

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA DEPARTMENT OF HUMAN SERVICES

In the Matter of Proposed
Adoption of Rules of the
Department of Human Services
Governing Eyeglass Services Under
Medical Assistance, Minn. Rules,
Part 9505.0277.

REPORT OF THE
ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Barbara L. Neilson on October 13, 1994, at 9:00 a.m. in Room 116A of the Department of Administration Building, 50 Sherburne Avenue, St. Paul, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20 (1992) to hear public comment, determine whether the Minnesota Department of Human Services (hereinafter referred to as "DHS" or "the Department") has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, assess whether the proposed rules are needed and reasonable, and determine whether or not modifications to the rules proposed by DHS after initial publication are substantially different from the rules as originally proposed.

Steven J. Lokensgard, Assistant Attorney General, Suite 200, 520 Lafayette Road, St. Paul, Minnesota 55155, appeared on behalf of the Department at the hearing. The Department's hearing panel consisted of Christine Dobbie, Supervisor, Ancillary Health Services Section, Health Services Policy Section; Rosemary Wilder, Policy Consultant; and Eleanor Weber, Supervisor of Rules and Bulletins. Six persons attended the hearing. Three persons signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules. The Administrative Law Judge received 2 public exhibits and 19 agency exhibits as evidence during the hearing. The Judge will also receive as evidence two additional agency exhibits submitted after the hearing: Exhibit 20, an article published in the March 1991 issue of Minnesota Medicine which contains a report of the Medical Benefits Task Force of the Minnesota Medical Association, included by DHS as an exhibit in accordance with a request at the hearing by a member of the public; and Exhibit 21, the Department's July 25, 1994, Fiscal Note with respect to the rules as originally proposed, copies of which were distributed at the hearing.

The record remained open for the submission of written comments until November 2, 1994, twenty calendar days following the hearing. Pursuant to Minn. Stat. § 14.15, subd. 1 (1992), five working days were allowed for the filing of responsive comments. At the close of business on November 9, 1994, the rulemaking record closed for all purposes. The Administrative Law Judge received written comments from interested persons during the comment period. The comment period set in this rulemaking proceeding is the maximum period allowed under Minnesota law.

The Administrative Law Judge received numerous written comments from interested persons during the comment period. The Department submitted written comments responding to matters discussed at the hearing and in the written submissions. In its written comments, the Department proposed further amendments to the rules.

The Department must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. § 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the Department of actions which will correct the defects and the Department may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which relate to the issues of need or reasonableness, the Department may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the Department does not elect to adopt the suggested actions, it must submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the Department elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the Department may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the Department makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the Department files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

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

FINDINGS OF FACT

Procedural Requirements

1. On July 29, 1994, the Department filed the following documents with the Chief Administrative Law Judge:

- (a) a copy of the proposed rules certified by the Revisor of Statutes;
- (b) the Order for Hearing;
- (c) the Notice of Hearing proposed to be issued;
- (d) the Statement of Need and Reasonableness (hereinafter referred to as the "SONAR");
- (e) the names of agency personnel and witnesses expected to testify on behalf of the Department at the hearing; and
- (f) an estimate of the number of persons who would attend the hearing and how long the hearing was expected to last.

2. On August 24, 1994, DHS 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 to the persons who appeared on the Department's list of additional persons to receive the Notice of Hearing.

3. On August 29, 1994, the Notice of Hearing and the proposed rules were published at 19 State Register 478.

4. On September 16, 1994, DHS filed the following documents with the Administrative Law Judge:

- (a) the Notice of Hearing as mailed;
- (b) the Department's certification that its mailing list was accurate and complete;
- (c) the Affidavit of Mailing the Notice to all persons on the Department's mailing list;
- (d) the Affidavit of Additional Mailing of the Notice fo persons on the discretionary list;
- (e) a copy of the State Register pages containing the Notice of Hearing and the proposed rules;
- (f) copies of the Notices of Solicitation of Outside Opinion published at 15 State Register 311 (July 30, 1992), and 17

State Register 852 (October 19, 1992), and all materials received pursuant to those notices; and

- (g) the names of agency personnel and witnesses called by the Department to testify at the hearing.

Nature of the Proposed Rules and Statutory Authority

5. Pursuant to Minn. Stat. § 256B.0625, subd. 12 (1992), persons receiving medical assistance in Minnesota are afforded eyeglass services in addition to the other services provided. Minnesota has sought and receives federal funding available under Title XIX of the Social Security Act (Medicaid) to help pay for medical assistance services. Under Minn. Stat. § 256B.04, subd. 4 (1992), DHS must cooperate with the U.S. Department of Health and Human Services "in any reasonable manner as may be necessary" to qualify for federal funds with respect to the medical assistance program. Minn. Stat. § 256B.04, subd. 12 (1992), provides that the Department may establish limitations regarding "the types of services covered by medical assistance, the frequency with which the same or similar services may be covered . . . for an individual recipient, and the amount paid for each covered service." Under Minn. Stat. § 256B.04, subd. 15(1) (1992), the Department must establish programs to protect against "unnecessary or inappropriate use of medical assistance services." Minn. Stat. § 256B.04, subd. 2 (1992), authorizes the Department to adopt rules to carry out its statutory obligations.

6. The proposed rules establish standards under which eyeglass providers will be eligible to receive payment under the medical assistance program. They define terms to be used in administering eyeglass services under medical assistance and define the services that will be covered and excluded in a manner that attempts to ensure compliance with federal statutes and regulations governing Medicaid reimbursement. The proposed rules would repeal the existing rules governing vision services set forth in Minn. R. 9505.0405 and delete outdated references to prior authorization and the manner in which providers bill for services, but retain without change many of the standards set forth in the existing rules. The Administrative Law Judge concludes that DHS has general statutory authority to adopt the proposed rules.

Small Business Considerations in Rulemaking

7. Minn. Stat. § 14.115, subd. 2 (1992), requires state agencies proposing rules that may affect small businesses to consider methods for reducing adverse impact on those businesses. In its SONAR, the Department maintained that the proposed rules fall within the exemption set forth at Minn. Stat. § 14.115, subd. 7(3) (1992), for rules relating to "service businesses regulated by government bodies, for standards and costs, such as . . . providers of medical care" The Administrative Law Judge agrees that the proposed rules fall within this exemption because the Department regulates the eyeglass services governed by the proposed rules for both standards and costs. DHS thus has satisfied the requirements of Minn. Stat. § 14.115, subd. 2.

Fiscal Note

8. Minn. Stat. § 14.11, subd. 1 (1992), requires agencies proposing rules that will require the expenditure of public funds in excess of \$100,000 per year by local public bodies to publish an estimate of the total cost to local public bodies for the two-year period immediately following adoption of the rules. The proposed rules govern the expenditure of state and federal money administered by the counties. In July, 1994, the Department prepared a fiscal note in which DHS indicated that the proposed rule would not result in additional state and local costs but, in fact, that state expenditures would decrease by \$19,931 in each of the first two years following adoption of the rules. Due to the Department's proposed modifications to the rules, the Department no longer anticipates that there will be a reduction in cost as a consequence of adoption of the rules.

9. Anne Henry, Attorney for the Minnesota Disability Law Center ("MDLC"), objected to the fiscal note as being inaccurate in light of the modifications proposed by the Department, and requested that a new fiscal note be prepared to indicate the effect of the rules as modified. The fiscal note requirement arises when the rules would increase costs to "local public bodies." Costs incurred by the State are not costs to local public bodies. There is no evidence that the proposed modifications would shift any costs to the counties or any other local public bodies. The proposed rules will not require expenditures by local governmental units or school districts in excess of \$100,000 in either of the two years immediately following adoption, and thus no notice is statutorily required. There is no statutory basis to require the Department to prepare a new fiscal note.

Impact on Agricultural Land

10. Minn. Stat. § 14.11, subd. 2 (1992), requires that agencies proposing rules that have a "direct and substantial adverse impact on agricultural land in the state" comply with the requirements set forth in Minn. Stat. §§ 17.80 to 17.84 (1992). Because the proposed rules will not have an impact on agricultural land within the meaning of Minn. Stat. § 14.11, these provisions do not apply to this rulemaking proceeding.

Analysis of the Proposed Rules

11. The Administrative Law Judge must determine, inter alia, whether the need for and reasonableness of the proposed rules has been established by the Department by an affirmative presentation of fact. The Department prepared a Statement of Need and Reasonableness ("SONAR") in support of the adoption of the proposed rules. The Department supplemented its SONAR with comments made by DHS representatives at the public hearing and with written post-hearing comments.

12. The question of whether a rule is reasonable focuses on whether it has a rational basis. The Minnesota Court of Appeals has held a rule to be reasonable if it is rationally related to the end sought to be achieved by the statute.

Broen Memorial Home v. Minnesota Department of Human Services, 364 N.W.2d 436, 440 (Minn. Ct. App. 1985); Blocher Outdoor Advertising Co. v. Minnesota Department of Transportation, 347 N.W.2d 88, 91 (Minn. Ct. App. 1984). The Supreme Court of Minnesota has further defined the burden by requiring that the agency "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken." Manufactured Housing Institute v. Pettersen, 347 N.W.2d 238, 244 (Minn. 1984). An agency is entitled to make choices between possible standards as long as the choice it makes is rational. If commentators suggest approaches other than that selected by the agency, it is not the proper role of the Administrative Law Judge to determine which alternative presents the "best" approach.

13. This Report is generally limited to the discussion of the portions of the proposed rules that received significant critical comment or otherwise need to be examined. Because some sections of the proposed rules were not opposed and were adequately supported by the SONAR, a detailed discussion of each section of the proposed rules is unnecessary. The Administrative Law Judge specifically finds that the Department has demonstrated the need for and reasonableness of the provisions of the proposed rules that are not discussed in this Report by an affirmative presentation of facts, that such provisions are specifically authorized by statute, and that there are no other problems that prevent their adoption.

14. Where changes are made to the rule after publication in the State Register, the Administrative Law Judge must determine if the new language is substantially different from that which was originally proposed. Minn. Stat. § 14.15, subd. 4 (1992). The standards to determine if the new language is substantially different are found in Minn. R. 1400.1100 (1993). Any language proposed by the Department which differs from the rules as published in the State Register and is not discussed in this Report is found not to constitute a substantial change.

Proposed Rule 9505.0277 - Eyeglass Services

15. Proposed rule 9505.0277 is comprised of three subparts. Subpart 1 establishes definitions to be used for the rule part. Subpart 2 indicates what eyeglass services are eligible for medical assistance payment. Subpart 3 lists services that are not eligible for payment under the medical assistance program.

Subpart 1 - Definitions

16. Subpart 1 contains 9 items, each defining a term used in these rule. Only the terms requiring discussion will be mentioned in this Report. The other definitions are found to be needed and reasonable.

Item A - Comprehensive Vision Examination

17. Item A defines "comprehensive vision examination" as "a complete evaluation of the visual system." MDLC questioned the difference between a "comprehensive vision examination" and an "intermediate vision examination," which is defined in item E as "an evaluation of a specific

visual problem." MDLC asked whether there were any medical procedures which were included in a "comprehensive vision examination" that could not be performed during an "intermediate vision examination." The distinction between the two was important under the approach originally taken in the proposed rules, because comprehensive vision examinations were limited to one every two years and intermediate vision examinations were limited to one every year. Pursuant to the modifications proposed by the Department at and after the hearing, both time limitations will be removed. Nevertheless, it is useful to retain the two definitions in order to indicate what services will be deemed to be covered eyeglass services under subpart 2. The SONAR asserts that the definitions were recommended by the optometrist on the Advisory Committee, are consistent with definitions contained in the Physicians' Current Procedural Terminology, and are consistent with current standards of medical practice. The Department has shown that items A and E are needed and reasonable as proposed.

Item F - Medically Necessary Eyeglasses

18. As originally proposed, item F of the rules defined the term "medically necessary eyeglasses" in the context of "initial eyeglasses" and "replacement eyeglasses." Item F(1) requires that a person need a correction of .50 diopters or more in either sphere or cylinder power in either eye to be eligible for medically necessary initial eyeglasses. As originally proposed, item F(2) required a change of .50 diopters in either sphere or cylinder power in either eye, or a shift in axis of greater than ten degrees in either eye, to be eligible for medically necessary replacement eyeglasses.

19. MDLC suggested that item F(2) be revised to refer to a "change in prescription" rather than "replacement eyeglasses" to more accurately reflect the intent of the proposed rule and avoid confusion with the term "identical replacement eyeglasses" that appears in other portions of the rule. The MDLC also recommended that a new subitem (3) be added to item F encompassing "identical replacement eyeglasses."

20. The Department agreed with MDLC regarding the suggested change in the language of item F(2) and proposed in its post-hearing submission that item F(2) begin with the phrase, "for a change in eyeglasses" rather than "for replacement eyeglasses." The Department declined to add a new item F(3) referring to identical replacement eyeglasses.

21. The Department has demonstrated that item F, as modified, is needed and reasonable to establish a standard which will require payment if the standard is satisfied. In its SONAR, the Department indicates that eleven of thirteen states surveyed use a diopter standard with respect to their Medicaid programs and further states that the Advisory Committee on the rules agreed on the use of a .50 diopter standard as consistent with accepted professional practice. The modification made to item F serves to clarify the rule as originally proposed and does not constitute a substantial change. The proposed rule part is not rendered unreasonable by its failure to include a new subitem relating to identical replacement eyeglasses, particularly where the circumstances under which identical replacement eyeglasses will be eligible for medical assistance payment are explicitly addressed in another provision of the proposed rules.

Subpart 2 - Covered Eyeglass Services

22. Proposed subpart 2 of the proposed rules lists the eyeglass services that are covered under the medical assistance program. As originally proposed, the subpart contained three items: item A limited medical assistance recipients to one covered comprehensive vision examination in a 24-month period; item B limited recipients to one covered intermediate vision examination in a 12-month period; and item C provided for one pair of medically necessary eyeglasses in a 24-month period, with certain exceptions (including one identical replacement within the 24-month period and a new pair of glasses due to a change in head size, a change in vision, or an allergic reaction to the frame material). Each of these

items and the modifications proposed by the Department are discussed in the paragraphs below.

23. At the hearing, the Department proposed changing the language in the first sentence of the subpart to clarify that the listed services are eligible for medical assistance payment. No one objected to the change. The opening language of the subpart is needed and reasonable, as modified, to clarify the intent of the proposed rule. The new wording is not a substantial change from the language originally proposed.

Item A - Comprehensive Vision Examinations

Item B - Intermediate Vision Examinations

24. As originally proposed, item A provided that medical assistance payment would be provided for one comprehensive vision examination per twenty-four month period and item B provided that medical assistance payment would be provided for one intermediate vision examination per twelve-month period. Numerous members of the public objected to the limitations on the frequency of comprehensive and intermediate vision examinations, including Nancy Vanderberg of the Minnesota Children with Special Health Needs program; Roy Harley, Vice President for Disability Services, Lutheran Social Services; Jacki McCormack, Director of Programs and Child Advocacy, Arc Ramsey County; Julie Hanson, Executive Director of Houston County Group Homes, Inc., Paul Odland, Chair of the Governor's Planning Council on Developmental Disability; Laura Lund, Associate Director of ARRM; Debby Felske; Charles Roach, M.D.; C. Gail Summers, M.D.; Stephen G. Harner, M.D.; and MDLC.

25. Many of these commentators indicated that persons with developmental disabilities and others with eye disorders, particularly children, experience rapid changes in visual acuity that can only be detected through comprehensive eye examinations. Dr. Summers emphasized that children with retinoblastoma, a cancerous growth within the eye, must receive comprehensive eye examinations every three months during the first two years after diagnosis and would risk loss of vision or even loss of life if they did not adhere to such an examination schedule. A position statement of the Minnesota Optometric Association and the Minnesota Academy of Ophthalmology submitted as Public Exhibit 1 points out the societal and human costs associated with undetected or untreated vision problems. The position statement indicates that half of the people suffering from glaucoma are unaware of the presence of the disease and that many eye conditions do not have symptoms that prompt people to seek an examination. MDLC and the Governor's Council asserted that the proposed limitations on the frequency of examinations were inconsistent with federal Early Periodic Screening, Diagnosis, and Treatment requirements for low-income children. The MDLC recommended that the proposed rule include language permitting more frequent exams where medically necessary, and the Governor's Council urged the Department to allow intermediate vision examinations as often as specific vision problems are presented. Several commentators requested that the Department retain in the rule the provision of the existing rule that permits additional examinations if prior authorization is obtained and recommended that the Department describe the appeals process.

26. Based on the comments received, the Department modified item (B) at the hearing to delete the limitation on the frequency of intermediate vision examination. The Department indicated that it had not been its intent to limit intermediate examinations that were medically necessary and appropriate to assess changes in vision. It thus decided to delete the limitation to ensure that recipients will have access to medically necessary services. Following the hearing, the Department also decided to modify item (A) to delete the proposed limitation on the frequency of comprehensive examinations. As a result, items (A) and (B) of subpart 2 have been modified to simply list "comprehensive vision examinations" and "intermediate vision examinations" as two types of covered eyeglass services. In modifying item (A), the Department again stated that it had not intended to deny recipients' access to medically necessary services. The Department noted that the proposed rule focuses only on the provision of eyeglass services, and that other medically necessary vision-related services such as eye surgery and treatment for diseases of the eye are physician services that are eligible for medical assistance coverage under Minn. R. 9505.0345 (1993). However, based upon the comments regarding the special needs of many medical assistance recipients and the ability of ophthalmologists to use a variety of CPT codes for billing vision services, the Department decided that it was reasonable to delete the 24-month limitation.

27. The Department indicated that it is now unnecessary to place prior authorization requirements in rules because Minn. Stat. § 256B.0625, subd. 25 (1992), authorizes the Commissioner of Human Services to publish a list of services that require prior authorization in the State Register. Because recipients will be able to obtain coverage of as many examinations as are medically necessary, the Department determined that it was not necessary to modify the rule to provide for prior authorization. In addition, the Department noted that appeals of denials of eyeglass services will be governed by Minn. Stat. § 256.045 (1992) and Minn. R. 9505.0130 (1993); there thus is no need to include a description of the appeals process in this set of rules.

28. Items A and B, as modified, have been shown by the Department to be both needed and reasonable. The modifications made in the language of the two items were responsive to public comments on the proposed rule and do not result in an impermissible substantial change from the rule as originally proposed.

Item C - Medically Necessary Eyeglasses

29. As originally proposed, item C indicated that one pair of medically necessary eyeglasses would be covered per 24-month period, with the following exceptions: (1) one identical replacement pair of eyeglasses would be covered within the twenty-four month period if the original pair was misplaced, stolen, or irreparably damaged; and (2) one new pair of glasses would be covered due to a change in head size or vision or an allergic reaction to the material of the eyeglasses. These restrictions were criticized by the MDLC; ARRM; the Governor's Planning Council on Developmental Disabilities; Lutheran Social Services; Houston County Group Homes; Cindy Larson, Supportive Living Coordinator; Nancy

Vanderberg of the Minnesota Children with Special Health Needs program; Brent Johnson, O.D.; Stephen Harner, M.D.; JoAnn Bokovoy; Arla Oftelie, R.N., Director of Health Services for Mount Olivet Rolling Acres; and Sandra Singer, Program Director, and Diane Greig, R.N., Health Services Coordinator, of the Oakwood Residence.

30. The commentators objected to the limitations set forth in the rules as originally proposed on the grounds that they were too restrictive. They pointed out that limiting the number of pairs of eyeglasses to one in 24 months did not adequately address the needs of recipients. In particular, it was emphasized that persons with developmental disabilities may lose or damage their glasses more often than other individuals due to behavioral issues or matters beyond their control and that prompt replacement is necessary to ensure adequate vision. Ms. Oftelie urged improving the efficiency of the prior approval method now used by the Department. Dr. Odland of the Governor's Council suggested that the Department eliminate some of the restrictions on replacement eyeglasses and ensure that the system is not abused by requiring prior approval. Ms. Larson, Dr. Johnson, ARRM, Houston County Group Homes, and several other commentators also supported the use of a prior authorization system. The MDLC reiterated its concern that the proposed rules conflicted with federal Early Periodic Screening, Diagnosis, and Treatment requirements and requested a modification permitting an identical replacement pair of glasses within the 24-month period if the situation bringing about the need for the replacement was beyond the recipient's control and prior authorization was obtained.

31. Based upon these comments, the Department modified this item at the hearing by separating item C(1) and (2) into items C, D, and E and altering the standards applied. The new item C indicates that an initial pair of medically necessary eyeglasses will be eligible for payment under medical assistance, and no longer includes a 24-month restriction. The new item D states that "a pair of eyeglasses that are an identical replacement of a pair of eyeglasses that was misplaced, stolen, or irreparably damaged" will be eligible for payment, and eliminates the prior 24-month limitation. Finally, the new item E states that a new pair of "medically necessary eyeglasses" will be eligible for payment if it is needed due to a change in the recipient's head size, an allergic reaction to the eyeglass material, or a change in vision after a comprehensive or intermediate vision examination shows that a change in prescription is medically necessary. In its post-hearing submission, the Department modified the version of subpart 2(E) proposed at the hearing to exclude the first reference to "medically necessary" and to refer in the last sentence to "part" rather than "item." Thus, items C, D, and E as finally proposed provide as follows:

C. ~~One~~ An initial pair of medically necessary eyeglasses, in a 24 month period except that a recipient shall receive:

~~(1)~~ D. A pair of eyeglasses that are an one identical replacement within the 24-month period if the of a pair of eyeglasses were that was misplaced, stolen, or irreparably damaged; or.

~~(2)~~ E. A new pair of eyeglasses due to a change in the recipient's head size, a change in vision after a comprehensive or intermediate vision examination shows that a change in eyeglasses is medically necessary, or an allergic reaction to the eyeglass frame material. For purposes of this part item, "change in eyeglasses" means a change in prescription.

32. In proposing these changes to the rule, the Department reviewed its records on payments for replacement eyeglasses. Over a two-year period, the Department found that 164 recipients received two or more pairs of replacement eyeglasses. Almost half of those recipients were under the age of 21. Accordingly, the Department estimated that the modification made to the proposed rules would have minimal fiscal impact. The Department also estimated that administrative costs that would be incurred if a prior authorization requirement were imposed might even exceed the costs of supplying the replacement eyeglasses. The Department contends that the addition of the new definition of medically necessary eyeglasses in subpart 1(F) of the proposed rules will strengthen the eligibility criteria and safeguard against the coverage of unnecessary services.

33. The Department has demonstrated that the changes to item C and the addition of items D and E are needed and reasonable. The modifications made to the proposed rule meet the concerns of commentators that persons will be denied vision services for reasons beyond their control, serve to clarify the rule provisions, and do not result in a rule that is substantially different from that originally proposed.

Subpart 3 - Excluded Services

34. Proposed subpart 3 lists eyeglass services that are ineligible for payment under the medical assistance program, such as services provided for cosmetic reasons or other services that are deemed unnecessary. The subpart is comprised of fourteen items. The only excluded service that received any comment was item C.

35. Item C provides that "[f]ashion tints, photo-chromatic lenses, polarized lenses, transition lenses, and sunglasses" are ineligible for payment under medical assistance. The existing rule provides that "[f]ashion tints that do not absorb ultraviolet or infrared wave lengths" are not covered. Minn. R. 9505.0405, subp. 4(C) (1993). The Department contends in its SONAR that the exclusion of the services listed in item C is consistent with the past practice of the Department. SONAR at 8. Anne Henry of MDLC argued that the complete prohibition of photochromatic or polarized lenses is unreasonable and inconsistent with past practice, which has permitted (with prior authorization) photochromatic lenses, U-V lenses, and certain tinted lenses. The Department agreed in its post-hearing submissions that the current Department practice is to make these available if a prior authorization approval is received based on the medical needs of the client. Ms. Henry further contended that the federal Early Periodic Screening, Diagnosis and Treatment law requires that photochromatic or polarized lenses be provided to eligible persons under 21 if medically necessary, and that it is reasonable to cover such lenses for all medical assistance recipients. Ms. Henry, Jacki McCormack of Arc Ramsey County,

and Drs. Roach and Odland asserted that protective tinting of lenses is medically necessary for individuals with certain eye conditions. In particular, Dr. Roach stated that photochromatic lenses or sunglasses should be authorized for persons with a diagnosis of albinism. Ms. McCormack urged the Department to continue to allow fashion tints that absorb ultraviolet or infrared wave lengths and stated that clip-on sunglasses would not solve the problem for all conditions.

36. Based upon these comments, the Department modified the proposed rule after the hearing. The Department deleted the reference to photochromatic lenses from item C and added a new provision, item O, relating to such lenses. As finally modified, item O excludes photochromatic lenses from eligibility for medical assistance payment "except for a person who has a diagnosis of albinism, achromatopsia, aniridia, blue cone monochromatism, cystinosis, retinitis pigmentosa, or any other condition for which such lenses are medically necessary." The Department's consultant on ophthalmological services, Dr. James Egbert, advised the Department that photochromatic lenses were medically necessary and appropriate for the identified conditions. The Department added the final clause to item O to ensure that the service is available to all persons for whom photochromatic lenses are medically necessary in the event that the list of conditions was not complete.

37. The SONAR indicates that the Advisory Committee on the rules had determined that the services listed in item C "should be excluded from coverage because they do not meet the standard of medical necessity." Agency panel members testified at the hearing that the polycarbonate lenses provided to medical assistance recipients also contain protection against ultraviolet rays and that polarized lenses reduce glare but do not necessarily contain UV protection. In its submissions following the hearing, the Department did not further address the recommendations of Ms. Henry and Ms. McCormack that the rule be modified to allow coverage of polarized lenses or fashion tints that absorb ultraviolet or infrared wave lengths if medically necessary. The Department did not provide any further testimony or materials supporting its position that such lenses are not medically necessary for certain conditions, nor did it provide any testimony or materials indicating whether photochromatic lenses would provide the necessary protection for such individuals.

38. The federal Early Periodic Screening, Diagnosis and Treatment ("EPSDT") program which has been effective since April 1991 requires that states provide vision services to covered children which include at a minimum "diagnosis and treatment for defects in vision, including eyeglasses" and provide "[s]uch other necessary health care, . . . treatment, and other measures . . . to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan." 42 U.S.C. § 1396d(r)(2)(b) and (5). A State Medicaid Manual Issuance put out by the Health Care Financing Administration to implement the EPSDT program notes that states have the authority to "define the service as long as the definition comports with the requirements of the statute in that all services . . . that are medically necessary to ameliorate or correct defects and physical or mental illnesses and conditions discovered by the

screening services are provided." State Medicaid Manual Issuance, § 5122(F), set forth in A. Bergman, "HCFA Issues Guidelines on EPSDT," Word from Washington at 18 (appended as Attachment A to MDLC's October 31, 1994, comment). While the regulations promulgated by the Health Care Financing Administration under Medicaid indicate that the State "may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures," 42 C.F.R. § 440.230(d), it appears that a case-by-case approach to medical necessity is contemplated under the EPSDT program.

39. The Administrative Law Judge thus finds that the complete exclusion of coverage of polarized and tinted glasses set forth in item C, as modified, with respect to children under the age of 21 who are covered by the EPSDT program has not been adequately shown to be needed and reasonable by an affirmative presentation of fact and thus is a defect in the proposed rules. The defect may be corrected by adopting one of the following approaches. First, the Department may modify item C by removing the reference to "transition lenses and sunglasses" and providing that fashion tints and polarized lenses will be excluded "unless medically necessary." A new item P could be created referring to "transition lenses and sunglasses." The Department may wish to utilize this approach if it desires to take a uniform approach with respect to the entire medical assistance population. In the alternative, the Department may modify item C to provide that such lenses will be excluded "unless medically necessary for individuals under age 21 who are covered under federal law relating to the provision of early periodic screening, diagnosis and treatment." The Department may wish to utilize this approach if it desires to limit such services to those falling under the EPDST program.

40. The Administrative Law Judge concludes that items C, O, and P, with the modifications discussed in Findings 36 and 39, have been shown to be needed and reasonable. The modifications made by the Department and suggested by the Administrative Law Judge are needed and reasonable to ensure that recipients of medical assistance receive medically necessary eyeglass services in compliance with applicable law, unnecessary costs are avoided, and a defect in the proposed rule is corrected. The modifications do not result in a rule that is substantially different from that originally proposed.

Content of SONAR

41. MDLC objected to parts of the Department's SONAR as inaccurate and inconsistent with the modified rule presented at the hearing. MDLC suggested that several portions of the SONAR should be deleted to protect the rulemaking record from misinterpretation in the event that the SONAR is later cited to support the rule. The Department objected to the MDLC's request and refused to amend the SONAR for that purpose.

42. The SONAR is prepared prior to the publication of a rulemaking notice and is required to summarize all of the evidence and argument which is anticipated to be presented by the agency at the hearing justifying the need for and reasonableness of the proposed rule. Minn. Stat. § 14.131 (1993); Minn. R. 1400.0300, subp. 1a (E) and 1400.0500 (1993). Throughout

the rulemaking process, modifications to the proposed rules are encouraged. See, e.g., Minn. Stat. § 14.05, subd. 2 (an agency may modify a proposed rule in accordance with the procedures of the Minnesota Administrative Procedures Act provided that the rule as finally proposed is not substantially different from the rule initially proposed); Conclusion 9 below (the agency is not precluded or discouraged from making further modifications to the proposed rules based upon public comments even after the ALJ's report is issued, as long as no substantial change is made and the rule as finally adopted is based upon facts appearing in the rulemaking record). When modifications are made, the new provisions of the rule must be supported by an affirmative presentation of facts showing the rule to be needed and reasonable. Minn. Stat. § 14.14, subd. 2 (1992). As a result of the modification process, statements made in the SONAR in support of the rule as originally proposed are often rendered inoperative. There is, however, no requirement under the Minnesota Administrative Procedures Act that the agency file a revised SONAR which eliminates any discussion which is no longer relevant. The Department's original version of the rule, the SONAR, and its later modifications of the rule and supporting statements, as well as the hearing testimony, comments made on behalf of MDLC and others criticizing the rule and/or the SONAR, and the report of the Administrative Law Judge, are part of the rulemaking record. Minn. Rule 1400.0900 (1993). Any future attempt to rely upon irrelevant portions of the SONAR should be readily discounted due to the inconsistency between SONAR and the rule as finally proposed for adoption. The Administrative Law Judge lacks authority to alter the rulemaking record.

Other Comments

43. Vicky Keller, the parent of a child with disabilities, and JoAnn Lawler, Family Support Services Coordinator for Arc Olmsted County, suggested that the rules should permit parents or guardians to add money to the medical assistance allotment to purchase glasses that are not in the "medical assistance box," such as those with spring hinges or a smaller nose bridge, to ensure durability or a better fit. The Department did not respond to these comments or propose any modification of the rules in this regard. None of the rule provisions explicitly address this area. The Department's failure to incorporate the suggested revision does not render the proposed rules unreasonable. The Department may, however, consider further modifications to the rules in response to this concern.

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

CONCLUSIONS

1. The Minnesota Department of Human Services (DHS) gave proper notice of this rulemaking hearing.

2. DHS has substantially fulfilled the procedural requirements of Minn. Stat. §§ 14.14, subds. 1, 1a and 14.14, subd. 2 (1992), and all other procedural requirements of law or rule so as to allow it to adopt the proposed rules.

3. DHS has demonstrated 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) (1992).

4. DHS 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) (1992), except as noted in Finding 39 above.

5. The additions and amendments to the proposed rules which were suggested by DHS after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. § 14.15, subd. 3 (1992), and Minn. R. 1400.1000, subp. 1, and 1400.1100 (1993).

6. The Administrative Law Judge has suggested action to correct the defect cited at Conclusion 4 as noted at Finding 39.

7. Due to Conclusion 4, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3 (1992).

8. Any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such.

9. A finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage DHS from further modification of the proposed 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 except where specifically otherwise noted above.

Dated this 9th day of December, 1994.

_____ s/ Barbara L. Neilson

BARBARA L. NEILSON
Administrative Law Judge

Reported: Taped, No Transcript Prepared