69-1800-7003-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE DEPARTMENT OF HUMAN SERVICES

In the Matter of the Proposed Adoption of Rules and Amendments to Rules of the State Department of Human Services Governing Hearing Services, Minnesota Rules, Pts. 9505.0175, 9505.0221, 9505.0287 and 9505.0365.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Steve M. Mihalchick on December 1, 1992, commencing at 8:00 a.m. in Rooms 2A and 2B, Department of Human Services, 444 Lafayette Road, St. Paul, Minnesota.

This report is a part of a rule hearing proceeding held pursuant to Minn. Stat. §§ 14.131-14.20, to determine whether the Department of Human Services has fulfilled all relevant substantive and procedural requirements of law, to determine whether the proposed rules are needed and reasonable, to determine whether the Department has statutory authority to adopt the rules and to determine whether the rules, if modified, are substantially different from those originally proposed.

Members of the agency panel appearing at the hearing included Kathleen Cota, Chris Dobbe, and Larry Grewach, all of the Health Care Management Division; Stephanie L. Schwartz, Rules Division; and Kim Buechel Mesun, Special Assistant Attorney General.

Several persons attended the hearing, 26 of whom signed the registration sheet. The hearing continued until all interested persons had had an opportunity to make comments and ask questions regarding the proposed rules. The record closed on December 15, 1992, upon close of the written response period.

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 rules. The agency may then adopt final rules or modify or withdraw its proposed rules. If the Commissioner of Human Services makes changes in the rules other than those recommended in this report, she must submit the rules with the complete hearing record to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of final rules, the agency must submit them 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 September 23, 1992, the Department filed the following documents with the Chief Administrative Law Judge pursuant to Minn. Rule 1400.0300:

(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.
(g) A Fiscal Note.

2. On October 14, 1992, 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 and also to the eighty-seven Minnesota county human service agencies, the six members of the Advisory Committee and to eleven additional persons considered to be interested in the proposed rules. The Notice of Hearing was a "dual notice" which stated that the non-controversial procedure for adopting the rules without a hearing would be followed unless 25 or more people requested that a hearing be held.

3. On October 19, 1992, a Notice of Hearing and a copy of the proposed rules were published at 17 State Register 842.

4. On November 6, 1992, 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.
(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 15 State Register 311 on July 30, 1990, and a copy of the Notice.
(h) Copies of eight requests for public hearing that had been received to that point.

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

5. On November 19, 1992, the Department filed a letter with the Administrative Law Judge stating that seventy persons had requested a public hearing on the proposed rules to that point and that, therefore, a public hearing would be held as provided in the Notice. Copies of those requests were attached to the letter.

6. The period for submission of written comment and statements remained open through December 8, 1992; twenty-three comments were received during that period. One comment was received after that date and has not been considered, but it did not raise any issues that had not been raised previously. The period for submission of written responses remained open through December 15, 1992. The only response filed was by the Department. One document calling itself a response was really a comment and was filed after December 15, 1992. It did not raise any new issues.

Statutory Authority

7. The Department cites Minn. Stat. § 256B.04, subds. 2, 4, 12 and 15, as providing authority to adopt the proposed rules and rule amendments. Those subdivisions, respectively, require the Department to make uniform rules for carrying out and enforcing the provisions of the Medical Assistance program in an efficient, economical and impartial manner; require the Department to cooperate with the federal government as necessary to qualify for federal aid in connection with the Medical Assistance program; require the Department to place limits on the types of services covered by Medical Assistance, the frequency with which the same or similar services may be covered by Medical Assistance and the amount paid for each covered service; and require the Department to establish a utilization review program to safeguard against unnecessary or inappropriate use of Medical Assistance services, excess payments and the like. The Department has demonstrated its general statutory authority to adopt the proposed rules and amendments.

Small Business Considerations

8. Minn. Stat. § 14.115, requires agencies to consider the effect on small businesses when they adopt rules. In particular, Minn. Stat. § 14.115, subd. 2, states:

> When an agency proposes a new rule, or an amendment to an existing rule, which may affect small businesses as defined by this section, the agency shall consider each of the following methods for reducing the impact of the rule on small businesses:
>
> (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.

In its statement of need and reasonableness, the agency shall document how it has considered these methods and the results.

9. A large majority of the hearing aid services providers affected by the proposed rules are small businesses as defined by the statute. In its Statement of Need and Reasonableness (SONAR), the Department explained how it addressed each of the factors set forth in Minn. Stat. § 14.115, subd. 2. SONAR at 17-20. Moreover, although not required by the statute, the Department also discussed how it considered the impact the rules would have on the potential for increased competition among the small businesses involved in providing hearing aid services.

10. The Department has considered and incorporated the applicable specific methods for reducing the impact of its rule on small businesses as required by Minn. Stat. § 14.15, subd. 2.

Other Rulemaking Requirements

11. The adoption of the rules will not result in additional spending by local public bodies. The fiscal note prepared by the Department estimates a cost savings of approximately $3,864.00 to the state in each of the next two years. The estimated cost savings is based upon the estimated impact of the proposed Minn. Rule 9505.0287, which restricts the number of replacement hearing aids authorized within a five-year period.

Nature of the Proposed Rules and Amendments

12. The proposed rules and amendments deal with Medical Assistance payments for hearing services, more particularly, payment for hearing aids and associated services. The proposals create a separate rule dealing only with hearing aid services, remove hearing aid services from the old rule, allow audiologists and otolaryngologists to sell hearing aids, restrict the number of replacement hearing aids, deny payment to hearing aid dispensers for audiologic evaluations and make several other changes.

Substantive Provisions of the Proposed Rules

13. The portions of the proposed rules that were subject to comment or raise significant issues are discussed below. Any rule or rule subpart not discussed is found to be needed and reasonable and in compliance with all relevant substantive and procedural requirements of law or rule.

Minn. Rule 9505.0175, Subp. 32, Definition of Performance Agreement

14. A Performance Agreement is a written agreement between the Department and a provider of medical equipment or supplies. The existing rule contains a reference to a hearing aid performance agreement as an example of a Performance Agreement. The proposed amendment would delete this reference because the Department intends to no longer use Performance Agreements. Rather, hearing aid service providers will be required to sign Provider Agreements as all other Medical Assistance providers do. The amendment is needed and reasonable as proposed.

Minn. Rule 9505.0221, the "Affiliate Rule"

15. This existing rule prohibits Medical Assistance payment for equipment, supplies or services prescribed or ordered by a physician if they are provided by a person that provides a kickback to the physician or a person that is an affiliate of the physician. The effect of this rule has been to prohibit audiologists and otolaryngologists from selling hearing aids to Medical Assistance recipients even though audiologists and otolaryngologists typically have permits from the Commissioner of Health to act as sellers of hearing instruments and do sell hearing aids to persons other than Medical Assistance recipients. The Department proposes to amend the affiliate rule by creating an exception making it nonapplicable to the sale of hearing aids by audiologists and otolaryngologists allowed in Minn. Rule 9505.0287, the new rule on hearing services. In particular, Minn. Rule 9505.0287, subp. 1E defines a "hearing aid services provider" to include a hearing instrument dispenser or an audiologist or otolaryngologist who has a permit from the Commissioner of Health as a seller of hearing instruments. The change in policy to allow audiologists and otolaryngologists to be paid for selling hearing aids is a significant change and was the subject of most of the comments in this matter. Predictably, audiologists and otolaryngologists supported the change while hearing aid dispensers opposed it.

16. In its SONAR the Department set forth two reasons for the change in policy: 1) the change would make Medical Assistance payment for hearing aids more "efficient, economical and impartial" as required by Minn. Stat. § 256B.04, subd. 2, and 2) is necessary to comply with federal law and regulations. With regard to its first argument, the Department stated:

> Currently, a recipient may be forced to make up to three stops to obtain a hearing aid: first, receive an examination from a physician; second, receive a prescription from an audiologist or otolaryngologist; and third, obtain a hearing aid from a hearing aid services dispenser. In rural areas of the state, such a regiment can be quite taxing and time-consuming, if not impossible, for, particularly, the elderly recipients who make up the bulk of medical assistance recipients. By allowing audiologists and otolaryngologists to dispense hearing aids, the Department ensures that this rule administers the medical assistance program efficiently, economically, and impartially. In sum, item E best serves medical assistance recipients by providing better access to hearing aids and services.

SONAR at 6.

With regard to changes in federal law and regulations, the Department is referring to 1991 amendments to the Federal Fraud and Abuse Regulations found at 42 CFR pt. 1001. A new section, 42 CFR § 1001.952, was added in 1991 providing a list of activities and arrangements that would not be considered criminal activities under the law. Therefore, the Department is proposing a section in its new rule at Minn. Rule 9505.0287, subp. 10J that denies payments for hearing aids or services if there is a violation of the federal law, subject to the exceptions listed in 42 CFR § 1001.952. While the federal law and regulations allow the change in policy to allow audiologists and otolaryngologists to also sell hearing aids, they do not require it as the Department apparently argues. Nonetheless, the new federal regulation does provide some support for the change in policy because the federal law and regulations define conflicts of interest and fraud and abuse that may be considered criminal activity. Thus, any conflict of interest that may be created by audiologists and otolaryngologists selling hearing aids does not rise to that level and need not be prohibited.

17. The Department's post-hearing comments, Ex. 23, provide a good summary of the public comments on the affiliate rule and set forth the Department's response to those comments as follows:

> Part 9505.0221 is the "affiliate rule" and is discussed on pages 3, 6, and 15-16 of the SONAR. This part clarifies that except for hearing services, its content remains department policy. This is necessary because proposed part 9505.0287 updates the affiliate rule language as it relates to hearing services, allowing affiliates of hearing aid dispensers (audiologists and otolaryngologists) to provide audiologic evaluations and sell hearing aids.
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> The Department's desire, as is the desire of hearing aid dispensers, audiologists, and otolaryngologists, is to provide the best hearing aid services to MA recipients. Specifically, the Department wishes to provide MA recipients with appropriate hearing aids, with access to professionals who can perform audiologic evaluations, with access to professionals who can dispense hearing aids, and with the minimum amount of required travel, time, and cost. In sum, the Department's concern is promulgating rules that are in the best interests of its customers and delivering services in the most cost-effective method possible.
>
> The Department believes that, to the extent possible, treating MA recipients like private pay patients when receiving hearing services best serves MA recipients. Because federal regulations and state law allow such uniformity, the Department has proposed affiliate rule amendment.

COMMENT: The Minnesota Medical Association wrote that its membership indicated that the exception for hearing services "does not make a substantive change," and that proposed part 9505.0287 "does not appear to set forth any exceptions to" part 9505.0221.

RESPONSE: On the contrary, the change excepting proposed part 9505.0287 from the affiliate rule language of part 9505.0221 makes quite a substantive change and does set forth exceptions to part 9505.0221. As stated in the SONAR at page 3, proposed part 9505.0287 updates the affiliate rule language as it relates to hearing services, now allowing affiliates to provide audiologic evaluations and sell hearing aids. This is a substantive change from current policy.

Sifting through the testimony and written comments, the Department notes that there are two other main areas upon which minds differ.

A. Allowing audiologists and otolaryngologists to both evaluate hearing and dispense hearing aids

COMMENTS: Public testimony was divided on excepting hearing services from the affiliate rule. Dispensers clearly wish to leave part 9505.0221 intact. On the other side of the coin, audiologists and otolaryngologists agreed with the Department that part 9505.0221 should be amended to exclude hearing services, thereby allowing audiologists and otolaryngologists to sell hearing aids, as well as perform audiologic evaluations.

The following hearing aid dispensers testified that part 9595.0221 should be amended (i.e., that audiologists and otolaryngologists who evaluate hearing and prescribe hearing aids should not also be able to dispense hearing aids):

- James P. Neve, Jr., Beltone Hearing Aid Centers/President of the Minnesota Hearing Aid Society
- John Thompson, Hiawatha Valley Hearing
- Charles Stone, audiologist and registered dispenser
- Greg Wales, Wales Hearing Center
- Dave Nygren, hearing aid dispenser

The main arguments advanced for not amending part 9505.0221 are: 1) a number of hearing aid clinics (Mr.

Neve quoted a figure of 300-400) will be forced to close if MA recipients can receive audiologic evaluations and hearing aids in one setting ("One-stop shopping"); 2) the closing of hearing aid clinics will reduce access to hearing aid services for MA recipients and cause more transportation and time to be spent on finding clinics; 3) the affiliate rule avoids "inevitable conflicts of interest"; and 4) MA recipients' freedom of choice will be reduced.

James P. Neve, Jr. testified that the number of clinics may decrease due to competition from audiologists and otolaryngologists, requiring even more travel for MA recipients and increased time waiting for appointments with audiologists and otolaryngologists. Charles Stone, an audiologist and registered hearing aid dispenser, stated that transportation costs will rise.

On the other hand, the following audiologists, otolaryngologists, associations and clinics testified or wrote letters urging that the affiliate rule be amended:

- Minnesota Speech-Language-Hearing Association
- David Geddes, M.A. and Minnesota Otolaryngology
- Hennepin County Medical Center (Hennepin County Bureau of Health)
- Linda Murrans
- Michael Howitz, Northstar Audiology
- Gregory Oja, Bemidji Regional Hearing Center
- Minnesota Masonic Home Care Center

The main arguments advanced for amending part 9505.0221 are: 1) dispensers will not really lose that much business; 2) the current barriers to MA recipients to "one-stop shopping" will be reduced; 3) transportation costs and time will be reduced because the number of trips from the audiologist's/otolaryngologist's to the dispenser's and back again will be reduced; 4) hearing aid dispensers do not have the same education and training as audiologists and otolaryngologists, particularly in fitting hearing aids in children; 5) the proposed rule language does not stop hearing aid dispensers from their current practice of dispensing to MA recipients (and non-MA recipients); and 6) "one-stop shopping" avoids the current risk of a MA recipient not coming back to the audiologist's/otolaryngologist's office for a check-up once they receive a hearing aid.

Lynn Choban from Hennepin County testified that transportation costs will be lowered by at least 50% because recipients can receive audiologic evaluations and their hearing aids all at one time and place. Reducing the number of trips, she noted, will reduce the amount paid out by MA for transportation.

RESPONSE: As discussed on pages 3, 6, and 15-20 of the SONAR, the Department carefully considered the effects of amendment of the affiliate rule, including the effects on small business. It is the Department's position that there is no objective evidence for the argument that allowing audiologists and otolaryngologists to dispense hearing aids will result in additional transportation and time spent on receiving hearing aids. Hearing testimony was divided on this issue, with some commentors stating that as many as two additional trips to a hearing aid dispenser who is not affiliated with an audiologist or otolaryngologist who prescribed or ordered the hearing aid is currently necessary.

The Department believes that allowing audiologists and otolaryngologists to test hearing and dispense hearing aids will likely lead to "one-stop shopping" for some MA recipients, thereby reducing transportation and time for these MA recipients, and cost for the MA program.

For a current example of "one-stop shopping" in the MA program, see part 9505.0405, covering vision care services. In that part, MA recipients are not required to make additional trips to a dispenser to obtain eyeglasses. Just as with vision care services, and all other covered MA services, it is reasonable to allow hearing aid service MA recipients their choice of where to buy their hearing aids, as long as it is allowed by federal regulations and state law.

42 CFR 440.240 requires that MA services be available to recipients uniformly in amount, duration, and scope. Minnesota Statutes, §256B.04, subdivision 2 requires the Department to "[m]ake uniform rules, not inconsistent with law, for carrying out" the MA program . . . in an "impartial manner, and to the end that the medical assistance system may be administered uniformly throughout the state . . . ." (emphasis added). Certainly, allowing MA recipients their freedom to choose a hearing aid dispenser (by allowing audiologists and otolaryngologists to dispense) is administering the MA program uniformly.

Hearing aid dispensers also commented that the number of hearing aid clinics will be reduced due to increased competition from audiologists and otolaryngologists. See the discussion on pages 17-20 of the SONAR regarding

small business considerations. It is the Department's position that: 1) it is uncertain how many, if any, clinics will close; and 2) in the modern age of marketplace competition the absolutism of the affiliate rule reserves an entire marketplace for hearing aid dispensers and cannot be justified given the direction of federal regulations and Minnesota Statutes, §256B.04, subdivision 2.

Refer also to the December 1, 1992 letter of audiologist David A. Geddes, who states that in "certain circumstances where it serves the patient best we will fit the hearing aid ourselves (if this is what the patient desires), and in others again where it serves the patient best, we will refer the patient to a hearing aid dispenser."

On another related issue, contrary to the testimony of hearing aid dispensers, the Department has no evidence to indicate that access to hearing aid services will be reduced if audiologists and otolaryngologists are allowed to dispense hearing aids. Hearing aid dispensers produced no empirical evidence to support this claim. Statements from audiologists and otolaryngologists proffered that, in fact, access will be increased because more people will be allowed to dispense hearing aids.

Hearing Exhibit #15, a letter written by, presumably, MA hearing services recipients, illuminates the viewpoints of MA recipients rather than MA providers. Brian and Kelly Wright's children have had testing and impressions done for ear molds. The Wright's note that: 1) "having all records in one office would save time and trouble if any questions arise"; 2) there will be a "closer working relationship" between parents and audiologists; 3) having one professional test and prescribe while another dispenses "is time consuming and somewhat impersonal"; and 4) they feel comfortable knowing that all hearing services are performed by the same person.

For the reasons covered in the SONAR and the reasons recounted here, it is necessary and reasonable to amend the affiliate rule to allow audiologists and otolaryngologists to dispense hearing aids.

B. Audiologists: Available to nursing home residents and in rural Minnesota?

COMMENTS: A number of registered hearing aid dispensers testified that audiologists do not regularly visit nursing homes outside of the seven-county metro area, so that there is no benefit to MA recipients by opening up the class of hearing aid dispensers.

On the other hand, audiologists testified that audiologists do, and are willing, to travel to outstate Minnesota to perform audiologic evaluations. Audiologist David Geddes testified that audiologic evaluations are available in "small town Minnesota." Michael Howitz of Northstar Audiology testified that his group tests in nursing homes in the immediate 12 county area, an area where more than one-half of the state's population resides.

RESPONSE: There was no evidence produced at the hearing that elimination of the affiliate rule will reduce hearing aid services to nursing home residents and MA recipients in rural Minnesota. Although at least one hearing aid dispenser, James P. Neve, predicted that all such services to these groups will be curtailed as a result of the proposed rule language, this is only speculation.

It is more than equally plausible to theorize that eliminating the affiliate rule as it applies to hearing aid services will have the opposite, beneficial, effect: Namely, audiologists and otolaryngologists will have access to a market that MA rules have previously barred to them. In sum, the force of any loss of service by dispensers may be vitiated by audiologists and otolaryngologists entering the marketplace.

Because the only "proof" to show that audiologists and otolaryngologists do not visit nursing homes or rural Minnesota to adequately provide hearing aid services was speculation, the Department declines to change the proposed rule language for part 9505.0221.

18. The Department has satisfactorily demonstrated that its change in policy to allow audiologists and otolaryngologists to be paid for hearing aids they sell is needed and reasonable. No doubt, some hearing aid dispensers will lose some business while some audiologists and otolaryngologists will gain some business. But there is no basis at this time for the Department to continue the current policy of favoring the hearing aid dispensers over the audiologists and otolaryngologists. Clearly, Medical Assistance recipients will benefit from more choices and greater convenience. Whether some number of hearing aid dispensers will be driven out of business thereby reducing the options available to Medical Assistance recipients seems unlikely, or at best speculative. If the hearing aid dispensers offer competitive products and services and maintain their referrals from audiologists and otolaryngologists, they should be able to continue in business. If they do not, it can be expected that audiologists and otolaryngologists will expand into under-served areas. The Department's obligation is to obtain and pay for medical services for Medical Assistance recipients and not to guarantee business to any particular provider group. Its proposed change in the "affiliate rule" carries out that obligation.

Minn. Rule 9505.0287, Subp. 1 - Definitions

19. This subpart defines seven terms used within Minn. Rule 9505.0287: Audiologic evaluation, audiologists, hearing aid, hearing aid accessory, hearing aid services provider, hearing services and otolaryngologists. Except as discussed below, there were no comments on the proposed definitions and they are needed and reasonable as proposed.

20. The Administrative Law Judge would note that he experienced some confusion upon first reading the rule because of the use of the term "hearing services." "Hearing services" is defined by item F to mean the services provided by a hearing aid services provider that are necessary to dispense hearing aids and provide hearing aid accessories and repairs. The term "hearing services" seems more broad than that and could be expected to include other services such as audiological evaluations. While the definition is made clear by item F, it would be more clear if the term "hearing aid services" was used instead of "hearing services" throughout the rule. The Department may consider adoption of such an amendment, which would not be a substantial change.

21. As originally proposed, item E stated:

> E. "Hearing aid services provider" means a person who is registered with the commissioner of health as a hearing instrument dispenser or an audiologist or otolaryngologist who has a permit from the commissioner of health as a seller of hearing instruments. A hearing aid services provider who is not an audiologist or an otolaryngologist must not perform an audiologic evaluation.

22. Under Minn. Stat. Ch. 153A, it is unlawful to sell a hearing instrument without a permit from the Commissioner of Health. The permitting statute does not set any particular standards regarding the qualifications of a hearing instrument "seller," other than to specify certain prohibited acts involving such things as false, misleading and fraudulent practices. Minn. Stat. § 153A.15. In addition to issuing permits to sellers, the Department of Health has adopted rules for the registration of "hearing instrument dispensers." See Minn. Rule 4745.0010-.1160. These rules were adopted under the authority of the Commissioner of Health to adopt rules for the credentialing of health-related and human services occupations in Minn. Stat. § 214.13. Under the registration rules, only a person who is properly registered may use the title of hearing instrument, or aid, dispenser, specialist, consultant or dealer. The rules also establish an examination procedure requiring demonstration of knowledge and ability in specified areas relating to the sale of hearing instruments. Audiologists and otolaryngologists typically obtain permits to sell hearing instruments from the Department of Health but do not register as hearing instrument dispensers because they are licensed or credentialed by other agencies.

23. In a letter sent to the Department of Human Services on November 30, 1992, the day before the hearing in this matter, the Commissioner of Health submitted a comment regarding the proposed rules. The Department of Health expressed its concern that limiting the providers to registered hearing

instrument dispensers, audiologists and otolaryngologists would restrict consumer access to hearing services and requested that the rule be amended to define hearing aid service provider as any "seller" of hearing instruments. The letter went on to inform the Department of Human Services that the Department of Health had been discussing the possibility of discontinuing the registration process because of the fact that the system had been accumulating annual deficits of almost $81,000 at the end of fiscal year 1992. Because state law requires registration fees to cover the cost of registration and because the Department believes that raising the fees would discourage most sellers from registering, they are exploring other alternatives. The letter went on to state that until the future of the registration system is determined, it does not make sense for the Department of Health to issue new registrations. The letter then reiterated the request of the Department of Health that the proposed rules be amended so as to allow any hearing instrument seller with a valid permit to provide such services. Ex. 1. The news that the Department of Health was considering discontinuing the registration of dispensers was a surprise to everyone involved in the hearing, especially the registered hearing aid dispensers. It is generally their feeling that the registration process establishes minimum standards of competence and lends credibility to their profession and they desire to see some form of registration continue.

24. In response to the possibility that the registration system will be discontinued, the Department of Human Services, in its post-hearing comments, has proposed to amend the proposed rule to read as follows:

> E. "Hearing aid services provider" means a person ~~who is registered with the commissioner of health as a hearing instrument dispenser or an audiologist or otolaryngologist~~ who has a permit from the commissioner of health as a seller of hearing instruments and, when applicable, meets the specific state licensure and registration requirements of the commissioner of health for the hearing aid services the person provides. A hearing aid services provider who is not an audiologist or otolaryngologist must not perform an audiologic evaluation.

25. On November 30, 1992, the Director of the Health Occupations Program of the Department of Health had also written to David Nygren, a hearing aid specialist who testified at the hearing, regarding the possibility of discontinuing the registration system. In that letter he pointed out that as of that date only 70 persons had registered of the 427 persons who held permits as sellers. Ex. 22. On December 2, 1992, the Director of the Health Occupations Program wrote to Mr. Nygren, Susan Ladwig and James Neve, both of whom also testified on behalf of hearing aid dispensers at the hearing, setting up a meeting to discuss the future of the registration system. Ex. 21. On December 9, 1992, the Department of Human Services contacted the Director of the Health Occupations Program regarding its revision to the definition of hearing aid services provider and was informed by him that the revision addressed the Department of Health's concerns and would be acceptable. Ex. 26 at 3.

26. The last sentence of item E prohibits a hearing aid services provider who is not an audiologist of otolaryngologist from performing an audiologic evaluation. Item A, the definition of audiologic evaluation, contains the same restriction and it also appears in Subpart 2. Many hearing aid dispensers feel that they are qualified by training or experienced to perform audiologic evaluations in connection with the sale of hearing aids. In fact, nothing in the law prevents them from doing so and they do make such examinations of patients who are not Medical Assistance recipients. The only restriction is that the Federal Drug Administration recommends that audiologic evaluations be done by audiologists or otolaryngologists and requires that hearing aid dispensers obtain signed waivers from patients before providing audiologic evaluations. The dispensers believe that their competence to perform audiologic evaluations is demonstrated by a registration system that requires such aptitude and conducts an examination to demonstrate it.

27. In its SONAR, the Department justified its refusal to pay for audiologic evaluations performed by dispensers on three bases. First, only audiologists and otolaryngologists have the education and training to perform such evaluations. Otolaryngologists are physicians specializing in diseases of the ear and larynx who are board eligible or board certified by the American Board of Otolaryngology and audiologists are persons with Masters degrees who hold a current Certificate of Clinical Competency in Audiology from the American Speech-Language-Hearing Association. Dispensers do not, necessarily, have such training. Second, audiologic evaluation procedure codes, used to receive Medical Assistance payments, are published by the American Medical Association and are therefore intended to be used only by audiologists and otolaryngologists and their designees. Third, only audiologists and otolaryngologists typically have the controlled environments necessary for proper audiologic evaluations. SONAR at 5. In its post-hearing comments, Ex. 23, noted that with the possible discontinuation of registration process for dispensers, and the revision of item E as discussed above, only the permitting system will remain and there will be no comparison at all between the credentials of audiologists and otolaryngologists and permitted hearing aid sellers.

28. The Department has demonstrated that item E, as modified in its post-hearing comments, is necessary and reasonable. This is not a black and white issue and the Department could have decided otherwise. Some dispensers may be competent to perform audiologic evaluations, but it is clear that all audiologists and otolaryngologists are competent to do so and have better training. The Department's position is not unreasonable. The modification proposed by the Department does not constitute a substantial change from the rule as originally proposed.

29. Item G defines otolaryngologist as a physician specializing in diseases of the ear and larynx who is board certified by the American Board of Otolaryngology. In response from a comment from the Minnesota Medical Association, DHS Prehearing Doc. No. 1, the Department proposes to modify the rule to include such a physician "who is board eligible or board certified . . ." The Minnesota Medical Association points out, and the Department agrees, that there are otolaryngologists practicing who have never taken the boards and yet are board eligible. As the Minnesota Medical Association points out, the existing rule would also have precluded a physician who completed his or her specialty training and starts practicing from ordering a hearing aid until

almost a year later when the boards had been completed successfully. The proposed rule as modified by the Department is necessary and reasonable. The modification is not a substantial change.

Minn. Rule 9505.0287, Subp. 2, Covered Hearing Services

30. This rule requires that hearing services must meet five requirements in order to be paid: 1) a physician's examination determines that the recipient does not have any conditions that contraindicate a hearing aid; 2) the physician refers the recipient for an audiological evaluation to determine if there is a communication disorder caused by a hearing loss and if a hearing aid is medically necessary; 3) the audiologist or otolaryngologist who conducts the audiologic evaluation orders a specific hearing aid based on the findings of the audiologic evaluation; 4) the hearing aid services provider provides the hearing aid recommended by the audiologist or otolaryngologist and 5) the audiologist or otolaryngologist determines the effectiveness of the hearing aid within 30 days or within the time period specified in a contract obtained through the competitive bidding process specified elsewhere (which is currently 90 days and applies to about 95 percent of the hearing aids dispensed in Minnesota.)

31. The proposed rule generally reflects current practice and is necessary and reasonable so that affected parties know what requirements must be met.

32. In its November 13, 1992, comments to the Department, DHS Prehearing Doc. No. 1., the Minnesota Medical Association points out that individuals often fail to return for the purpose of assessing the effectiveness of a hearing aid and, thus, it would be very difficult to satisfy the requirement that the audiologist or otolaryngologist determine the effectiveness within 30 days or within a time period specified by the contract. Again, the Department agreed with the Minnesota Medical Association's concern and, in its post-hearing comments, Ex. 23, proposed to modify the proposed rule as follows:

> E. The audiologist or otolaryngologist must inform the recipient of the need to schedule a follow-up visit and must request that the recipient schedule a follow-up visit to determine the effectiveness of the hearing aid within 30 days of providing the aid or within the time period specified in the contract obtained through the competitive bidding process under part 9505.0200, whichever is longer.

The Department has demonstrated that this rule, as modified, is necessary and reasonable and is not a substantial change from the rule as originally proposed.

Minn. Rule 9505.0287, Subp. 3 - Eligibility for Replacement Hearing Aid

33. This rule prohibits a Medical Assistance recipient from receiving a replacement hearing aid within five years unless prior authorization is obtained. The criteria for prior authorization specified in the rule are that

the present hearing aid is no longer effective because the recipient has had an increase in hearing loss or the hearing aid has been misplaced, stolen or damaged due to circumstances beyond the recipient's control so that it cannot be repaired. The rule goes on to provide that the recipient's degree of physical and mental impairment must be considered in determining whether the circumstances were beyond the recipient's control and in any event, if the hearing aid was misplaced, stolen or irreparably damaged more than two times in a five-year period, the recipient cannot receive a replacement hearing aid.

34. In its SONAR, the Department stated that the limit on the number of replacement hearing aids is necessary to control Medical Assistance expenditures and that even if the recipient has some physical and mental impairment, an alternative other than replacement should be pursued if the hearing aid is misplaced, stolen or damaged more than twice in five years. A study by the Department, Ex. 2, shows that of a total of 10,453 people who received hearing aids in a five-year period, 123 (1.2 percent) required three hearing aids, 22 (0.2 percent) required four hearing aids and 1 (a very small percent) required five hearing aids. Thus, 23 (0.2 percent) required four or more hearing aids and probably would have been affected by the new rule.

35. It was pointed out by testimony at the hearing that such hearing aids might be replaced under the required 24 month warranty. In its post-hearing comments, the Department states that if one hearing aid is replaced under the 24 month warranty, it is conceivable that a recipient could receive <u>six</u> hearing aids in a five-year period. The Administrative Law Judge does not understand that interpretation; in the absence of a warranty replacement a first hearing aid could be purchased, then damaged; a second hearing aid could be purchased, then damaged; and a third hearing aid could be purchased. But when the third one was damaged, a fourth one could not be purchased. Warranty coverage might pay for a fourth hearing aid.

36. The principal objection to this rule was from those who provide residential services to developmentally-disabled people. For example, RESA, Inc., operates a group home certified as an intermediate care facility for the mentally retarded and has three people ranging in age from 54 to 69 who use hearing aids. Even though the staff supervises the cleaning and insertion of the hearing aids, the residents have to adjust and manipulate the hearing aids when staff are not around and because of their more limited physical coordination, they drop or damage the hearing aids more frequently than other persons would. Ex. 7. In her post-hearing comments, Jean Searles, the Director of RESA, Inc. suggested that a provision be added to the rule as follows:

> Exceptions will be made for persons with physical or mental disabilities when an interdisciplinary team, (including the physician, audiologist, guardian, care-giving staff) and the DHS Developmentally Disabilities Division supply documentation to the effect that lack of a hearing aid will result in unusual hardship for the individual, or the resultant behavior from auditory sensory deprivation puts the individual or his/her environment at risk. Present practice to avoid future loss, breakage, to the extent possible, will be documented.

Ex. 17. Ms. Searles goes on to point out that under Minn. Rule 9525.2730, subp. 2E, which is a part of the rules dealing with the use of aversive and deprivation procedures in licensed facilities serving persons with mental retardation, totally or partially restricting a person's senses is prohibited. To her, "it doesn't seem right that the state of Minnesota should be able to do this either."

37. In its post-hearing comments, Ex. 23, the Department points out that it is required by law to place appropriate limits on services based on criteria such as medical necessity or on utilization control procedures. It also points to court decisions that interpret 42 CFR § 440.230(d), which requires each service to be sufficient in amount, duration and scope to reasonably achieve its purpose. The cases cited by the Department have upheld Medical Assistance programs that meet the needs of a substantial majority of the individuals requiring a particular service. As found above and as emphasized by the Department, its proposed rule would have paid for all the hearing aids required by all but 0.2 percent of the recipients who needed them and, even in those cases, it would have paid for three out of the four, or in one case five, hearing aids required. If the warranty applies, even that number is dramatically reduced. It cannot be said that such a rule is unreasonable.

38. The Department has demonstrated that this rule is necessary and reasonable.

Minn. Rule 9505.0287, Subp. 7 - Hearing Services to Resident of Long-Term Care Facility

39. This subpart adds a requirement that for a resident of long-term care facility, that resident's hearing services must result from a request by the recipient, a referral by a nurse employed by the facility or a referral by the recipient's family, guardian or attending physician. Ms. Searles recommended that "consulting nurse" be added to the list of those who may refer the recipient for hearing aid services in order to clarify that nurses under contract with long-term care facilities are also employees for purposes of the rule. In its post-hearing comments, Ex. 23, the Department points out that the definition of "employee" which appears at Minn. Rule 9505.0175, subp. 12, applies to this rule here and includes both regular employees and a person who is a self-employed vendor who has a contract with a provider to provide health services. While the existing definition probably satisfies Ms. Searles' concern, the Department desires to make it clear that a consulting nurse may also make referrals and proposes to modify the rule as follows:

> Subp. 7. **Hearing services to resident of long-term care facility.** For a resident of a long-term care facility to be eligible for medical assistance payment, the resident's hearing services must result from:
>
> A. a request by the recipient~~,~~;
>
> B. a referral by a registered nurse, ~~or~~ licensed practical nurse, or consulting nurse who is employed

by the long-term care facility~~;~~ or

C. a referral by the recipient's family, guardian, or attending physician. . . .

The modification does clarify the rule and does not constitute a substantial change. The rule is necessary and reasonable as modified.

Minn. Rule 9505.0287, subp. 10, Hearing Services Not Covered

40. This subpart lists ten circumstances under which Medical Assistance payments will not be made for hearing aids. Item G prohibits payments for hearing aid drying kits, battery chargers, swim molds or adaptors for telephones, television or radio.

41. In a prehearing comment to the Department, Jeffrey C. Reynolds, M.D., of the Fargo Clinic, stated that he was informed that Medical Assistance no longer covered earplugs in children with transtympanic middle ear ventilation tubes. He recommended that Medical Assistance pay for earplugs for such children because if water gets in the ear, infection will result, leading to increased expenses for systemic antibiotics and antibiotic eardrops that would more than outweigh the $40.00 cost of a set of earplugs. DHS Prehearing Doc. No. 1. In its post-hearing comments, Ex. 23, the Department responded that such earplugs are the same as swim molds which have never been covered by Medical Assistance. Since the rule is just restating existing policy and because the Department feels swim molds are not medically indicated over earplugs, the Department declined to now include them as a Medical Assistance covered service.

42. The Department has demonstrated that the rule is necessary and reasonable as proposed.

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

CONCLUSIONS

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

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

3. 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. 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. The additions and amendments to the proposed rules that were suggested by the Department after publication of the proposed rules in the

State Register and those modifications suggested by the Administrative Law Judge in this Report do not result in rules that 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. A finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department 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 14th day of January, 1993.

STEVE M. MIHALCHICK
Administrative Law Judge