Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	RECEIVED 2003 OCT 22 PM 3:43 INDEPENDENT REGULATORY REVIEW COMMISSION
(2) I.D. Number (Governors Office Use) DOH Reg. No. 10-165	IRRC Number: 2278
(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: Ian 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?
Proposed Rulemaking	x No
x 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.

Regulatory Analysis Form

(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						

Regulatory Analysis Form

(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.

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(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

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INDEPENDENT REGULATORY REVIEW COMMISSION
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Copy below is hereby approved as to form and legality. Attorney General.	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or independent Agencies.
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY Tanya C Hubbard
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-165	10/2/03 DATE OF APPROVAL
	DATE OF ADOPTION: _____	Asst. (~~Deputy~~ General Counsel) (~~Chief Counsel, Independent Agency~~) (Strike inapplicable title)
	BY: Calvin B. Johnson, M.D., M.P.H.	
Check if applicable. Copy not approved. Objections attached.	TITLE: Secretary of Health	Check if applicable. No Attorney General approval or objection within 30 days after submission.

FINAL 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).

The Department of Health (Department) hereby adopts amendments to Part III of Title 28 (relating to prevention of diseases) by amending Chapter 25 (relating to controlled substances, drugs, devices, and cosmetics) to read as set forth in Annex A.

A. ***Purpose and Background***

The Hearing Aid Sales Registration Law (Act) (P.L. 1182, No. 262) (35 P.S. §§6700-101 -- 6700-802) 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 Act was amended in 1998. The changes made by Act 1998-153 (P.L. 1190, No. 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. Act 1998-153 required the Department to promulgate regulations to effectuate the continuing education requirements imposed by it.

Prior to Act 1998-153, certain portions of the Act were preempted 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 conflicted 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). This final rulemaking is responsive to the preemption issues raised by the Federal regulations, and is intended to clarify the state of the law.

B. ***Summary***

This final rulemaking breaks 28 Pa. Code Chapter 25, currently entitled "Controlled Substances, Drugs, Devices and Cosmetics," into two subchapters in order to differentiate the regulations adopted under the Act and pertaining to hearing aid sales and registration from the rest of the chapter, which otherwise consists entirely of regulations adopted under the Controlled Substance, Drug, Device and Cosmetic Act (P.L. 233, No. 64) (35 P.S. §§780-101-780-144). Newly created subchapter A is also titled "Controlled Substances, Drugs, Devices and Cosmetics." Subchapter B includes the regulations adopted under the Act, and is entitled "Hearing Aid Sales and Registration."

The Department received four comments to the proposed rulemaking. The commentators included the Independent Regulatory Review Commission (IRRC); James P. Rametta of the Rametta Audiology and Hearing Aid Center; Dorothy Kardos of Central Pennsylvania Eye and Ear; and Dorothy Kardos, President of the Pennsylvania Hearing Aid Alliance (PHAA), on behalf of PHAA. The comments and the Department's responses to them appear in this summary of final rulemaking.

C. ***Comments***

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

Subchapter A. Controlled Substances, Drugs, Devices and Cosmetics

* * * *

Subchapter B. Hearing Aid Sales and Registration

Section 25.201 (relating to application).

This section explains to whom the regulations apply. No comments were received regarding this section. This section is adopted as proposed.

Section 25.202 (relating to definitions).

This section defines terms used in Subchapter B. IRRC commented that the terms "hearing aid user," "purchaser," and "prospective hearing aid user" should also be defined in order to avoid confusion. The Department accepts this recommendation, and has added definitions of these terms.

IRRC also questioned whether Commonwealth residents would be permitted to seek medical treatment for hearing problems from out-of-state physicians, given that the definition of "physician" included in the proposed regulations is an individual who has a currently registered license to practice medicine or osteopathic medicine in this Commonwealth. Commonwealth residents may seek medical treatment from whomever they wish. However, the Act requires an examination and recommendation from a physician, unless waived by the prospective purchaser. Since § 403 of the Act permits the registrant to accept a medical recommendation from any licensed physician, the Department has deleted the proposed definition in response to the IRRC comment.

Section 25.203 (relating to the Hearing Aid Advisory Council).

This section establishes the Hearing Aid Advisory Council and requires annual meetings. The proposed amendment would delete the specific requirements as to the frequency and time of notice of meetings. This section did not engender comment. It is adopted as proposed.

Section 25.204 (relating to application for and renewal of registration).

This section establishes how registration certificates may be applied for and renewed. Proposed amendments to subsection (d) would require registrants to apply to renew a registration certificate at least 30 days before it expired. IRRC suggested that, since all registration certificates expire on April 15, the subsection should state specifically that renewals must be submitted by March 16. The Department accepts this comment, and has changed the subsection to include the date by which registrants must apply for renewal.

The Department clarified proposed amendments to subsection (e), which would provide that an expired registration certificate may be renewed within 5 years of its expiration by applying for renewal, paying the renewal fee and any delinquency fee due, and satisfying the applicable continuing education requirements. The Department has clarified that this also applies to registration certificates that their holders request be placed on inactive status. When a registration is placed on inactive status, it may be renewed for up to 5 years from the date it was made inactive. Although the statute does not specifically mention inactive certificates, the 5-year limit on renewal ensures that an individual who is "out of practice" cannot simply resume practicing after more than five years have passed, without demonstrating competency to do so. The 5-year time limit therefore logically applies to individuals who have in effect directly informed the Department that they will not be practicing.

Proposed amendments to subsection (f) would permit an applicant to petition for more than two renewals of a temporary registration certificate, for good and sufficient cause. IRRC commented that the subsection should set forth the process for applicants to be able to do this. The Department accepts this comment, and has included language that requires applicants to

send a letter stating their reasons for requesting an additional renewal to the Division's address. The Department will then determine whether or not the cause is sufficient so as to merit the additional renewal.

Proposed subsection (g), intended to inform registrants that a renewal not requested 30 days prior to the expiration of a registration certificate may not be received on time, did not specifically state the expiration date for registration certificates. IRRC again suggested that the specific date of April 15 be used. The Department accepts this comment, and has changed the subsection to state that a registrant who files for renewal after March 16 may not receive a renewal before the certificate expires.

Section 25.205 (relating to additional registration requirements).

This section establishes additional requirements to receive temporary and regular registration certificates. IRRC pointed out that proposed amendments to subsection (d)(3), which list the requirements for an apprentice hearing aid fitter to change sponsors, use the word "affirmed" to apply to statements which must be filed by the apprentice giving reasons for the desired change, and by the prospective sponsor. IRRC suggested that the Department should explain how affirmation is accomplished. The Department accepts this comment, and has changed section 25.205(d)(3) to make clear that affirmation may be given in any form so long as it is in writing, signed, and contains a statement to the effect that it is truthful.

IRRC also asked whether subsections (d)(3) and (4), having to do with how an apprentice may change sponsors or how a sponsor may terminate responsibilities with regard to an apprentice, require good cause to be shown. The Department will not require good cause. An explanation is required when an apprentice desires to change sponsors, largely to enable the Department to ensure that a sponsor is not repeatedly failing in his or her duties when the

sponsor agrees to take on an apprentice. However, a simple representation that the relationship is not working out to the satisfaction of one or both parties will suffice. The Department has made no changes to the subsection in response to the comment.

Section 25.206 (relating to examinations).

This section establishes a schedule for the fitter examinations. IRRC commented that the Department should provide the actual address to which a prospective exam taker should write to obtain the date of the next examination, and should also clarify whether it would be possible to request an examination date by e-mail or telephone. The Department accepts these comments, and has modified subsection (b) to refer to the address in section 25.204(a). The subsection has also been changed to state that individuals may telephone or e-mail the Division, and also provides the Department's website, on which the Department intends to post the examination dates and contact information.

Section 25.207 (relating to categories of registrations; fee schedule).

This section establishes registration fees and requirements for registration certificates. IRRC commented that the Department could reword the proposed amendments to subsection (h) to make it more understandable. The Department accepts this comment, and has reworded the subsection as suggested.

Section 25.208 (relating to display of registration certificates; offices).

This section sets out requirements for the information contained on registration certificates. IRRC asked that the Department explain the process for filing a notice of a change in the registrant's place of business, as required in the proposed amendments to subsection (d). The Department has modified subsection (d) to state that registrants should file notice of a

change in their business addresses by writing to the Department at the address given in section 25.204(a).

Section 25.209 (relating to facilities, procedures and instrumentation).

This section includes requirements for physical facilities, testing and fitting procedures, and standards for instruments. IRRC pointed out that the Department proposed to delete from subsection (b)(1) a list of persons who the fitter should verify performed the test, and to substitute the phrase, "individual authorized by law." IRRC suggested that the Department should restore the phrase in order to facilitate understanding of who the Department considers to be individuals who are authorized by law. However, the Department feels that without the change, the subsection could lead a registrant to believe that anyone supervised by a physician, audiologist or fitter is authorized by law to perform such hearing tests, which is not necessarily the case. In order to clarify the proposed changes to the subsection and to respond to concerns, the Department has revised subsection (b)(1) to state that a registrant may rely on a representation made by an appropriately licensed individual under whose auspices the testing is being done, that the testing was performed by an appropriately authorized individual.

IRRC pointed out that subsection (c)(1) (requiring test instruments to be calibrated in accordance with current standards set by the American National Standards Institute) refers to standards that were published in 1969. The most recent A.N.S.I. standards in this area were published in 1996. The Department has revised the subsection to reference the 1996 A.N.S.I. standards.

Section 25.210 (relating to receipt, disclosure agreement, and money back guarantee to purchaser-purchaser protection).

This section lists requirements for receipts, establishes a form disclosure agreement/money back guarantee, and provides instructions for its use. All of the commentators

indicated that initial screening and testing would be necessary to determine whether a patient needs a hearing aid. However, proposed subsection (b), which included the disclosure agreement requirements, required completion of the entire disclosure agreement and money back guarantee form to be completed prior to the provision of any services. Given the variety of hearing aids available, costs cannot be accurately estimated prior to completing an examination. The commentators indicated that the form should be restructured to accommodate the order in which the activities of testing, fitting, and selecting a hearing aid are done. IRRC specifically stated that the regulations should require that Part A of the form be completed with the patient's signature, date and time prior to testing. Once the testing has been finished, Part B should be completed.

The Act, however, requires registrants to provide a disclosure agreement that is to be explained in detail and signed by the registrant and the consumer prior to the provision of any service. The disclosure agreement must contain a complete description of what the fitting procedure does and does not include, and an itemization and disclosure of any and all fees associated with the fitting procedure or process and the sale and delivery of a hearing aid or similar device, including any cancellation fees authorized by the Act.

In deference to these comments, particularly from the practitioners who indicate that it is necessary for them to be able to do the disclosure agreement in stages, the Department has revised the disclosure agreement/money back guarantee form and proposed subsections (b) and (c), in order to accommodate both the statutory requirements and the needs of the commentators. Subsection (b) has been revised to clarify that the disclosure agreement/money back guarantee must be provided and explained in detail in accordance with subsection (c), before the provision of any service.

The revisions to subsection (c)(1) require registrants to complete and explain Part A of the disclosure agreement/money back guarantee in detail, in deference to the statutory requirement that a complete description of what the fitting procedure or process includes must be given, and any fees associated with the fitting procedure or process and the sale and delivery of the hearing aid must be itemized and disclosed. This is intended to ensure that purchasers understand what services they are paying for, and requires registrants to break out each service separately. Registrants should be especially certain to separate those services which are rendered in connection with the fitting process from those which are connected with the sale and delivery of a hearing aid, and which might occur after a hearing aid is actually delivered. This statutory requirement is particularly important to understand in light of the fact that, if a purchaser cancels an order for a hearing aid prior to delivery, any monies paid for services not yet rendered must be refunded. These services must, therefore, be itemized separately.

Registrants would also be required to preliminarily explain Part B, including any cancellation fees that might be incurred if an individual purchases and then returns a hearing aid. Subsection (c)(1) states that, if registrants do not charge fees for services, they should note that in Part A of the disclosure agreement.

Revised subsection (c)(2) requires the registrant to sign and have the prospective user or authorized representative sign the disclosure agreement after Part A has been explained and completed, and Part B has been preliminarily explained. The disclosure form itself has changed to permit both the registrant and the customer to sign the disclosure agreement/money back guarantee under Part A at this juncture. The statement below Part A, which has been added to the proposed form, states that the disclosure agreement was provided, Parts A and B were explained, and Part A was completed before any services were provided, and that Part B was

completed after services were provided and before any payment was made. The disclosure agreement thus contemplates the possibility that the registrant or prospective hearing aid user may elect not to proceed after testing by stating that, "If Part B is not completed, it is because a hearing aid was not recommended or not desired." This allows for the fact that the prospective user may not need a hearing aid, the registrant may not wish to recommend one, or the prospective user may not wish to purchase one at the time the testing is done. These possibilities are reflected in subsection (c)(3), which instructs the registrant how to proceed if Part B becomes inapplicable. If Part B is completed, it must also be fully explained at that time, before any payment is provided.

The next step in the process is for the registrant to explain the money-back guarantee. If the prospective user or authorized representative decides to purchase a hearing aid, the purchaser and registrant sign the signature lines under the guarantee, and the purchaser should complete the time and date line. See subsection (c)(4). Proposed subsections (c)(4) through (c)(6) have been deleted and replaced in accordance with the revisions to the disclosure agreement. The information in those subsections that is relevant to the revised form has been included elsewhere in subsection (c).

Subsection (c)(5) makes clear that a registrant may still extend the money back guarantee beyond 30 days if the registrant wishes to do so and that the 30 day period starts on the date of delivery of the hearing aid. Subsection (c)(6) explicitly instructs the registrant to provide the customer with a copy of the disclosure agreement after it is fully completed except for the serial number of the hearing aid and the block that is concerned with the date and time of delivery.

IRRC also questioned why it is necessary to have the time and date recorded twice on the form, if the entire form must be completed prior to rendering any services. It is important to

recognize the separation between the services that are rendered in connection with the fitting of the hearing aid, the sale of the hearing aid, and the delivery of the hearing aid to the purchaser. The form as proposed did allow for the prospective user to sign before any fitting services were provided, and then sign again when the decision to purchase was made. It is important that the registrant provide the required information and services before the prospective user agrees to the sale. Recording the time that each signature is made is intended to provide some evidence that the time between the initial explanation of the form and the decision of the prospective user or authorized representative to purchase the hearing aid has allowed for the provision of services. If the serial number is not known until the hearing aid is delivered, this information may be filled in or updated at that time. Now that the Department has clarified the fact that the first signatures are to be completed before any services are provided, and the second signatures are to be contemporaneous with the sale, the time of each signature remains an important piece of evidence that registrants have properly followed the process as outlined in subsection (c). In addition, the requirement to record the date of delivery on the form provides evidence of the start of the 30 day money back guarantee period.

IRRC further suggested that the Department allow for registrants to use forms other than those provided by the Department. The Department accepts this comment, and has revised subsection (b) to include the words, "or on a form approved by the Department."

Two commentators pointed out that ear molds are not part of the hearing aid, and should not be included in the price of the hearing aid for refund purposes. Because the ear molds are not returnable to a manufacturer (as hearing aids are), registrants should be able to retain the entire cost of the ear mold even if the hearing aid is returned. However, as one of the commentators indicated, the Act itself mandates that a purchaser is entitled to a refund of the price of the

hearing aid and accessories together, except for a cancellation fee of the lesser of $150 or 10 % of the price of the hearing aid and accessories. Ear molds are included in "accessories." The Department, therefore, has made no changes to the regulations in response to these comments.

Commentators also referenced a statement in the preamble to the proposed rulemaking, which stated that registrants do not suffer a great financial loss when a purchaser returns a hearing aid, since manufacturers give credit for such returns. The commentators pointed out that return of a hearing aid has an ultimate financial impact on registrants and end users alike. Pursuant to FDA regulations, manufacturers cannot resell a returned hearing aid as new or use any part of it in a hearing aid that is to be designated as new. Any losses suffered by manufacturers as a result of a return are recovered in the prices of new hearing aids. More returns must necessarily result in higher prices for hearing aids. The commentators did not suggest changes to the regulations in connection with this point. As the Act establishes the return policy, and FDA regulations govern when a hearing aid may be considered new, the Department made no changes to the regulations in response to these comments.

Section 25.211 (relating to medical recommendations and waiver forms).

This section requires registrants to obtain medical recommendations or waiver forms signed by the prospective user before selling a hearing aid. IRRC pointed out that proposed amendments to subsection (a) incorrectly allow an individual who is "18 years of age" to sign a waiver form. In fact, the Act requires a medical examination for individuals 18 years of age or younger who are buying a new hearing aid. The language has been corrected to read "older than 18 years of age."

IRRC stated that the phrase "a legally proper waiver" as used in proposed subsection (b) is unclear, and questioned whether both the State and Federal medical waiver forms are legally

proper. Both the State and Federal waiver forms are legally proper where the sale of a used hearing aid is concerned. Subsection (b) has been revised to explicitly state that a legally proper waiver in this limited circumstance is either the State or Federal waiver form.

Section 25.212 (relating to medical recommendations by examining physicians).

This section as proposed sets out the requirements for medical recommendations provided by physicians. No comments were received regarding this section. This section is adopted as proposed.

Section 25.213 (relating to consumer review).

This section establishes additional documentation that must be provided to a prospective hearing aid user, and incorporates certain requirements of the Unfair Trade Practices and Consumer Protection Law. IRRC expressed concern with subsection (b), which permits consumers to avoid contracts for sale entered into in connection with a contact with or call on a purchaser at the purchaser's home. The proposed amendments to subsection (b) state that a notice of rescission is effective "when deposited" in the United States mail. IRRC asked when the notice is considered to be "deposited." This common legal presumption does allow for a rescission to be effective when it is deposited in the mail, even though the registrant will not be aware of the rescission until it is delivered. In this way, the consumer has the full three days to change his or her mind; if the consumer had to ensure that the rescission was delivered within the three days, there would effectively be no "cooling off" period. The issue pointed out by IRRC is a possible evidentiary problem, which could arise in the context of a dispute as to when the notice was deposited, particularly in the absence of a postmark or other written evidence as to

when the notice was deposited (such as a receipt for certified mail). The evidentiary question at that point would rest with the factfinder in the dispute.

IRRC was also concerned that subsection (b) is not clear enough as to the other permissible ways that the registrant may be given notice of rescission, and recommended that the Department list those ways. The Department will not implement this recommendation. These requirements are found in the Unfair Trade Practices and Consumer Protection Law (73 P.S. §§201-1 et seq.) (UTPCPL). They are applicable whether or not incorporated in the Department's regulations; they are so incorporated because the Act permits the Secretary to deny, suspend or revoke a registrant's certificate for untruthfulness or bad reputation in general, and more specifically for being enjoined from a violation of the UTPCPL. Incorporation in this manner places a registrant on more specific notice of the UTPCPL requirements. However, the Attorney General has primary responsibility for enforcement of the UTPCPL. The Department believes that specifically listing methods of service by which registrants are placed on notice of rescission could prove to be misleading to registrants, since the Attorney General's Office may ultimately interpret what is permitted under the UTPCPL differently than the Department. The Department has combined subsections (b) and (c) to clarify that all the requirements discussed are drawn directly from the UTPCPL and that the statute is controlling in this matter.

Section 25.214 (relating to recordkeeping).

This section contains recordkeeping requirements for registrants. No comments were received regarding this section. This section is adopted as proposed.

Section 25.215 (relating to denial, revocation or suspension of a registrant's certificate).

This section as proposed listed reasons for which a registration certificate may be denied, revoked, or suspended. No comments were received regarding this section. The reference to the

"United States Department of Health, Education and Welfare" was corrected to say, "United States Department of Health and Human Services." This section is otherwise adopted as proposed.

Section 25.216 (relating to continuing education requirements).

This section as proposed established continuing education requirements and stated how they relate to the renewal of a registration certificate. The Department has changed the phrase "would need to," found in subsection (b), to "shall." This enhances the clarity and grammatical correctness of the provision, but does not change the requirement therein. IRRC properly pointed out that the date on which the first two-year period for which continuing education requirements are applicable did not begin on April 15, 2002, as stated in the preamble in the Department's submission to IRRC, but on April 15, 2003. This correction was made by the Legislative Reference Bureau prior to publication of the proposed rulemaking.

Section 25.217 (relating to approval of continuing education programs).

This section as proposed would establish requirements for continuing education programs. IRRC commented that the content of proposed subsection (a)(1) is adequately covered in proposed subsection (a)(2). The Department has deleted proposed subsection (a)(1). IRRC questioned how the Department will enforce the requirement in proposed subsection (a)(4) (adopted as subsection (a)(3)) that materials will be "well written." The Department has responded to this comment by requiring that written materials used in continuing education programs must be "clear, informative and grammatical," which the Department believes may be ascertained by reading the materials.

IRRC also asked what it meant to be a "qualified" instructor, as stated in proposed subsection (a)(5) (adopted as subsection (a)(4)). The Department does not wish to implement

rigid standards having to do with credentials or being approved by certain national organizations that fulfill such functions. Some fitters who have submitted and led their own continuing education programs have done an excellent job, and the Department would like such individuals to continue to contribute to the continuing education process. In order to be responsive to IRRC's concerns, the Department has deleted the word "qualified" and substituted the phrase, "experienced and knowledgeable in the subject matter taught." Whether an instructor is experienced and knowledgeable will be evaluated on a number of factors including qualifications, experience, the quality of the materials submitted in support of the program, and any other relevant information that can be obtained, including any feedback offered by registrants who are familiar with the instructor or the program.

Finally, IRRC questioned what is meant by a "suitable setting," as that phrase is used in proposed subsection (a)(5) (adopted as (a)(4)). The Department does not intend, nor have the resources, to investigate all of the physical areas in which programs may be offered. However, it is anticipated that complaints may be received if the setting in which a continuing education course was offered was particularly inappropriate in some aspect. If such complaints prove to be valid, including this requirement will enable the Department to ensure that a provider does not continue to provide a course in an inappropriate setting. The Department has therefore reworded this subsection to require "a setting conducive to learning the material being taught, including any necessary equipment or facilities."

A commentator suggested that no more than one third of all continuing education credits should be able to be obtained from any one manufacturer, and stated that certain manufacturers exclude persons from educational programs they offer. The commentator further stated that no continuing education credits should be accepted from any group that does not open their

seminars to all fitters. In accordance with subsection (a)(5) (proposed as subsection (a)(6)), continuing education programs must be open to all persons with a current, suspended or expired registration certificate in order to be approved by the Department.

Section 25.218 (relating to credit for continuing education).

This section as proposed sets out the requirements for obtaining continuing education credits. Proposed subsection (e) (adopted as subsection (f)), required registrants to supply the Department with the materials the Department requests for evaluation prior to pre-approving a self-study continuing education course. In its comments, IRRC asked what materials are to be provided. The Department has changed the subsection to clarify that the Department may require any of the materials to be used in the course to be provided for review. The Department also clarified, in response to IRRC's comments, that approval may be applied for after the course is taken, although the Department cannot guarantee that it will approve a course which has already been taken.

IRRC further commented that proposed subsections (c) and (g) deal with similar issues and should be combined. The Department respectfully disagrees. Proposed subsection (c) permitted a fitter to receive continuing education credits for serving as an instructor, with the caveat that only half of the required credit hours for a renewal may be fulfilled through instruction; the other half must be acquired by attending continuing education programs. Proposed subsection (g) stated that the same program may not be attended or taught for credit towards a single renewal of a fitter's registration certificate, but that the same program may be taught or attended again for a subsequent renewal. The Department considers these to be two different subjects, which should be placed in separate subsections. Because both of the provisions are related in that they do discuss teaching for continuing education credit, proposed

subsection (g) was moved to become subsection (d) so that it could be read and compared more easily with subsection (c). It is intended that the subsections will be understood more clearly as a result. The remainder of the section has been renumbered accordingly.

The Department has changed proposed subsection (a) to state that no credit shall be "given," rather than "received" if the person offering the program determines that a fitter has not participated in a continuing education program adequately to earn the credit. This change contributes to grammatical correctness and clarity, but does not change the requirement stated in the subsection.

It should be noted that section 311 of the Act requires fitters to have completed, during the two years immediately preceding the expiration date of the certificate, twenty credits of continuing education. The practical effect of the requirement not permitting the same program to have been taught or attended twice for the renewal of a registration, means that during the 2-year "look back" period for that renewal, the same course cannot appear as having been taught or attended twice. The first full two-year period begins April 15, 2003. On April 15, 2005 (the first renewal for which the full 20 credits will be required), a fitter cannot have taken or taught the same course twice for credit. If a fitter took one particular course May 1 of 2003, that course could be taken again for credit toward the April 15, 2006 renewal, because the 2-year look back period for the April 2006 renewal would run from April 15, 2004, to April 15, 2006, so the credits acquired May 1, 2003 would no longer be valid. If the fitter took the same course on May 1 of 2004, however, the course could not be taken again until after April 15, 2006, because the course would be included in the 2-year look back for the April 15, 2006 renewal.

Section 25.219 (relating to responsibilities of persons offering continuing education programs).

This section as proposed imposed certain requirements on providers of continuing education programs. No comments were received regarding this section. This section is adopted as proposed.

Section 25.220 (relating to the right to enter, inspect and obtain records).

This section as proposed established under what circumstances a Department representative may inspect or obtain records from a registrant. No comments were received regarding this section. This section is adopted as proposed.

Section 25.221 (relating to exceptions).

This proposed section would permit the Department to grant exceptions to the regulations for good cause, except for statutory requirements repeated therein. No comments were received regarding this section. This section is adopted as proposed.

D. ***Fiscal Impact***

The final rulemaking adopts 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, almost all costs directly attributable to the 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 by registrants due to having used the Department's 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 each hearing aid with accessories, so it is unlikely that registrants will suffer actual financial loss due to the new requirement.

E. ***Paper Requirements***

The final rulemaking 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.

The final rulemaking attempts to reduce necessary paperwork by enabling registrants to use alternative forms of payment to pay fees, including credit cards, and by including the Department's website, which will contain much of the information that registrants need to fulfill the regulatory requirements.

F. ***Effective date/Sunset date***

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

G. ***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.

H. ***Regulatory Review***

Under section 5(a) of the Regulatory Review Act (71 P.S. §§745.1-745-15), the Department submitted a copy of proposed rulemaking 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 for review and comment. In compliance with section 5(c) of the Act, the Department also provided IRRC and the Committees with copies of all comments received.

In compliance with section 5.1(a) of the Act, the Department submitted a copy of the final-form regulations to IRRC and the Committees on June 30, 2003. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and a copy of a detailed Regulatory Analysis Form. A copy of this material is available to the public upon request.

In preparing these final-form regulations the Department considered all comments received from IRRC, the Committees and the public.

These final-form regulations were deemed approved by the House Health and Human Services Committee and the Senate Public Health and Welfare Committee on _____. IRRC met on _____ and approved the regulations in accordance with section 5.1(e) of the Act. The Office of Attorney General approved the regulations on _____.

I. *Contact Person*

Questions regarding these final-form regulations may be submitted to Theresa A. Ritchie, R.Ph., Director, Hearing Aid Program, Department of Health, P.O. Box 90, Harrisburg, PA 17108, Ph.: (717) 783-1379. Persons with disabilities who require an alternative format of these regulations (for example, large print, audiotape, Braille) should also contact Ms. Ritchie so that necessary arrangements may be made, or, for speech and/or hearing impaired persons, V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Services at 1-800-654-5984.

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

* * * *

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 pursuant to] This subchapter is adopted under the act [262].

§ 25.202. Definitions.

The following words and terms, when used in [these §§25.201–25.215 (relating to hearing aid sales and registration) shall have] this subchapter have the following [meaning] meanings, 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.

* * * * *

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] those instruments or devices, 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.

HEARING AID USER – AN INDIVIDUAL WHO USES A HEARING AID.

* * * * *

PROSPECTIVE HEARING AID USER – AN INDIVIDUAL WHO IS CONSIDERING BUYING A HEARING AID OR WHOSE HEARING IS BEING EVALUATED BY A REGISTRANT.

PURCHASER – AN INDIVIDUAL WHO HAS AGREED TO PURCHASE A HEARING AID FROM A REGISTRANT.

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

* * * * *

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 (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~~ A registrant ~~may~~ SHALL apply to renew ~~that~~ A CURRENT REGISTRATION certificate BY MARCH 16 PRIOR TO THE CERTIFICATE'S EXPIRATION, 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 OR INACTIVE 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. AN APPLICANT MAY PETITION THE DEPARTMENT FOR AN ADDITIONAL RENEWAL. THE PETITION SHALL INCLUDE THE REASONS FOR WHICH THE ADDITIONAL RENEWAL IS REQUESTED. AN APPLICANT SHALL SEND A PETITION FOR ADDITIONAL RENEWAL TO THE DIVISION AT THE ADDRESS GIVEN IN §25.204(A). THE DEPARTMENT WILL THEN DECIDE WHETHER TO ISSUE THE RENEWAL.

(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~~ AFTER MARCH 16 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. AN AFFIRMED STATEMENT MAY BE GIVEN IN ANY FORM SO LONG AS IT IS IN

WRITING, SIGNED, AND CONTAINS A STATEMENT TO THE EFFECT THAT IT IS TRUTHFUL.

(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] this Commonwealth 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~~ DIVISION AT THE ADDRESS GIVEN IN SECTION 25.204(A), BY CHECKING THE DEPARTMENT'S WEBSITE AT WWW.HEALTH.STATE.PA.US, OR BY PHONE OR E-MAIL TO THE DIVISION.

(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] is $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] is $100 for both dealers and fitters.

(c) For a hearing aid [fitters] fitter's registration certificate, the initial registration fee [shall be $100, $75] is $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] is $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] is $200, $150 of which [will be refunded] is for the examination. 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] is $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] is $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 PREVIOUSLY failed ~~a previous~~ THE examination [shall be $25] is $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~~ AFTER MAY 15. The delinquency fee [shall be $25] is $50.

(j) For renewal of a suspended registration certificate, the fee [shall be $50] is $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 this 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 BY WRITING TO THE DEPARTMENT AT THE ADDRESS GIVEN IN SECTION 25.204(A).

(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. THE REGISTRANT MAY RELY ON A REPRESENTATION BY THE PHYSICIAN, AUDIOLOGIST OR FITTER WHO PERFORMED OR SUPERVISED THE TESTS THAT THE INDIVIDUAL WHO PERFORMED THE TESTS WAS AUTHORIZED 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 changes] speech reception threshhold.

(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] 1996 A.N.S.I. STANDARDS OR APPLICABLE 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:

* * * * *

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

* * * * *

(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).

* * * *

(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, AND SHALL EXPLAIN IT IN DETAIL IN ACCORDANCE WITH SUBSECTION C. 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 OR BE ON A FORM APPROVED BY THE DEPARTMENT:

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**

THIS DISCLOSURE AGREEMENT WAS PROVIDED, PARTS A AND B WERE EXPLAINED, AND PART A (FEES FOR SERVICES NOT PART OF THE PRICE OF THE HEARING AID) WAS COMPLETED AT _____(time) ON _____(date), BEFORE ANY SERVICES WERE PROVIDED. PART B (CANCELLATION FEES THAT WILL BE INCURRED IF A HEARING AID IS RETURNED UNDER THE 30-DAY MONEY BACK GUARANTEE BELOW), WAS COMPLETED AND EXPLAINED AFTER SERVICES WERE PROVIDED AND BEFORE ANY PAYMENT WAS MADE. IF PART B IS NOT COMPLETED, IT IS BECAUSE A HEARING AID WAS NOT RECOMMENDED OR NOT DESIRED.

_____ Customer's Signature

_____ Registrant's Signature

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.					

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~~ BEFORE PROVIDING ANY SERVICES INCIDENTAL TO THE POSSIBLE SALE OF A HEARING AID TO THE PROSPECTIVE HEARING AID USER, THE registrant shall ~~fill in the appropriate spaces on~~ EXPLAIN PART A OF the disclosure agreement/money back guarantee TO THE PROSPECTIVE HEARING AID USER OR AUTHORIZED REPRESENTATIVE AND SHALL COMPLETE PART A. THE REGISTRANT SHALL ALSO GIVE A PRELIMINARY EXPLANATION OF PART B, INCLUDING ANY CANCELLATION FEES THAT MAY BE RETAINED IF A PURCHASER DECIDES TO RETURN A HEARING AID. 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, THE REGISTRANT SHALL NOTE THAT IN Part A ~~may be left blank.~~

(2) AFTER PARTS A AND B HAVE BEEN EXPLAINED AND PART A HAS BEEN COMPLETED, THE REGISTRANT SHALL HAVE THE PROSPECTIVE HEARING AID USER OR AUTHORIZED REPRESENTATIVE COMPLETE THE TIME AND DATE LINES PROVIDED UNDER PART A. THE PROSPECTIVE HEARING AID USER OR

AUTHORIZED REPRESENTATIVE AND REGISTRANT SHALL ALSO SIGN UNDER PART A WHERE APPROPRIATE.

~~(2)~~(3) ~~The~~ AFTER COMPLETING THE NECESSARY TESTING, IF IT IS DETERMINED THAT A HEARING AID WILL BE RECOMMENDED, THE registrant shall ~~itemize in~~ EXPLAIN AND COMPLETE Part B, ITEMIZING any cancellation fee associated with the sale and delivery of a hearing aid and its accessories~~,~~ by designating that amount as "not refundable." PART B SHALL BE FULLY EXPLAINED AND COMPLETED BEFORE ANY PAYMENT IS MADE. IF PART B BECOMES INAPPLICABLE DUE TO A DECISION BY THE REGISTRANT, PROSPECTIVE HEARING AID USER OR AUTHORIZED REPRESENTATIVE NOT TO PROCEED FURTHER AFTER TESTING, THE DISCLOSURE AGREEMENT/MONEY BACK GUARANTEE NEED NOT BE FULLY COMPLETED. THE REGISTRANT SHALL PROVIDE A COPY OF THE PARTIALLY COMPLETED DISCLOSURE AGREEMENT/MONEY BACK GUARANTEE TO THE PROSPECTIVE HEARING AID USER OR AUTHORIZED REPRESENTATIVE.

(4) IF THE REGISTRANT AND THE PROSPECTIVE HEARING AID USER OR AUTHORIZED REPRESENTATIVE DECIDE TO PROCEED, THE REGISTRANT SHALL EXPLAIN THE 30-DAY MONEY BACK GUARANTEE. IF THE PROSPECTIVE USER OR AUTHORIZED REPRESENTATIVE DECIDES TO PURCHASE A HEARING AID, THE REGISTRANT SHALL HAVE THE PURCHASER SIGN THE SECOND SIGNATURE LINE ON THE DISCLOSURE AGREEMENT/MONEY BACK

GUARANTEE AND COMPLETE THE LINE FOR DATE AND TIME OF SALE, AND SHALL ALSO SIGN WHERE APPROPRIATE.

~~(3)~~(5) 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 FROM THE DATE OF DELIVERY.

~~(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.~~

(6) AFTER THE DISCLOSURE AGREEMENT/MONEY BACK GUARANTEE IS FULLY COMPLETED EXCEPT FOR THE DATE OF DELIVERY BLOCK AND THE HEARING AID SERIAL NUMBER(S), THE REGISTRANT SHALL PROVIDE A COPY OF IT TO THE HEARING AID USER OR AUTHORIZED REPRESENTATIVE.

(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 AND SERIAL NUMBER(S) is inserted in the block OR SECTION provided for that purpose on the disclosure agreement/money back guarantee. After the block is completed with the initials or signature and date AND THE SERIAL NUMBER(S) IS INSERTED, 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 the 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 [signed] sign 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. FOR PURPOSES OF THIS SUBSECTION, A LEGALLY PROPER WAIVER INCLUDES A MEDICAL WAIVER FORM AS PROVIDED UNDER §403 OF THE ACT AND DESCRIBED IN SUBSECTION A, OR A FEDERAL MEDICAL WAIVER FORM AS APPROVED BY THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(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 under 18 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] under 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 [patient's] registrant shall ensure that the 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. THESE AND ~~Additional~~ ADDITIONAL PROVISIONS RELATING TO THE SALE OF GOODS IN THE PURCHASER'S HOME, INCLUDING SPECIFIC ITEMS WHICH SHALL BE INCLUDED ON THE PURCHASE RECEIPT, ARE HEREBY MADE A PART OF THIS SECTION BY INCORPORATION OF SECTION 7 OF THE UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW (73 P.S. §201-7).

~~(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] under §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.

* * * * *

(v) Word discrimination test results expressed in percentage indicating the test words used, presentation level, masking level (if applicable), and signal to noise ratio (if 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 [recommendation] 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:

* * * * *

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

* * * *

(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.

* * * * *

(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~~ AND HUMAN SERVICES, 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] if applicable, that any guarantee made by the [dealer] registrant which is not backed up by the manufacturer is offered by the [dealer] registrant only.

* * * * *

(15) Making [guarantees, warranties, or any promises] a guarantee, warranty, or promise which, under normal conditions, [are] is impractical of fulfillment [or] ~~of~~ 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 shall] registrant may 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]. A [dealer] registrant may not 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 shall] registrant may 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] those 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 shall] registrant may not do any of the following:

* * * * *

(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 [certain] a 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 shall] registrant may 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 accessories] part, accessory or [components] component. A [hearing aid dealer shall] registrant may 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 shall] registrant may 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; or] true.

(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] applies 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, trade names, brands] trademark, trade name, 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:

* * * * *

(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.

* * * * *

(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 2 years immediately preceding the expiration of the current registration certificate. If the applicant for renewal has had a registration certificate for less than 2 years, the required number of continuing education hours shall

be calculated by prorating the number of credit hours required over a 2-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 2 years immediately preceding the filing of the application for renewal, provided that the application for renewal is filed within 5 years after expiration of the previous registration certificate. If more than 5 years have passed since the registration certificate expired, the registration certificate may not be renewed. Instead, the individual ~~would need to~~ SHALL 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 2-year period for which continuing education requirements shall be required BEGAN 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)~~(1) The program shall contribute directly to the professional competence, skills and education of a hearing aid fitter.

~~(3)~~(2) The program instructors shall possess the necessary practical and academic skills to conduct the program effectively.

~~(4)~~(3) Program materials shall be ~~well written~~CLEAR, INFORMATIVE,

GRAMMATICAL, carefully prepared, readable and distributed to attendees at or before the time the program is offered whenever practical.

~~(5)~~(4) The program shall be presented by a ~~qualified~~ responsible instructor WHO IS EXPERIENCED AND KNOWLEDGABLE IN THE SUBJECT MATTER BEING TAUGHT, in a ~~suitable~~ setting THAT IS CONDUCIVE TO LEARNING THE MATERIAL BEING TAUGHT, INCLUDING ANY NECESSARY EQUIPMENT AND FACILITIES, AND IS devoted to the educational purpose of the program.

~~(6)~~(5) 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 3 years.

(c) If renewal of the Department's approval of a continuing education program is desired, at least 90 days before expiration of the 3-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 1 hour of credit for each 50 minutes of instruction in a continuing education program presented in a classroom setting. Credit ~~will~~ SHALL not be ~~received~~ GIVEN 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) *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 TOWARD 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.

~~(d)~~(E) *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)~~(F) *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, WHICH MAY INCLUDE ANY OF THE MATERIALS USED IN THE COURSE. 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. IF THE MATERIALS ARE UNAVAILABLE TO THE FITTER PRIOR TO TAKING THE COURSE, THE FITTER MAY APPLY TO THE DEPARTMENT FOR CREDIT AFTER COMPLETING IT. HOWEVER, THE DEPARTMENT RESERVES THE RIGHT TO DISAPPROVE THE COURSE FOR CREDIT AFTER IT HAS BEEN

COMPLETED IF IT DOES NOT MEET THE STANDARDS PRESCRIBED IN THIS SUBCHAPTER.

~~(f)~~(G) *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 4 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 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

THE SECRETARY

October 21, 2003

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

Re: Department of Health – Final Regulations No. 10-165
Hearing Aid Sales and Registration (28 Pa. Code Ch. 25, Subchapter B)

Dear Mr. Nyce:

Enclosed are final-form regulations for review by your Committee in accordance with the Regulatory Review Act (71 P.S. §§ 745.1-745.15). These regulations are intended to facilitate implementation of the changes made to the Hearing Aid Sales Registration Law (35 P.S. §§ 6700-101 – 6700-802)(act), which governs the sale of hearing aids and regulates the related activities of hearing aid dealers and fitters. The regulations also are responsive to Federal preemption of certain portions of the act due to regulations promulgated by the Federal Food and Drug Administration.

Section 5.1(a) of the Regulatory Review Act, 71 P.S. §§ 745.5(a), provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Committee a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. Their comments were previously forwarded to the Committee by the Department.

Section 5.1(e) of the Regulatory Review Act, 71 P.S. § 745.5a(e), provides that the Commission may have until its next scheduled meeting which occurs no less than 30 days after receipt of these regulations, to approve or disapprove the final-form regulations.

POST OFFICE BOX 90, HARRISBURG, PA 17108 717-787-6436

The Department will provide the Committee with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Dawn Jackson, Director of the Office of Policy and Legislative Affairs, at (717) 787-4525.

Sincerely,

Calvin B. Johnson, M.D., M.P.H.
Secretary of Health

List of Commentators
Requesting Final-Form Regulations

Dorothy A. Kardos, RN, BC-HIS
Central Pennsylvania Eye and Ear
620 North Third Street
Harrisburg, PA 17101

Dorothy A. Kardos, President
Pennsylvania Hearing Aid Alliance
C/o Robert A. Stewart
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James Rametta
413 4th Avenue, Suite 1A
Tarentum, PA 15084

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

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

TYPE OF REGULATION

Proposed Regulation

X 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

RECEIVED
2003 OCT 22 PM 3:43
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
10/22/03	Matthew McKinney	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
10/22/03	J. Chan	
10/22/03	Kristi Knelson	
10/22	Robert A. Payne	SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
10/22/03	Elena Payne	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

October 2, 2003