

JOHN R. MCGINLEY, JR., ESQ., CHAIRMAN  
ALVIN C. BUSH, VICE CHAIRMAN  
ARTHUR COCCODRILLI  
ROBERT J. HARBISON, III  
JOHN F. MIZNER, ESQ.  
ROBERT E. NYCE, EXECUTIVE DIRECTOR  
MARY S. WYATTE, CHIEF COUNSEL



PHONE: (717) 783-5417  
FAX: (717) 783-2664  
irrc@irrc.state.pa.us  
<http://www.irrc.state.pa.us>

**INDEPENDENT REGULATORY REVIEW COMMISSION**  
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 5, 2002

Honorable Robert Zimmerman, Jr., Secretary  
Department of Health  
802 Health and Welfare Building  
Harrisburg, PA 17108

Re: Regulation #10-165 (IRRC #2278)  
Department of Health  
Hearing Aid Sales and Registration

Dear Secretary Zimmerman:

Enclosed are the Commission's Comments which list objections and suggestions for consideration when you prepare the final version of this regulation. These Comments are not a formal approval or disapproval; however, they specify the regulatory criteria which have not been met.

The Comments will soon be available on our website at [www.irrc.state.pa.us](http://www.irrc.state.pa.us). If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce  
Executive Director

wbg

Enclosure

cc: Honorable George T. Kenney, Jr., Majority Chairman, House Health and Human Services Committee  
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee  
Honorable Harold F. Mowery, Jr., Chairman, Senate Public Health and Welfare Committee  
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee  
Nia Wilson, Legal Counsel, House Health and Human Services Committee  
Stanley Mitchell, Chief Counsel, House Health and Human Services Committee

# Comments of the Independent Regulatory Review Commission

on

## Department of Health Regulation No. 10-165

### Hearing Aid Sales and Registration

September 5, 2002

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which have not been met. The Department of Health (Department) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

#### **1. General. – Clarity.**

The terms “prospective hearing aid user,” “purchaser” and “hearing aid user” are used throughout the regulation. To avoid confusion, these terms should be defined in Section 25.202.

#### **2. Section 25.202. Definitions. – Clarity; Reasonableness.**

The definition of “physician” includes the phrase, “An individual who has a currently registered license to practice medicine or osteopathic medicine in this Commonwealth.” For the purpose of obtaining a medical recommendation under Section 25.212, will Commonwealth residents be permitted to seek medical treatment for hearing problems from out-of-state physicians? If so, the definition should be revised to reflect this. If residents will not be permitted to seek treatment from out-of-state physicians under this regulation, the Department should explain why.

#### **3. Section 25.204. Application for and renewal of registration. – Clarity; Reasonableness.**

##### *Subsection (d)*

The Preamble states that “all registration certificates expire on the same date--April 15 of each year.” Subsection (d) contains the phrase “At least 30 days before the expiration of a registration certificate....” For increased clarity, the Department should replace the language cited above with “By March 16 of each year.”

##### *Subsection (f)*

This subsection contains language barring issuance of more than two renewals of a fitter’s temporary registration certificate. It includes the phrase, “except upon petition of an applicant for good and sufficient cause shown.” How is the petition submitted? The Department should

insert language that clearly sets forth the process that will be followed to petition for good and sufficient cause.

*Subsection (g)*

This subsection contains the phrase “the expiration of the registration certificate.” The Preamble states that this expiration occurs on April 15 of each year. For clarity, the Department should replace this phrase with “April 15,” or provide examples of when this would not apply.

**4. Section 25.205. Additional registration requirements. – Clarity; Reasonableness.**

*Subsection (d)(3)*

In this subsection, the word “affirmed” is used twice. For clarity, the Department should explain how affirmation is accomplished.

*Subsections (d)(3) and (4)*

These subsections state that an apprentice hearing aid fitter or a sponsor of an apprentice may terminate the mentor/apprentice relationship. In this situation, would either party have to show good cause for termination of the relationship? The Department should explain this in the final-form regulation.

**5. Section 25.206. Examinations. – Clarity.**

Subsection (b) states, “The date of an examination may be obtained by writing to the Department.” For clarity, the Department should provide the actual address in this section of the final-form regulation or a citation to the applicable address.

Further, is it possible to request the date of an examination by e-mail or telephone? If so, the Department should put these methods in the regulation.

**6. Section 25.207. Categories of registrations; fee schedule. – Clarity; Reasonableness.**

Subsection (h) is unclear. To improve clarity, the Department should reword Subsection (h) to make it more understandable to the reader. For example, the Department could say, “The fee to retake the fitter’s examination for an applicant who has previously failed the examination is \$50.”

**7. Section 25.208. Display of registration certificates; offices. – Clarity.**

Subsection (d) states, “a registrant shall file notice of a change in the registrant’s place of business.” It is unclear where the registrant is required to send this notice. The Department should explain the process for filing the required notice.

**8. Section 25.209. Facilities, procedures and instrumentation. – Clarity.**

*Subsection (b)(1)*

The Department has deleted the following language from this section, “a physician, surgeon, audiologist, or registered fitter or by an individual supervised by any of the aforementioned persons.” In its place, the phrase “an individual authorized by law” had been added. To facilitate compliance and an understanding of who the Department considers “an individual authorized by law,” the Department should restore the above-mentioned language to the final-form regulation or define the phrase.

*Subsection (3)(c)(i)*

This subsection makes reference to the American National Standards Institute standards for pure tone speech and audiometry as identified by A.N.S.I. S3.6-1969. The Department has indicated that “1969” should be “1996.” This typographical error should be fixed in the final-form regulation.

**9. Section 25.210. Receipt, disclosure agreement and money back guarantee to purchaser -- purchaser protection. – Need; Reasonableness.**

We have an issue and two questions pertaining to Subsection (b).

First, commentators indicate that an initial screening and further testing are necessary to determine if a patient will need a hearing device. However, the regulation requires the entire disclosure form to be completed prior to any services being provided. Given the variety of hearing aids available, it will be difficult to accurately estimate costs for a hearing aid without first completing an examination.

The Department should restructure this form to require the completion of Part A on the disclosure form with the patient’s signature, date and time prior to testing. Once the testing is finished, and it has been determined that a hearing aid is needed, Part B on the disclosure form should be completed.

Second, the “HEARING AID DISCLOSURE AGREEMENT/MONEY BACK GUARANTEE” form in this subsection includes a space for the time that the form was completed. If the entire form must be completed prior to rendering any services, what is the purpose of requiring the time of completion?

Finally, licensees may want to use forms other than those provided by the Department. Has the Department considered also including language, “or on a form approved by the Department,” in this subsection?

**10. Section 25.211. Medical recommendations; waiver forms. – Clarity.**

*Subsection (a)*

This subsection contains the phrase "...is 18 years of age...." However, the Department has indicated that this phrase should be "is *at least* 18 years of age." (Emphasis added.) This change should be made in the final-form regulation.

*Subsection (b)*

The phrase, "a legally proper waiver" is used in this subsection. This phrase is unclear. Does this include both the Federal and state waiver forms? The Department should clarify what constitutes a "legally proper waiver" in this subsection.

**11. Section 25.213. Consumer review. – Clarity; Reasonableness.**

We have two concerns with Subsection (b). First, it states that the notice of rescission is effective "when deposited" in the mail. The phrase "when deposited" is unclear. When would a piece of mail be considered officially "deposited," when it is postmarked?

Second, the phrase, "when service is made in another manner which gives the registrant notice of rescission" is included. What other ways are acceptable to give notice of rescission? If there are other ways in which notice of rescission may be given, they should be included in the regulation.

**12. Section 25.216. Continuing education requirements. – Clarity.**

Subsection (d) states that the continuing education requirements will become effective on April 15, 2003. However, the version printed in the *Pennsylvania Bulletin* uses the date "April 15, 2002." This discrepancy should be corrected in the final-form regulation.

**13. Section 25.217. Approval of continuing education programs. – Clarity.**

*Subsection (a)(1)*

This subsection is not needed and should be deleted. Its contents are adequately covered in Subsection (a)(2).

*Subsection (a)(4)*

This subsection contains the phrase "materials shall be well written." How will the Department enforce this standard?

*Subsection (a)(5)*

This subsection stipulates that a "qualified" instructor shall present a program. Who is a qualified instructor? How does one become qualified? How will it be determined that an instructor is qualified?

This subsection also contains the phrase “suitable setting.” Who makes this determination? What will qualify as a suitable setting?

**14. Section 25.218. Credit for continuing education. – Clarity; Reasonableness.**

*Subsection (e)*

The Department requires the submission of “materials” prior to the pre-approval of the continuing education course. What materials are to be provided to the Department? Also, what is the procedure if the necessary materials are not available until after the course registration? Can a registrant request approval after taking the course? If the Department will consider approving a course after completion, the final-form regulation should include that provision.

*Subsections (c) and (g)*

These two subsections deal with similar issues and should be combined in the final-form regulation.