STATE OF MINNESOTA COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health Governing the Issuance, Suspension, and Revocation of Permits For Hearing Instrument Sellers. STATEMENT OF NEED AND REASONABLENESS

BACKGROUND

Minnesota regulation of hearing instrument sales and sellers began in 1973. Prior to that year the sellers of hearing instruments were not specifically regulated in Minnesota. Minnesota Statutes sections 145.43; 145.44; and 145.45 (Laws 1973, Chapter 383) provided the first means of regulation of the hearing instrument selling industry in the State. Minnesota Statutes section 145.43 defined hearing aids and prohibited the sale of a hearing instrument without a written prescription. It also stated that the seller could not also be the prescriber. Minnesota Statutes section 145.44 listed medical conditions of the ear which, if identified by a seller, prevented that seller from selling an aid before a licensed doctor or audiologist was consulted. The statute also included a waiver provision for those under 60 years of age who could exempt themselves from the provisions of section 145.43 if they signed a waiver form. Minnesota Statutes section 145.45 provided the penalties for violations of the preceding sections. Any person who violated sections 145.43 to 145.45 was guilty of a misdemeanor.

In 1976 the federal government began to regulate this area with the adoption of the "Medical Device Amendments of 1976" (P.L. 94-295, section 2; 90 Stat. 574; 21 U.S.C. 360K). These amendments preempted any state law that differed from the federal law. Minnesota Statutes sections 145.43, 145.44, and 145.45 were, in fact, different from the federal laws and therefore were preempted. The Minnesota Attorney General unsuccessfully applied for exemption from this preemption pursuant to 21 C.F.R. sections 808.01 - 808.35 and by federal rule in 1980 this petition was denied. Although the federal law preempted sections 145.43, 145.44, and 145.45, these statutes were not repealed until 1984. Along with the repeal of these sections, the legislature enacted section 145.43 which provides for a 30-day written money-back guarantee for any hearing instrument sold.

In 1985 Minnesota Statutes chapter 153A was enacted (Minnesota Laws 1985, Chapter 290). Chapter 153A is significant in that it authorized the Commissioner of Commerce to regulate hearing instrument sellers through licensure. This chapter regulated all aspects of licensing including exemptions, prohibited acts, examinations, qualifications, reciprocity, bonding, advertising, and internships. However this chapter was not effective until 12 months after completion of a study required by Minnesota Laws 1985, Chapter 290, section 13. Section 13 required the Commissioner of Health to perform a credentialing study to reconsider the application of speech language pathologists and audiologists. The reconsideration was to be completed in accordance with Minnesota Statutes section 214.13. Section 13 further

required that the Commissioner of Health include a study of hearing instrument selling by physicians, audiologists, and hearing instrument dispensers.

Section 214.13 outlines the Commissioner's policy on recognizing human service occupations and outlines procedures used in deciding on applications for regulation.

In response to the 1985 legislation, the Minnesota Hearing Aid Society submitted a formal application for licensure to the Minnesota Department of Health in 1987. A public forum was held on March 26, 1987. The review process is one that is dictated by Minnesota Statutes section 214.001 (1986) et seq. The statute requires that any regulation must be imposed only for the "safety and well being of the citizens of the state." In addition to this standard there are four factors to be considered in each application for regulation. These are as follows:

- (a) Whether the unregulated practice of an occupation may harm or endanger the health, safety and welfare of citizens of the state and whether the potential for harm is recognizable and not remote;
- (b) Whether the practice of an occupation requires specialized skill or training and whether the public needs and will benefit by assurances of initial and continuing occupational ability;
- (c) Whether the citizens of this state are or may be effectively protected by other means; and

(d) Whether the overall cost effectiveness and economic impact would be positive for citizens of this state.

M.S. sec. 214.001, subd. 2. In addition to considering these factors, the statute requires that the least restrictive regulatory scheme be chosen, if any regulation is appropriate. See M.S. sec. 214.001, subd. 3.

Based on a thorough review of the applications, the recommendations of the Human Services Occupations Advisory Council, and the recommendations of the Minnesota Department of Health staff, and after evaluating the criteria for regulation set out in Minnesota Statutes section 214.001, subd. 2, the Commissioner concluded that licensure was not necessary and that regulation through a consumer protection system would be appropriate. In February of 1988, she requested that the legislature amend chapter 153A to repeal the provisions for licensure and enact a consumer protection package in its stead. The Commissioner found that there was insufficient evidence to show actual harm to the public from improperly trained hearing instrument sellers. The evidence did not meet the statutory requirements of Minnesota Statutes section 214.001 because the concerns related to the potential for harm in the screening, testing, and evaluation of hearing loss. Although Department of Health staff supplied evidence of some actual harm to the public in sales of hearing instruments, this harm was not due to improperly trained hearing instrument sellers, but rather to improper business practices of some sellers. The Commissioner concluded that a strengthening of the existing mechanisms would be effective in preventing the existing harm to the public.

Minnesota Statutes chapter 153A was amended in 1988 to require every person who sold a hearing instrument to obtain a permit, and mandate the establishment of a consumer information center within the Department of Health.

STATUTORY AUTHORITY

The Commissioner's statutory authority to adopt rules relating to hearing instrument selling is set forth in Minnesota Statutes section 153A.14, subd. 5, which requires the Commissioner to adopt rules under Minnesota Statutes chapter 14 to implement Minnesota Statutes sections 153A.13 to 153A.18. Under this statute, the Commissioner is authorized to propose and adopt these permit rules.

ADDITIONAL REQUIREMENTS

1. Approval of the Commissioner of Finance.

Pursuant to Minnesota Statutes section 16A.128, subd. 1a, if a fee is required to be fixed by rule, the Commissioner of Finance must approve the fee, and the Commissioner's approval must be in the statement of need and reasonableness. The Commissioner's approval of the fees established in the proposed permit rules is contained in the attached addendum, which is incorporated into this Statement of Need and Reasonableness.

2. Small Business Considerations.

Minnesota Statutes section 14.115 requires administrative agencies, when

proposing rules, to consider various methods for reducing the impact of the proposed rules on small businesses and to provide the opportunity for small businesses to participate in the rulemaking process. The policy behind this statute is clearly to protect small businesses. However, section 14.115, subd. 7, mandates that "agency rules that do not affect small businesses directly" are not to be bound by this section. (emphasis added). The proposed hearing instrument seller permit rules do not directly affect the small businesses within the meaning of the statute. The small business protection policy is specifically addressed within the five methods for reducing the impact of the proposed rules on small businesses. Minnesota Statutes, section 14.115. The agency is required to consider the impact on small businesses when the proposed rules establish compliance or reporting requirements or design or operational standards for businesses. Here, the proposed hearing instrument seller permit rules do not set up compliance or reporting requirements or design or operational standards for businesses. proposed rules regulate individuals, not businesses. Minnesota Statutes, chapter 153A requires the Commissioner of Health to regulate sellers of hearing instruments, not manufacturers and not businesses that sell hearing instruments. Subdivision 5 of Minnesota Statutes, section 153A.13 defines a seller of hearing instruments as "a <u>natural</u> <u>person</u> who engages in hearing instrument selling...(emphasis added)."

Individuals or natural persons are required to obtain permits to sell hearing instruments, not businesses. Minnesota Statutes, chapter 153A regulates the practices of hearing instrument sellers independent of whether

or not the sellers are operating as part of a small business. Section 14.115 is designed to require agencies to consider minimizing the impact of proposed rules that directly require small businesses to meet compliance or reporting requirements within specified schedules or deadlines or to meet design or operational standards. It is not designed to require agencies to consider indirect effects of their rules. Minnesota Statutes, section 14.115 and Report of Administrative Law Judge, In the Matter of the Proposed Amendments to the Rules Relating to the Sale of Credit Life Insurance, at p. 12.

It is the Commissioner's position that, although a large majority of hearing instrument selling businesses in Minnesota are small businesses within the definition of Minnesota Statutes section 14.115, subd. 1, the proposed permit rules will not affect small businesses directly, and therefore are exempt from the small business statute pursuant to Minnesota Statutes, section 14.115, subd. 7(b). The Commissioner's position is based on the fact that the regulation scheme set forth in Minnesota Statutes chapter 153A requires the permitting of people, not businesses, and regulates the practices of hearing instrument sellers independent of whether or not the sellers are operating as part of a small business.

However, should these proposed rules in some way be construed as directly affecting small businesses, the Commissioner has reviewed the five suggested methods listed in section 14.115, subdivision 2, for reducing the impact of the proposed rules on small businesses. The five suggested methods enumerated in subdivision 2 are as follows:

(a) the establishment of less stringent compliance or reporting

requirements for small businesses;

- (b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- (c) the consolidation or simplification of compliance or reporting requirements for small businesses;
- (d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule; and
- (e) the exemption of small businesses from any or all requirements of the rule.

As part of her review the Commissioner considered the feasibility of implementing each of the five suggested methods, and considered whether implementing any of the five methods would be consistent with the statutory objectives that are the basis for this rulemaking.

a. It would not be feasible to incorporate any of the five suggested methods into these proposed rules.

Methods (a)-(c) of subdivision 2 relate to lessening compliance or reporting requirements for small businesses either by (a) establishing less stringent requirements, (b) establishing less stringent schedules or deadlines for compliance with the requirements, or (c) consolidating or simplifying the requirements. Since the Commissioner is not proposing any compliance or reporting requirements for either small or large businesses, it follows that there are no such requirements for the Commissioner to lessen with respect to small businesses. If, however, these proposed rules are viewed as compliance

or reporting requirements for businesses, then the Commissioner finds that it would be unworkable to lessen the requirements for those hearing instrument sellers who are in a business setting with fewer than 50 employees, since that would include the vast majority of hearing instrument sellers. Method (d) suggests replacing design or operational standards with performance standards for small businesses. The Commissioner is not proposing design or operational standards for businesses, and therefore there is no reason to implement performance standards for small businesses as a replacement for design or operational standards that do not exist. Finally, method (e) suggests exempting small businesses from any or all requirements of the rules. Under the Commissioner's view that these proposed rules do not in any way regulate the business operation of hearing instrument sellers, there are no rule requirements from which to exempt small businesses. However, if these proposed rules are viewed as regulating businesses insofar as they regulate hearing instrument sellers, then it would hardly make sense for the Commissioner to exempt from these rules those hearing instrument sellers who practice in a business setting with fewer than 50 employees, since they constitute the vast majority of hearing instrument sellers. For all of these reasons, it is not feasible for the Commissioner to incorporate into these proposed rules any of the five methods specified in subdivision 2 of the small business statute.

b. Reducing the impact of these rules on small businesses would undermine the objectives of Minnesota Statutes, chapter 153A. Pursuant to the Minnesota hearing instrument selling law, Minnesota Statutes, chapter 153A,

the Commissioner is charged with the duty of regulating sellers of hearing instruments and enforcing the regulatory scheme set forth in chapter 153A. Pursuant to Minnesota Statutes, sec. 153A.14, subd. 5, the Commissioner is specifically mandated to "adopt rules under chapter 14 to implement sections 153A.13 to 153A.18." Given these statutory mandates, it is the Commissioner's duty to establish permitting procedures which apply to and govern all applicants and permit holders, regardless of the size of their business setting. As stated above, it is the Commissioner's position that the proposed rules will not directly affect small businesses, and certainly do not have the potential for imposing a greater impact on hearing instrument sellers in a setting with fewer than 50 employees than on hearing instrument sellers in a large business setting. It has also been explained above that the Commissioner considers it infeasible to implement any of the five suggested methods enumerated in subdivision 2 of the small business statute. Nonetheless, to the extent that the proposed rules may affect the business operation of a hearing instrument seller and to the extent it may be feasible to implement any of the suggested methods for lessening the impact on small businesses, the Commissioner believes it would be unwise and contrary to the purposes to be served by these rules for her to exempt one group of hearing instrument sellers - indeed, the majority of hearing instrument sellers - from the requirements of these proposed rules.

The statutory intent of Chapter 153A is to protect the hearing instrument consumer. If small businesses were allowed different hearing instrument permit standards, the consumer who chooses to buy from that small business may

be less protected than one who buys a hearing instrument from a large business. While it is true that applying different standards to small businesses would be less burdensome for them, such an action would badly frustrate the intent of chapter 153A to protect the hearing instrument consumer. In fact, applying lesser standards to small businesses may actually weaken the small business market for hearing instruments because consumers may choose larger companies that offer more protections through chapter 153A. Therefore, if the permit requirements were less for small businesses, they may not be as competitive in a market with larger businesses that are required to comply strictly with chapter 153A.

The Commissioner believes it would be contrary to her statutory mandate for her to adopt one set of regulations that would apply to those hearing instrument sellers who work in a large business setting and adopt another, less stringent, set of regulations to be applied to those hearing instrument sellers who work in a small business setting. The proposed hearing instrument seller permit rules largely represent the statutory requirements found in chapter 153A. The Commissioner has no authority to reduce the requirements imposed by statute. It is the Commissioner's view that these proposed rules must apply equally to all hearing instrument sellers if the public whom they serve is to be adequately protected.

Sellers of hearing instruments, regardless of whether they are considered as individuals or small businesses, will have an opportunity to participate in the rulemaking process. A notice of the proposed rulemaking will be mailed to the following organizations which will likely represent any entity affected by

the rules which might claim to be a small business:

- 1. Minnesota Hearing Aid Society;
- Minnesota Speech, Language, and Hearing Association;
- 3. American Association for Retired Persons; and
- 4. Minnesota Foundation for Better Hearing and Speech.

A notice of the proposed rulemaking will also be mailed to over 400 individuals who sell hearing instruments and to all those who have requested to be on the Department of Health's mailing list.

3. Other Statutory Requirements.

The Commissioner has determined that Minnesota Statutes sections 14.11; 17.80 to 17.84; 115.43; 116.07, subd. 6; and 144A.29, subd. 4 do not apply to the proposed permit rules. Therefore, this Statement of Need and Reasonableness does not address the topics referenced in those statutes.

STATEMENT OF NEED AND REASONABLENESS

A. General Statement of Need.

In addition to the statutory authority requiring the Commissioner to implement the permit system, there are two public policy reasons for a permit system in this state. First, a permit system will enable the state to develop a central registry of all those who engage in hearing instrument selling in the state. The central registry will consist of a list of all those who applied for and received a permit from the Commissioner. This registry list will include personal data about the seller such as full name; address

(business and home); phone number (business and home); name of seller's supervisor, if applicable; social security number; and information about seller's education, training, and experience in human hearing and fitting hearing instruments. This information will be useful in keeping a record of all sellers of hearing instruments in Minnesota. Without this permit system, the state has no complete list of those who are selling hearing instruments within its boundaries.

The second public policy reason for this permit system relates to the consumer protection responsibilities of the state. The central registry list will enable the state to hold the permit holder accountable to consumers more easily and quickly than was before possible. The proposed permit rules provide the state with a mechanism for disciplining hearing instrument sellers by denying issuance of a permit, denying renewal of a permit, suspending a permit, and revoking a permit. These disciplinary tools will be used in response to violations of state and federal laws committed by hearing instrument sellers. Prior to this proposed permit system, the state has been limited in its ability to effectively discipline sellers of hearing instruments. The state was limited to mediating consumer complaints against hearing instrument sellers and when mediation was unsuccessful, filing suit against the seller for injunctive relief. While lawsuits are effective ways to enjoin conduct that violates state and federal laws, these lawsuits are costly and time consuming. The permit system will provide a more expedient way to resolve cases involving hearing instrument sellers violating state and federal law. It also will provide a less costly alternative to a lawsuit for

injunctive relief. Therefore, this central registry provides not only an informational list of all of the permitted hearing instrument sellers in Minnesota, but also a new mechanism for the state to effectively monitor its permittees, and enforce state and federal laws.

1. The unregulated practice of hearing instrument sellers may harm or endanger the health, safety and welfare of citizens of the state and the potential for harm is recognizable and not remote.

In relation to the number of hearing aids sold in Minnesota on a yearly basis, the number of hearing instrument complaints is small. However, some harm has actually occurred in the industry and the potential for harm is real. Among the types of harm that have been identified are misleading information in mass marketing materials, poor servicing of instruments, misrepresentation on levels of competency, high pressure sales tactics, misfitting instruments, and sales by sellers who may have no regular place of business in the state. Also the consumers are typically elderly and many suffer from a number of other mental and physical handicaps in addition to their hearing impairment.

Until August 1, 1988, the Attorney General's Office in Minnesota handled complaints by consumers of hearing instruments. In the years 1985 and 1986 the number of complaints about hearing instrument sales was 77. So while the potential for harm is recognizable and not remote, the relative number of complaints in the state is low. Based on that conclusion, the Commissioner did not recommend licensure for hearing instrument dispensers, but recommended the strengthening of the consumer protection and consumer information systems.

The consumer protection system is based on consumer complaints and consumer-seller mediation by Minnesota Department of Health staff. The consumer information system will work to facilitate sharing of information among seller organizations, hearing impaired organizations, and the consuming public. The permit system will enable the state to more effectively monitor its hearing instrument sellers and it will be used in conjunction with both the consumer protection and information systems.

2. The practice of hearing instrument selling does not require specialized skill or training and the public does not need assurances of initial and continuing occupational ability.

The Commissioner concluded that it was not clear what type of training would be helpful in the practice of hearing instrument selling. The number of complaints stemming from ineffectively trained hearing instrument sellers is unknown. The harm shown was not derived from poorly trained sellers, but from business practices. Therefore, specialized training is not necessary to protect consumers. The consumer protection mediation process and the consumer information center, along with the permit system, will adequately protect the citizens of Minnesota.

3. The citizens of Minnesota are not effectively protected by other means.

Even though there are existing federal laws and state consumer laws in place to protect consumers, the Commissioner determined that they did not

adequately protect consumers. While these existing legislative schemes serve a useful function, the introduction of the permit system will strengthen the existing system and allow for a more uniform enforcement of the laws. Under Federal law, the Food and Drug Administration prohibits the sale of an aid to a minor without a physician prescription, and persons 18 years and older may waive the requirement of a medical evaluation. In addition, the seller must note and look for eight medical conditions of the buyer; if the buyer shows any of these eight conditions, the seller is required to refer the buyer to a physician and there can be no waiver. In addition, federal law requires that each buyer receive from the seller a User Information Booklet. Federal law also requires the seller to retain on file a record of the physician prescription, or a signed medical waiver for a period of three years. The same Food and Drug Act requires that if an aid is rebuilt or used, some labelling be directly on the aid to inform the consumer of that fact.

Minnesota state law also protects hearing instrument consumers in conjunction with the proposed permit rules. Minnesota Statutes, sections 325F.68, 325F.69, and 325F.70 protect the consumer in connection with the sale of any merchandise. These statutes prohibit such acts as fraud, false pretense, false promise, misrepresentation, making misleading statements, and deceptive practices. Enforcement of these sections is within the exclusive domain of the Attorney General's Office and the only sanction allowed is the injunction.

4. The overall cost effectiveness and economic impact would be positive for citizens of Minnesota.

Pursuant to Minnesota Statutes, section 153A.17, the application fees for the permit will be borne by the hearing instrument sellers. The fact that the hearing instrument seller population will bear the cost of the application fees and any fines that may be ordered by the Commissioner, means that the very group to be regulated will be paying the cost of its administration. The hearing instrument consumers of Minnesota may ultimately have to bear the costs due to increased product and service costs reflecting the costs of hearing instrument sellers' permit fees, but these consumers are also the primary beneficiaries of the regulatory activity. The proposed permit fees do not exceed the administrative costs.

B. <u>Specific Statement of Need and Reasonableness for Proposed Permit Rules.</u>

PROPOSED PERMIT RULES FOR HEARING INSTRUMENT SELLERS

4692.0010 PURPOSE.

CHAPTER 4692 ESTABLISHES PROCEDURES FOR APPLYING AND OBTAINING A PERMIT TO SELL HEARING INSTRUMENTS. THE PURPOSE OF THIS CHAPTER IS TO ESTABLISH A CENTRAL REGISTRY OF PERSONS WHO SELL HEARING INSTRUMENTS AND TO ESTABLISH PROCEDURES FOR ISSUING, SUSPENDING, AND REVOKING PERMITS.

This introductory section outlines the public policy reasons for the permit rules. It is necessary to outline these policy reasons in this

introductory section to facilitate a general understanding of the purpose of these proposed permit rules. It is reasonable to outline the reasons for the permit rules as the central registry system and as a way to monitor hearing instrument sellers because these two goals will be achieved when the proposed permit rules are adopted. The central registry serves as a mechanism for the state to have one complete informational listing for all hearing instrument sellers in Minnesota. No such centralized listing currently exists. The rules also serve to establish procedures for issuing, refusing to issue, denying a renewal, suspending, and revoking permits. These procedures will provide the state with a mechanism for disciplining the permit holders where no such mechanism previously existed.

4692.0015 DEFINITIONS.

Subpart 1. SCOPE. FOR PURPOSES OF THIS CHAPTER, THE FOLLOWING TERMS HAVE THE MEANINGS GIVEN TO THEM.

The definitions in this section are for those words which are key to understanding the business of hearing instrument selling. "Seller", "selling", and "hearing instrument" are defined. These terms may seem easy to understand, but it is necessary to specifically identify who is a "seller" and who is engaging in "selling". These definitions are based on statutory language. It is both necessary and reasonable to uniformly apply these definitions.

Subpart 2. APPLICANT. "APPLICANT" MEANS A PERSON WHO APPLIES WITH THE COMMISSIONER FOR A PERMIT TO SELL HEARING INSTRUMENTS.

Throughout these rules "applicant" will mean an applicant for the hearing instrument selling permit. It is necessary to define an applicant as one who is applying for the hearing instrument selling permit in order to reduce confusion and ambiguity. The definition is reasonable because it clarifies that an applicant is one who has submitted an application to the Commissioner of Health, but who has not yet received a permit.

Subpart 3. COMMISSIONER. "COMMISSIONER" MEANS THE COMMISSIONER OF HEALTH.

It is necessary to define the term "Commissioner" as the Commissioner of the Department of Health in order to reduce confusion and ambiguity. It is reasonable to define Commissioner as the Commissioner of Health because it is consistent with the definition provided in the authorizing statute, Minnesota Statutes section 153A.13, subd. 2 (1988).

Subpart 4. HEARING INSTRUMENT. "HEARING INSTRUMENT" IS AS DEFINED IN MINNESOTA STATUTES, SECTION 153A.13, SUBDIVISION 3.

It is reasonable and necessary to define "hearing instrument" as it is defined in the authorizing statute for these permit rules. By directing the reader to the statute, the reader is assured that the rules use the same definition for this term as is used in the authorizing statute.

Subpart 5. HEARING INSTRUMENT SELLING. "HEARING INSTRUMENT SELLING" IS AS DEFINED IN MINNESOTA STATUTES, SECTION 153A.13, SUBDIVISION 4.

It is reasonable and necessary to define "hearing instrument selling" as it is defined in the authorizing statute. It makes it clear to the reader that this term has the same meaning in the permit rules as in the authorizing

statute, and thereby reduces confusion.

Subpart 6. PERMIT HOLDER. "PERMIT HOLDER" MEANS A PERSON WHO HAS BEEN ISSUED A VALID PERMIT BY THE COMMISSIONER.

It is necessary to include this definition in the rules because the phrase "permit holder" is referred to in the rules, and this person has certain rights and responsibilities. It is reasonable to define "permit holder" as a person who has been issued a permit because it is consistent with the common usage of the term.

Subpart 7. PERMIT NUMBER. "PERMIT NUMBER" MEANS THE NUMBER ASSIGNED TO EACH PERMIT BY THE COMMISSIONER.

It is necessary to include this term in the definitions section because the permit number will be used to identify the permit holder on documents used by the permit holder. This number will be assigned to the permit by the Commissioner, and only that permit holder will have that number. The definition is reasonable because it clarifies where the permit number originates.

Subpart 8. SELLER OF HEARING INSTRUMENTS. "SELLER OF HEARING INSTRUMENTS" IS AS DEFINED IN MINNESOTA STATUTES, SECTION 153A.13, SUBDIVISION 5.

It is necessary to define "seller of hearing instruments" as it is defined in the authorizing statute, Minnesota Statutes section 153A.13, subd.

5. It makes it clear to the reader that this term is defined by the authorizing statute, and thereby reduces confusion.

4692.0020 REQUIREMENT TO APPLY FOR A PERMIT AND TIME PERIODS.

Subpart 1. WHO MUST APPLY. A PERSON WHO SELLS HEARING INSTRUMENTS IN MINNESOTA MUST APPLY FOR A PERMIT FROM THE COMMISSIONER ON FORMS PROVIDED BY THE COMMISSIONER.

This section specifies that anyone who sells hearing instruments, as defined in the previous sections, must apply for a permit from the Commissioner. This section is necessary because the statute requires that the permit system be mandatory. Anyone who sells hearing instruments must have a valid permit issued by the Commissioner of the State Department of Health. Minnesota Statutes, section 153A.14, subd. 4 (1988). This subpart is reasonable because it clarifies who is required to apply for a permit to sell hearing instruments.

The application forms are provided by the Commissioner. Only those forms provided by the Commissioner may be used. This section is necessary because Minnesota Statutes section 153A.14, subd. 1, requires the Commissioner to provide the forms. It is reasonable to require the applicants to use forms provided by the Commissioner because it is important to maintain uniformity. The Commissioner wants to receive the same information from each applicant, and one of the best ways to assure this is to require that all applicants use the same form.

Subpart 2. TIME PERIOD FOR INITIAL APPLICATION. A SELLER WHO IS SELLING HEARING INSTRUMENTS IN MINNESOTA ON THE EFFECTIVE DATE OF THIS CHAPTER MUST APPLY FOR A PERMIT FROM THE COMMISSIONER WITHIN 120 DAYS AFTER THE

EFFECTIVE DATE OF THIS CHAPTER.

This subpart makes allowances for the first-time applicant during the initial start-up period of this permit system. All first-time applicants have four months from the effective date of the rules to submit the application. It is necessary to inform applicants that there is a deadline for compliance. This period of time is reasonable in that it gives the first-time applicant ample time to complete the application form and send it to the Commissioner for review. The Commissioner anticipates that the initial start-up time for this permit system will require an adjustment by the members of the industry trying to comply with a new set of rules. It is important to recognize this adjustment period and accomodate those who attempt to comply with the rules. This four month period will also provide a sufficient amount of time for all of the applications to be thoroughly reviewed by the Commissioner.

Subpart 3. TIME PERIOD AFTER INITIAL APPLICATION PERIOD. ONE HUNDRED
TWENTY DAYS AFTER THE EFFECTIVE DATE OF THIS CHAPTER, A PERSON WHO SELLS
HEARING INSTRUMENTS MUST FIRST HAVE A VALID PERMIT ISSUED BY THE COMMISSIONER
AND THE 120-DAY PERIOD IN SUBPART 2 DOES NOT APPLY.

This subpart clarifies that the 120-day period is just for use in the initial start-up period of the permit system. After this 120-day period is over, anyone wishing to sell hearing instruments in the State of Minnesota must first obtain a permit from the Commissioner. This requirement is necessary because it will prevent sellers from selling in the state without a permit and then leaving the state before the 120-day period expires. It is reasonable because if sellers were allowed to come into Minnesota for a

brief time and sell hearing instruments without a permit for less than four months, the occurrence of fraud and illegal sales would most likely rise, and the state would not have legal standing to discipline those sellers once they left the state again. This section will protect consumers from the sellers who travel from state to state in their practice without establishing a permanent location in Minnesota.

Also, this section requires that anyone who wants to sell hearing instruments can do so as long as he or she obtains a valid permit issued by the Commissioner. This is a necessary and reasonable requirement because it is consistent with the authorizing statute's objectives and requirement that anyone who sells hearing instruments must have a permit. Minnesota Statutes section 153A.14, subd. 4 (1988).

4692.0025 PROCEDURE FOR APPLYING FOR A PERMIT.

Subpart 1. APPLICATION FORMS. THE APPLICANT MUST:

A. APPLY TO THE COMMISSIONER FOR A PERMIT TO SELL HEARING INSTRUMENTS ON THE FORMS PROVIDED BY THE COMMISSIONER;

It is necessary to set out the requirements for the application forms. These requirements are the minimum requirements necessary for a permit application to be considered by the Commissioner. The first requirement is that the applicant make application to the Commissioner on forms provided by the Commissioner. Only the forms provided by the Commissioner can be used by the applicant. This is reasonable because use of one type of application form establishes uniformity in the information requested from all of the applicants.

B. INCLUDE WITH THE APPLICATION A STATEMENT THAT THE STATEMENTS IN THE APPLICATION ARE TRUE AND CORRECT TO THE BEST OF THE APPLICANT'S KNOWLEDGE AND BELIEF:

This provision requires the applicant to include a statement that all of the information on the application is true and correct to the best of the applicant's knowledge. This requirement is necessary because it forms the basis for any disciplinary procedures or actions that the Commissioner may take. This requirement is reasonable because without a sworn statement by the applicant, the Commissioner would not have reliable information on which to base an enforcement action affecting the rights of the applicant.

C. INCLUDE WITH THE APPLICATION A NONREFUNDABLE APPLICATION FEE SPECIFIED IN PART 4692.0040;

The application fee requirement is necessary because the authorizing statute specified that the consumer protection and information programs would be funded by the fees and fines collected from the hearing instrument sellers. Minnesota Statutes section 153A.17 (1988). The application fee is necessary to support the cost of administering these programs. It is necessary to inform applicants that the fee is nonrefundable and is required to be submitted with the application for the permit, in order to put applicants on notice. The nonrefundable fee requirement is reasonable because the administrative costs begin when the Commissioner sends the application form to the applicants, and continues when the Commissioner receives the applications for review. If the applicant was denied a permit and was allowed a refund of

the money, then the Commissioner would not be reimbursed for the costs of mailing the applications and reviewing them. Failure to cover these costs would not be in compliance with Minnesota Statutes section 153A.17.

D. INCLUDE WITH THE APPLICATION THE INFORMATION REQUIRED BY MINNESOTA STATUTES, SECTION 153A.14, AND DESCRIBE THE APPLICANT'S EXPERIENCE, INCLUDING THE NUMBER OF YEARS AND MONTHS THAT THE APPLICANT HAS SOLD HEARING INSTRUMENTS AS DEFINED IN MINNESOTA STATUTES, SECTION 153.A.13;

This provision is consistent with the statutory provision requiring that the application contain all of the information that was specifically set forth in the authorizing statute, Minnesota Statutes section 153A.14, subd. 1 (1988). It is necessary and reasonable to specify in the rules that these requirements must be met as a part of the application process. This rule specifies that the description of experience include the number of months and years that the applicant has been selling hearing instruments. This is necessary so that the Commissioner has some knowledge of the particular skills and experience of applicants. It is reasonable because it is in the best interests of the Department of Health to have all the relevant information available on an applicant. Such information will help the Commissioner mediate complaints and when necessary, take enforcement action appropriate to the applicant.

E. INCLUDE WITH THE APPLICATION THE APPLICANT'S BUSINESS ADDRESS AND PHONE NUMBER, OR HOME ADDRESS AND PHONE NUMBER IF THE APPLICANT CONDUCTS HIS OR HER BUSINESS OUT OF THE HOME; AND IF APPLICABLE, THE NAME OF THE APPLICANT'S SUPERVISOR, MANAGER, AND BUSINESS OWNER;

This provision requires information regarding the applicant's business location and work setting. This additional information is necessary because if the applicant has no regular office address, as in the case where there is one central office and agents sell hearing instruments on their own outside of that central location, then the Commissioner needs another more reliable way to contact the seller. The Commissioner needs to have a reliable mailing address for the seller to be able to inform him or her about anything that may affect his or her permit to sell hearing instruments and to contact the seller if it is necessary to mediate a consumer complaint. It is reasonable to request this information from the applicant because it would not be burdensome on the applicant to do so but it would be difficult for the Commissioner to obtain it from another source.

F. INCLUDE WITH THE APPLICATION A WRITTEN AND SIGNED AUTHORIZATION
WHICH AUTHORIZES THE COMMISSIONER TO MAKE INQUIRIES TO APPROPRIATE REGULATORY
AGENCIES IN THIS OR ANY OTHER STATE WHERE THE APPLICANT HAS SOLD HEARING
INSTRUMENTS; AND

This provision requires that the applicant provide the Commissioner with legal authorization to investigate the applicant or permit holder. It is necessary because the Commissioner has an interest in verifying a positive record of an applicant who has practiced in other states. If the Commissioner needs to make such an investigation, the authorization will provide the Commissioner the right to do so legally. The authorization will also provide the applicant with notice that the Commissioner may investigate his or her hearing instrument selling background. This requirement is reasonable because the purpose of the legislation is to strengthen the consumer

protection through monitoring the sales activity of hearing instrument sellers. Without authority to thoroughly investigate applicants and permit holders when allegations of violation of state and/or federal law arise, the Commissioner's ability to appropriately sanction hearing instrument sellers for illegal conduct would be diminished significantly.

G. COMPLETE THE APPLICATION IN SUFFICIENT DETAIL FOR THE COMMISSIONER
TO DETERMINE IF THE APPLICANT MEETS THE REQUIREMENTS FOR FILING. THE
COMMISSIONER MAY ASK THE APPLICANT TO PROVIDE ADDITIONAL INFORMATION NECESSARY
TO CLARIFY INCOMPLETE OR AMBIGUOUS INFORMATION SUBMITTED IN THE APPLICATION.

This requirement is necessary because an incomplete application form would not comply with the minimum requirements necessary for a complete application pursuant to Minnesota Statutes, section 153A.14 (1988).

Additionally, it is reasonable to require completeness in the permit application to ensure uniformity in the information received from applicants. If completeness were not a requirement, applicants would be providing the Commissioner with insufficient or different types of information. If the Commissioner received different types of information from its regulated sellers, it would be more difficult to apply enforcement actions equally to sellers. The Commissioner, the hearing instrument sellers, and the hearing instrument consumers have an interest in maintaining equal enforcement of state and federal laws by the Commissioner.

Subpart 2. REQUIREMENT TO MAINTAIN CURRENT INFORMATION. A SELLER MUST NOTIFY THE COMMISSIONER WITHIN 30 DAYS OF OCCURRENCE OF ANY ONE OR MORE OF THE FOLLOWING:

A. A CHANGE OF NAME, ADDRESS, AND HOME OR BUSINESS PHONE NUMBER;

This provision requires the applicant to update the Commissioner when information on the application form changes. It is necessary for a seller to inform the Commissioner of a name, address, or phone change so that the Commissioner is able to contact the seller to timely resolve a consumer complaint or otherwise notify sellers. It is reasonable to make the sellers responsible for letting the Commissioner know of these changes within a reasonable time after their occurrence because such information is soley within the knowledge of the sellers. The 30 day time period allows the applicant a reasonable time to submit the new information with the Commissioner.

B. THE OCCURRENCE OF CONDUCT PROHIBITED BY MINNESOTA STATUTES, SECTION 153A.15;

This provision requires the permit holder to inform the Commissioner of the occurrence of any conduct that is prohibited by the state law. It is an affirmative requirement on the permit holder to inform the Commissioner of these acts. The rationale behind this requirement is that a seller of hearing instruments engages in a personal and intimate relationship with potential buyers. The very nature of testing hearing, fitting hearing instruments, making ear molds, selecting and recommending hearing instruments and ultimately the sale of hearing instruments is personal, and the buyer relies upon and trusts the skill and experience of the seller. Not only is the nature of hearing instrument selling personal, but the majority of the hearing instrument clients are elderly, and often come into the dealership

with a variety of other physical and mental problems. In addition, many of these sales are completed in the consumer's home which adds to the potential for vulnerability. For these reasons, hearing instrument sales are unique and require special treatment. If the seller has acted in a way that was prohibited by state law, then the seller is obligated to inform the Commissioner of this fact pursuant to these proposed rules. It is necessary to inform sellers that they are required to submit this information to the Commissioner, because they may be the only source of the information. It is a reasonable requirement because the extent to which sellers admit violations is evidence to the Commissioner that the seller is cognizant of buyer reliance and trust, and this, in turn may enable the Commissioner to mitigate Commissioner sanctions in the event of a buyer complaint against the seller.

C. A SETTLEMENT OR AWARD BASED ON THE NEGLIGENCE OR INTENTIONAL ACTS
COMMITTED IN THE SELLING OF HEARING INSTRUMENTS BY THE SELLER; AND

This provision is similar to the above section in its rationale. The nature of selling hearing instruments may often involve a vulnerable or potentially vulnerable buyer. The physical aspect of the relationship, the potentially vulnerable hearing instrument consumer, together with the seller's discretion in advising the consumer create a need for protection against unscrupulous persons with a record of improper conduct. Such sellers may be denied a permit to sell hearing instruments. It is necessary to inform sellers that they are required to submit this information to the Commissioner, in order to put them on notice of the requirement. It is a reasonable

requirement because the Commissioner is charged with the responsibility of protecting the consumer, and the Commissioner must have available to her any information that is related to the seller's history in the selling of hearing instruments. If the Commissioner is deprived of that information, the Commissioner's ability to investigate a case thoroughly and mediate complaints is diminished.

D. A PHYSICAL OR MENTAL DISABILITY THAT MAY AFFECT A SELLER'S ABILITY TO SELL HEARING INSTRUMENTS.

This provision is necessary to provide the Commissioner with additional information helpful in protecting the consumer. For example, if the seller is taking medication for a psychiatric problem, it is necessary so that in the event of a complaint against the seller, the Commissioner can mediate the complaint effectively, and appropriately regulate the seller in order to protect consumers. It is reasonable to require sellers to provide this information because they may be the only source of the information.

4692.0030 COMMISSIONER ACTION ON PERMITS.

Subpart 1. ISSUANCE OF PERMIT. THE COMMISSIONER WILL REVIEW THE PERMIT APPLICATION TO DETERMINE WHETHER OR NOT THE APPLICANT HAS MET THE APPLICATION REQUIREMENTS OF PART 4692.0025. IF THE PERMIT APPLICANT HAS MET THE REQUIREMENTS OF PART 4692.0025, THEN THE COMMISSIONER WILL ISSUE A PERMIT TO THE APPLICANT.

This subpart is necessary in order to comply with the statutory requirements of Minnesota Statutes, section 153A.14, subdivision 2 (1988), and

Minnesota Statutes, section 153A.15, subdivision 1, (1988). These statutes set forth certain requirements necessary for an applicant to provide before a permit will be issued by the Commissioner. If these statutory requirements are not met, then a permit cannot be issued. It is reasonable to include this section in the proposed permit rules in order to inform the applicant of the circumstances under which a permit will be issued.

Subpart 2. PROHIBITIONS. THE PERMIT IS NOT TRANSFERABLE TO ANY OTHER PERSON. IT MAY NOT BE DISPLAYED, PUBLISHED, OR DUPLICATED IN ANY WAY.

This subpart is necessary in order to comply with Minnesota Statutes, section 153A.14, subdivision 3 (1988), which prohibits the transfer of a permit. Publication, display, and duplication of a permit are also prohibited by these proposed permit rules. It is necessary to inform applicants that they cannot publish, display, or otherwise duplicate their permits in order to put them on notice as to the prohibition. It is a reasonable requirement because a permit is not evidence of the holder's qualifications or credentials to sell hearing instruments. If permittees were allowed to publish, display, or duplicate their permits, then consumers might be misled into believing that the permittee had earned special qualifications in the hearing instrument profession and that the state granted him or her the permit in recognition of the special training, which is not the case.

Minnesota Statutes, section 153A.15, subdivision 1(2) (1988), prohibits a seller from "representing through any advertising or communication to a consumer that a person's permit to sell hearing instruments indicates state approval, endorsement, or satisfaction of standards of training or skill". It

is important that the consumer know that a permit is not a license in that a permit does not require proof of any minimum skills or training in the profession of selling hearing instruments. If the seller were allowed to display the permit on a wall or publish it in an advertisement, a consumer would most likely assume that the permit was a type of recognition by the State of Minnesota, and that the seller had earned it through some special training in the profession. This section is consistent with Minnesota Statutes, section 153A.15, subdivision 1(2) (1988), because it provides the sellers with more guidance as to accepted uses of the permit. This section clarifies the statutory language relating to "communication", and makes it clear that these three types of conduct or communication are prohibited.

Subpart 3. REQUIRED USE OF PERMIT NUMBER. THE PERMIT HOLDER SHALL USE THE PERMIT NUMBER ON ALL CONTRACTS, BILLS OF SALE, AND RECEIPTS USED IN THE SALE OF HEARING INSTRUMENTS.

This subpart requires the permit holder to use the permit number on all contracts, bills of sale, and receipts used in the sale of hearing instruments. This is a necessary requirement to provide the consumer with greater protection in the hearing instrument marketplace and enable the Commissioner to easily correlate sellers to transactions. For each permit number subject to investigation by the Commissioner, there is one permit holder. It will be easier for the state to identify sellers who are not permitted, and who are selling hearing instruments in Minnesota in violation of Minnesota Statute section 153A.14, subd. 4 (1988). In addition,

noncompliance with this requirement may alert the consumer that the salesperson may not be permitted. It is reasonable to require permit holders to place their permit number on contracts and bills of sale because it would not be burdensome on the permit holder to do so, and having that information would enable the Commissioner to better protect the consumer.

Subpart 4. DENIAL OF APPLICATION FOR PERMIT.

- A. THE COMMISSIONER MAY DENY AN APPLICATION FOR A PERMIT IF:
- (1) THE APPLICATION DOES NOT CONTAIN THE INFORMATION REQUIRED BY MINNESOTA STATUTES, SECTION 153A.14, SUBDIVISION 1 AND PART 4692.0025, SUBPART 1 AND THE APPLICANT FAILS TO PROVIDE THE COMMISSIONER WITH THE REQUIRED OR ADDITIONAL INFORMATION WITHIN 30 DAYS AFTER THE DATE REQUESTED BY THE COMMISSIONER;

This provision gives the Commissioner the option of denying the issuance of a permit to an applicant when the applicant has not completed the application properly. It is necessary for the Commissioner to have the discretion to deny a permit to an applicant who has failed to submit a completed application because if an application is not completed and all the information is not provided, then the Commissioner may not have sufficient information on the applicant to enforce the requirements of state law. It is reasonable for the Commissioner to have this discretion because she has the statutory authority to enforce the law.

This proposed rule allows for a 30-day period in which to submit the requested information by the Commissioner. It is necessary to inform applicants that they will have a certain amount of time to comply with the

application requirements once the Commissioner requests such compliance. This 30-day period is reasonable because it allows the applicant an adequate amount of time to gather information, and submit it to the Commissioner.

(2) THE APPLICANT HAS SUBMITTED FALSE OR MISLEADING INFORMATION ON THE APPLICATION;

This provision allows the Commissioner to deny issuance of a permit to an applicant who submits false or misleading information. It is necessary to be consistent with Minnesota Statutes, section 153A.15, subd. 1, which allows the Commissioner to deny issuance of a permit based on the submission of false or misleading information. This requirement is reasonable because without accurate information, the regulatory system could not function properly. The Commissioner must have information that she can reasonably rely upon.

(3) THE APPLICANT FAILS TO FULLY DISCLOSE ACTIONS TAKEN AGAINST THE APPLICANT OR THE APPLICANT'S LEGAL AUTHORIZATION TO SELL HEARING INSTRUMENTS IN THIS OR ANOTHER STATE;

This provision requires applicants to make full disclosures about their disciplinary history. Hearing instrument sellers from other states may move to Minnesota. It is necessary for the Commissioner to require that applicants submit information about any previous disciplinary actions that have taken place in other states, because they may be the only source of such information. It is reasonable because it is limited to that information which pertains to hearing instrument selling.

(4) THE APPLICANT FAILS TO AUTHORIZE THE COMMISSIONER AS REQUIRED IN PART 4692.0025, SUBPART 1, ITEM F, TO OBTAIN INFORMATION FROM THE APPROPRIATE REGULATORY AGENCIES IN THIS OR ANY OTHER STATE WHERE THE APPLICANT HAS SOLD HEARING INSTRUMENTS:

It is necessary for the Commissioner to be able to conduct a background check on applicants. Minnesota Statutes section 153A.15, subd. 1 (3) (1988) specifies that an application for a permit may be rejected by the Commissioner if the applicant is "being disciplined through a revocation, suspension, restriction, or limitation by another state for conduct subject to action under subdivision 2." This requirement is necessary in order to be consistent with the authorizing statute. Furthermore, if the Commissioner does not have access to relevant information and the ability to obtain it, then the Commissioner's duty to protect the public may be impaired. The Commissioner must have access to information in order to make appropriate determinations on issuance of permits. It is reasonable for the Commissioner to have the discretion to deny a permit on this basis because this authority is granted in Minnesota Statutes, section 153A.15, subd. 1(3).

(5) THERE IS EVIDENCE THAT THE APPLICANT HAS NOT MADE GOOD FAITH EFFORTS TO COMPLY WITH THE COMMISSIONER'S INTERNAL OPERATING PROCEDURES FOR THE HEARING INSTRUMENT CONSUMER COMPLAINT SYSTEM;

This provision is necessary to inform applicants and permittees that they must make a good faith effort when dealing with the Commissioner during the complaint investigation and the mediation process. Minnesota Statutes, section 153A.15, subdivision 1(6) (1988) prohibits sellers from "engaging in

conduct likely to deceive, defraud, or harm the public; or demonstrating a willful or careless disregard for the health, welfare, or safety of a consumer". Among other things, this language protects consumers from sellers who are unwilling to comply with established complaint mediation procedures. Good faith is an objective standard based on what a reasonable person would do in the same or similar situation. Examples of bad faith include sellers who refuse to comply with procedures previously described to them, sellers who admit a violation of state or federal law, but refuse to comply with the law, or sellers who display a careless disregard for the health, welfare, or safety of consumers during the course of the consumer complaint investigations. It is reasonable to include this as a basis for the Commissioner to deny a permit because it is consistent with Minnesota Statutes, section 153A.15, subd. 1(6).

(6) THERE IS EVIDENCE THAT THE APPLICANT HAS ENGAGED IN BEHAVIOR
THAT IS SPECIFICALLY PROHIBITED BY MINNESOTA STATUTES, SECTION 153A.15; OR

This subpart allows the Commissioner to deny issuance of a permit if the Commissioner has evidence that the applicant has violated provisions of Minnesota Statutes section 153A.15. The consumer protection and mediation system has been in effect within the Department of Health since the effective date of the statute (August 1, 1988). If the Commissioner finds that there is evidence that the applicant has violated one of the prohibited acts, then this section allows the Commissioner to deny issuance of a permit. This section is necessary because it directly correlates with the Commissioner's authority under Minnesota Statutes section 153A.15 (1988). It is reasonable to allow

the Commissioner to deny issuance of a permit when there is evidence that the applicant has violated provisions of Minnesota Statute section 153A.15 (1988) because it is consistent with her statutory authority under Minnesota Statutes, section 153A.15, subd. 1.

(7) THERE IS EVIDENCE THAT THE APPLICANT HAS VIOLATED A STATE OR FEDERAL COURT ORDER OR JUDGEMENT ISSUED TO MANAGE THE ACTIVITIES OF THE APPLICANT IN SELLING HEARING INSTRUMENTS.

This provision gives the Commissioner the discretion to deny issuance of a permit to those who have violated either a federal or state court order or judgement pertaining to hearing instrument selling. This discretion is necessary because the purpose of the permit requirement is to be able to effectively monitor and discipline permittees who have violated the law, and court orders and judgements have the force and effect of law. It is reasonable to expect permittees to comply with any court order or judgement having to do with hearing instrument selling and to allow the Commissioner to deny issuance of a permit until an order or judgement is satisfied because it encourages compliance with other enforcement mechanisms related to the selling of hearing instruments.

B. THE COMMISSIONER MUST NOTIFY AN APPLICANT IN WRITING IF THE APPLICATION IS DENIED AND INCLUDE REASONS FOR DENYING THE APPLICATION.

This subpart protects the applicant whose application for a permit was denied. Fairness requires the Commissioner to inform the applicant in writing as to the reasons why the application was denied. This writing requirement is necessary to protect the due process rights of the denied applicant. It is

reasonable because an applicant who receives such a notice will then be able to further inquire into and take action based on the reasons for the denial.

C. AN APPLICANT MAY APPEAL THE COMMISSIONER'S DECISION TO DENY
ISSUANCE OF A PERMIT. AN APPEAL MUST BE MADE IN ACCORDANCE WITH THE CONTESTED
CASE PROCEDURES OF MINNESOTA STATUTES, CHAPTER 14. ONCE AN APPEAL IS TIMELY
MADE, THE COMMISSIONER'S DECISION WILL BE STAYED UNTIL RESOLUTION OF THE
CONTESTED CASE.

In addition to the requirement that the Commissioner put in writing the reasons for denying issuance of the permit, the applicant may appeal the decision pursuant to Minnesota Statutes chapter 14. This requirement is necessary in order to comply with Minnesota Statutes section 153A.14, subd. 7 (1988) and to ensure that the applicant has access to an appeal process pursuant to the Administrative Procedures Act. This provision is reasonable because it further protects the applicant's due process rights.

D. AT ANY TIME AFTER THE COMMISSIONER HAS DENIED AN APPLICANT'S

APPLICATION FOR A PERMIT, AN APPLICANT MAY SUBMIT A NEW PERMIT

APPLICATION WITH THE COMMISSIONER, WHICH MUST BE ACCOMPANIED BY A NEW FILING

FEE, EXCEPT WHEN THE ORIGINAL APPLICATION WAS DENIED FOR TYPOGRAPHICAL ERRORS.

This subpart provides that an applicant whose application was denied may at any time after denial reapply for a permit. It is necessary because it allows an applicant who mistakenly omitted information, or submitted incorrect information, to correct his or her error. This is reasonable because the Commissioner wants to encourage applicants to disclose their experience and background and allow applicants opportunity to make corrections right away without having to go through an appeal process.

This provision also states that those applicants who were denied a permit because of typographical errors are not required to pay another application fee when they submit their corrected application. It is necessary to include this exception to the application fee in the proposed permit rules in order to inform applicants that they will not be penalized for innocent mistakes. This is a reasonable exception because although the Commissioner must require that applications contain accurate information, it would be unreasonable to expect an applicant to pay two application fees because of a typographical error.

SUBPART 5. SUSPENSION OR REVOCATION OF A PERMIT. THE COMMISSIONER SHALL FOLLOW THE PROCEDURES IN ITEMS A TO E FOR SUSPENDING OR REVOKING A PERMIT.

- A. THE COMMISSIONER MAY SUSPEND OR REVOKE A PERMIT TO SELL HEARING INSTRUMENTS IF:
- (1) THERE IS EVIDENCE THAT THE PERMIT HOLDER ENGAGED IN CONDUCT PROHIBITED BY MINNESOTA STATUTES, SECTION 153A.15;

This provision specifies that the Commissioner has the discretion to suspend or revoke a permit when there is evidence that the permittee violated the prohibited acts set forth in Minnesota Statutes, Section 153A.15, et.seq. When the Commissioner suspends or revokes a permit, the former permit holder would not be able to sell hearing instruments during the period of suspension or revocation. It is necessary to inform permit holders that certain acts can result in such actions by the Commissioner because it is consistent with her authority under Minnesota Statutes, section 153A.15 (1988). Suspension or revocation is reasonable when the Commissioner finds evidence of statutory violations because it is consistent with her authority under

Minnesota Statutes, section 153A.15, subd. 2.

(2) THERE IS EVIDENCE THAT THE PERMIT HOLDER SUBMITTED FALSE OR MISLEADING INFORMATION TO THE COMMISSIONER; OR

This provision is necessary in order to be consistent with Minnesota Statutes section 153A.15, subd. 1 (1988). It is reasonable to allow the Commissioner the option of suspending or revoking a permit when there is evidence that the permit holder submitted false or misleading information to the Commissioner on his or her application or in response to a request for information during an investigation or mediation of a complaint because the Commissioner needs sanctions to discourage applicants from submitting false or misleading information. The application process for the permits and the consumer complaint mediation process must be taken seriously by applicants and permit holders, and the applicants and permit holders must know that their sworn statement obligates them to submit accurate information. Without an accurate foundation of information, the Commissioner would be unable to rely on any applicant's statement. It is reasonable for the Commissioner to have the discretion to suspend or revoke a permit under these circumstances because it is consistent with her authority under Minnesota Statutes, section 153A.15, subd. 2.

(3) THERE IS EVIDENCE THAT THE PERMIT HOLDER VIOLATED A STATE OR FEDERAL COURT ORDER OR JUDGEMENT ISSUED TO MANAGE THE ACTIVITIES OF THE APPLICANT IN THE HEARING INSTRUMENT SELLING BUSINESS.

This section provides the Commissioner with the option of suspending or

revoking a permit when the permit holder violates a state or federal court order or judgement pertaining to hearing instrument selling. This is necessary because court judgements and orders have the force and effect of law and therefore a violation of a judgement or an order constitutes a violation of the law. Since the Commissioner is required to enforce the law pursuant to Minnesota Statutes, section 153A.14, it is reasonable to expect permittees to comply with any court order or judgement having to do with hearing instrument selling and to revoke or suspend a permit if they fail to do so.

(4) THERE IS EVIDENCE THAT THE PERMIT HOLDER HAS NOT MADE GOOD FAITH EFFORTS TO COMPLY WITH THE COMMISSIONER'S INTERNAL OPERATING PROCEDURES FOR THE HEARING INSTRUMENT CONSUMER COMPLAINT SYSTEM.

This provision is necessary because it informs permittees that a good faith effort is required when dealing with the Commissioner during the complaint investigation and mediation process. Furthermore, it is necessary for the Commissioner to have the discretion to suspend or revoke a permit on this basis in order to fulfill her enforcement duties under Minnesota Statutes, section 153A.15. Minnesota Statutes, section 153A.15, subd. 1(6) (1988) prohibits sellers from "engaging in conduct likely to deceive, defraud, or harm the public; or demonstrating a willful or careless disregard for the health, welfare, or safety of a consumer". Among other things, this language protects consumers from sellers who are unwilling to comply with the established complaint mediation procedures. It is reasonable for the Commissioner to have this discretion because it is consistent with her

statutory authority. In addition, it is reasonable to expect sellers to make a good faith effort to comply with the standard internal operating procedures for the consumer complaint system because good faith is an objective standard based on what a reasonable person would do in the same or similar circumstances. Examples of bad faith include sellers who refuse to comply with procedures previously outlined for them, sellers who admit a violation of state or federal law but refuse to comply with the law, or sellers who display a careless or willful disregard for the health, welfare, or safety of a consumer during the course of the consumer complaint investigation.

B. THE COMMISSIONER MUST NOTIFY A PERMIT HOLDER IN WRITING IF THE PERMIT IS SUSPENDED OR REVOKED AND INCLUDE THE REASONS FOR THE SUSPENSION OR REVOCATION.

This provision is necessary to protect the due process rights of the permit holder whose permit is revoked or suspended. It is reasonable and fair that the Commissioner be required to provide reasons for the suspension or revocation in writing to the permit holder because suspension and revocation are serious actions that take away a permit holder's right to practice their vocation and/or livelihood. In such cases, it is reasonable for adequate notice to be given to the permit holder so that an appeal may be timely made.

C. A PERMIT HOLDER MAY APPEAL THE COMMISSIONER'S DECISION TO SUSPEND OR REVOKE THE PERMIT. AN APPEAL MUST BE MADE IN ACCORDANCE WITH THE CONTESTED CASE PROCEDURES OF MINNESOTA STATUTES, CHAPTER 14. ONCE AN APPEAL IS TIMELY MADE, THE COMMISSIONER'S DECISION WILL BE STAYED UNTIL RESOLUTION OF THE CONTESTED CASE.

This provision allows a permit holder to make an appeal of the Commissioner's decision according to Minnesota Statutes chapter 14. This requirement is necessary because it is consistent with Minnesota Statutes, section 153A.14, subd. 7 (1988). The appeal process requirement is reasonable because it safeguards the rights of the permit holder and keeps the Commissioner's discretion in check.

D. THE COMMISSIONER MAY NOT SUSPEND A PERMIT TO SELL HEARING
INSTRUMENTS FOR A PERIOD TO EXCEED ONE YEAR. THE COMMISSIONER MAY NOT REVOKE
A PERMIT TO SELL HEARING INSTRUMENTS FOR LONGER THAN THREE YEARS.

This provision specifies the maximum duration of suspensions and revocations. It is necessary to include this provision because it clarifies the limits of the Commissioner's discretion. It is reasonable to establish and state these limits because it puts permit holders on notice and it keeps the Commissioner's discretion in check. It is reasonable to have lesser and greater sanctions so that the Commissioner may discipline hearing instrument sellers commensurate with the seriousness of the violations.

E. WHEN THE SUSPENSION OR REVOCATION PERIOD IS OVER, THE PERMIT HOLDER MAY PETITION THE COMMISSIONER TO REMOVE THE SUSPENSION OR REVOCATION. IF THE COMMISSIONER FINDS THAT THE PETITIONER HAS COMPLIED WITH THE TERMS OF THE SUSPENSION OR REVOCATION ORDER AND HAS MET THE REQUIREMENTS SPECIFIED IN PART 4692.0025, THE COMMISSIONER WILL REINSTATE A PERMIT TO THE PETITIONER.

This subpart provides the procedure for petitioning the Commissioner when the suspension or revocation period is over. The Commissioner makes decisions

on the petition for removal of suspension or revocation. If the Commissioner finds that the petitioner has complied with the terms of the suspension or revocation order, and the petitioner has complied with the permit application process, the Commissioner will remove the suspension or revocation, and the petitioner may resume selling hearing instruments. It is necessary to include this provision because it informs former permit holders of their rights to petition for reinstatement of their permits. It is reasonable because it provides safeguards for these individual's rights to know how to obtain a permit again but it also requires the former permit holder to comply with the suspension or revocation order by the Commissioner before a new permit will be issued.

4692.0035 RENEWAL OF PERMITS.

Subpart 1. PERMIT RENEWAL NOTICE. PERMIT HOLDERS MUST RENEW THEIR
PERMITS ANNUALLY. AT LEAST 30 DAYS BEFORE THE DATE THE PERMIT MUST BE RENEWED
ACCORDING TO SUBPART 2, THE COMMISSIONER SHALL SEND OUT A RENEWAL NOTICE TO
THE PERMIT HOLDER'S LAST KNOWN ADDRESS. THE NOTICE SHALL INCLUDE A RENEWAL
APPLICATION AND NOTICE OF FEES REQUIRED FOR RENEWAL. A PERMIT HOLDER IS NOT
RELIEVED FROM MEETING THE APPLICABLE DEADLINE FOR RENEWAL ON THE BASIS THAT
THE PERMIT HOLDER DID NOT RECEIVE THE RENEWAL NOTICE. IN RENEWING A PERMIT,
A PERMIT HOLDER SHALL FOLLOW THE PROCEDURES FOR APPLYING FOR A PERMIT
SPECIFIED IN PART 4692.0025.

This subpart provides that the permit period is one year long and is necessary in order to inform applicants and permit holders of the effective

dates of the permit. This duration is reasonable because the Commissioner needs to have updated information on a regular basis on the sellers within her regulatory jurisdiction. An annual renewal will ensure that she has up to date information on the sellers without creating an unreasonable application burden for the sellers. The Commissioner will give notice that the permit is up for renewal, but the permit holder has an obligation to renew his or her permit according to the schedule without being reminded. It is necessary to inform the permit holders and applicants that even though the Commissioner will be providing notices that renewal is due, they are still required to follow the renewal schedule because it puts permit holders and applicants on notice of their duties. This is reasonable because although the purpose of the notice mailing by the Commissioner is to encourage prompt compliance with the permit requirement, the Commissioner cannot guarantee that each permit holder will actually receive the notice that is mailed.

- Subpart 2. RENEWAL DEADLINE. THE RENEWAL APPLICATION AND FEE MUST BE
 POSTMARKED ON OR BEFORE THE DATE THE PERMIT MUST BE RENEWED ACCORDING TO ITEMS
 A TO E. PERMITS MUST BE RENEWED ACCORDING TO THE FOLLOWING SCHEDULE:
- A. FOR PERMIT HOLDERS WHOSE LAST NAME BEGINS WITH THE LETTER "A E" FEBRUARY 1;
- B. FOR PERMIT HOLDERS WHOSE LAST NAME BEGINS WITH THE LETTER "F L" APRIL 1;
- C. FOR PERMIT HOLDERS WHOSE LAST NAME BEGINS WITH THE LETTER "M P"
 JUNE 1;
 - D. FOR PERMIT HOLDERS WHOSE LAST NAME BEGINS WITH THE LETTER "Q U" AUGUST 1; AND

E. FOR PERMIT HOLDERS WHOSE LAST NAME BEGINS WITH THE LETTER "V - Z" OCTOBER 1.

This subpart sets out the renewal schedule for the permit holders. The schedule allows for staggered applications. It is necessary to inform applicants and permit holders of the renewal schedule so that everyone can anticipate when they will be required to renew their permits. It is reasonable to stagger the schedule to prevent all of the renewal applications from being submitted at one time and causing delays in their review. This schedule provides the Commissioner with an adequate amount of time to review applications, investigate them, and obtain further information, if necessary, and issue a permit within an appropriate amount of time and without undue delay.

4692.0040 FEES.

Subpart 1. FIRST TIME APPLICANTS AND REAPPLICANTS FOR PERMITS. THE COMMISSIONER SHALL PRORATE THE PERMIT FEE FOR FIRST TIME APPLICANTS AND REAPPLICANTS ACCORDING TO THE NUMBER OF MONTHS THAT HAVE ELAPSED BETWEEN THE DATE THE PERMIT IS ISSUED AND THE DATE THE PERMIT MUST BE RENEWED ACCORDING TO PART 4692.0035, SUBPART 2.

This subpart provides that for the initial application and reapplication process, those whose renewal periods begin less than one year from the time they received the permit will only pay a proportionate amount of their first time permit fee. The formula is as follows: X/12 times the annual permit

fee; X equals the number of months between the month of application or reapplication for a permit and the month the applicant or reapplicant is scheduled for renewal. This requirement is necessary in order to allow for equal treatment of all applicants and reapplicants. This requirement is reasonable because those who have less than one year until their renewal should pay for only that portion of the year for which they were permitted.

Subpart 2. ANNUAL PERMIT FEE. THE ANNUAL PERMIT FEE IS \$140.00.

This subpart sets the permit fee. It is necessary because pursuant to Minnesota Statutes, sections 214.06, 214.13 and 16A.128, the Commissioner of Health, with the approval of the Commissioner of Finance, must assess fees in an amount that closely approximates the anticipated expenditures under the regulation system. This amount is reasonable because the permit fee of \$140.00 is derived from the estimated fiscal note and budget for the first year of permit issuance and renewal. The estimated budget for fiscal year 1990 is \$56,103.75. There are an estimated number of 400 persons in the applicant group. \$56,103.75 divided by 400 equals \$140.25. This number was rounded down to \$140.00 for the permit fee.

Subpart 3. SURCHARGE FEE. IN ADDITION TO OTHER APPLICABLE FEES, EACH APPLICANT MUST PAY A SURCHARGE FEE OF \$29.00. THE SURCHARGE FEE APPLIES TO ALL PERSONS APPLYING FOR A PERMIT OR RENEWAL OF A PERMIT UNDER THIS CHAPTER DURING THE FIRST FIVE YEARS FOLLOWING THE EFFECTIVE DATE OF THIS CHAPTER.

This subpart is necessary because pursuant to Minnesota Statutes, section 214.06, an occupation regulated after July 1, 1984 by the Commissioner of Health, must include a surcharge fee that recovers the amount necessary to pay

for the adoption of rules. This surcharge fee must be recovered over a five year period. This amount is reasonable because the surcharge fee of \$29.00 was derived from the following formula: the estimated expenditures for fiscal year 1989 are \$57,737.66, and this must be divided by five representing the number of years the surcharge fee is in effect, which in turn is divided by the number of estimated permit applicants, or 400. The end result is \$28.86. This number was rounded up to \$29.00.

4692.0045 BONDS

Subpart 1. EVIDENCE OF COMPLIANCE WITH MINN. STAT. SEC. 153A.16. BONDS SHALL BE SUBMITTED TO THE COMMISSIONER ON BOND FORMS PROVIDED BY THE COMMISSIONER.

This subpart relates to the bond requirement set forth in Minnesota Statutes, section 153A.16 (1988). Minnesota Statutes, section 153A.14, subdivision 5 (1988) provides the Commissioner with rulemaking authority regarding the bond requirement. This section is necessary to provide notice to applicants that the Commissioner will provide the necessary bond form for applicants. It is reasonable that the Commissioner provide these forms to the applicants to ensure that the bond is in full compliance with the state laws regulating bonds.

Dated: May_9, 1989

Sister Mary Madonna Ashton Commissioner of Health

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STATEMENT OF NEED AND REASONABLENESS

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Need

Laws of Minnesota for 1988, Chapter 689, Article 2, Section 56, require a seller of hearing instruments to apply for and receive a permit from the Commissioner of Health in order to sell hearing instruments. The 91011 Commissioner must adopt rules for operating the permit program. As /\ required by Chapter 16A.128, the cost of operating the permit program must be recovered through a fee collection process.

Reasonableness

The Department has proposed to adopt two fees.

The first fee is an annual fee/renewal fee to recover the ongoing costs of operation. It was developed by calculating the estimated cost to process applications to issue permits and enforcement activities (see attached Fee Review) and dividing by the estimated number of applicants.

 $[\$56,104.00 \div 400 = \$140.25 \text{ (rounded to $140.00)}]$

This fee will be prorated for the number of months in the permit period.

The second fee proposed is a surcharge fee to recover the cost of adopting rules. This was developed by taking the estimated cost of fee adoption and dividing by the number 5 (the number of years allowed to recover this cost in Minnesota Statutes 214.13) then dividing by the estimated number of applicants.

 $[\$51,738.00 \div 5 \div 400 = \$28.87 \text{ (rounded to $29.00)}]$

Upon review of the above information justifying the reasonableness of the proposed fee and pursuant to the authority vested in the Department of Finance under Minnesota Statutes 16A.128, (1987) the fees set forth in this proposal of the Department of Health are hereby approved.

Bruce Reddemann, Director

Budget/Operations and Support

FI-00194-06 (12/87

Department of Finance FEE REVIEW

			-	02/27/89					
Department/Agency:	Budget Activity		7						
Health, Department	of		Health S	<u>ystems Developm</u>	nent				
Fee Name: Hearing Instrument	Saller Permit								
Legal Citation:	Fee Set By:	I x							
M.S. § 153A.14 Purpose of Fee:		Law _^ Agency							
To regulate the se not limited to rul	llers of hearin e making, issui	g instrument ng permits,	s; activition investigation	es which including complaints.	le but are				
Dedicated				Revenue Code: 300					
APID: Fund: 40000:99 10	Accumulated Differ	ence Thru 1986	Dollars in Thousands (137,522 = 137.5)						
Fiscal Year	Actual F.Y. 87	Actual F.Y. 88	Estimated Reques		d Requested F.Y. 91				
Actual/Anticipated Receipts			12	68	68				
Less Actual/ Anticipated Costs			57	56	58				
Current Difference			(45) 12		10				
Accumulated Difference		· · - · · · · · · · · · · · · · · · · ·	(45)	(33)	(23)				
Number Paying Fee			400 400		400				
Present Fee			\$40.00 (permit) \$29.00 (surcharge)						
Date Fee Last Changed									
emarks:				J.					
				·					
				•	•				
	Department Authorized Signature								
		_	·		-				
nance Department Recommend	ation:	·							
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		•							

Department of Finance FEE REVIEW – Details of Costs

Date Prepared: 02/27/89 Department/Agency: Budget Activity: Health Systems Development Health, Department of Fee Name: Hearing Instrument Seller Permit Actual Actual **Estimated** Requested Requested Fiscal Year F.Y. 87 F.Y. 88 · F.Y. 89 F.Y. 90 F.Y. 91 Dollars in Thousands (137,522 = 137.5) Detailed Listing of Items Included as Costs on Fee Review Form FI-00194-06 51 (1)48 (2) 50 Agency Direct Expenditures XXXXXXXX XXXXXXXX XXXXXXXX 2 2 Salary increases (3) (3) (3) Attorney General 1 1 1 Statewide Indirect 5 5 5 Agency Indirect Totals - Fee Review Form 57 56 58 Remarks: (1) (2) Salaries \$40,130 \$40,130 Rule Making 6,000 Supplies/Equipment 2,875 590 Communication 1,000 637 Enforcement 5,000 Travel 1.000 Permit/Renewal Issuance 1,000 1,000 Total \$51,005 \$48,357 Salary Increases 1,513 Indirect Cost 6,732 6,233 \$57,737 \$56,103

⁽³⁾ Included in above total.

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