate.

(c) *Requirements for renewal of a suspended registration certificate.* The continuing education requirement for renewal of a hearing aid fitter's registration certificate which has been suspended is the same as in subsections (a) and (d). If the individual does not satisfy the continuing education requirement during the period in which the hearing aid fitter's registration certificate is suspended, the suspended registration certificate shall be considered to have expired, and the continuing education requirements in subsection (b) shall apply for renewal of the expired registration certificate.

(d) *Phase-in requirements.* The first two-year period for which continuing education requirements shall be required will begin on April 15, 2003.

(e) *Subject matter requirements.* Any subject matter that contributes directly to the professional competence, skills and education of a hearing aid fitter is acceptable subject matter for a continuing education program. At least one half of all continuing education credit hours by which the hearing aid fitter seeks to qualify for renewal of the registration certificate shall be secured in some combination of the following core subject matter: hearing evaluation, hearing instrumentation technology, ear mold technology, hearing aid repair and maintenance, technical devices to assist the hearing-impaired, psychology of the hearing-impaired, and office procedures and compliance with the act.

§ 25.217. Approval of continuing education programs.

(a) A person may apply to the Department for approval of a continuing education program by submitting to the Department an application on a form supplied by the Department. The applicant shall supply all information requested in the application, including specification of whether the program is fully or partially devoted to any of the core subjects specified in §25.216(e) (relating to continuing education requirements). The Department will grant approval of a continuing education program and designate whether the program is assigned full or partial credit in one of the core subjects, if the applicant satisfies the Department that the program the applicant will offer will meet the following minimum standards:

(1) The program shall be of intellectual and practical content.

(2) The program shall contribute directly to the professional competence, skills and education of a hearing aid fitter.

(3) The program instructors shall possess the necessary practical and academic skills to conduct the program effectively.

(4) Program materials shall be well written, carefully prepared, readable and distributed to attendees at or before the time the program is offered whenever practical.

(5) The program shall be presented by a qualified responsible instructor in a suitable setting devoted to the educational purpose of the program.

(6) The program shall be open to all persons who have a current, suspended or expired hearing aid fitter's registration certificate.

(b) Approval of a continuing education program shall be effective for three years.

(c) If renewal of the Department's approval of a continuing education program is desired, at least 90 days before expiration of the three-year period the person who offered the program shall apply to the Department to renew the Department's approval of that program. The criteria and process applicable to the Department's initial approval of a continuing education program shall apply to renewal of the approval of that program.

§ 25.218. **Credit for continuing education.**

(a) *Credit hour.* A hearing aid fitter shall receive one hour of credit for each 50 minutes of instruction in a continuing education program presented in a classroom setting. No credit shall be received if attendance or other participation in the program is not adequate to meet the educational objectives of the program as determined by the person offering the program. For completing a continuing education program that is not presented in a classroom setting, the hearing aid fitter shall receive the number of credit hours assigned to the program by the Department.

(b) *Program completion.* A hearing aid fitter shall receive no credit for a continuing education program not completed, as evidenced by satisfaction of the check-in/check-out process for a continuing education program presented in a classroom setting and the continuing education report verifying that the hearing aid fitter completed the program, both of which are submitted to the Department by the person who offered the program. The program shall also not be considered completed if the hearing aid fitter does not satisfy other program completion requirements imposed by this subchapter and the continuing education provider.

(c) *Continuing education credit for instruction.* A hearing aid fitter shall receive credit equal to the number of hours served as an instructor in a continuing education program approved by the Department, or in a program that satisfies requirements for initial certification as a hearing aid fitter, except that only half of the credit hours necessary for renewal of a hearing aid fitter's registration certificate may be obtained through serving as an instructor. The remaining credits necessary to renew a certificate shall be obtained through attendance at continuing education programs.

(d) *Continuing education credit through endorsement.* A hearing aid fitter who attends or teaches a continuing education program offered outside this Commonwealth may apply to the Department to receive credit for the program. The hearing aid fitter shall have the burden of demonstrating to the Department that the course meets standards substantially equivalent to the standards imposed in this subchapter. The Department will assign credit to the program, including the possibility of no credit or partial credit, based upon considerations of whether the program bears entirely upon appropriate subject matter and whether the method of presenting the program meets standards substantially equivalent to those prescribed in this subchapter.

(e) *Continuing education credit assigned to self-study courses.* Credit may be sought from the Department for a self-study continuing education program. The hearing aid fitter shall submit an application to the Department to approve the self-study program for credit before commencing the program and shall supply the Department with the materials the Department requests to conduct the evaluation. The Department will assign credit to the program based upon considerations of whether the program addresses appropriate subject matter and whether the method of completing the program meets standards substantially equivalent to those prescribed in this subchapter. The Department may require modifications to the proposed self-study as a precondition to approving it for credit.

(f) *Continuing education credit assigned to courses not presented in a classroom setting.* A hearing aid fitter shall be awarded credit for completing a continuing education program without the hearing aid fitter physically attending the program in a classroom setting, provided the program has been approved by the Department for credit when presented in that manner.

(g) *Repeat completion or teaching of a continuing education program.* The Department will not accept more than one completion or teaching of a continuing education program for credit towards renewal of a fitter's registration certificate, but will accept a subsequent completion or teaching of the same continuing education program for a subsequent renewal of a fitter's registration certificate.

(h) *Resolution of discrepancies.* The Department will resolve all discrepancies between the number of continuing education credits reported and the number of continuing education credits a hearing aid fitter alleges to have earned. To help resolve disputes, the hearing aid fitter should retain the original certificate of completion of a continuing education program if a certificate of completion has been received by the hearing aid fitter.

§ 25.219. Responsibilities of persons offering continuing education programs.

(a) *Record of attendance.* A person who offers a continuing education program shall maintain a record of attendance for a program presented in a classroom setting by maintaining a check-in/check-out process approved by the Department, and shall assign at least one person to ensure that all individuals attending the course check in when entering and check out when leaving. If an individual enters a course after the starting time, or

leaves a course before the finishing time, the assigned person shall ensure that the time of arrival or departure is recorded for the individual.

(b) *Reporting attendance.* A person who offers a continuing education program shall report to the Department, in the manner and format prescribed by the Department, attendance at each continuing education program presented in a classroom setting.

(c) *Course evaluation.* A person who offers a continuing education program shall develop and implement methods to evaluate the program to determine its effectiveness. The methods of evaluation shall include providing a program evaluation form to each person who attends the continuing education program, and requesting each person to complete the form.

(d) *Record retention.* A person who offers a continuing education program shall retain the completed program evaluation forms and the check-in/check-out record for a program presented in a classroom setting. The person shall retain the records for at least four years from the presentation of the program.

(e) *Providing records.* A person who offers a continuing education program shall promptly provide the Department with complete and accurate records relating to the program as requested by the Department.

(f) *Program not presented in a classroom setting.* A person who offers a continuing education program shall be exempt from the requirements of subsections (a) and (b) for a program which is not presented in a classroom setting, if the program is approved by the Department for credit when presented in that manner. When presenting the program to the Department for approval for credit, the person shall present a procedure for monitoring, confirming and reporting hearing aid fitter participation in a manner that achieves the purposes of subsections (a) and (b).

(g) *Monitoring responsibilities.* A person who offers a continuing education program shall ensure that the program was presented in a manner that met all of the educational objectives for the program, and shall determine whether each hearing aid fitter who enrolled in the program met the requirements of this subchapter and of the continuing education program to receive credit for completing the program.

(h) *Program completion.* A person who offers a continuing education program shall report to the Department, in a manner and format prescribed by the Department, completion of a continuing education program by a hearing aid fitter who completes the program, and shall identify to the Department a hearing aid fitter who seeks credit for a program but who did not meet the requirements of the program or this subchapter to receive continuing education credit. The person who offers a continuing education program shall also provide a hearing aid fitter who completes the program with a document certifying completion of the program.

§ 25.220. **Right to enter, inspect and obtain records.**

Upon request of a Department representative during regular and usual business hours, or at other time when that representative possesses a reasonable belief that a violation of this subchapter may exist, and upon the representative presenting documentation to identify himself or herself as a representative of the Department, a registrant or person who offers a continuing education program shall:

(1) Produce for inspection equipment and supplies maintained pursuant to this subchapter.

(2) Produce for inspection, permit copying, and provide within a reasonable period of time, records maintained pursuant to this subchapter.

§ 25.221. **Exceptions.**

The Department may grant an exception to a requirement of this subchapter for good cause shown, except for a statutory requirement that is repeated in this subchapter.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

June 24, 2002

Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Department of Health Proposed Regulation No. 10-165
Hearing Aid Sales and Registration

Dear Representative Nyce:

Attached are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). The proposed regulations amend the Department of Health's regulations relating to Hearing Aid Sales and Registration (28 Pa. Code §25.201 et seq.). The proposed regulations are being promulgated under the Hearing Aid Sales Registration Law (35 P.S. §6700-101 et seq.), and are responsive to Act 1998-153, which amended the Hearing Aid Sales Registration Law and required the Department to issue regulations. The proposed regulations include continuing education requirements, disclosure requirements, and money-back guarantee provisions.

Section 5(g) of the Regulatory Review Act (71 P.S. §745.5(g)), provides that the Commission shall, within 10 days after the expiration of the Standing Committee review period, notify the proposing agency of any objections to the proposed regulations. The regulations are expected to be published July 6, 2002. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act (71 P.A. §745.5a(a)) provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received and the text of the final form regulations which the agency intends to adopt.

The Department will provide the Commission within 5 days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Deborah Griffiths, Director of the Office of Legislative Affairs at (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Attachments

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-165
SUBJECT:	Hearing Aid Sales & Registration
AGENCY:	Department of Health

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
6/24	Nancy Thompson	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
6/24	A. Rucker	
6/24/02	Kristi Knueven	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
6/24	M. Walker	
6/24	E. Pagán	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
6/24/0	C. Lee-Brown	LEGISLATIVE REFERENCE BUREAU

May 30, 2002