5-0900-4098-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health Governing the Registration of Hearing Instrument Dispensers.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Howard L. Kaibel, Jr., Administrative Law Judge, on December 18, 1989, in the Veterans Service Building in St. Paul.

This is a rulemaking proceeding under Minn. Stat. §§ 14.131 - 14.20 held to determine whether the Department of Health has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of rules, whether the proposed provisions are needed and reasonable, and whether any suggested modifications would constitute impermissible substantial changes. The Department staff panel consisted of: Penny Troolin, Special Assistant Attorney General; Jean Klosowski, Rule Development Specialist at the Department of Health; and Tom Hindelmeier, Director of Health Occupational Licensing.

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rule(s). The agency may then adopt a final rule or modify or withdraw its proposed rule. If the Commissioner makes changes in the rule other than those recommended in this report, she must submit the rule with the complete hearing record to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of a final rule, the agency must submit it to the Revisor of Statutes for a review of the form of the rule. The agency must also give notice to all persons who requested to be informed when the rule is adopted and filed with the Secretary of State.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

Procedural Requirements

1. On October 3, 1989, the Department filed the following documents with the Chief Administrative Law Judge:

(a) A copy of the proposed rules certified by the Revisor of Statutes.
(b) The Order for Hearing.
(c) The Notice of Hearing proposed to be issued.
(d) A Statement of the number of persons expected to attend the hearing and estimated length of the Agency's presentation.

(e) The Statement of Need and Reasonableness.
(f) A Statement of Additional Notice.

2. On November 13, 1989, a Notice of Hearing and a copy of the proposed rules were published at 14 State Register 1160-1170.

3. On November 9, 1989, the Department mailed the Notice of Hearing to all persons and associations who had registered their names with the Department for the purpose of receiving such notice.

4. On November 21, 1989, the Department filed the following documents with the Administrative Law Judge:

(a) The Notice of Hearing as mailed.
(b) The Agency's certification that its mailing list was accurate and complete.
(c) The Affidavit of Mailing the Notice to all persons on the Agency's list.
(d) An Affidavit of Additional Notice.
(e) The names of Department personnel who will represent the Agency at the hearing together with the names of any other witnesses solicited by the Agency to appear on its behalf.
(f) A copy of the State Register containing the proposed rules.
(g) All materials received following a Notice of Intent to Solicit Outside Opinion published at 13 State Register 1109, October 31, 1989, and a copy of the Notice.

The documents were available for inspection at the Office of Administrative Hearings from the date of filing to the date of the hearing.

5. The period for submission of written comments and statements remained open through January 8, 1990, the period having been extended by order of the Administrative Law Judge to 20 calendar days following the hearing. The record closed on January 11, 1990, the third business day following the close of the comment period.

Fiscal Note

6. Minn. Stat. § 14.11, subd. 1, requires the Department to prepare a fiscal note estimating the total cost to all Minnesota local governments of rule implementation for the two years immediately following adoption, if the estimated total costs exceed $100,000 in either of those first two years. The notice of hearing included the Department's position that promulgation of these proposed rules will not result in the expenditure of public monies by local public bodies. No one disagreed with this contention. The Department has thus fully complied with the provisions of Minn. Stat. § 14.11.

Small Business Considerations

7. The notice of hearing alerted the public to the Department's belief that the proposed rules would not have any adverse impact on any small businesses. The Department's Statement of Need and Reasonableness (SONAR) sets forth the rationale for this conclusion at length. No one at the hearing (including the spokesman for most of the potentially affected professionals) or in the extensive written comments filed before and after the hearing, disagreed

with this determination. Minn. Stat. § 14.115 requiring consideration of the effect of rules on small businesses, exempts agency rules which do not affect small businesses directly. Because the voluntary provisions of these rules do not have such a direct effect, the Department was not required to detail this impact.

Statutory Authority

8. The statutory authority to adopt the proposed rules is found in Minn. Stat. § 214.13, subd. 1. It specifically requires the Commissioner to "promulgate by rule standards and procedures relating to the credentialing of persons practicing" human services occupations such as sales of hearing aids. No one questioned the authority of the Commissioner to adopt the provisions at any point in this proceeding. Department staff has adequately documented the jurisdiction of the Commissioner of Health to consider and adopt all of the proposed requirements.

Nature of the Proposed Rules

9. These proposed rules are part of a 17-year effort by the Minnesota Legislature to regulate hearing aid sales practices. The approach chosen by the Commissioner of Health after careful study, was a three-pronged supplement to federal consumer protection laws: a mandatory permit system; a voluntary registration system; and a consumer-information center.

The mandatory permit rules have been promulgated and are being implemented. This proceeding involved the second prong of the program: establishing a voluntary registration system.

The proposed rules would establish protected titles, signifying state regulation of particular dealers who meet minimum qualifications. Sellers would be required to register to use the titles and would be subject to continuing education and disciplinary requirements.

10. Some members of the public urged the Department "to throw everything out and start again" by establishing a comprehensive single licensing system for everyone involved in hearing aid testing and selling. However, such action would clearly exceed her statutory power in the authorizing legislation which unequivocally requires that:

> If the commissioner determines that credentialing of an occupation is appropriate, the commissioner is empowered only to register the occupation. (Minn. Stat. § 214.13, subd. 1).

The Commissioner conducted a legislatively mandated study and concluded on January 25, 1988 that:

> The public can be effectively protected by a combination of registration (title protection) and a consumer protection system that regulates hearing aid dispensers. Registration is a less stringent form of regulation than licensing.

Minnesota Statutes § 214.001, subd. 3 also specifically mandates adoption of registration rather than licensing wherever registration will adequately protect the public. Department staff has adequately documented the need for, reasonableness of and statutory authority for the general regulatory approach taken here.

11. Other members of the public took the position that no dealer should be "authorized by any source to test hearing." They were concerned that state registration would cloak unscrupulous dealers with a mantle of government respectability. They urged that such testing should be limited to physicians, audiologists and otolaryngologists who do not have an inherent financial conflict of interest in selling hearing devices (neglecting to note that many of these professionals have the same conflict). Some cited specific examples of dealers trying to avoid medical diagnosis. The Hearing Society of Minnesota, which recognizes that some registration is appropriate but feels these rules are not strict enough, submitted extensive documentation of the sales practices of some hearing aid dealers -- arguing for more protection.

Most of these concerns have already been dealt with specifically in detailed federal Food and Drug Administration regulations which preempt contradictory state provisions. Copies of these requirements were included in comments submitted by an attorney representing otolaryngologists. They are reproduced and attached to this Report for the benefit of those readers who may not be fully aware of the specific protections that are already in force.

Without reiterating them in detail here, those provisions already require separate testing by qualified physicians, specific prescribed warnings, et cetera. The Department of Health is empowered to enforce these safeguards against all hearing aid sellers and the recently adopted permit rules will assist in that process.

The rules proposed here would further help the public by identifying the most responsible dealers, who voluntarily submit to additional Department testing and education safeguards. There are clearly some "bad apples" in Minnesota hawking hearing devices. The general approach taken in these rules is a needed and reasonable step in the direction of isolating and eliminating them.

12. This hearing process was a model of proficient rulemaking. The staff of the Department deserves commendation for thoughtful and thorough responsiveness. From the outset, public input was encouraged. Numerous meetings were conducted on drafts and redrafts. The process in this case was particularly difficult because of the depth of disagreement between the various interests, which was often irreconcilable. Even after issuance of the Department's notice of hearing, extensive revisions were agreed to by the Department in response to further prehearing comments. Similarly, after the hearing, the Department agreed to further extensive revisions to accommodate legitimate concerns in its final and responsive written comments. In short, this was an outstanding example of a state agency thoughtfully exercising judgment rather than exerting its will.

13. Because the Department turned over every stone, there is no need here for a detailed discussion of each subpart of the proposed rules. That has been done in the SONAR which details the need for and reasonableness of each of the

provisions and in the 60-page final written comments which deal assiduously with all of the public concerns. Any provisions not commented on in this Report are specifically found to be needed and reasonable. All of the concerns expressed at the hearing and in written comments have been carefully considered. Department staff's proposed revisions in response to those concerns are also found to be needed and reasonable, based on the Department's affirmative presentation of facts. None of their proposed revisions are "substantial changes" requiring a new hearing.

Specific Provisions

14. The one thing everyone reviewing these rules agreed on was the need to add "hearing aid dealer" and "hearing instrument dealer" to the titles protected in part .0020, subpart 1a. This was urged by the Minnesota Hearing Aid Society (MHAS) which is the state association of hearing instrument dealers. It was not opposed by any of the interests that often vigorously disputed other provisions -- including the Minnesota Speech-Language Hearing Association (MSHA) which represents audiologists and speech pathologists. The Department staff agreed to this revision in its final written comments. The addition is needed, reasonable and is not a substantial change.

15. There was no similar unanimity on the proposal that registrants be forced to wear name tags in part .0020, subpart 1c. The proposal was very strongly objected to by MHAS which labeled it "ridiculous". Many certified audiologists, who have met higher professional standards, also objected to being forced to wear such tags which they felt would be demeaning. However, others including Susan Weber, another audiologist, vigorously supported such tags to insure that the public would not be dealt with by clerical staff while a registrant is out of the office. Considering the difficulty of enforcement, Department staff agreed in final written comments to delete the requirement. The deletion is needed, reasonable and not a substantial change.

16. Temporary registration was a legitimate concern of many participants, particularly in light of the two years allowed for development of testing procedures. It is clear that such temporary registrants should not be allowed to call themselves "registered" until they actually pass the state examination or are registered by reciprocity. The Department staff remedied this concern in final written comments by adding this clarification to part .0020, subpart 1, item B. It is a needed, reasonable and insubstantial change.

17. MHAS and others urged that ANSI calibration of equipment be specified throughout the rules. The Department staff agreed at the hearing to include such clarification and there was no objection from the public at or after the hearing. It is an appropriate, insubstantial specification.

18. MHAS urged that the rule relating to use of otoscopes, .0025, subpart 2a(2)(f) be revised to strike "or an equivalent illuminator". Standards were requested at the hearing for guidance in assessing "equivalence" and none were forthcoming at or after the hearing. The Department staff consequently agreed in final written comments to the revision which would eliminate unnecessary ambiguity and potential appeals. The change is needed, reasonable and insubstantial.

19. The National Hearing Aid Society makes a claim in written comments to an exclusive right to use the title "hearing instrument specialist". The proposed rules would not abridge this alleged right of exclusivity. They would only require that anyone using that title in Minnesota must be a legal registrant.

20. One of the few other places where both MSHA and MHAS agreed was the appropriate time frame for approving continuing education courses in .0045, subpart 3a. They both urged cutting the lead time for such approval from 90 days to 60 days. In accord with its practice of accommodating reasonable requests for revisions, Department staff has agreed to process such requests in 60 days. The change is needed, reasonable and insubstantial.

21. MHAS objected to the proposed grounds for disciplinary action, particularly .0055, subpart 3c and f, which it contended were overly broad. MHAS promised proposed language at the hearing to tighten up these provisions, but did not provide them in written comments. The Department staff had already made several revisions tightening these important provisions after issuance of the Notice of Hearing in its revised hearing draft. That language is specifically found to be needed, reasonable and statutorily authorized, considering the contested case hearing protections provided to assure that discipline will not be arbitrarily or unfairly administered.

22. Department staff responded very constructively to many diverse suggestions for improving the provisions related to advisory council membership. Its final proposal in final written comments does an excellent job of accomodating these divergent interests.

MSHA objected to the requirement that one advisory council member "must be a registered hearing instrument dispenser who is also an audiologist". They urged changing the requirement to an "audiologist who is dispensing hearing instruments" to avoid forcing double registration and fees plus permit fees on this member if s/he does not wish to be a registered dispenser. Department staff agreed at the hearing to take the matter under advisement and ultimately agreed in final written comments to change the membership to an "audiologist who is a hearing instrument seller". The change is appropriate and insubstantial.

The Minnesota Medical Association (MMA) and others urged strongly that there should be a physician, preferably an otolaryngologist on the advisory council. The final comments of Department staff clarified the Department's intent which is to include a physician on the council to fill the "seventh seat" if a qualified applicant, preferably a otolaryngologist, can be located. The alternative of utilizing another audiologist to fill this seat is included in the rule only to avoid a vacancy if no physician applies. The language as initially proposed is consequently needed, reasonable and statutorily authorized.

The MMA and others also objected to limiting physician membership on the advisory council to persons with no financial conflict of interest in hearing aid sales. As explained in the SONAR, it is reasonable to reserve one seat on the council for detached physician expertise. As noted in Department staff's final comments, the same detachment is required by statute of the two public members. The restriction is a necessary and reasonable furtherance of the legislative intent in establishing a council that will maximize protection of the consumer.

The Hearing Society of Minnesota objected that reserving a majority of seats on the advisory council for registered dispensers is like "placing a fox in charge of the chicken coop." The Department staff responded in final written comments by limiting registrant seats to three of the seven members. The balance on this resulting council will compare very favorably with other occupational regulatory boards. The Board of Medical Examiners, for example, has eight doctors and three public members. The Board of Dentistry has two public members, five dentists, one dental hygienist and one registered dental assistant. The Board of Nursing has three public members and eight nurses. The Chiropractic Board has two public members and five chiropractors. The Board of Law Examiners is made up of seven attorneys and two public members.

For the reasons discussed above, with the revisions agreed to in final written comments, the membership provisions of .0060, subpart 1 are specifically found to be needed and reasonable. The revisions are not substantial changes.

23. MSHA was concerned that many audiologists choosing protected titles will be forced to comply with double registration and continuing education requirements. The Department staff partially accommodated these concerns in final written comments by agreeing to allow six of the hours of continuing education to be acquired in general areas relating to hearing aid sales. It will be up to audiologists to decide whether to use either or both titles. Those who choose to use the titles protected by these rules should properly be required to comply like every other registrant with the requirements that go with those titles.

24. Concern was expressed at the hearing and in written comments over the interface between these registration rules and the recently adopted mandatory permit rules that apply to all sellers. The rules were submitted by Department staff and have been carefully reviewed. Department staff in final written comments proposed to modify these rules to require the permit number on applications for registration and to add permit revocation as a ground for discipline. The revisions are needed, reasonable and insubstantial clarifications.

25. MMA and others urged adding the American and Minnesota Academies of Otolaryngology -- Head and Neck Surgery to the list of preapproved sponsors of continuing education. No one objected to this addition in final responsive comments. The Department staff has agreed in final written comments to make this revision which is needed, reasonable and insubstantial.

26. Some commentators urged changing "continuing education" to "inservice training" as a way of emphasizing that the rules do not require formal education for registration. However, education will be required of all registrants to pass the examination, so subsequent required course work is accordingly properly denominated "continuing education". The nomenclature utilized in the rules as initially proposed is reasonable.

27. The MMA contends in its final responsive comments that the proposed revision of the continuing education provisions to require that 14 of the 20 contact hours be "directly related" to hearing instrument selling is a "substantial change" which can only be adopted after a new notice and hearing, pursuant to Minn. Stat. § 14.15, subd. 3:

> Persons who will be affected by these rules may well have been comfortable with a requirement of 20 hours of continuing education. A person may have reviewed the courses they had taken in past years, determined that they were offered by sponsors included in the "pre-approved" category of the proposed rule, and been satisfied that they would meet the requirements and that they need not comment on the rule.
>
> The specification proposed could very well create for that person a substantial burden that they could in no way have foreseen. The courses that they had taken, and thought would meet the requirements, might not fit the categorization of 20 hours of continuing education. A person may have reviewed the courses they had taken in past years, determined that they were offered by sponsors included in the "pre-approved" category of the proposed rule, and been satisfied that they would meet the requirements and that they need not comment on the rule.

This is the only allegation in the record by anyone that any of the department's revisions subsequent to issuance of the notice of hearing is a substantial change. It is a colorable claim that has been carefully considered.

It is noteworthy that no one else involved in the hearing process has joined in the MMA contention, including: the MHAS whose member dealers will be the overwhelming majority of affected registrants; MSHA whose audiologist members will make up nearly all of the remaining registrants; counsel for the otolaryngologists whose members might seek registration if they are engaged directly in selling instruments and desire to use one of the protected titles; and consumer advocates who repeatedly urged such "tightening up" of educational and other standards.

The proposed change arose in part because of some latent ambiguity in the rules noticed for hearing. Those rules listed pre-approved "sponsors" for continuing education courses and went on to provide for Department approval of courses offered by other sponsors. The Administrative Law Judge interpreted those rules as requiring approval of all eligible courses, but the Department indicated that its intent was to automatically approve all courses offered by pre-approved sponsors, to save administrative paperwork.

The problem with this approach is that many of the pre-approved sponsors offer other courses that have little or nothing to do with hearing instruments, sales or testing. Although everyone assumed that qualifying continuing education courses must relate to improving registrants' occupational proficiency, as instrument dispensers, the rules did not spell this out.

MHAS proposed at the hearing to clarify the provisions (and avoid potential future appeals) by explicitly stating that course work must be related and at least 14 of the 20 hours must be directly related to instrument sales. Department staff took the proposal under advisement, soliciting input from other affected interests at the hearing and in written comments, ultimately agreeing to the MHAS clarification in its final written comments.

Minn. Rule 1400.1100, subp. 2 spells out the considerations that must be applied in assessing whether a revision constitutes a substantial change. These standards, fairly applied, require the conclusion that this proposed clarification is not such a change.

The first consideration is "the extent to which it affects classes of persons who could not have reasonably been expected to comment on the proposed rules at the rulemaking hearing." A state agency cannot notice, for example, a rule for strawberry growers and later change it to add tomato growers, without re-noticing the rule -- because tomato growers would be a new class of people who would not have been expected to comment on strawberry rules. Here we have no such new class of people. The class of affected people is sellers wishing to use protected titles who were all on notice that continuing education requirements would be involved. No new class of regulated persons is being "blindsided" by the revision.

The second consideration is "goes to a new subject matter of significant substantive effect or makes a major substantive change that was not raised by the original notice of hearing in such a way as to invite reaction at the hearing". Agencies cannot propose rules on strawberry growing and later add packaging, without renoticing the new provisions. Here there is no such new subject matter. The subject of continuing education was properly noticed in the original proposed rules in such a way as to invite reaction at the hearing (which was in fact received, leading to the proposed clarification).

The last consideration is "results in a rule fundamentally different in effect from that contained in the notice of hearing". An agency cannot propose rules on strawberry fertilizing and later add a limit on the size of farms, without renoticing its proposal. Here, the clarified rule is not fundamentally different in effect from the one originally noticed. Potential registrants knew they would have to complete 20 hours of continuing education updating their occupational skills. None of those potential registrants reasonably believed that unrelated courses such as "safe food preparation" would satisfy that requirement just because it was offered by the Department of Health which is one of the pre-approved sponsors. All reasonably assumed that the courses must relate to their registration. The revision makes this explicit and allows six of the hours to be only "in areas generally related". The resulting rule is not "fundamentally different in effect" from the requirement originally proposed.

In short, the revision is not a substantial change requiring a new hearing or deletion of the clarification. Perhaps it would have been better to establish a process for pre-approval of all qualifying courses, which as a practical matter may still have to be done by Department staff on a case-by-case basis. However, no one sought such an approach and the rule as proposed is a needed and reasonable exercise of the Department's statutory mandate.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. That the Department of Health gave proper notice of the hearing in this matter.

2. That the Department has fulfilled the procedural requirements of Minn. Stat. §§ 14.14, and all other procedural requirements of law or rule.

3. That the Department has documented its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i) and (ii).

4. That the Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii).

5. That the additions and amendments to the proposed rules which were suggested by the Department after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3, Minn. Rule 1400.1000, Subp. 1 and 1400.1100.

6. That any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

7. That a finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Commissioner from further modification of the rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

It is hereby recommended that the proposed rules be adopted consistent with the Findings and Conclusions made above.

Dated this 19TH day of January, 1990.

HOWARD L. KAIBEL, JR.
Administrative Law Judge

device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions:

(1) In such a manner that it generates ozone at a level in excess of 0.05 part per million by volume of air circulating through the device or causes an accumulation of ozone in excess of 0.05 part per million by volume of air (when measured under standard conditions at 25° C (77° F) and 760 millimeters of mercury) in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product.

(2) To generate ozone and release it in the atmosphere in hospitals or other establishments occupied by the ill or infirm.

(3) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed 0.05 part per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of 0.05 part per million.

(4) In any medical condition for which there is no proof of safety and effectiveness.

(5) To generate ozone at a level less than 0.05 part per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

(d) This section does not affect the present threshold limit value of 0.10 part per million (0.2 milligram per cubic meter) of ozone exposure for an 8-hour-day exposure of industrial workers as recommended by the American Conference of Governmental Industrial Hygienists.

(e) The method and apparatus specified in 40 CFR Part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

§ 801.415 Use of chlorofluorocarbon propellants.

The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in § 2.125 of this chapter.

(Secs. 301, 402, 409, 501, 502, 505, 507, 512, 601, 52 Stat. 1042-1043 as amended, 1046-1047 as amended, 1049-1054 as amended, 1055, 57 Stat. 463 as amended, 72 Stat. 1785-1788 as amended, 82 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b, 361) sec. 102(2), 83 Stat. 853 (42 U.S.C. 4332))

[43 FR 11318, Mar. 17, 1978]

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and § 801.421.* (1) "Hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) "Ear specialist" means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) "Audiologist" means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) "Sale" or "purchase" includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) "Used hearing aid" means any hearing aid that has been worn for any period of time by a user. However,

EXHIBIT A

a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids*—(1) *General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(*a*) Use of the hearing aid.

(*b*) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(*c*) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c)(2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section.

(xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

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

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

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

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

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

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that

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

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

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

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

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

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing id users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard Specification of Hearing Aid Characteristics, ANSI S3.22-1982 (Revision of S3.22-1976) (ASA 7-1982), which is incorporated by reference. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or are available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (HF-Average SSPL 90).

(iv) Average full-on gain (HF-Average full-on gain).

(v) Reference test gain.

(vi) Frequency range.

(vii) Total harmonic distortion.
(viii) Equivalent input noise.
(ix) Battery current drain.
(x) Induction coil sensitivity (telephone coil aids only).
(xi) Input-output curve (ACG aids only).
(xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

(i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and

(ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK-116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

[42 FR 9294, Feb. 15, 1977, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 30154, July 24, 1985]

§ 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements*—(1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by _____ _____(Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) *Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User In-

structional Brochure for the hear
aid or the name and address of
manufacturer or distributor fr
whom a User Instructional Broch
for the hearing aid may be obtained

(2) In addition to assuring tha
User Instructional Brochure accom
nies each hearing aid, a manufactu
or distributor shall with respect to
hearing aid that he manufactures
distributes:

(i) Provide sufficient copies of
User Instructional Brochure to sel
for distribution to users and pros
tive users;

(ii) Provide a copy of the User
structional Brochure to any hea
aid professional, user, or prospec
user who requests a copy in writing

(d) *Recordkeeping.* The disper
shall retain for 3 years after the
pensing of a hearing aid a copy of
written statement from a physician
quired under paragraph (a)(1) of
section or any written statement w
ing medical evaluation required un
paragraph (a)(2)(iii) of this section.

(e) *Exemption for group audi
trainers.* Group auditory trainers,
fined as a group amplification sys
purchased by a qualified school or
stitution for the purpose of comm
cating with and educating individ
with hearing impairments, are exe
from the requirements of this sect

[42 FR 9296, Feb. 15, 1977]

§ 801.425 Nonrestricted devices in
pressurized containers with ch
fluorocarbon propellants.

(a) The label on each package
nonrestricted device in a self-pres
ized container in which the propel
consists in whole or in part of a
halogenated chlorofluoroall
(chlorofluorocarbon) shall bear
following warning:

Warning—Contain a chloroflu
carbon that may harm the pu
health and environment by redu
ozone in the upper atmosphere.

(b) The warning required by
graph (a) of this section shall ap
on an appropriate panel with
prominence and conspicuousness
render it likely to be read and u
stood by ordinary individuals u
normal conditions of purchase.
warning may appear on a firml

structional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

[42 FR 9296, Feb. 15, 1977]

§ 801.425 Nonrestricted devices in self-pressurized containers with chlorofluorocarbon propellants.

(a) The label on each package of a nonrestricted device in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contain a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(b) The warning required by paragraph (a) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, sticker or similar overlabeling attached to the package. The warning shall appear prominent and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background, but in no case may the letter be less than 1/16 inch in height.

(c) The warning in paragraph (a) of this section is not required and should not be used for products intended for metered-dose adrenergic bronchodilators for oral inhalation, and for cytology fixative uses.

(d) The warning required by paragraph (a) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

(Secs. 201(n), 301, 402, 403, 501, 502, 505, 507, 512, 601, 602, 52 Stat. 1041-1043 as amended, 1046-1048 as amended, 1049, 1051-1053 as amended, 1054, 57 Stat. 463 as amended, 82 Stat. 343-351 (21 U.S.C. 321(n), 331, 342, 343, 351, 352, 355, 357, 360b, 361, 362); sec. 101(2), 83 Stat. 853 (42 U.S.C. 4332))

[42 FR 22034, Apr. 29, 1977]

§ 801.427 Professional and patient labeling for intrauterine contraceptive devices.

(a) This section applies to intrauterine devices (IUD's) that are not subject to new drug requirements under § 310.502 of this chapter. IUD's subject to this section (device IUD's) include:

(1) IUD's fabricated solely from inactive materials, e.g., inactive plastics or metals.

(2) IUD's with substances added to improve the physical characteristics if such substances do not contribute to contraception through chemical action on or within the body and are not dependent upon being metabolized for the achievement of the contraceptive purpose.

(3) IUD's that contain a component, such as barium, added exclusively for the purpose of visualization by x-ray.

(b) The intrauterine contraceptive device (IUD) is a popular method of contraception used by several million women in the United States. Although