

IN THE MATTER OF THE PROPOSED
ADOPTION OF DEPARTMENT OF HUMAN
SERVICES RULES AND AMENDMENTS TO
RULES GOVERNING HEARING SERVICES,
MINNESOTA RULES, PARTS 9505.0175,
9505.0221, 9505.0287 AND 9505.0365.

MINNESOTA DEPARTMENT
OF HUMAN SERVICES

STATEMENT OF NEED
AND REASONABLENESS

INTRODUCTION

The above-entitled proposed rules and rule amendments are authorized by Minnesota Statutes, §256B.04, subdivisions 2 (requires the Department to "[m]ake uniform rules, not inconsistent with law, for carrying out" the state medical assistance program "in an efficient, economical, and impartial manner"); 4 (requires the Department to cooperate with the federal government in order to qualify for federal aid in connection with the medical assistance program); 12 (requires the Department to "[p]lace limits on the types of services covered by medical assistance" and the "frequency with which the same or similar services may be covered by medical assistance for an individual recipient"); and 15 (requires the Department to safeguard against the unnecessary and inappropriate use of medical assistance services).

Minnesota Rules, parts 9505.0170 to 9505.0475 govern the administration of the medical assistance program, establish the services and providers that are eligible to receive medical assistance payments, and establish the conditions a provider must meet to receive payment. The Minnesota medical assistance program is the joint federal-state program that implements the provisions of Title XIX of the Social Security Act by providing for the medical needs of low income or disabled persons and families of dependent children. Title 42, section 431.10 of the Code of Federal Regulations (42 CFR 431.10) requires each state to designate a state agency to supervise the administration of its medical assistance program: the Department of Human Services is Minnesota's designated agency. See Minnesota Statutes, §256B.04, subdivision 1.

Additionally, 42 CFR 431.10(b)(2)(ii) requires the Department to make rules and regulations that it will follow in administering the state's medical assistance plan, the comprehensive written commitment of the Department to administer and supervise the medical assistance program according to federal requirements. 42 CFR 440.230(d) states that the Department "may place appropriate limits on a service based on such criteria as medical necessity or utilization control procedures." Thus, authority for these proposed rules and rule amendments are found in state and federal law and regulations.

The Legislative Commission to
Review Administrative Rules

OCT 15 1992



HISTORY

Parts 9505.0170 to 9505.0475 govern the administration of the medical assistance program, establish the services and providers that are eligible to receive medical assistance payments, and establish the conditions a provider must meet to receive payment. Parts 9505.0235 to 9505.0420 set forth the specific health services that are eligible for payment under the medical assistance program. Hearing services (proposed part 9505.0287) is one such service.

Prior to 1973, sellers (providers) of hearing instruments were not specifically regulated in the state. In 1973, state law was passed prohibiting sellers of hearing instruments from prescribing hearing instruments.

In 1978, the Department adopted rules governing covered medical assistance services and provider eligibility. Minor amendments were made the next year. In 1987, the Department promulgated new parts 9505.0170 to 9505.0420 to replace the then-current rules relating to covered services. Part 9505.0365, governing prosthetic and orthotic devices, and hearing services, was one of these new rule parts.

Proposed new part 9505.0287 is necessary in order to place in Minnesota Rules, chapter 9505 an updated rule relating to hearing services, a rule which for the first time allows select audiologic services providers to sell hearing instruments. It is reasonable to split the current rule (part 9505.0365) governing hearing services and prosthetic and orthotic devices in order to make chapter 9505 easier to read.

The amendments to parts 9505.0175 and 9505.0221 are necessary to update these parts, and amendments to part 9505.0365 are necessary to update the part and because sections of its content are now found in new part 9505.0287.

On July 30, 1990 at 15 *State Register* 311, the Department published a Notice of Solicitation of Outside Information or Opinions. On October 2, 1990 an Advisory Committee composed of representatives from the Minnesota State Academy for the Deaf, Associated Hearing Instruments, the Minnesota Speech-Language-Hearing Association, and the Departments of Health and Human Services met to discuss the proposed draft. The language of the proposed rule and rule amendments reflects input received from the committee.

SPECIFIC RULE PROVISIONS

The above-entitled rules are affirmatively presented by the Department in the following narrative in accordance with the provisions of the Minnesota Administrative Procedure Act, Minnesota Statutes, chapter 14 and the rules of the Attorney General's Office.

9505.0175 DEFINITIONS.

Subpart 32. Performance agreement.

It is necessary to amend this subpart because hearing aid performance agreements will no longer be used by the Department and reasonable because proposed part 9505.0287 incorporates the provisions of the outdated performance agreements. In the future, hearing aid services providers will sign the same provider agreements as all other medical assistance providers, allowing the Department to use only one form.

9505.0221 PAYMENT LIMITATION; PARTIES AFFILIATED WITH A PROVIDER.

Part 9505.0221 states that a physician who prescribes or orders equipment, supplies, or services will not receive medical assistance reimbursement if the equipment, supplies, or services are supplied by someone or an entity providing payment to the physician, or upon or as a result of direct referral by the physician to an "affiliate." However, proposed part 9505.0287 updates the medical assistance affiliate language as it relates to hearing services, allowing affiliates (audiologists and otolaryngologists) to provide audiologic evaluations and sell hearing aids. See proposed part 9505.0287, subpart 10, item J.

Therefore, it is necessary to amend part 9505.0221 to clarify that its language is correct except as allowed in part 9505.0287. It is reasonable to update this rule so that this part of the medical assistance rule is consistent with the new language of proposed part 9505.0287.

9505.0287 HEARING SERVICES.

Subpart 1. Definitions.

Item A. Minnesota Statutes, chapter 153A governs hearing instrument dispensing. The Department of Health regulates hearing instrument dispensing. Minnesota Statutes, §153A.13, subdivision 4 provides that "hearing instrument selling" means "fitting and selling hearing instruments, assisting the consumer

in instrument selection, selling hearing instruments at retail, or testing human hearing in connection with these activities." (emphasis added).

In the context of this medical assistance rule, the query is what is meant by "testing human hearing in connection with these activities" (in this rule, called "audiologic evaluations") and who may receive medical assistance payment for audiological testing and evaluations. It is helpful to look to legislative history. In 1989, the legislature amended Minnesota Statutes, §153A.13, subdivision 4, to read:

Subd. 4. **Hearing instrument selling.** "Hearing instrument selling" means fitting and selling hearing instruments, assisting the consumer in instrument selection, selling hearing instruments at retail, and or testing human hearing in connection with these activities.

The clear implication is that either a seller may fit and sell hearing instruments, or test hearing. Certainly, given this choice of alternatives, it is not good business practice for a hearing aid services seller to only test hearing, but it is good business practice to fit and sell hearing instruments. In the business world, this is just what happens.

Therefore, a distinction is made in proposed part 9505.0287, item E, below, between hearing aid services providers (sellers) who are not audiologists or otolaryngologists, and audiologists and otolaryngologists; only audiologists and otolaryngologists may perform audiologic evaluations. Accordingly, it is necessary to define in item A what is meant by "audiologic evaluation," and reasonable to provide affected persons notice that although someone who sells hearing instruments may "test" as the term is used in Minnesota Statutes, chapter 153A, not every hearing aid services provider may perform an audiologic evaluation pursuant to the state's medical assistance program.

Item B. The term "audiologist" is taken from the definition in part 9505.0390, subpart 1, item A, which in turn is based on 42 CFR 440.110(c). It is necessary to define this term, as it is used throughout part 9505.0287, and it is reasonable to use an already existing definition.

Item C. This definition of "hearing aid" is based on the definition in current part 9505.0365, subpart 1, item C. It is necessary to define this term as it is used throughout this part, and reasonable to use an already existing definition. The definition is also an expanded version of Minnesota Statutes, §153A.13, subdivision 3, which defines "hearing instrument," but that definition is more narrow than the meaning of "hearing aid," and so has not been used verbatim.

Item D. It is necessary to define "hearing aid accessory" because these accessories are mentioned in subpart 8 as covered hearing services. It is reasonable to provide affected persons a definition, as there are many items that the Department gathers together in its working definition of "hearing aid accessory."

Item E. It is necessary to define "hearing aid services provider" to clarify who may receive medical assistance payment for providing hearing instruments to medical assistance recipients. This definition is an expanded version of current part 9505.0365, subpart 1, item D.

Minnesota Statutes, §153A.13, subdivision 4 defines "hearing instrument selling" (see the discussion in item A, above), and Minnesota Statutes, §153A.13, subdivision 5 defines a "seller of hearing instruments." It is reasonable to use the content of this statute to define what is meant by "hearing aid services provider."

Minnesota Statutes, §153A.13, subdivision 5 states that a seller is someone, whether or not registered or licensed, who sells hearing instruments. Item E expands upon this, stating that a hearing aid services provider is either someone (not an audiologist or an otolaryngologist) registered with the Health Department, or an audiologist or otolaryngologist. Audiologists and otolaryngologists have permits from the Health Department to dispense hearing instruments. This makes sense, because someone who is a physician and certified by the American Board of Otolaryngology, or someone who has a masters degree and holds a current certificate of clinical competence in audiology (meaning they are nationally certified in audiology by the American Speech-Language-Hearing Association) should not have to take a test and become registered, whereas it is common sense public policy to require someone who has substantially less or no training to pass a qualifying test and receive registration before being allowed to provide hearing aids.

It is necessary to state that a registered hearing aid services provider must not perform audiologic evaluations for three reasons. First, only audiologists and otolaryngologists have the education and training to perform such evaluations. Second, audiologic evaluation procedure codes, used to receive medical assistance payment, are published by the American Medical Association, and are therefore intended to be used only by audiologists and otolaryngologists (and their designees). Lastly, only audiologists and otolaryngologists have the controlled (sound-proof) environments necessary for proper audiologic evaluations. Registered hearing aid services providers who dispense hearing aids in stores, in long-term care facilities or in homes do not have the proper environment in which to perform audiologic evaluations.

If only audiologists and otolaryngologists may perform audiologic evaluations, then it is reasonable that only these persons may receive medical assistance payment for such evaluations. Again, this is necessary because these persons have the appropriate educational and professional qualifications.

While it is true that item E allows audiologists and otolaryngologists to now dispense hearing aids, prompting competition for registered hearing aid services providers who, up to now, have been the sole dispensers of hearing aids, it is necessary to allow new dispensers of hearing aids in order to follow the federal law and regulations discussed for the "affiliate rule" on pages 15 - 16 and in order to comply with Minnesota Statutes, §256B.04, subdivision 2, which requires the Department to make rules to carry out the medical assistance program "in an efficient, economical, and impartial manner." 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 regimen 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.

Item F. It is necessary to define "hearing services" as the term is used throughout the rule, and reasonable to use already existing definitions of "health services" in parts 9505.5005, subpart 8 and 9505.0175, subpart 14.

Item G. It is necessary to define "otolaryngologist" as the term is used in this subpart, and reasonable because it is based on the definition found in *Stedman's Medical Dictionary*, 25th Edition (1990). An otolaryngologist is a physician who specializes in diseases of the ear and larynx and is certified by the American Board of Otolaryngology.

Subpart 2. Covered hearing services.

This subpart is necessary so that affected parties know what requirements hearing services must meet in order to be eligible for medical assistance payment, and it describes the present medical assistance process.

Item A. This item is reasonable as it is taken from current part 9505.0365, subpart 4; that subpart provides that a

"hearing aid must be ordered by a physician" This implies that it is necessary that there first be an examination determining that the recipient does not have medical or surgical conditions that would prohibit fitting the recipient with a hearing aid.

Item B. Likewise, this item is found in current part 9505.0365, subpart 4, which states that a hearing aid is ordered by a physician "in consultation with an audiologist."

Item C. It is reasonable to allow the audiologist or otolaryngologist, the persons with specific expertise and training, to order the hearing aid they deem best for the recipient in order to provide sufficient services. Furthermore, audiologists' and otolaryngologists' correct prescriptions comply with Minnesota Statutes, §256B.04, subdivision 2, which requires the Department to make rules to carry out the medical assistance program efficiently; it makes sense to have audiologists and otolaryngologists prescribe (and dispense) hearing aids based on their own audiologic evaluations.

It is reasonable to give discretion to the audiologist or otolaryngologist in prescribing hearing aids, as they are trained professionals. See the discussion for subpart 1, item E on page 5.

Item D. This item is necessary to clarify that the audiologist's or otolaryngologist's prescription must be followed by a hearing aid services provider. This language is reasonable in order to bring the rule up to date with current practice: Hearing aid services providers follow audiologists' and otolaryngologists' prescriptions.

Item E. This item is necessary because a hearing aid should be checked for effectiveness to provide the best service for the recipient. It does not make sense to pay for a hearing aid that does not improve a recipient's hearing.

The period in which an audiologist must determine a hearing aid's effectiveness is either: 1) within 30 days of providing the hearing aid; or 2) within the time specified in the contract obtained through the medical assistance competitive bidding process of part 9505.0200, whichever is longer. The time specified in the contract obtained through the competitive bidding process is currently 90 days.

Approximately 95% of the hearing aids dispensed in Minnesota are obtained through the competitive bidding process; therefore, only about 5% will come within the shorter 30 day time period. These time periods are reasonable because: 1) 30 days is the standard in the industry (within a month, if there is a problem

with a hearing aid, it should be apparent); and 2) the Rule Advisory Committee approved this time period.

Subpart 3. Eligibility for replacement hearing aid.

Subpart 3 provides that a recipient cannot receive a replacement hearing aid through the medical assistance program within five years after receiving the hearing aid unless prior authorization is obtained from the commissioner. This language is simply a restatement of current part 9505.0365, subpart 4, item A. In general, this subpart complies with 42 CFR 440.230(d) (the Department "may place appropriate limits on a service based on . . . medical necessity . . .") and Minnesota Statutes, §§256B.04, subdivision 12 (requires the Department to place limits on the "frequency with which . . . services may be covered by medical assistance") and 256B.0625, subdivision 25 (authorizes the commissioner to decide whether prior authorization is required for a health service).

The subpart then continues by listing two criteria for prior authorization.

Item A. It makes sense that if a recipient's hearing aid is not working because of the recipient's increased hearing loss, then a replacement hearing aid should be made available.

Item B. It also makes sense to allow prior authorization when "due to circumstances beyond the recipient's control," a recipient's hearing aid has been misplaced, stolen or damaged so that it cannot be repaired. However, it is practical to consider the recipient's degree of "physical and mental impairment" when determining if the circumstances were truly beyond a recipient's control; if not, then the recipient receives nothing, due to the recipient's neglect. The language of this item is similar to that found in part 9505.0270, subpart 4, covering medical assistance payment for dental services.

Pursuant to Minnesota Statutes, §256B.04, subdivision 12, a limit on the number of replacement hearing aids is necessary to control medical assistance expenditures. Even if the recipient has some physical or mental impairment, an alternative remedy (rather than replacement) should be pursued if the hearing aid was misplaced, stolen or damaged more than twice in five years. That is why prior authorization is needed.

The "two times in a five-year period" limit was the recommendation of the consultants on the Advisory Committee. They agreed that if a recipient goes through more than three hearing aids in five years, alternative remedies should be used. This is reasonable, because data studied by the Department shows that of a total of 10,435 people who received hearing aids in a five year period, 9,303 (approximately 90%) needed only one

hearing aid, 1,004 (approximately 10%) needed one replacement hearing aid, 128 (approximately 1%) needed two replacement hearing aids, and only 20 (.2%) adults received three or more replacement hearing aids.

For this insignificant percentage of adults who went through more than three hearing aids in a five-year period, examples of alternative remedies are:

- ▶ an amplifier for television/telephone
- ▶ assistive listening device (larger than a hearing aid and worn in the pocket)

These alternative remedies are reasonable because they are cheaper and sturdier than hearing aids, and they are much less likely to be lost or broken.

Subpart 4. Condition for payment; availability of hearing aid through contract purchase.

This subpart requires that when the Department has sought vendors of hearing aids through the Department's competitive bidding process (part 9505.0200), medical assistance will pay for a recipient's hearing aid from a vendor designated through the bidding process.

Procuring hearing aids through the competitive bidding process is necessary in order to run the state's medical assistance program efficiently and economically. This reasonable business practice complies with Minnesota Statutes, §256B.04, subdivision 2, which requires the Department to carry out the medical assistance program "in an efficient, economical, and impartial manner."

If there are no hearing aids available through the competitive bidding process that are "consistent with the results of the audiologic evaluation," hearing aids are provided to recipients by a review through the prior authorization process.

Subpart 5. Hearing aid services provider payment.

Subpart 5 specifies the types of services for which a hearing aid services provider will be paid during the warranty period. It is necessary to specify these services to ensure that recipients can properly use their hearing aids when they are dispensed, and ensure that recipients know that defective hearing aids can be returned to the manufacturer for repair. Providing an initial supply of batteries, instructions and counseling on use and care of the hearing aid, a copy of the manufacturer's warranty, and returning (if necessary) the

hearing aid to the manufacturer are all necessary for best operation and use of a hearing aid.

These services are reasonable as they are typically provided by hearing aid services providers when new hearing aids are dispensed.

It is reasonable to require that the hearing aid services provider wait until the hearing aid is dispensed before requesting payment in order that the state pay only for services rendered, thereby administering the state's medical assistance program "in an efficient, economical . . . manner." Minnesota Statutes, §256B.04, subdivision 2.

Subpart 6. Replacement batteries.

This language is necessary and reasonable because it restates (and clarifies) current part 9505.0365, subpart 4, item D. Furthermore, it complies with Minnesota Statutes, §256B.04, subdivision 2, which requires the Department to carry out the medical assistance program economically. Certainly, it is economical if only that number of replacement batteries necessary to operate a hearing aid is paid for by medical assistance.

Medical assistance payment is available for no more than 90 days to pay for replacement batteries. This three month time limit is reasonable because medical assistance eligibility is determined on a month by month basis -- stockpiling batteries is therefore unacceptable. Further, the Department's Surveillance and Utilization Review program staff recommended the 90 day limit, as three months is the standard time limit for all nondurable supplies.

Subpart 7. Hearing services to resident of long-term care facility.

This subpart states that for a resident of a long-term care facility to be eligible for medical assistance hearing services, the resident must receive hearing services if: 1) the resident asked for hearing services; 2) the resident was referred by a registered nurse or licensed practical nurse employed by the long-term care facility; or 3) the resident was referred by his or her family, guardian, or attending physician.

Current part 9505.0175, subpart 23 defines "long-term care facility" as a residential facility certified by the Department of Health as a skilled nursing facility or an intermediate care facility for the mentally retarded. The United States Department of Health and Human Services' final regulations regarding Medicare and Medicaid requirements for long-term care facilities found at 54 *Federal Register* 5316 (February 2, 1989)

require that skilled nursing facilities participating in the Medicaid (medical assistance) program "will be known as nursing facilities"; therefore, it is necessary to use the federal terminology in this subpart's definition of long-term care facility.

This subpart's language is taken directly from part 9505.0350, subpart 4 (requires a limitation on medical assistance payment for podiatry services for residents of long-term care facilities), as well as picking up the substance of current part 9505.0365, subpart 4, item E (medical assistance payment is available for the service to "test, prescribe, or fit a hearing aid for a resident of a long-term care facility when need for the hearing aid is established in the resident's plan of care.").

This subpart is included to speak to the practice of some hearing aid services providers who visit residents of long-term care facilities in order to drum up business, whether or not the business is necessary and appropriate. Therefore, language complying with Minnesota Statutes, §245B.04, subdivision 15 (requires the Department to safeguard against unnecessary or inappropriate use of medical assistance services) is necessary to ensure that hearing services to residents of long-term care facilities are medically necessary and appropriate. This language, taken from the rule parts noted above, is reasonable because the attending physician and nursing staff are knowledgeable of the necessary conditions, and the resident, and his or her family or guardian, is responsible for requesting hearing services.

Subpart 8. Other covered hearing services.

Other hearing services for which medical assistance will pay are ear molds (with limitations) and hearing aid accessories.

Item A. It is necessary that medical assistance pays for ear molds because they are essential in the use of hearing aids. It is reasonable to pay for ear molds separately, but only when they are not included as part of the hearing aid.

Item B. Hearing aid accessories are defined in part 9505.0287, subpart 1, item D. It is necessary that medical assistance pays for hearing aid accessories because, like ear molds, they are required to properly use hearing aids. It is reasonable to reimburse hearing aid services providers separately for these items to ensure that hearing aids are used efficiently, and because these are devices customarily used by hearing aid recipients.

These are the only two other covered hearing services. By limiting the number of other covered hearing services, this rule

complies with 42 CFR 440.230(d) (allows the Department to place appropriate limits on a service) and with Minnesota Statutes, §256B.04, subdivision 12, which requires the Department to place limits on the types of services covered by medical assistance.

Subpart 9. Trial period for audiologist's or otolaryngologist's evaluation of hearing aid.

Item A. Item A requires a hearing aid services provider to allow a recipient at least a 30 day trial period, or the period covered by the contract between the state and the hearing aid manufacturer, whichever is longer, to allow an audiologist or otolaryngologist to ascertain whether the hearing aid works properly. This trial period begins on the date the hearing aid is provided.

In order for audiologists and otolaryngologists, trained professionals, to determine if the hearing aid is working precisely, it is necessary to allow a trial period to catch any "bugs" in the device. Further, it is reasonable to allow such a trial period in order to ensure that the state medical assistance program pays for working hearing aids, and allowing for further audiologic services if the hearing aid does not meet the recipient's needs.

It is necessary to inform the recipient of the beginning and ending dates of the trial period so that the recipient knows his or her rights under the medical assistance program. It is reasonable that this information be given by the hearing aid services provider.

Item B. This item requires the audiologist or otolaryngologist to inform the recipient of the availability of additional audiologic services if the audiologist or otolaryngologist determines the hearing aid is not meeting the needs of the recipient.

This is another method of making sure a recipient's hearing is working properly; if a hearing aid isn't working, further audiologic services are performed. This is reasonable, as it promotes the appropriate use of the state's medical assistance program funds, as well as stating in rule the existing standard of community practice.

Here, "further audiologic services" must meet the requirements of part 9505.0390, subpart 4 (rehabilitative and therapeutic services eligible for medical assistance payment), which states that a recipient's "functional status" is expected to progress toward or achieve objectives in the plan of care within 60 days, and that the audiologic services are specified in a plan of care. It is necessary to define "further audiologic services" because this is not defined in subpart 1. It is reasonable to

let recipients know what further audiologic services are available if the hearing aid does not meet their needs.

Additionally, this item requires that an audiologist or otolaryngologist must order any necessary changes during the trial period should the hearing aid not meet the recipient's needs. It is necessary that the audiologist or otolaryngologist order any changes during the trial period, because medical assistance will pay for the changes. It is reasonable to require these professionals to determine whether the hearing aid meets the recipient's needs because they are trained professionals with the education and training essential for a correct analysis. See the discussion for subpart 1, item E on page 5.

Subpart 10. Hearing services not covered.

By listing for the reader what services are not covered, this rule complies with 42 CFR 440.230(d), which allows the Department to place appropriate limits on a service based on "medical necessity," and with Minnesota Statutes, §256B.04, subdivisions 12 (requires the Department to place limits on the types of services covered by medical assistance) and 15 (requires the Department to safeguard against the unnecessary and inappropriate use of medical assistance services). The following are reasonable limitations.

Item A. It is necessary to disallow medical assistance payment for a hearing aid that is not medically necessary in order to comply with the letter of 42 CFR 440.230(d) and with Minnesota Statutes, §256B.04, subdivision 15. Its content is taken from part 9505.0365, subpart 6, item B, which applies to excluded prosthetic and orthotic devices.

Item B. This item is necessary because replacement batteries, other than as specified in subpart 6 (covering medical assistance payment for replacement batteries for no more than 90 days), provided regardless of need may require the state to pay unnecessary medical assistance payments. There have been instances of hearing aid services providers shipping excess batteries to long-term care facilities in order to receive medical assistance payment. Therefore, excluding unnecessary batteries from payment is common sense. Further, this item complies with 42 CFR 440.230(d) and Minnesota Statutes, §256B.04, subdivision 15.

Item C. It is necessary and reasonable to require that charges for picking up and delivering a hearing aid that are billed on a separate claim are not eligible for medical assistance payment because no medical assistance provider is ever paid for pick up and delivery; this is a part of doing business and is already included in the state's medical assistance payment for services.

This does not affect services to recipients who live outside long-term care facilities, because they are reimbursed by their county human services agencies for travel to medical appointments; for recipients living in long-term care facilities, the facilities arrange for the costs to repair hearing aids.

Item D. It is necessary to require that repairs to hearing aids (and other hearing services provided by contract) during the contract's warranty period that are already provided are not eligible for medical assistance payment because the state does not pay for a service already covered for under warranty. It is reasonable that if a hearing service is already covered by a contract's warranty, the state should not pay for repairs.

Item E. Pursuant to part 9505.0200, the state follows the terms of the contracts obtained through the medical assistance competitive bidding process. It is necessary, then, to provide that purchase of a non-contract hearing aid, without prior authorization, will not receive medical assistance payment. This is reasonable as most recipients will receive proper (i.e., effective) contract hearing aids. On the slight chance that a recipient needs a hearing aid that is not available on the contract, it is logical to require prior authorization before purchase.

Item F. It is necessary to require that hearing services billed separately when the payment for the hearing services is already included in the dispensing fee are not eligible for medical assistance payment because the state does not pay for a service already covered. It is reasonable that if a hearing service is already covered in the dispensing fee, the state should not pay.

Item G. It is appropriate to exclude from medical assistance payment "hearing aid drying kits, battery chargers, swim molds, or adapters for telephones, television, or radio" because these items are not medically necessary for operation of hearing aids and should not be considered hearing aid accessories. Therefore, it is reasonable to limit payment on hearing aid accessories to those necessary to operate a hearing aid; these items are not necessary. By excluding these items, item G complies with 42 CFR 440.230(d) and Minnesota Statutes, §256B.04, subdivision 15.

Item H. A hearing aid services provider selling canal hearing aids will not receive medical assistance payment because canal hearing aids fill a cosmetic purpose, are difficult to use and require more repairs than other hearing aids. In order to comply with Minnesota Statutes, §256B.04, subdivision 2 (the Department must make rules to carry out the medical assistance program in an "economical" manner), it is reasonable to require

payment for the most cost efficient types of hearing aids, and canal hearing aids do not come within this category.

Item I. Without a request or a referral from the recipient, the recipient's family, guardian, or attending physician, routine cleaning, checking, and other maintenance of hearing aids will not result in medical assistance payment. This is necessary in order to eliminate reimbursement for unnecessary services and therefore comply with 42 CFR 440.230(d) and Minnesota Statutes, §256B.04, subdivision 15. In order to ensure that medical assistance pays only for essential services, it is reasonable to require that cleaning, checking and other maintenance of hearing aids be done only when the recipient or these other people so request.

Item J. This item provides that hearing aids prescribed, or hearing services ordered by a physician are not eligible for medical assistance payment if the hearing aids or the hearing services "are provided by a person or entity that commits a felony listed" in federal law, subject to the exceptions listed in federal regulations.

This item is necessary to administer regulations, effective July 29, 1991, promulgated to implement section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93. The regulations, found at 42 CFR 1001.952, list various payment practices which, although potentially capable of inducing referrals of business under Minnesota's medical assistance program, will be protected from criminal prosecution or civil sanctions. This list sets forth business and payment practices that are given "safe harbor" from what otherwise are considered criminal acts subject to the criminal penalties of 42 U.S.C. §1320a-7b, part of the Social Security Act.

The types of criminal acts listed in federal law specifically include kickbacks, bribes and rebates made directly or indirectly, overtly or covertly, for cash or in kind (42 U.S.C. §1320a-7b(b)). This prohibited conduct includes remuneration intended to induce referrals of patients, as well as the purchasing, leasing, ordering, or arranging for any good, facility, service or item paid for by our medical assistance program. Because the federal statute is broad, it was argued by health care providers that many relatively harmless, or even beneficial, commercial arrangements are covered by the statute. Hence, the 1991 federal regulations providing "safe harbor" from the federal law.

It is necessary to promulgate this rule with an exclusion from medical assistance payment to comply with federal law and regulations, and reasonable to cite those correct parts of the federal law and regulations for the benefit of affected parties.

Additionally, this language is reasonable as it is an update of the "affiliate rule" language found in part 9505.0365, subpart 6, items I and J as these items apply to hearing services. As discussed on page 2, current part 9505.0365 governs prosthetic and orthotic devices, and hearing services. Subpart 6 prevents "consultants" and "affiliates" (audiologists and otolaryngologists) from benefitting financially by prohibiting medical assistance payment if they perform audiologic evaluations and dispense hearing aids. As discussed at subpart 1, item E, audiologists and otolaryngologists may now dispense hearing aids. Therefore, this item J is an updated version of the affiliate rule.

Additionally, federal regulations at 42 CFR 1001.952 list the various payment practices that will be provided "safe harbor" from criminal prosecution or civil sanctions for audiologists (and otolaryngologists) who may now dispense hearing aids. In order to comply with these federal regulations, it is necessary to update the language of part 9505.0365, subpart 6, items I and J and move their content into proposed part 9505.0287.

9505.0365 PROSTHETIC AND ORTHOTIC DEVICES.

Subpart 1 is amended, and subpart 4 repealed, because their current contents are now found in new part 9505.0287.

Subpart 1. Definitions.

Item B. This item is repealed because it is now placed in new part 9505.0287, subpart 1, item B.

Item C. This item is repealed because it is now placed in new part 9505.0287, subpart 1, item C.

Item D. This item is repealed because it is now placed in new part 9505.0287, subpart 1, item E.

Subpart 4. Payment limitation; hearing aid.

This subpart is repealed in its entirety; its content is now found in subparts 2, 3, 6, 7 and 8. Each subpart is discussed in detail in this document.

Subpart 6. Excluded prosthetic and orthotic devices.

Items I and J. It is necessary and reasonable to delete the references to subpart 4 because subpart 4 has been repealed.

Item K. It is necessary and reasonable to delete this item because there are no prosthetic or orthotic devices that use batteries (part 9505.0365 having been updated to govern only prosthetic and orthotic devices); batteries are used only in hearing aids, which are the subject of proposed part 9505.0287.

SMALL BUSINESS

When proposing rules, Minnesota Statutes, §14.115 requires agencies to consider various methods for reducing the impact of the proposed rules on small businesses and to provide the opportunity for small businesses to participate in the rulemaking process. Minnesota Statutes, §14.115, subdivision 7, clause (2) states that "agency rules that do not affect small businesses directly" are not to be bound by this law.

Small businesses are defined in Minnesota Statutes, §14.115, subdivision 1 as business entities that (a) are independently owned and operated; (b) are not dominant in the field; and (c) have less than 50 full-time employees or have gross annual sales of less than \$4,000,000. A large majority of hearing aid services providers in Minnesota are small businesses within the definition of Minnesota Statutes, §14.115, subdivision 1. It is the Department's position that proposed part 9505.0287 will not directly affect every small business, although it will directly affect some.

Approximately 400 individuals have permits from the Health Department to sell hearing aids. The Health Department cannot make a determination as to how many of the 400 individuals are audiologists, although it estimates that this number would be only a minority. The use of "permit" is here used deliberately. Even though the majority of these 400 individuals are not audiologists or otolaryngologists, and therefore, may also be registered with the Health Department, the Health Department's registration examination is not yet completed. At least 69 people have registered to take the registration examination.

The Department of Human Services does know that approximately 130 hearing aid businesses in Minnesota are enrolled in the medical assistance program to sell hearing aids. Some of these businesses are run by audiologists, which under this rule would now be able to perform audiologic evaluations and dispense hearing aids. However, the Department does not know the number of individuals in each of the 130 businesses and how many of these individuals are audiologists. Therefore, although the Department anticipates that proposed part 9505.0287 will not directly affect every small business (as it is unlikely that an increased number of hearing aid services providers will mean increased competition to every hearing aid services provider who

is not an audiologist or an otolaryngologist), this part will directly affect at least some hearing aids services providers.

For those small businesses that may now prescribe and dispense hearing aids (after performing audiologic evaluations), proposed part 9505.0287 is welcomed, for it will increase medical assistance payments. For those small businesses that provide hearing aids, but are prohibited from performing audiologic evaluations, proposed part 9505.0287 is seen as opening up possible new avenues of competition by allowing select audiologic services providers to now perform audiologic evaluations and dispense hearing aids. Anecdotal reports suggest that due to a shortage of audiologists in rural Minnesota who will perform audiologic evaluations alone, at least some audiologists are already enrolled in the medical assistance program to dispense hearing aids, and these audiologists will not present new competition for registered hearing aid services providers.

On the other hand, for those small business owners who are not audiologists or otolaryngologists, the effect of proposed part 9505.0287, subpart 1, item E (definition of "hearing aid services provider") will be to compel these individuals to register with the Health Department, offering them the benefit of using protected titles under part 4745.0020. Part 4745.0020 is the Health Department's rule requiring that specific titles, including "hearing aid dispenser," "hearing instrument specialist," "hearing instrument consultant," and "hearing aid specialist" be used only by someone registered with the Department.

The Department has carefully considered the potential for increased competition on small businesses. Currently, registered hearing aid services providers have less competition from audiologists and otolaryngologists regarding dispensing of hearing aids due to part 9505.0365, subpart 6, items I and J, part of the "affiliate rule" discussed on pages 15 - 16. Now, proposed part 9505.0287 updates the affiliate rule to allow permitted hearing aid services providers to dispense hearing aids, necessary to follow federal law and federal regulations. Therefore, while there may be increased competition on certain hearing aid services providers (those who are not audiologists or otolaryngologists), the Department is compelled to follow federal law and regulations.

Further, as discussed on page 6, providing convenience and accessibility to hearing services and hearing aids for recipients is a benefit for recipients and is consistent with Minnesota Statutes, §256B.04, subdivision 2, which requires the Department to make rules for carrying out the medical assistance program "in an efficient, economical, and impartial manner...."

It is efficient to allow recipients, especially those in rural Minnesota, to receive hearing aids and hearing services from their audiologists, rather than making them seek out, in one or more trips, a registered hearing aid services provider. It is impartial to show no discrimination regarding who may dispense hearing aids, particularly when the category of person now allowed to dispense has more training and specialized education than the hearing aid services provider currently selling hearing aids.

Additionally, the factors in Minnesota Statutes, §14.115, subdivision 2 that must be considered to reduce "the impact of the rule on small businesses" are inapplicable, with one exception.

Minnesota Statutes, §14.115, subdivision 2, paragraph (a) requires a consideration of "the establishment of less stringent compliance or reporting requirements for small businesses." Amended part 9505.0175, subpart 32 (see page 3) is the only part governing compliance requirements. Part 9505.0175, subpart 32 is the definition of "performance agreement," a "written agreement between the department and a provider that states the provider's contractual obligations for the sale and repair of medical equipment and medical supplies eligible for medical assistance payment." It specifically lists a "hearing aid performance agreement between the department and a hearing aid dispenser" as an example of a performance agreement. Because such performance agreements will no longer be used by the Department (from now on, hearing aid services providers will sign the same provider agreements as all other medical assistance providers), the Department has complied with the statutory requirement to consider "the establishment of less stringent compliance requirements for small businesses."

As regards the rest of proposed 9505.0287, for the reasons listed in the discussion of proposed part 9505.0287, subpart 1, items A and E, it is unreasonable to have less stringent compliance (i.e., education and training) requirements for hearing aid services providers who do not have the education and training of audiologists or otolaryngologists.

Minnesota Statutes, §14.115, subdivision 2, paragraph (b) requires consideration of less stringent schedules or deadlines for compliance or reporting requirements for small businesses, and paragraph (c) requires consideration of consolidation or simplification of compliance or reporting requirements. As noted in the discussion above, with the amendment of part 9505.0175, subpart 32's "performance agreement," proposed part 9505.0287 does simplify compliance procedures by requiring hearing aid services providers to sign the same provider agreement all medical assistance providers sign.

Minnesota Statutes, §14.115, subdivision 2, paragraph (d) requires consideration of establishing performance standards for small business "to replace design or operational standards required in the rule." Because the proposed language does not cover design or operational standards, paragraph (d) is inapplicable.

Finally, Minnesota Statutes, §14.115, subdivision 2, paragraph (e) requires consideration of exempting small businesses from any or all of the rule requirements. First, small businesses cannot be exempted from these rule requirements, because the majority of hearing aid services providers are small businesses. Secondly, as discussed in proposed part 9505.0287, subpart 1, items A and E, there are necessary and reasonable grounds why certain hearing aid services providers may now prescribe and dispense hearing aids. If the rest of the hearing aid services providers (i.e., those only registered with the Department of Health) were exempted from the standards of this new part, all hearing aid services providers would be allowed to prescribe and provide hearing aids, removing at least some of the basis for promulgation of proposed part 9505.0287.

EXPERT WITNESSES

If this rule is heard in public hearing, the Department does not intend to have outside expert witnesses testify on its behalf.

AGRICULTURAL LAND

The proposed rule amendments do not have a direct or substantial adverse effect on agricultural land as defined in Minnesota Statutes, §17.81, subdivision 3 and referenced in Minnesota Statutes, §14.11, subdivision 2.

Dated: September 9, 1992.



NATALIE HAAS STEFFEN
Commissioner