IN THE MATTER OF THE PROPOSED RULE OF
THE DEPARTMENT OF HUMAN SERVICES GOVERNING
ELIGIBILITY TO RECEIVE PAYMENT AS A PROVIDER
IN THE MEDICAL ASSISTANCE PROGRAM
PARTS 9505.0170 to 9505.0475

STATEMENT OF NEED
AND REASONABLENESS

Minnesota Rules, parts 9505.0170 to 9505.0475 are proposed by the Department of Human Services as the standards to receive payment as a provider of health services to medical assistance recipients.

The medical assistance program in Minnesota 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. (See United States Code, title 42, section 1396a, hereafter abbreviated as 42 U.S.C.1396a.) Code of Federal Regulations, Title 42, section 431.10, (hereafter abbreviated as 42 CFR 431.10), requires a state to designate a single state agency to supervise the administration of a state's medical assistance program. The Department of Human Services has been so designated in Minnesota Statutes, section 256B.04, subdivision 1. Furthermore, 42 CFR 431.10 requires the state agency so designated to make rules and regulations that it will follow in administering the State Plan. The State Plan is the comprehensive written commitment of the department to administer and supervise the medical assistance program according to federal requirements. Correspondingly, Minnesota Statutes, section 256B.04, subd. 2 requires the Commissioner of Human Services to establish "uniform rules and regulations, not inconsistent with law" to ensure that the medical assistance program will be carried out in an efficient, economic, and impartial manner. Further justification for the rule is found in Minnesota Statutes, section 256B.04, subd. 4 which states, in part, that the department shall cooperate with the federal government "in any reasonable manner as may be necessary to qualify for federal aid in connection with the medical assistance program...". Thus, authority for the rule is derived from both federal and state law. It is through proposing these rules, and the holding of a public hearing thereon, that the public, all interested parties, and all persons affected by the rules are afforded the opportunity to comment upon the procedures and standards the department uses to carry out the mandates.

Rules to administer Minnesota's medical assistance program are necessary because they set uniform standards which can be objectively applied. Furthermore, these rules inform the public and affected persons of the medical assistance requirements that a provider must meet to receive medical assistance payment for health service to a recipient.

Parts 9505.0235 to 9505.0420 set forth the specific health services that are eligible for payment under the Minnesota medical assistance program. The services must be consistent, first, with federal regulations and, second, with Minnesota Statutes. 42 CFR, part 440, "interprets section 1905 (a) of the (Social Security Act) which establishes the services included in the term "medical assistance", sections 1905 (c), (d), (f)-(i), (l), and (m) define some of those services, and section 1915 (c) defines as "medical assistance" certain home and community-based services provided under waivers under that section. Services so identified include

those a state must provide and the optional services a state may provide to receive federal financial participation. Minnesota Statutes, chapter 256B, establishes a statewide program of medical assistance and specifies in section 256B.02, subd. 8 those mandatory and optional services that are eligible for medical assistance payment in Minnesota. As required in Minnesota Statutes, sections 256B.04, subdivisions 2 and 12, parts 9505.0240 to 9505.420, and 9505.0430 establish limits on the types and frequency of health services to an individual recipient that are eligible for medical assistance payment. 42 CFR 440.230 (d) permits the state to place appropriate limits on a service based on criteria related to medical necessity or utilization control procedures. Furthermore, 42 CFR 440.230 (b) requires each service to be "sufficient in amount, duration, and scope to achieve its purpose." Additionally, 42 CFR 440.240 (b) requires comparability of service for all recipients within a recipient group, that is, a categorically needy group or a covered medically needy group.

The department adopted the present rules related to covered services, eligibility to be a provider, and billing procedures in 1978. Minor amendments were made in 1979. Proposed parts 9505.0170 to 9505.0425, if adopted, will replace the present rules related to covered services other than chemical dependency, community mental health, psychiatric, psychological, rehabilitation agency, and rehabilitative and therapeutic services. (See the repealer clause, which appears on the last page of the proposed rules.) The department plans to propose new rules related to these services within the coming months.

The department was assisted by an advisory committee in developing these proposed rules. A list of the committee members is attached as an appendix. Additionally, the department has obtained comment and advice from providers and recipients who are concerned about specific rule provisions affecting them. A list of these persons and the rule parts on which their input was sought is also attached as an appendix.

9505.0170 APPLICABILITY

Part 9505.0170 sets forth the purpose and scope of the proposed rule and lists the federal and state laws and the federal regulations which authorize the department to adopt these rules and which state the requirements for the content of these rules. This provision states in part that these rules must be read in conjunction with Minnesota Statutes, chapters 256 and 256B. The department has chosen to call attention to these chapters of Minnesota Statutes as they are the ones that authorize the program, establish the eligible services, and thus have the greatest impact on its regulation under these rules. The department is aware, however, that other statutes also establish the conditions for these rules and will cite these statutes in the statement of need and reasonableness for the appropriate rule part. Therefore, this part is necessary and reasonable to inform persons affected by the medical assistance program.

In Minnesota, for FY 1985, the monthly average of persons receiving covered services in the medical assistance program was 143,600. Furthermore, Minnesota has approximately 20,000 health service providers. Medical assistance payments to these providers for fiscal year 1986 totaled one billion, 20 million dollars.

Some medical assistance services that meet the standards of parts 9505.0170 to 9505.0475 require specific department approval before they are given to a recipient in order to be eligible for payment. The procedures and standards for these services are established in the prior authorization and second surgical opinion rules, parts 9505.5000 to 9505.5105. Thus, it is necessary and reasonable to cite these rules so that affected persons are aware of all eligibility requirements.

9505.0175 DEFINITIONS

Subpart 1. Scope. This part defines terms that have a meaning specific to parts 9505.0170 to 9505.0475. The definitions are necessary to inform persons affected by these rules. Terms used in a manner consistent with current common usage in the health services industry will not be defined. Furthermore, definitions which are solely for the purpose of identification will be presumed both needed and reasonable without further justification. An example of such a definition is that of "Commissioner".

Subp. 2. Attending physician. The phrase "attending physician" is an abbreviation used in these rules to identify the specific physician responsible for managing the care of the recipient. A definition is necessary to clarify its meaning. The definition is reasonable because it is consistent with standards accepted by the medical community about who is responsible for a patient's care.

Subp. 3. Business agent. The term "business agent" identifies an intermediary in the business relationship between the provider and the medical assistance program. The definition is consistent with the common business practice of an agent acting on a client's behalf. The definition is consistent with 42 CFR 447.10(f) which permits billings by and medical assistance payments to a business agent such as a billing service or an accounting firm acting on a provider's behalf.

Subp. 4. Clinic. The definition is necessary to clarify a term used in these rules to identify those providers whose services are eligible for federal financial participation under the classification of "Clinic Services" in 42 CFR 440.90. The term "clinic" in these rules applies to those entities that are not part of a hospital and that provide outpatient services under the direction of a physician or dentist. The definition is consistent with the cited federal regulation.

Subp. 5. Commissioner. "Commissioner" means the commissioner of human services or his or her designee. It is an abbreviation used to shorten these rules.

Subp. 6. Covered service. The term "covered service" is an abbreviation used in these rules in referring to health services that meet the requirements of parts 9505.0170 to 9505.0475 and, thus, are eligible for payment under the medical assistance program. A definition is necessary to clarify its meaning Minnesota Statutes, section 256B.02, subd.8 states in general terms the health services whose costs may be paid from MA. Furthermore, Minnesota Statutes, section 256B.04, subd.12 authorizes the department to adopt rules that place limits on the types and frequency of services that "may be covered by medical assistance for an individual recipient, and the amount paid for each covered service." Therefore this definition is reasonable as it distinguishes between health services in general and those for which these rules set the limits required by statute.

Subp. 7. Dentist. A definition is necessary to clarify the meaning of the term in these rules. The definition is consistent with statute.

Subp. 8. Department. Department is an abbreviation used to shorten the length of these rules. A definition is necessary to clarify its meaning.

Subp. 9. Drug formulary. Minnesota Statutes, section 256B.02, subd. 8 authorizes the commissioner to establish a drug formulary. The term is used in these rules. Therefore, a definition is necessary to inform persons affected by the rules. The definition is consistent with statute.

Subp. 10. Durable medical equipment. The term "durable medical equipment" refers in these rules to a standard for equipment that is used by recipients in their residences or that must be provided by a long term care facility or hospital as part of the per diem payment.from medical assistance funds. The definition is necessary to clarify the term's meaning. The definition is consistent with Minnesota Statutes, section 256B.04, subd.14 (4)(a) to (h) which characterizes medical equipment by example. It is reasonable to specify that the need for the equipment be determined by the recipient's medical condition because the medical assistance program is premised on the medical necessity of services to a recipient. Furthermore, defining the equipment as appropriate for use in the recipient's residence is consistent with 42 CFR 440.70 (c) and the definition of "residence" in subpart 43.

Subp. 11. Emergency. Because the term "emergency" is used as a standard throughout these rules, it is necessary to clarify its meaning. The definition is consistent with Minnesota Statutes, section 256B.02, subd.8(4), which defines "emergency services."

The term "condition" is used in the definition as a generic reference to the health status of a recipient. "Condition" encompasses both physical and mental health problems which the involved health professional believes must receive immediate treatment to avoid or minimize further deterioration of the recipient's health condition. It is reasonable to include labor and delivery as emergency conditions because these conditions require immediate treatment.

Subp. 12. Employee. It is necessary to clarify the term "employee" because it is used to set a standard in these rules. A health service is not always provided to a recipient directly by the enrolled, licensed vendor, that is the provider, of the health service. The health service may sometimes be provided by an individual who works for the provider. Because 42 CFR 447.10 limits eligibility for medical assistance payments to a person or entity that is a provider, it is reasonable to define the status of the provider's employee in terms of the provider's financial relationship to the employee or contractual relationship to a self-employed vendor.

The American Heritage Dictionary of the English Language (New College Edition, 1978) defines "employee" as a "person who works for another in return for financial or other compensation." Thus, the definition is reasonable because it is consistent with a commonly accepted standard for an employee-employer relationship.

Further clarification of the employee-employer relationship is necessary because some persons who receive compensation from providers are independent contractors who, as self-employed persons, contract to provide certain services for the providers. State and federal laws do not require the withholding of taxes from payments made to such self-employed persons but do require withholding taxes from the compensation of employees. Thus, item B is reasonable as it distinguishes between employees and persons who are self-employed contractors.

The two criteria, items A and B, reflect the diverse employment patterns used to deliver health services. Examples of these patterns are: a physician assistant or nurse who may be employed by a physician; a psychologist who contracts with several mental health clinics to provide a specific psychologic service. Both the doctor and the mental health clinic are eligible to be providers and thus receive medical assistance payments.

The definition is consistent with the one used by Minnesota Blue Cross and Blue Shield in identifying the employer-employee relationship which qualifies for insurance claim payments.

Subp. 13 Health care prepayment plan or prepaid health plan. "Health care prepayment plan" or "prepaid health plan" are terms used in these rules to refer to an entity eligible to be a provider under Minnesota Statutes, section 256B.02, subd.8,(13) and 42 CFR, part 434. Minnesota STatutes, Chapter 60A specifies licensure requirements for organizations insuring medical, hospital, surgical, and other related expenses. Minnesota Statutes, Chapter 62A specifies that health and accident insurance issued in Minnesota must obtain the approval of the Commissioner of Commerce and, furthermore, specifies the policy requirements necessary to obtain the approval. Minnesota Statutes, Chapter 62C specifies the licensure requirements for nonprofit health service plans. Minnesota Statutes, Chapter 62D regulates health maintenance organizations Therefore, the definition is consistent with the statutory requirements for licensure and operation of the forms of prepaid health plans that may be established in Minnesota

Subp. 14. Health service. The definition is necessary to clarify a term used in these rules. Minnesota Statutes, section 256B.02, subd.8 establishes the "care and services" for which medical assistance may pay all or part of the costs. Thus, the definition is consistent with the statute.

Subp. 15. Home health agency. Minnesota Statutes, section 256B.02, subd. 8 (6) establishes "home health care services" as an allowable health service in the medical assistance program. A "home health agency" is a provider of these services and is a term used in these rules. Therefore, a definition of "home health agency" is necessary to clarify its meaning. 42 CFR 440.70 (d) states that a home health agency is "a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in Medicare." The definition is consistent with this federal regulation, which sets a condition for federal financial participation, and with Minnesota Statutes, section 256B.04 subd.4, which requires the department to act in "any reasonable manner as may be necessary to qualify for federal aid." 42 CFR 405.1201 to 405.1230 specify the Medicare conditions of participation for a home health agency.

Subp. 16. Hospital. "Hospital" is a term used in these rules in connection with "inpatient hospital services" which are medical assistance services authorized under 42 CFR 440.10 and Minnesota Statutes, section 256B.02, subd.8, (1). Therefore a definition is necessary to clarify its meaning. Minnesota Statutes, sections 144.50 to 144.58 and 144.696 define and specify the conditions for licensure and operation of Minnesota hospitals. The definition is consistent with statute. Furthermore the definition is consistent with 42 CFR 440.10 (a) (3) (i) and (ii) which require the inpatient hospital services to be provided in an "institution

that is maintained primarily for the care and treatment of patients with disorders other than tuberculosis or mental diseases;" and that "is licensed or formally approved as a hospital by an officially designated authority for State standard-setting" in order for the services to be eligible for federal financial participation.

Subp. 17. Inpatient. "Inpatient" is a term used in these rules. Therefore a definition is necessary to clarify its meaning. The definition is reasonable as it is consistent with the accepted usage of an inpatient being someone living in a hospital. When an inpatient is absent from a hospital on a pass ordered by a physician, the person, the physician, and the hospital expect the absence to be temporary, and the same as the period authorized on the pass, and to be consistent with the physician-approved plan of care and that the person will return to the hospital to complete the plan of medically necessary services. The period may be a few hours, overnight, or longer. However, when an inpatient leaves the hospital without a pass ordered by a physician, that is against medical advice, it is not known whether or when the patient will return to the hospital. Thus it is reasonable to limit the definition of "inpatient" to a person who is receiving or is expected to receive medically necessary services under a plan of care.

Subp. 18. Licensed consulting psychologist. The term is used in these rules. It is defined solely for identification purposes and is consistent with Minnesota Statutes, section 148.91, subd. 4.

Subp. 19. Licensed practical nurse. The term is used in these rules. It is defined solely for identification purposes and is consistent with Minnesota Statutes, section 148.29 to 148.299.

Subp. 20. Licensed psychologist. The term is used in these rules. It is defined solely for identification purposes. The definition is consistent with Minnesota Statutes, section 148.91, subd. 5.

Subp. 21. Local agency. "Local agency" is a term used in these rules. It is defined solely for identification purposes. It is the agency that administers the medical assistance program on a day to day basis subject to the supervision of the Department of Human Services.

Subp. 22. Local trade area. "Local trade area" is a term used in these rules. The definition is the same as the one in part 9505.5005, subpart 11, which applies to the procedures related to the prior authorization of health services to recipients of medical assistance. Using the same definition applicable to services to recipinets under another rule is reasonable because it ensures consistency of standards and avoid possible confusion.

Subp. 23. Long-term care facility. 42 CFR 440.40 and 440.150 authorize federal financial participation for skilled nursing facilities and intermediate care facilities respectively. "Long-term care facility" is used in these rules as an abbreviation for the terms skilled nursing facility, intermediate care facility, and intermediate care facility for the mentally retarded in order to shorten the length of these rules. A definition is necessary to clarify its meaning. Limiting the definition to the facilities certified by the Minnesota Department of Health is reasonable because the certification is necessary to qualify medical

assistance payments to the facility for federal financial participation. Obtaining such participation is necessary to comply with Minnesota Statutes, section 256B.04, subd.4.

Subp. 24. Medical assistance. It is necessary to identify the particular program governed by these and related rules that exist to assist in paying the costs of health services to persons who are determined eligible for assistance. The definition is solely for purposes of identification.

Subp. 25. Medically necessary or medical necessity. Medical assistance payment for a health service is based on the assumption that the service is health related (medical) and necessary for the recipient's well being. Under Minnesota Statutes, section 256B.04, subd. 15 the department must determine whether the use of a medical assistance service is necessary and must investigate the presentment of claims for service not medically necessary. Thus, it is necessary to define the standard of medical necessity that determines whether a particular health service is eligible for medical assistance payments.

The American Heritage Dictionary of the English Language defines diagnosis as "the act or process of identifying or determining the nature of a disease through examination";..."an analysis of the nature of something." Thus, the diagnosis of a health condition analyzes its nature and is used to determine the treatment that is medically necessary to correct or improve the recipient's health. Therefore, it is reasonable to require the health service to be consistent with the recipient's diagnosis or condition as only such a service can be presumed to correct or improve the recipient's health condition.

Item A. Minnesota Statutes, section 256B.04, subd.15 requires the commissioner to determine medical necessity in consultation with a provider advisory committee, whose members are recommended to the commissioner by the appropriate provider organizations. Therefore, item A is consistent with statute.

A provider's peer group will discard a less effective service as soon as a more effective service is available. On the other hand, until the effectiveness or absence of possible detrimental effects of an investigative or experimental service is established, the provider's peer group does not accept it as the prevailing standard or current practice. Thus, defining "medical necessity" or "medically necessary" in terms of the prevailing standard or current practice is reasonable because it ensures medical assistance payment will be made only for services effective in treating a health condition and furthermore safeguards against inappropriate use of medical assistance services.

Item B. Part 9505.1750, subpart 8 defines "medically necessary" for the purposes of the surveillance and utilization review program which is authorized in Minnesota Statutes, 256B.04, subd.15. Item B is consistent with this definition. A serious physical or mental disability may result in decreasing or removing a person's ability to be self-supporting; it also may increase a person's need for health services. However, treating a condition that could result in serious physical or mental disability may prevent or reduce the disability and thus remove or limit the possible loss of income or need for increased health services. Therefore the health service would be cost effective. It is reasonable to include such a health service within the definition of medical necessity to ensure a program that operates in an efficient and economical manner as required by Minnesota Statutes, section 256B.04, subd.2. Similarly, health care associated with pregnancy, labor, and delivery can significantly reduce

infant mortality rates, the incidence of births with low birth weights, and post-pregnancy debilitation of the mother. All of these adverse conditions increase the costs of care of the mother or the infant. Thus it is reasonable to include care for the mother and child through the maternity period as a medical necessity because such care is cost effective as required by Minnesota Statutes, section 256B.04, subd.2. Furthermore care of the mother and child through the maternity period is the prevailing standard of current medical practice and thus is consistent with item A.

42 CFR 440.130 (d) states that "rehabilitative services" are eligible for federal financial participation under medical assistance. Furthermore 42 CRF 440.130 (d) defines these services to include "any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts.....for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level." The similar langauge in item B about restoration of physical or mental function to an achievable level is consistent with the federal regulation.

Item C. 42 CFR 440.130 (c) states that "preventive services" are eligible for federal financial participation under medical assistance. Thus, item C is consistent with the federal regulation.

Thus, the complete definition of "medical necessity" implements the concept that the health and well-being of the eligible medical assistance population depends on the use of a spectrum of services which range from reactive emergency services to proactive preventive services. The definition in its entirety is reasonable because it takes into account the diversity of the health conditions of the eligible medical assistance population. The definition is consistent with 42 CFR 440.2 (a) which states within the definition of "patient", "an individual receiving needed professional services that are directed....toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain."

Subp. 26. Medicare. Medicare means the health insurance program for the aged and disabled under Title XVIII of the Social Security Act. The definition is necessary for purposes of identification.

Subp. 27. Mental health practitioner. "Mental health practitioner" is used in part 9505.0345, subpart 1, item A to refer to certain persons who are physicians' employees. Furthermore, this term is used in connection with the provision of certain psychological and psychotherapy services in parts of the present rule which are being retained until later this year. A definition is necessary to clarify its meaning and establish a standard. Minnesota Statutes do not define this term nor require such a category of persons to be licensed. Therefore, it is reasonable to use a standard from an already adopted rule, part 9520.0760, subpart 17, which sets the standards for mental health practitioners in mental health centers and clinics seeking department approval for insurance and subscriber contract reimbursement purposes. Use of this standard ensures consistency between rules related to the medical assistance program.

Subp. 28. Mental health professional. "Mental health professional" is used in these rules to refer to certain persons who are physicians' employees. Furthermore, this term is used in connection with the provision of certain psychological and psychiatric services in parts of the present rule which are being retained until later this year. A

definition is necessary to clarify its meaning and establish a standard. Minnesota Statutes do not define this term nor require such a category of persons to be licensed. Therefore it is reasonable to use a standard from an already adopted rule, part 9520.0760, subpart 18, which sets the standards for mental health professionals in mental health centers and clinics seeking department approval for insurance and subscriber contract reimbursement purposes. Use of this standard ensures consistency between rules related to the medical assistance program.

Subp. 29. Nondurable medical equipment. "Nondurable medical equipment" is a term used in these rules. A definition is necessary to clarify its meaning. The American Heritage Dictionary of the English Language defines durable as "able to withstand wear and tear or decay; lasting". "Nondurable" is the opposite of "durable". Therefore, the definition is reasonable because it is consistent with common usage and clearly distinguishes "durable" from "nondurable".

Subp. 30. Nurse practitioner. "Nurse practitioner" is a term used in these rules to refer to a person whose services may be eligible for medical assistance payment. Therefore a definition is necessary to clarify its meaning and set a standard. Minnesota Statutes do not define the term. However two national professional organizations of nurses, the American Nurses Association and the National Board of Pediatric Nurse Practitioners and Associates, recognize and set certification requirements for the nursing specialty of "nurse practitioner." The definition is reasonable because it incorporates the standards of the peer groups qualified to make a determination of nursing credentials.

Subp. 31. On the premises. "On the premises" is a phrase used in subpart 47 in regard to the physical nature of supervision, that is, to ensure the services of unlicensed personnel are provided in proximity to a trained, licensed enrolled provider who could intervene if necessary. The definition is consistent with Minnesota Statutes, section 256B.02, subd.8(4) which requires at least one physician to be "on the premises" when a physician-directed clinic is open and also requires all services in the clinic to be under the direct supervision of the physician who is on the premises. Thus requiring the provider to be physically within the facility is reasonable because it is consistent with the direct supervision required by statute. Services within a hospital are customarily organized by departments that specialize in a particular area of practice and that are headed by a physician trained in the specialty. In many hospitals the locations of these departments are physcially separated from each other. Thus, requiring the provider to be physically located in the department within the hospital is reasonable because it is consistent within a common practice of hospitals and assures that a knowledgeable supervising physician will be readily at hand to make decision about a recipient's acute care needs.

Subp. 32. Performance agreement. The term "performance agreement" is used in these rules to distinguish between the provider agreement required of all vendors as a condition of eligibility for medical assistance payment and an agreement that sets forth performance requirements for certain types of medical supplies and equipment. A definition is necessary to clarify its meaning. The definition is reasonable because it contains the usual elements of a contract and including the elements that are the specific obligations of a vendor of such supplies and equipment.

Subp. 33. Physician. The term "physician" is used throughout these rules. A definition is necessary to clarify its meaning and set the standard. The definition is consistent with 42 CFR 440.50 which identifies a "physician service" (for purposes of medical assistance reimbursement) as one "within the scope of practice of medicine....as defined by State law."

Subp. 34. Physician assistant. "Physician assistant" is a term used in these rules. A definition is necessary to clarify its meaning and set a standard. Minnesota Statutes do not define the term or set the qualifications of the profession. However, The Board of Medical Examiners has promulgated a rule setting the standards for the registration of physician assistants. The definition is consistent with the rule, parts 5600.2600 to 5600.2665.

Subp. 35. Plan of care. "Plan of care" is a term used in these rules as a requirement placed on a provider in order to receive MA payment for otherwise covered services. A definition is necessary to clarify its meaning and set the standard to enable provider compliance. As used in these rules, a plan of care sets out the medical management of a recipient. Therefore, the plan must contain all the components necessary for the medical management of the recipient's care. This concept is consistent with the requirements of 42 CFR 441.102 and 42 CFR 442.319. Furthermore, 42 CFR 441.102 requires the plan to be "recorded". During the time a recipient is in a long term care facility or a hospital or is receiving physician services, the recipient's attending physician is responsible for the recipient's care. Other providers are responsible for other covered services. Thus, item B is reasonable because it is consistent with customary medical practice. It is also reasonable to provide an exception from requiring physician or provider review and approval before implementation in an emergency because attention in an emergency situation must focus on the care medically necessary to remove the patient from a life-threatening situation and the required review and approval are carried out only after the care is given . The proposed definition is consistent with part 4655.6000, the Minnesota Department of Health rule that defines plans for patient care in nursing homes.

Subp. 36. Podiatrist. "Podiatrist" is a term used in these rules. A definition is necessary to clarify its meaning and set a standard. The definition is consistent with the podiatrist licensing requirements of Minnesota Statutes.

Subp. 37. Prior authorization. "Prior authorization" is a medical assistance program procedure used by the department to assess the need for and appropriateness of a certain health service in relation to a recipient's diagnosis before the provider begins the service. The term is used in these rules. Thus a definition is necessary to clarify its meaning. The cited part, 9505.5010, governs the standards of the procedure.

Subp. 38. Provider. "Provider" is a term used in these rules to distinguish between a person who furnishes health services and has chosen or is eligible to choose to enroll in the MA program and a person who furnishes health services and is not eligible, or chooses not to enroll in the MA program. A definition is necessary to clarify its meaning. The definition is consistent with 42 CFR 400.203, which states, "Provider

means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency." The definition is also consistent with part 9505.1705, subp.11

Subp. 39. Provider agreement. "Provider agreement" is a term used in these rules. Therefore, a definition is necessary to clarify its meaning. The definition is consistent with 42 CFR 431.107 and part 9505.0195.

Subp. 40. Psychiatrist. "Psychiatrist" is a term that appears in part 9500.1070, subpart 4, item B and subpart 23 which are being retained for amendment later this year. It is used in these rules to identify a person who is eligible to choose to be a provider in the medical assistance program. A definition is necessary to clarify its meaning and set a standard. Minnesota Statutes do not define or set qualifications for psychiatry. However, the American Board of Psychiatry and Neurology is the national organization that accredits post graduate programs to train physicians in psychiatry. The Board requires a candidate to successfully complete a three year program. Therefore, the definition is reasonable because it incorporates a standard set by the national organization of peers who practice psychiatry.

Subp. 41. Recipient. "Recipient" is an abbreviation used in these rules to refer to persons who are eligible for health services paid for by medical assistance. A definition is necessary to clarify its meaning. The definition is consistent with 42 CFR 431.50 B and Minnesota Statutes, section 256B.02, subd.8 and 256B.05.

Subp. 42. Registered nurse. "Registered nurse" is a term used in these rules. A definition is necessary to clarify its meaning. The definition is reasonable because the cited statute specifies the qualifications required to register as a licensed nurse in Minnesota.

Subp. 43. Residence. These rules limit or prohibit medical assistance payment for certain services provided in the "residence" of the recipient. Therefore, a definition is necessary to clarify the meaning of the term and set a standard for payment eligibility. Webster's New World Dictionary (Second College Edition, 1974) defines "residence" as "the fact or status of living or staying in a place...long enough to qualify for certain, rights, privileges, etc." and "the place in which a person...resides; dwelling place; abode, esp. a house." The proposed definition is reasonable as it consistent with accepted usage that considers the recipient's intent to stay in a place as a deciding factor.

Subp. 44. Screening team. "Screening team" is a term used in these rules. A definition is necessary to clarify its meaning and set a standard. The definition is consistent with Minnesota Statutes, section 256B.091. Extending the screening team definition to populations other than applicants for admission to nursing homes is reasonable to ensure consistency of standards between the various medical assistance programs and thus avoid confusion and duplication of effort.

Subp. 45. Second surgical opinion. "Second surgical opinion" is a term used in these rules to refer to a specific requirement of the medical assistance program. A definition is necessary to clarify its meaning. The definition is reasonable because it provides the readers the citation to the rule governing the requirement.

Subp. 46. Supervision. This term describes the degree of a provider's professional oversight of an employee's services if the services are to be eligible for payment under medical assistance. A definition is necessaryto clarify its meaning and set a standard. The American Heritage Dictionary of the English Language defines "supervise" as "to direct and inspect the performance of workers; oversee; superintend." The proposed definition mirrors this usage. It is reasonable to place full professional responsibility on the provider because the provider has the contract with the department and thus is responsible to provide the services according to the contract. A supervisee usually has less experience and training than the provider-supervisor and therefore may require guidance in furnishing the health services. Thus, it is reasonable to require a supervising provider's direct involvement in the instruction and direction of the supervisee because such instruction and direction will aid in ensuring health services are properly provided to a recipient.

Item A. Hospital calls, conferences, and home vists sometimes require a provider to leave the office. It is not reasonable to assume that a provider's employees must stop work while the provider is gone because the provider has the ability to judge what the supervisee is qualified to do and therefore can assign the employee tasks that the employee is able to perform during the provider's absence. However, a standard of time the provider must be present is necessary so that the department can uniformly administer the supervision requirement. The requirement of at least 50 percent on-site supervision is the same as the policy established by Blue Cross and Blue Shield of Minnesota in Provider Bulletin No. P15-83 of July 12, 1983. (See Exhibit---.) The bulletin provided in part that the "employing M.D. or D.O. must be physically present and immediately available in the same office suite the majority of the time (greater than 50%) when the employed health care professional is providing services." Therefore, the 50 percent standard proposed in this item is reasonable because it is the standard now used by a major Minnesota carrier of health insurance in determining services eligible for payment under its insurance plans. Exempting community mental health centers from the standard is reasonable because program and supervision requirements for their professional services are governed by parts 9520.0750 to 9520.0870.

Item B. Requiring the provider to review the diagnosis is reasonable because it ensures that the person approved by the department to participate in the program has an opportunity to review the employee's work. Requiring the provider's signature is reasonable because a person's signature is customarily accepted as evidence that the person had an opportunity to review and approve the document's contents before signing it.

Item C. Requiring the provider to approve the plan of care before treatment is begun is reasonable because it ensures that the person approved by the department as fully qualified has an opportunity to review the plan and thus determine whether the plan specifies the care necessary and appropriate for the recipient's diagnosis. Furthermore, it is reasonable to distinguish between emergency and non-emergency treatment when dealing with a required approval of the care plan because withholding treatment for an emergency until the provider approves the plan is contrary to the best interests of the recipient who requires immediate treatment. (See subpart 11, Emergency.)

Item D. One condition of eligibility for medical assistance payment is that a recipient's treatment (that is, health services) must be carried out under a plan of care. Requiring the provider to review the record of

treatment is reasonable because it ensures that the person approved by the department to participate in the program has an opportunity to review whether the prescribed treatment has been given. The provider's signature is a reasonable requirement because it is evidence that the provider has had an opportunity to review the record. That the review occur as soon as possible after treatment is reasonable to ensure any treatment corrections or modifications are made in a timely manner. Thus a standard is necessary. Five working days is a reasonable period to complete the review as it balances the possible need for modification or correction against the workload of the provider-supervisor. It is reasonable to exempt community mental health centers from the five day review requirement because standards for the health services of community mental health centers are set in parts 9520.0750 to 9520.0870.

Subp. 47. Surgical assistant. "Surgical assistant" is a term used in these rules. A definition is necessary to clarify the meaning because of the similarity between two terms: assistant surgeon and surgical assistant. The definition is reasonable as it distinguishes between licensed persons such as physicians, dentists, and podiatrists whose scope of practice includes surgical procedures and unlicensed persons without legal authority to perform such procedures.

Subp. 48. Third party. "Third party" is a term used in these rules to refer to a party with an obligation to pay health services bills on behalf of a recipient. A definition is necessary to clarify its meaning. The definition is consistent with 42 CFR 433.136 as amended and with the definition found in part 9505.0070 which sets a requirement for medical assistance eligibility.

Subp. 49. Usual and customary. "Usual and customary" is a term used in these rules to set a standard for payment of certain health services. A definition is necessary to clarify its meaning and inform providers of appropriate medical assistance billing procedures. Furthermore, the definition is necessary to clarify the difference between "usual and customary" in the medical assistance program and the term "customary charges" as defined for use in Medicare in 42 CFR 405.503. 42 CFR 447.271(a) states that the department may not pay a provider more than the provider's customary charges to the general public for the services. 42 CFR 447.325 states that the department may pay the customary charges of the provider but not more than the "prevailing charges in the locality for comparable services under comparable circumstances." Furthermore, 42 CFR.447.331 (a) states that the department "may not pay more for prescribed drugs than the lower of ingredient cost plus a reasonable dispensing fee or the provider's usual and customary charge to the general public." HCFA in its letter to the department on July 17, 1981 clarified the meaning of "general public" and stated that 42 CFR 447.431 neither makes nor gives authority to make separate categories of usual and customary charges for cash customers and charge customers (See exhibit). Thus, the proposed definition is consistent with federal limitations placed on payments for covered services. Furthermore, it is reasonable to include third party payers as a category of payer because third party payers may constitute the largest category of payers billed by a provider for services to the provider's non-medical assistance clientele.

Subp. 50. Vendor. Vendor is a term used in these rules. A definition is necessary to clarify its meaning. The definition is consistent with Minnesota Statutes, section 256B.02, subd.7, which defines "vendor of medical care" as "any person or persons furnishing, within the scope of his respective license" certain categories of medical care. It is necessary for purposes of these rules to clarify the relationship between a vendor and a provider as "vendor" is the term used in applicable statutes and "provider" is used in applicable federal regulations and these rules. "Provider" is applied in these rules to the vendors who have signed provider ag- ments with the department to provide the medical assistance health services authorized in Minnesota Statutes, section 256B.02, subd.7. See subpart 38.

9505.0180 SURVEILLANCE AND UTILIZATION CONTROL PROGRAM

Subpart 1. This subpart is necessary to identify the monitoring and review mechanisms which federal regulations require in the medical assistance program and thereby inform affected persons. The definitions are consistent with the rule that governs the surveillance activity in the medical assistance program, that is, parts 9505.1750 to 9505.2150.

Subpart 2. A state must have a Surveillance and Utilization Control Program in order to qualify for federal financial participation. Specifically, 42 CFR 456.3 states, "The Medicaid agency must implement a statewide surveillance and utilization control program....." This proposed subpart is necessary and reasonable to maximize federal financial participation as required by Minnesota Statutes, section 256B.04, subd.4 and also to ensure that persons affected by the standards set in the rule for surveillance (parts 9505.1750 to 9505.2150) and in the federal requirements (42 CFR 455) are aware of the program. Further, it is reasonable to adopt the utilization control function established under 42 CFR 456 to ensure that the department is in compliance with federal regulations and is not subject to paybacks resulting from federal disallowances due to lack of compliance.

Subpart 3. 42 CFR 456.3 requires a program to safeguard against unnecessary or inappropriate use of Medicaid services and against excess payments; to assess the quality of those services; to provide for the control of the utilization of services. 42 CFR 456.23 requires the department to have a postpayment review process that allows the state to review recipient utilization and provider service profiles and also to identify exceptions so that the department can correct misutilization practices of providers and recipients. Minnesota Rules, parts 9505.1750 to 9505.2150 govern that program. Therefore the provision is necessary and reasonable to make affected persons aware of the mandatory program.

Subpart 4. The program of Utilization Control must be implemented as required in 42 CFR 456 in order to maximize federal participation as specified in Minnesota Statutes, section 256B.04, subd.4. Section 1905(g)(1) of the Social Security Act provides for a reduction of Federal Medicaid funds if a state does not demonstrate satisfactorily that an effective Utlilization Control program is in place. Therefore the proposed subpart is necessary and reasonable to make affected persons aware of the mandatory requirements.

9505.0185 PROFESSIONAL SERVICES ADVISORY COMMITTEE

Minnesota Statutes, sections 256B.04, subd. 15 and 256B.064, subd. 1a require that "the determination of whether services are reasonable and necessary shall be made by the commissioner in consultation with a professional services advisory group appointed by the commissioner". This part is necessary to clarify the membership of the committee, its duties, and operation.

Subpart 1. Appointees. The inherent premise behind review by an advisory committee is to obtain a peer review by professionals possessing academic and experience qualifications for deciding questions of the necessity and reasonableness of care. Licensure or certification is evidence of professional qualification; familiarity with the health needs of low-income population groups provides the experiential base for evaluating a particular service in light of the health needs of medical assistance recipients who are part of the low-income population. That the committee's members be representative of the types of covered services is necessary to ensure that the members are qualified to appropriately review the service and is consistent with the Minnesota Statutes cited above. Requiring at least 15 members ensures the availability of the different provider types who comprise the spectrum of health services and experiences necessary to make an informed, reasonable recommendation to the commissioner.

Items A to C are necessary to establish the procedure of choosing persons to serve on the committee. An open appointment process permits interested qualified persons who may not be known to the appointing authority to apply to be committee members. Such an approach ensures a pool of interested potential members. The provision is reasonable because the State Register is the official publication used to inform persons affected by state actions. As previously discussed, utilization review by peers requires appropriate peer representation on the review committee.

Subp. 2. Condition of appointment. Minnesota Statutes, Section 16B.17 establishes the standards for contracting for professional and technical services. This subpart is consistent with the statute and is necessary to inform affected persons.

Subp. 3. Committee organization. A chairperson is necessary to effective committee operation. Appointment of a chairman by the commissioner is reasonable because the commissioner has responsibility for implementing medical assistance, is knowledgable about the expertise needed to serve as a professional adviser to the department, and, therefore, should have the right to decide who is qualified to assume the leadership role necessary to ensure effective committee operation. The diversity of the medical assistance program does not permit committee members to be knowledgeable about all aspects of the program even though they are knowledgeable about broader policy issues. Thus, a meeting of the whole committee may be unnecessary if the policy being discussed requires special expertise in a limited area. A subcommittee of individuals with appropriate knowledge and expertise is more efficient and more equitable to the provider group and to the recipient population. Thus permitting a subcommittee to act for the committee is reasonable because a knowledge-based decision will be efficiently obtained. In some instances only one committee member may be needed to provide the necessary professional expertise. Thus the rule is reasonable as it allows organizational flexibility.

Subp. 4. Committee meetings. It is reasonable to specify that the committee meet at the call of the committee's chair or the department as they are best informed about what work is necessary and can avoid unnecessary meetings. Including telephone conferences within the term meetings is reasonable because a telephone conference is cost effective, permits an effective use of time and professional resources, and enables a quick response to situations that may require immediate discussion and recommendation.

Subp. 5. Duty to advise commissioner. Minnesota Statutes, section 256B.04, subd. 15, requires the determination of whether services are necessary and reasonable to be made by the commissioner in consultation with an appointed professional services advisory group. This subpart is necessary to establish the matters about which the advisory group shall, upon request, advise the commissioner. The items A to H are consistent with the content of a utilization review program as established under Minnesota Statutes, section 256B.04, subd. 15. The items are reasonable and necessary to inform the committee of its duties.

Subp. 6. Other duties. Qualified health care professionals are the persons who are knowledgeable in their areas of expertise and, therefore, are most likely to be aware of changes and problems in these areas. Because the commissioner needs knowledge and advice about current health practices and service problems, this provision is necessary and reasonable to enable the consultants to initiate discussions and recommendations on matters related to the utilization review program.

9505.0190 RECIPIENT CHOICE OF PROVIDER

This part is consistent with Minnesota Statutes, section 256B.01 and with 42 CFR 431.51 which requires the MA program to provide each recipient a free choice of vendor except under the circumstances specified in 42 CFR 431.54. Additionally, this part is consistent with Minnesota Statutes, section 256B.69 and parts 9505.1750 to 9505.2150. The circumstances permitting the department to restrict a choice of vendor are: those situations where a cost effective yet suitable alternative is in place, such as a prepaid health plan and competitive bidding; and those situations where a pattern of service utilization indicates abusive practices and thus contraindicates free choice by the recipient. In safeguarding both the health needs of the recipient and the financial needs of the program it is reasonable to limit choice if care is not also limited. Therefore, this part is necessary and reasonable to inform affected persons.

It is reasonable to restrict a recipient enrolled in a prepaid health plan to that plan so that duplication of payments is avoided. The per capita payment to a prepaid plan on behalf of a recipient covers all medically necessary care. Failure to restrict a recipient to the plan could easily result in excessive payments.

It is reasonable to restrict recipients to providers within Minnesota or within the recipient's local trade area because, since state and county tax dollars pay approximately 48% of Medicaid expenditures, the state's MA program should act to keep those dollars within the state. Thus, the restriction is consistent with Minnesota Statutes, section 256B.04, subd.2. However, a recipient who lives near the state's border may be accustomed to a local trade area in an adjoining state or may find services nearer at hand in an adjoining state. Thus it is probably more cost effective for the state and less burdensome on the recipient to permit the recipient to use the same nearby out-of-state health service providers as the person located in the recipient's area who is not a recipient.

Furthermore, if necessary health care is not available in Minnesota, it is reasonable to permit a recipient to seek those services wherever they are, including outside of the state. Requiring the department's prior authorization of services provided outside of Minnesota is reasonable as the department has the information necessary to determine which services are available in Minnesota and which must be sought outside of Minnesota and thereby to ensure consistency with Minnesota Statutes, section 256B.04, subd.2.

It should be noted that 42 CFR 431.55 (f) requires the department to obtain the federal government's approval of any additional restrictions of free choice of provider beyond the health maintenance organization restriction and a recipient restriction as a result of abuse.

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9505.0195 PROVIDER PARTICIPATION

Subpart 1. Department administration of provider participation. Minnesota Statutes, section 256B.04, subdivision 1 authorizes the department to supervise the administration of the Medicaid program, including carrying out and enforcing provisions of rule and law so that medical assistance is administered throughout the state in a uniform and impartial manner. To that end, the department must ensure that vendors who meet minimum standards defined by law and who act within any required legal constraints are available to provide health services. Therefore, this subpart is necessary and reasonable to inform affected persons of the department's functions in carrying out these responsibilities.

A. In order to ensure that providers are potentially capable of providing quality health care, it is necessary that the department determine whether a provider possesses the minimum credential or experience necessary to comply with federal credentialing requirements, and state licensure law. This provision is reasonable because it makes the reader aware of the sections of the rule which contain the credential and experience standards.

B. The department must complete the necessary administrative functions to establish eligibility for medical assistance payment. The administrative process requires determination of a date of enrollment for a provider to be eligible to be paid for services to a medical assistance recipient. The provision is reasonable as it balances the need for a uniform standard and the need of a non-enrolled vendor who provided services to a recipient in good faith to be paid for those services. A time limit on retroactive enrollment is necessary to ensure the conduct of medical assistance in an efficient manner as required in Minnesota Statutes, section 256B.04, subd.2. The limits chosen are consistent with the department's present practice.

C. An enrollment mechanism for vendors outside of Minnesota is necessary so that payment can be made if a recipient receives health care from a vendor located in another state. Therefore, it is reasonable to require the department to enroll such vendors as the department has the responsibility to administer the program and establish the standards for enrollment. See also the SNR for subpart 8.

D. A necessary part of effectively administering provider participation is to ensure that the enrolled vendor is following the rules and regulations of the program. In addition to the requirements of item A, an enrolled vendor must comply with parts 9505.1750 to 9505.2150. Furthermore, it is reasonable to expect the department to enforce the vendor's compliance with the terms of the provider agreement as the vendor is presumed to be knowledgeable about the contracts requirements and has willingly entered into the contract as a condition of particpation and eligibility for payment. It is reasonable to state the department's obligation to enforce these requirements so that the affected persons are aware of their obligations.

Subp. 2. Application to participate. Participation in the medical assistance program is voluntary. Providers who wish to receive medical assistance payments must apply and are the most able to provide the information necessary to permit the department's assessment of their qualifications. Furthermore, because acceptance of medical assistance payments obligates the provider as specifed in subpart 1, item D, the terms of participation must be openly stated and acknowledged in the

enrollment material. Therefore, the provision is necessary to clarify the application process. The process is reasonable as it states the information required, who must furnish it, and where to send it. The subpart is consistent with 42 CFR 431.107, concerning provider agreements.

Subp. 3. Department review of application. This subpart is necessary to establish the criteria the department will use to determine a vendor's eligibility to enroll as a provider. It is reasonable because all of the criteria applicable to provider participation are found in the cited rules.

Subp. 4. Notice to vendor. Requiring the department to notify a vendor of the department's action on the vendor's application is necessary and reasonable because it protects the provider's rights. A complete application is necessary and reasonable so that the department has all the information required under the applicable rules and can apply a uniform standard in determining the provider's qualifications. A time limit for the department's action on a vendor's application is necessary so that the vendor will receive timely information about eligibility for payment of services to recipients and thus be assured of payment for recipient's health services that are within the limitations of these rules. A thirty day determination period is reasonable because it balances the time the department requires to verify qualifications, to establish eligibility, to make necessary changes in the invoice processing/payment system, and the right of the applicant to receive a determination as soon as possible. Beginning the thirty-day period upon receipt of the complete application is reasonable because the complete application is necessary to the department's determination. It is reasonable to require the department's notice to be written in order to provide a record and avoid misunderstandings.

A. This item is reasonable because it informs the applicant about his status in regard to the medical assistance program.

B. This item is also reasonable because it informs the applicant about his status in regard to participation. Denial of the right to participate affects a provider's ability to conduct his business. Therefore, it is reasonable to inform the provider of the specific reasons for the denial so that the provider has an opportunity to give more information, act to meet the qualification criteria imposed in these rules, and thereby protect his right to due process.

C. Circumstances such as incomplete information may delay the department's ability to decide about an applicant's participation. Thus, this item is necessary to cover these circumstances. It is reasonable to require the department to notify the applicant, state the reasons for the delay, and request any additional information needed to complete the decision because such notice will give the applicant an opportunity to comply.

Subp. 5. Duration of provider agreement. This subpart is necessary to set the duration of the agreement so that both the department and the provider are informed and misunderstandings are avoided.

A. If the duration is specified in the agreement and the provider freely completes that agreement, the duration becomes a mutually agreed upon contract term. Therefore, the provision is reasonable because it has been agreed to by both parties.

B. The department needs a means of dealing with a provider who has not

complied with the obligations the provider agreed to. Thus, this item is reasonable because it bases agreement termination on the provider's failure to comply with the terms of his agreement.

It should be noted that provider agreements with long-term care facilities have terms that differ from items A and C. For example, the agreement is for a period of one year and is renewable contingent upon the provider's continued compliance with nursing home standards. Furthermore, a 90 day notice is required if the department is going to terminate the agreement. These requirements are necessary and reasonable because they protect both the health of the recipients in the long-term care facility and their right to receive covered services by providing time to arrange for their transfer to another long-term care facility that does have a provider agreement with the department.

D. A provider agreement establishes a contractual relationship between the two parties signing the agreement, the provider and the department. An individual or entity who purchases or receives ownerhsip or control of a provider's assets was not a signatory to the agreement and, thus, may be unaware of or unwilling to agree to the terms of the agreement. Thus, it is reasonable to end a provider's agreement if the provider's assets are sold or transferred because the termination provides the opportunity for the buyer or the individual or entity assuming control to review the conditions for participation and to make a clear decision about agreeing to the conditions.

D. From time to time the department revises the provider agreement. For example, the revision may be needed to clarify the language of the agreement or standards of participation may change because of changes in prevailing standards of practice among a providers' peer group. Therefore, it is reasonable to require a provider to sign a new agreement at such time because such a requirement will ensure all providers of a particular health service are being held to a uniform standard. This requirement is consistent with Minnesota Statutes, section 256B.04, subd.2, which requires the department to administer medical assistance uniformly throughout the state. 30 days notice of termination of the agreement is reasonable because it provides a period in which the provider can thoroughly review the new agreement and decide whether to enter into it.

E. Since participation in the medical assistance program is voluntary, a provider can reasonably discontinue participation at his discretion.

Subp. 6. Consequences of failure to comply. This subpart is necessary to inform affected persons of the consequences of failure to comply with these rules. Minnesota Statutes, section 256B.04, subd. 10 authorizes the department to promulgate rules governing the control of fraud, theft and abuse in Minnesota's medical assistance program. Because parts 9505.1750 to 9505.2150 were promulgated pursuant to this statute to control fraud, theft and abuse, and set the consequences of failure to comply, it is reasonable to cite them here.

Subp. 7. Vendor who is not a provider. Minnesota Statutes, section 256B.04, subd. 2 requires the department to administer the medical assistance program uniformly throughout the state in an efficient and impartial manner. This subpart is consistent with statute because it ensures that all parties who provide recipients covered services are subject to the requirements of these rules. Although a provider agreement

is a condition of participation, human or computer error may cause or permit a non-enrolled vendor to receive a provider identification number and to receive payments under the program. The submission of claims and acceptance of medical assistance payments constitutes an implied contract which should have the same force and effect as a duly completed provider agreement. Therefore, the provision is reasonable because it establishes the same standard - the applicability of these rules - to persons who accept medical assistance payments regardless of completion of a provider agreement.

Subp. 8. Sale or transfer of entity providing health services. As stated above in subpart 5, item C, a provider's agreement with the department ends at the time the provider sells or transfers ownership, assets, or control of an entity enrolled to provide medical assistance services. Thus, it is reasonable to require such a provider to notify the department because the notice is necessary to enable the department to maintain accurate records about providers and to monitor compliance with the provider agreement as required in subpart 1, item D. Likewise, it is reasonable to require the purchaser or transferee to notify the department so that the department may review the qualifications of the purchaser or transferee to determine whether the purchaser or transferee is eligible to enroll (see subpart 1, item A) and provide an opportunity for the purchaser or transferee that is qualified to agree to the conditions required to receive medical assistance payment. The 30 day notice period is necessary and reasonable because it provides a uniform period of sufficient length to carry out the requirement. Requiring the seller to give notice before the effective and the buyer or transferee after the effective date is reasonable because this is consistent with their obligations as seller and buyer. Specifying the consequences of failure to provide the notices in a timely manner is necessary to encourage compliance and inform affected parties. Making the purchaser or transferee subject to monetary recovery of payments resulting from error or abuse is consistent with Minnesota Statutes, section 256B.04, subd. 10 and with parts 9505.1750 to 9505.2150.

Subp. 9. Out-of-state vendor. 42 CFR 431.52 requires state Medicaid agencies to pay for health services rendered to a recipient while he is in another state. Criteria are necessary to provide uniform standards to determine the out-of-state vendor's eligibility for payment. An out-of-state vendor may be unfamiliar with the enrollment requirements and procedures of Minnesota's medical assistance program. Therefore, permitting the out-of-state vendor to enroll back to the date of service is reasonable because it allows time for the out-of-state vendor to complete the procedures of an unfamiliar program. Furthermore, permitting enrollment back to the date of service ensures that payment can be made for services provided a recipient while traveling out-of-state as required in 42 CFR 431.52. A definition of t he term "out-of-state vendor" is necessary to clarify its use within this subpart. It is reasonable to relate the definition to the site at which the recipient receives the service as this is consistent with the recipient's free choice of provider under part 9505.0190.

A. It is reasonable to adopt the same minimum standards for licensing and certification which are required for vendors within the state where the service is given because Minnesota standards do not apply to a person who practices in a place other than Minnesota.

B. It is reasonable that an out-of-state vendor be subjected to the same administrative requirements as an in-state vendor in order to ensure equitable, consistent treatment of in-state and out-of-state vendors.

C. It is reasonable to require the vendor to obtain department approval because the department has the responsibility and authority to administer the program.
D. It is reasonable that an out-of-state vendor comply with, and be held to, the same administrative limits and requirements of an in-state vendor in order to ensure equitable treatment of all vendors. Such treatment is consistent with the requirements of Minnesota Statutes, section 256B.04, subd.2.

Subp. 10. Condition of participation. This subpart is necessary and reasonable to inform affected persons of the applicability of federal and state civil rights laws and thus to encourage provider compliance in the provision of services to recipients. Furthermore, this subpart ensures that a recipient is not subjected to a lesser standard of care than that available to other Minnesota residents. It is consistent with Minnesota Statutes, Chapter 363 (The Human Rights Act) and section 256B.48, subd. 1 (d) and (e); 42 CFR 440.230 (c) and 42 CFR 440.240. It is identical in scope to Michigan Statutes, section 400.111b. Because the provider signs an agreement with the department that sets out the terms of the provider's participation, it is reasonable to require a provider to disclose any restrictions or criteria for choosing health conditions or persons it will treat so that the department will be able to monitor whether the provider meets the requirements of parts 9505.0170 to 9505.0475.

9505.0200 COMPETITIVE BIDDING

Minnesota Statutes, section 256B.04, subd. 14, requires the Commissioner to utilize volume purchase through competitive bidding for certain specific items. Furthermore, the cited statute states that competitive bidding for durable medical equipment is not limited to the items specified in the statute. Therefore this part is necessary to set the conditions which require competitive bids. It is reasonable to require competitive bidding of an item of equipment that is available from more than one source because competitive bidding can only occur if more than one source supplies the same item. For example, if only one retailer sells the required item, competition for the sale does not exist.

A. A concept of competitive bidding is that competition will lead to a range of prices for the same item offered by competing providers. Thus the department can save program funds by choosing the bid with the lowest price. Therefore it is reasonable to compare estimated savings achieved by competitive bidding against the estimated costs of the bidding procedure to determine whether the concept is achievable. It is necessary to specify a method of projecting the savings in order to have a uniform standard. Because the actual bids are known only when the formal bidding process is completed, it is reasonable to to estimate the expenditure using competitive prices based on historical experience.

B. An item of durable medical equipment may have entered the market place so recently that an historical cost is not available on which to base potential cost effectiveness. In this situation, the department reasonably relies on the cost savings which would be realized if the competitive bid price is lower than the price the department would have to pay to ensure that enough providers would participate to service the needs of the recipients (see 42 CFR section 447.204).

9505.0205 PROVIDER RECORDS.

This part specifies the record to be kept by a provider who participates in the medical assistance program. 42 CFR 431.107 states that each provider furnishing services must agree to keep "any records necessary to disclose the extent of services the provider furnishes to recipients." Parts 9505.1800 to 9505.1820 establish the requirements for keeping medical and health care records, financial records of providers, and exceptions to the record keeping requirements. Therefore the provision is consistent with federal regulations and other rules governing the medical assistance program. This part is necessary to inform providers of a reimbursement requirement. To require providers to continue to use a record-keeping system that is already required by another rule is reasonable because no additional burden or expense is imposed on them. The inclusion of appointment books and billing transmittal forms as part of the required financial records is consistent with the department's present practice of examining a provider's claims for reimbursement. The inclusion is reasonable because the department has found these two types of records to be essential pieces of evidence in verifying billings. They are listed here as examples for purposes of clarification.

9505.0210 COVERED SERVICES; GENERAL REQUIREMENTS

This part is necessary to establish requirements applicable to all health services and thereby assure consistency in determining which health services are eligible for medical assistance payments. This part is consistent with 42 CFR 440.230 (d) which permits the department to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures."

A. This item lists in subitems (1) to (4) criteria that are the same as those in the prior authorization program which is governed by parts 9505.5000 to 9505.5030. Under Minnesota Statutes, section 256B.04, subd.15, the department must determine whether a health service is necessary to achieve and maintain good health and must safeguard against unnecessary or inappropriate use of medical assistance services and against excess payments from public funds. Furthermore this same statute authorizes the commissioner to use a professional services advisory group to determine the necessity and reasonableness of services to persons eligible for medical assistance. Such a group is comprised of persons who are licensed or certified in their professions and who are familiar with prevailing community standards and customary practice and usage. (See part 9505.0185 and its SNR.) Thus, subitem (1) is consistent with statute. Minnesota Statutes, section 256B.04, subd. 2 requires the department to carry out the MA program in an efficient and economical manner within a uniform administrative structure. It is reasonable therefore to evaluate a health service on the basis of the appropriateness and expected effectiveness of the service in meeting the medical needs of the recipient in order to avoid unnecessary expenditure of MA funds. Subitem (3) is necessary to ensure that the health services provided by the MA program are of a high standard. It is a recognized fact that certain health services are more effective or stand a greater chance of success according to when they are given. Therefore, it is reasonable to require a health service to meet a standard of timeliness because timeliness ensures the service is appropriate considering the nature and present stage of the recipient's condition. It is also reasonable to require a health service to meet a quality standard so that factors such as the credentials of the provider can be monitored. Subitem (4) is necessary and reasonable because the criterion of cost effectiveness recognizes that the resources of the MA program are finite and the criterion is consistent with the efficient and economical use of health services as required by Minnesota Statutes, section 256B.04, subd.2 while ensuring that recipients are provided appropriate treatment of their medical needs.

B. This item is consistent with Minnesota Statutes, section 256B.04, subdivisions 2 and 15. It is reasonable to require an effective and appropriate use of medical assistance funds because the requirement will safeguard against unnecessary and inappropriate use of services and, thus, safeguard against excess payments.

C. 42 CFR 440.230 permits the department to establish "appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." Minnesota Statutes, section 256B.04, subd. 12 likewise authorizes the department to place limits on covered services. The service limits are established in parts 9505.0170 to 9505.0480. This item is both reasonable and necessary to inform persons affected by the rules that payment for services will be governed by these service limits so that they can make informed choices about health care.

D. This item is necessary to specify who must provide the health service in order for the service to be eligible for medical assistance payment. The department determines whether a vendor who applies for enrollment as a provider in the medical assistance program meets the quality standard of training and experience set in these rules. Therefore, it is reasonable to specify that the service must be furnished by the provider personallyas the provider has been determined to meet the quality standards required in item A, subitem (3). Standards necessary to achieve quality depend on the nature of the health service. In some professions, providers are assisted by paraprofessionals. An example of this assistance is found in the work of physicians' assistants. (See part 9505.0345, subpart 3, item C.) Thus, it is reasonable to permit an exception to the requirement of the provider's personally furnishing the health service because such paraprofessionals are directed or supervised by the provider.

E. The requirement that services provided to recipients residing in long-term care facilities be established in a written plan of care is reasonable because it provides a way to monitor whether the service itself is medically necessary, is furnished by a provider who is in compliance with these rules, and is within the service limitations of these rules. Therefore a written plan is a safeguard against unnecessary or duplicative services and fosters continuity of care through a coordinated plan. Most residents in a long-term care facility are physically frail and subject to conditions such as acute respiratory infections which cannot be anticipated and yet require timely treatment to reduce the likelihood of their exacerbation. Therefore, it is necessary to provide exemptions from the requirements that a service be in a written plan of care and its cost included in the facility's per diem in order to assure that the emergency health needs of the residents receive timely effective and appropriate care. Providing an exception for health services included in the facility's per diem rate is necessary and reasonable because the recipient's need for these services has been determined by a screening team under Minnesota Statutes, sections 256B.091 and 256B.092 and furthermore payment for these services is not made on a separate fee schedule but is included in the per diem rate set to reimburse the facility for the recipient's daily care. The exclusion is reasonable because it is consistent with 42 CFR 456.280 for skilled nursing care and 42 CFR 456.380 for intermediate care.

42 CFR 431.52 (b) states that the state plan "must provide that the State will furnish Medicaid to: (1) A recipient who is a resident of the State while that recipient is in another State, to the same extent that Medicaid is furnished to residents in the State...". This provision is necessary to establish the parameters which govern payment for services by out-of-state providers to such Minnesota residents.

A. This item is consistent with 42 CFR 431.52, as parts 9505.0170 to 9505.0475 govern the provision of services to state residents regardless of the resident's location.

B. The basic premise of the medical assistance program is that a health service must be medically necessary in order to be eligible for payment. Therefore, item B is consistent with 42 CFR 431.52 (b) which requires that services be available to a recipient who is a resident while in another state "to the same extent that Medicaid is furnished to residents of the State". Furthermore, the item is consistent with 42 CFR 431.52 (b) (1)(iv), which requires payment if it is the "general practice for recipients in a particular locality to use medical resources in another State." It is probably more cost effective for the state and less burdensome on the recipient to permit the recipient to use the same nearby out-of-state health service providers as a person located in the recipient's area who is not a recipient.

Emergency services that are necessary because of a condition requiring immediate care must be given the recipient as close as possible to the place where the emergency occurs, as a delay during which the recipient travelled to Minnesota might endanger the recipient's health. (See 42 CFR 431.52 (b) (1) (i) and (ii).)

If necessary health service is not available in Minnesota, it is reasonable to permit a recipient to seek those services elsewhere. Requiring the department's prior authorization of services provided to a Minnesota recipient outside of Minnesota is reasonable because the department's review can determine which services are available in Minnesota and which services must be sought elsewhere. Thus the prior authorization of services outside of Minnesota ensures consistency with Minnesota Statutes, section 256B.04, subdivision 2 in regard to equitable standards of assistance and efficient, economical administration.

C. 42 CFR 431.52 (b)(2) requires that states must furnish Medicaid services to a foster child who is a Minnesota resident but is placed in a home out-of state. Furthermore, a child who is considered a Minnesota resident and whose adoption is subsidized under Minnesota Statutes, section 259.40 or by funds from title IV-E of the Social Security Act is eligible for medical assistance while residing out-of-state. Item C, therefore, is consistent with federal regulation and law and state statute.

D. 42 CFR 431.52 (b) (1)(i) requires that payment must be provided for emergency services received out-of-state. Item D, therefore, is consistent with federal regulation. Its inclusion is reasonable to inform affected persons.

9505.0220 HEALTH SERVICES NOT COVERED BY MEDICAL ASSISTANCE.

Some health services are ineligible for medical assistance payment because they are not necessary or reasonable as specified in Minnesota Statutes, section 256B.04, subd. 15. It is necessary to inform persons who provide or request these services about this ineligibility for payment so that the providers and recipients can make informed choices about the services. Items A to W delineate such ineligible services.

A. Other parts of this rule prohibit medical assistance reimbursement of a health service that already has been paid for by another source. The prohibition is necessary and reasonable to prevent a double payment. However, an exception to the rule is necessary in the case of an eligible service furnished to and paid for by a recipient in a period of retroactive eligibility established under Minnesota Statutes, section 256B.061. Item A is consistent with the cited statute and is reasonable because it informs affected persons of their rights.

B. Minnesota Statutes, section 256B.02, subd. 8(11) authorizes the commissioner to establish a drug formulary that specifies the names of drugs which are eligible for medical assistance payment. Further, this statute authorizes the commissioner, with the consent of the drug formulary committee, to require prior authorization before certain formulary drugs are eligible for payment. Thus, this item is consistent with Minnesota Statutes, section 256B.02, subd. 8(11). This item is necessary and reasonable to inform affected persons of the requirements for a drug to be eligible for medical assistance payments.

C. Minnesota Statutes, section 256B.04, subd. 15, requires the department to establish prepayment and postpayment review systems to determine if utilization of a medical assistance service is necessary and reasonable and to safeguard against unnecessary or inappropriate use. Priorauthorization is a method the department uses to determine the necessity and reasonableness of a proposed medical assistance service. Thus, the item is consistent with the cited statute. The item is necessary and reasonable to inform affected persons of a limitation on eligibility for payment.

D. An autopsy is not a health care service to a person eligible for medical assistance as MA eligibility ends at the time of the person's death. Thus an autopsy is not eligible for MA payment as Minnesota Statutes, section 256B.02, subd. 8 limits payment to those services provided to eligible individuals. The item is consistent with statute. It is necessary and reasonable because it informs affected persons of a payment prohibition.

E. A person who misses or cancels an appointment has not received a service. This item is consistent with Minnesota Statutes, section 256B.02, subd. 8 which defines medical assistance or medical care in terms of care and services to eligible persons. The item is necessary and reasonable to inform affected persons of a payment prohibition.

F. Telephone calls and and other non face-to-face communications between a provider and a recipient do not provide direct care and service to a recipient, except in certain specific instances. These exceptions are defined in parts 9505.0170 to 9505.0475. Thus, the item is consistent with Minnesota Statutes, section 256B.02, subd. 8. The item is necessary and reasonable to inform affected persons of a payment prohibition.

G. A report required solely for insurance or legal purposes is not a service to a recipient. Thus the item is consistent with Minnesota Statutes, section 256B.02, subd. 8. However, when the local agency or department requests a provider's report in the course of performing its administrative responsibility, including preparation of reports required under Minnesota Statutes, section 256B.04, the cost of the report is properly assigned to medical assistance program administration and, therefore, is eligible for payment. The item is necessary and reasonable to inform affected persons of a payment limitation.

H. Certain therapeutic procedures possess the potential for serious physical, mental, and emotional harm to a recipient if they are improperly implemented. These procedures are called aversive or deprivation procedures. Minnesota Statutes, section 245.825 requires the department to promulgate a rule to govern aversive procedures. The rule will set the standards for the use of procedures which are potentially dangerous. Considerable work and discussion have taken place on that proposed rule but it has not yet been completed. It is necessary and reasonable to prohibit payment until such a rule is promulgated because the rule will specify the prohibited practices and the specific conditions under which permitted practices are to be carried out. The exclusion is consistent with the requirement of Minnesota Statutes, section 256B.04, subd. 15 concerning safeguards against unnecessary or inappropriate use of medical assistance services.

I. This item clarifies the fact that any health service not in compliance with these rules is not eligible for medical assistance payment. As duly promulgated rules, parts 9505.0170 to 9595.0475 establish the conditions of eligibility for reimbursement. Therefore, demanding compliance is reasonable. The item is necessary and reasonable so that all affected parties are fully informed about the scope of the payment limitations and can make an informed choice about complying.

J. A provider's overhead costs incurred to prepare bills are usually included in the provider's fee for a health service. Therefore, it is necessary and reasonable to prohibit payment of separate charges in order to prevent double billing of the MA program.

K. Mileage costs incurred by a provider in the course of providing health services to a recipient are usually included in the provider's fee for service. A prohibition of separate charges is necessary and reasonable in order to prevent double billing of the MA program.

L. This item clarifies the concept inherent in several other items of this part, i.e., that medical assistance payment is available only for medical and health services provided directly to a recipient. The concept is consistent with Minnesota Statutes, section 256B.02. In those instances where a service has direct impact on the recipient's health care needs even if the service is not given directly to the recipient, payment can be made if authorized as a provision of a duly promulgated rule. It is reasonable to focus Medicaid dollars on services to a client as required in Minnesota Statutes, section 256B.04, subd. 15 and to be cognizant of times when exceptions are necessary.

M. Minnesota Statutes, section 256B.04, subd. 15, requires the department to establish a program to safeguard against unnecessary or inappropriate use of medical assistance services. Except in some instances of referral, concurrent care by more than one provider of the same type of provider for the same diagnosis is neither necessary nor appropriate. The item is

consistent with the cited statute. In those instances where a valid second opinion is needed, the second opinion will be eligible for payment if that necessity and formal referral process are well documented and available for postpayment review. The item is necessary and reasonable to inform affected persons of a limitation. Furthermore, it is necessary and reasonable to specify who will receive payment if two claims are submitted when an appropriate medical referral has not occurred in order to avoid misunderstanding and confusion and to establish a uniform procedure. It is reasonable to pay the first submitted claim as the department can not predict that a second provider will submit a claim.

N. All components of this item are related to a determination of the necessity and appropriateness of a health service as required under Minnesota Statutes, section 256B.02, subd. 15. A person requiring care has the right to decide, based on medical advice, whether the care being sought is necessary and whether to consent to receive it. For example, see Minnesota Statutes, section 144.651, which defines the right of a patient or resident to participate in the planning of treatment. A physician by training and experience is qualified to determine what health services are necessary and appropriate. The physician's order is evidence of the physician's determination. A plan of care is the written record of the recipient's condition and prescribed treatments. Therefore the provision is necessary to inform affected persons of payment limitations. It is reasonable because it relates the limitation to the rights of the recipient, determination of necessity by a qualified person, and documentation of the qualified person's determination.

O. Part 9505.1800, establishes the documentation required in medical and health care records as a condition of medical assistance reimbursement. This item is necessary to inform affected persons of the requirement; it is reasonable as it is consistent with a procedure already familiar to and used by health care providers and, thus, does not impose an additional burden on the providers.

P. As stated for item N, a physician's written order is evidence that a qualified person has determined a health care service to meet the standard of necessity and appropriateness required by Minnesota Statutes, section 256B.04, subd. 15. Also, as stated for item N, the plan of care is a medical record that can be examined in a utilization review to determine necessity and appropriateness. Thus, this item is consistent with statute. Inclusion of this item is necessary and reasonable to inform affected persons of payment limitations.

Q. Medical assistance payment for abortion services is limited under 42 CFR 441.200 to 441.208 and Minnesota Statutes, sections 256B.02, subd 8(14)and 256B.40. This item is necessary to inform affected persons about payment limitations for abortion services.

R. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types of services covered by medical assistance. Furthermore, Minnesota Statutes, section 256B.04, subd.15 requires the department to safeguard against inappropriate or unnecessary services. A service that is of a lower standard of quality than the prevailing profeessional standard is neither appropriate nor necessary. It is necessary to specify who will bear the cost of such a service in order to set a standard and avoid confusion. Requiring the provider to bear the cost is reasonable because the action prevents the recipient from being billed for an unnecessary and inappropriate service and places the burden on the provider who did not deliver a necessary service.

S. Minnesota Statutes, section 256B.02, subdivisions 7 and 8 specify the types of medical and health care and services that may receive medical assistance payment. Furthermore, Minnesota Statutes, section 256B.04, subd.15 requires the department to safeguard against inappropriate medical assistance services. It is necessary to exclude from reimbursement those services which are solely educational or vocational because they are without a direct correlation with health. Although a client may need these services, they are the responsibility of other social service programs and, therefore, their exclusion from medical assistance payment is reasonable.

T. Although common sense dictates that the program not pay for the same service twice in one day, e.g., consultation for a recipient by the same provider twice in the same day, experience shows that such two-times-per-day consultations occur. Therefore, it is necessary to establish an administrative limit on the number of services by the same provider to the same recipient on the same day. However, there may be emergency situations that require such consultations. This item is reasonable because it establishes a necessary limitation, but provides for emergencies.

U. Similar to item T, item U establishes a necessary limit of one per day for number of home, office, hospital, and long-term care facility visits by the same provider to the same recipient. Additional services, excluding emergencies, could reasonably not be considered medically necessary and, thus, are not eligible for payment. This limitation, as well as all others proposed in this rule, is within the department's authority as established in Minnesota Statutes, section 256B.04, subd. 12 and is permitted under federal regulations at 42 CFR 450.230. Furthermore, this limitation is reasonable because it does not deny payment for a medically necessary emergency service.

V. The reasons cited for item U also apply to limiting home health agency visits to one visit per particular type of home health service per recipient per day unless the recipient's plan of care calls for more frequent visits. Tying more than one visit per day to the plan of care ensures that the patient's care is being coordinated. This item is reasonable to inform affected persons.

W. This item is consistent with the requirements of part 9505.0205. Its inclusion in this part is necessary to clarify that record keeping is an integral part of any service and therefore its cost is part of the cost of service and is not eligible for separate payment. Inclusion of this item is reasonable to ensure affected providers are fully informed of requirements applicable to all health services.

X. This item is consistent with Minnesota Statutes, section 256B.04, subd. 15 which requires the department to safeguard against unnecessary use of medical assistance services. It is also consistent with 42 CFR 440.230 (d) which permits the department to adopt service limits based on medical necessity.

9505.0221 PAYMENT LIMITATION; PARTIES AFFILIATED WITH A PROVIDER

This part is necessary to avoid a possible conflict of interesst between the prescriber of a service and the person who provided the prescribed supply. Cite CFR to be added. The provision is similar to those found in part 9549.

9505.0225 REQUEST TO RECIPIENT TO PAY

Subpart 1. Payment for covered service. This subpart clarifies limitations of requesting or collecting payments from recipients that participation in the medical assistance program places on a provider. It prohibits a provider from requesting or receiving additional funds from recipients for a service covered under Medical Assistance. This part is necessary as a protection for recipients with limited resources and is required by 42 CFR 447.15 as a condition of participation in the medical assistance program. The limitation is specific only to services covered by medical assistance and does not infringe on a provider-recipient contractual relationship for health care services not eligible for medical assistance payment. This subpart is consistent with Minnesota Statute, section 256B.01 which establishes the medical assistance program for "needy persons whose resources are not adequate to meet the cost of such care." Federal regulations and state law provide two exceptions to this requirement. First, cost sharing, although not implemented in Minnesota at present, is authorized under 42 CFR 447.50 to 447.59. Furthermore, Minnesota Statutes, section 256B.063 authorizes the state to adopt cost sharing if appropriate rules are promulgated. The second exception permits recipient payment for a covered service if the payment is required as a condition of eligibility. For example, a recipient who has excess income must spend-down excess income in order to become eligible for medical assistance. It is reasonable to remit those funds to be paid to providers to the extent necessary for establishing eligibility because doing so will conserve the use of public funds. Thus, the part is consistent with statute and federal regulation. The subpart is necessary and reasonable to inform affected persons of their rights and obligations.

Subp. 2. Payment for noncovered service. As stated above in subpart 1, the Minnesota medical assistance program is established for needy persons whose resources are not adequate to meet the cost of medically necessary care. However, the state cannot and does not restrict a recipient from spending his or her own resources on an elective non-covered service. Although a provider may not request or receive payment from a recipient for a covered service, the provider may receive payment for a non-covered service provided to a recipient. This subpart is necessary to clarify the application of the limitation. However, a recipient has the right to make an informed decision about whether to incur a financial obligation. Therefore, it is reasonable to require the provider, as a condition for receipt of payment, to inform the recipient before providing the non-covered service because the recipient will then have the information to decide about his ability to pay the cost of the service. This subpart is consistent with a similar Medicare provision, 42 CFR 489.32.

9505.0235 ABORTION SERVICES

Subpart 1. Definition. This subpart is necessary to inform recipients, providers, and other affected persons of the meaning of the phrase "abortion-related services" which is used in this part.

Public Law 97-12, enacted June 5, 1981, restricted the use of federal medical assistance funds to only those abortions performed because the life of the mother would be endangered by carrying the fetus to term. HCFA regulatory interpretation and guidelines, HCFA-AT-79-43, dated May 7, 1979, established that neither abortion or directly related services are eligible for federal medical assistance funding unless conditions specified under federal law are met. State law regarding the use of medical assistance funds for abortions limits reimbursement to situations where abortion is medically necessary to prevent the death of the mother, or where the pregnancy results from criminal sexual conduct or incest. Except under these circumstances, Minnesota Statutes, section 256B.40 prohibits medical assistance payment for abortion services or services provided in connection with an abortion.

The department sought guidance from several sources to establish the definition of services directly related to or provided in connection with an abortion. In a letter dated July 11, 1979 to Barbara Ble, Commissioner of the New York State Department of Social Services from Arthur J. O'Leary, Regioal Medicaid Director, clarification was sought regarding HCFA-AT-78-66, governing the funding of abortions. The letter stated in part:

> The limitations placed upon the federal funding of abortions apply to all services and procedures which are directly related to the abortion. For example, tests and physician's visits made for the determination of pregnancy, or procedures necessary to treat complications after an abortion would not be directly related to that service, and therefore, the federal regulations governing Federal funding of abortions would not be applicable for FFP in those procedures. However, anesthesiologist bills, the costs of a hospital stay which is necessary for the performance of an abortion, and normal post operation physician's visits would be directly related and the regulations cover FFP in these procedures.

In a February 13, 1981, Department of Health and Human Services memorandum from the Director of the Office of Coverage Policy, BBP, an interpretation was given as to lab tests and drugs which would be considered directly related to an abortion. The memorandum notes that services such as urinalysis, pregnancy test, hematocrit, pap test, syphilis and gonorrhea test, patient conference with physician or counselor and office visits are pregnancy related services and reimbursable under Medicaid regardless of whether the requirements for abortion have been met. According to the memorandum, services considered directly related to abortions and ineligible for FFP unless federal abortion requirements are met include hospital stay, anesthesiologist, assistant surgeon, and certain lab procedures and drugs provided on the same date the abortion was performed, that is, pathological examination of aborted tissue and decidua and medication prescribed to prevent complications following an abortion.

42 CFR 440.230, item c, prohibits state Medicaid agencies from arbitrarily denying or reducing the amount, duration, or scope of a required service to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition of the recipient. Pregnancy related services fall under the category of physician services, which states are required to provide under 42 CFR 440.210 and 440.220 Thus, federal regulations would not allow denial of medical assistance reimbursement for services such as physical examination, pap smears, or pregnancy tests that are routinely provided to pregnant women, regardless of whether the woman's intent at the time the service was rendered was to carry the fetus to term or to terminate the pregnancy. Indeed, it cannot be conclusively determined whether a woman's intent is to carry the fetus to term or to abort it until the point at which services that could only be performed for the sole purpose of an abortion are provided. For the department to so infer and deny payment for services characterized as pregnancy related would constitute an arbitrary and unreasonable action.

42 CFR 441, Subpart E specifies the conditions required for federal financial participation in paying for abortion services. Minnesota Statutes, section 256B.02, subd. 8(14) specifies the conditions under which abortion services may be a covered service. However, neither the federal regulation nor the statute differentiate between those services that are required only to carry out an abortion and those that are necessary for diagnosis and treatment of a pregnancy. This definition is necessary to clarify the difference and establish a uniform standard. It is reasonable to exclude from the definition those services that would ordinarily be provided in the course of a pregnancy as those services are medically necessary to diagnose pregnancy, identify any conditions that may require the woman to receive preventive services during the pregnancy (see part 9505.0355), and thus ensure the health and safety of the pregnant woman and unborn child. Furthermore, it is reasonable to specify that the definition applies to services connected with an elective abortion, that is an induced abortion that is the free choice of the pregnant woman, because an abortion to save the life of a pregnant woman is a medical necessity and not a free choice. The examples of abortion-related services included in this subpart are those services which are used and are necessary only when an abortion is performed. Thus, their identification as abortion-related is reasonable as they are not used in connection with other services. The examples of medically necessary services that are not considered to be abortion-related include only services that are considered as part of the prevailing professional standard of practice in providing services to a pregnant woman.

Subp. 2. Payment limitation. This subpart is necessary in order to inform affected persons of the conditions that must be met to receive medical assistance payment for abortion services to recipients. Both Minnesota Statutes, section 256B.02, subd.8 (14) and 42 CFR 441, Subpart E state that an abortion service is eligible for medical assistance payment if the abortion is a medical necessity because the life of the woman is endangered. The statute requires a written statement from two physicians indicating that the abortion is "medically necessary to prevent the death of the mother....." The federal regulation requires a written statement from only one physician. Thus the provisions of Item A

are consistent with the cited statute and regulation. As required by statute, Item A is more stringent than the federal regulation which requires only one physician to verify in writing that the pregnancy may endanger the life of the mother. Although state law is more stringent than federal regulations, incorporating the statutory requirement does not jeopardize federal financial participation in expenditures for the abortion services specified in item A as the state has the authority under Minnesota Statutes, section 256B.04, subd.12 to place limits on services covered by medical assistance.

Minnesota Statutes, section 256B.02, subd. 8(14) states that abortion services are eligible for medical assistance payment if the pregnancy is the result of criminal sexual conduct or incest. Furthermore, the statute specifies as a condition of payment eligibility that the conduct must be reported to a valid law enforcement agency. In the case of rape, the report must be made within 48 hours after the incident or, if the victim is physically unable to report within this time, the report must be made within 48 hours after the victim is physically able to do so. Thus, items B and C are consistent with statute. Previous to 1981, federal regulations also permitted medical assistance payment for abortions of pregnancy resulting from rape or incest. However, section 402 of the Supplemental Appropriations and Recession Act of 1981, Public Law 97-12, enacted June 5, 1981, repealed this portion of the medical assistance program. (Although the regulation was repealed, it has not been been deleted from the CFR revised as of October 1, 1985.) Thus, abortions for recipients whose pregnancy is a result of rape or incest are paid entirely from state funds.

9505.0240 AMBULATORY SURGICAL CENTERS.

Subpart 1. Definition; ambulatory surgical center. "Ambulatory surgical center" is a term used in this part. A definition is necessary to clarify its meaning and set a standard. The definition is consistent with 42 CFR, part 416, which requires that the center "be operated exclusively for the purpose of providing services to patients not requiring hospitalization", "must be recognized under state law", and must meet the requirements of 42 CFR 416.25 to 416.49. Minnesota Statutes, section 256B.02, subdivision 8 (4) and subdivision 8(18), as amended in 1985, establish the medical assistance payment eligibility of ambulatory surgical centers that are licensed under state law. Parts 4675.0100 to 4675.2800, adopted pursuant to Minnesota Statutes, section 144.56, establish the conditions of licensure applicable to ambulatory surgical centers. Thus, the definition is consistent with federal regulations and state statutes and regulations. It is reasonable because consistency with federal requirements is necessary to obtain federal financial participation as required under Minnesota Statutes, section 256B.04, subdivision 4.

Subp. 2. Payment limitation; surgical procedures. Minnesota Statutes, section 256B.02, subdivision 12 requires the department to place limits on the amount paid for covered services. This subpart is necessary to specify the required limits. 42 CFR 447.321 states that the department "may not pay more than the combined payments the (outpatient hospital service) provider gets from beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under Medicare." It is consistent with the requirement of Minnesota Statutes, section 256B.02, subdivision 8 (4), as amended in 1985, which subjects hospital outpatient departments to the same reimbursements as other providers. Under this limitation all procedures that are commonly performed in an ambulatory surgical center are classified into one of four groups. All procedures within a group are reimbursed at a single rate. The payment amount for all procedures within a group is the average of ambulatory surgical center charges for those surgical procedures as indicated by a 1981 survey conducted by Medicare with the assistance of the Freestanding Ambulatory Surgical Association and as adjusted to reflect the local wage index. It is reasonable to set medical assistance payments for surgical procedures performed in ambulatory surgical centers at the same level applicable to other providers performing the same procedures because this provides the standard necessary to administer the program in an impartial and uniform manner as required by Minnesota Statutes, section 256B.04, subd. 4. This subpart is also reasonable because it meets federal eligibility standards for obtaining federal financial participation, a requirement placed on the department under Minnesota Statutes, section 256B.04, subdivision 4.

Subp. 3. Payment limitation; items and services. Minnesota Statutes, section 256B.04, subdivision 15 requires the department to safeguard against excess medical assistance payments. Throughout parts 9505.0170 to 9505.0475, the department proposes payment limitations that exclude from separate payment those components of a health service that are customarily provided as a component of the health service. This limitation prevents duplicate medical assistance payments. This subpart specifies items and

services that are the customary components of the facility services of an ambulatory surgical center. They are furnished by the ambulatory surgical center in connection with surgical procedures. Therefore, excluding items A to G from separate payment is reasonable as these items are necessary components of surgical procedures and their reimbursement is included in the payment for the procedure. The subpart is consistent with the Medicare standards in 42 CFR 416.65. It is reasonable to apply Medicare standards to the services provided by these ambulatory surgical centers as the centers are certified by Medicare.

A. This item includes all services in connection with covered procedures furnished by nurses, technical persons, orderlies and other employees of the center who are involved in patient care.

B. This item includes operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the recipient or offered for use by the recipient's relatives in connection with the recipient's care.

C. This item includes all drugs, biologicals, surgical dressings, supplies, splints, casts, appliances, and equipment that are commonly furnished by a center in connection with surgical procedures.

D. Examples of this item are diagnostic tests such as urinalysis and hemoglobin.

E. This item includes the general administrative functions necessary to run the ambulatory surgical center. They include scheduling, cleaning, utilities, and rent.

F. Covered procedures are limited to those not expected to result in extensive loss of blood. However, in some cases, blood and blood products may be required. When there is a need for blood and blood products, these substances are considered facility services and no separate charge is permitted.

G. It is reasonable to include anesthetics and the material necessary to administer the anesthetics as a component of the surgical procedure rather than to pay for them on a separate schedule as these items are essential to conducting the surgery according to accepted community standards and, therefore, reimbursement for them is included in the procedure code for the surgical procedure.

9505.0245 CHIROPRACTIC SERVICES

Subpart 1. Definitions. This subpart defines words and phrases used only in this part to set a standard for eligibility for medical assistance payment.
A. Chiropractic service. This term is necessary to identify a particular type of health service that is available for federal financial participation under 42 CFR 440.60 (b). The definition is reasonable as it is consistent with the requirement that the service must be medically necessary as specified in Minnesota Statutes, section 256B.04, subd. 15.
B. Chiropractor. The definition is necessary to clarify a term used in this part. Because 42 CFR 440.60 (b) (1) requires that chiropractic services be restricted to those provided by a chiropractor licensed by the State, it is reasonable to define the term by the statutes which establish the terms and scope of chiropractic licensure, Minnesota Statutes, section 148.01 to 148.101.

Subp. 2. Payment limitation. This subpart is necessary to set the standard for services that are eligible for medical assistance payment. The standard chosen is consistent with 42 CFR 440.60 (b) (2) which restricts eligibility for federal financial participation of chiropractors' services to "treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform." Minnesota Statutes, section 256B.04, subd. 4, requires the department to cooperate with the federal government "in any reasonable manner as necessary to qualify for federal aid" for the medical assistance program. The service limitation in this subpart is consistent with the scope of chiropractic specified in Minnesota Statutes, section 148.01. This statute includes within chiropractic practice analytical x-ray of skeletal bones as necessary to determine whether a chiropractic condition is present or absent. Although the use of x-rays is not mentioned in the cited federal regulation, the Minnesota Supreme Court in 1981 (citation) decided that the medical assistance program must pay for x-rays in the case of a medical assistance recipient who seeks chiropractic service to diagnose a possible chiropractic condition. Pursuant to the Court's decision, the state has followed the policy in effect under Minnesota's Catastrophic Health Expense Protection Program (CHEPP) in 1981 which was to pay for those x-rays solely of a nature to diagnose a subluxation of the spine. Thus the payment limitation is reasonable because it complies with federal regulation, Minnesota Statutes, court decision, and usual practice in another Minnesota health care program.
A. 42 CFR 440.230 (d) permits a state to place appropriate limits on a service based on the criterion of medical necessity. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types and frequency of services covered by medical assistance. The limits proposed in this item are the same as the limits in the present rule, part 9500.1070, subpart 6,item A. Manual manipulation of the spine is used to reduce subluxations of the spine which may be causing pain or conditions such as muscle spasms. Usually three or four treatments are necessary before the chirpractor is able to determine the exact nature of the recipient's condition and thus the length of necessary treatment. Some conditions may be relieved by a few treatments; others will require prolonged treatment. The limit of six treatments per month is reasonable

because it balances the chiropractor's information about the recipient's condition and response to treatment and the responsibility of the department to safeguard against unnecessary and inappropriate services as required under Minnesota Statutes, section 256B.04, subd. 15. Thus the chiropractor who judges that additional treatment is necessary may obtain prior authorization of the additional treatments by submitting to the department information about the recipient's medical condition that documents the medical necessity of continued treatment. Furthermore, the limit of 6 treatments provides an interval long enough for the chiropractor to obtain the necessary information, submit it to the department, and obtain prior authorization without interrupting the course of treatment. In like manner, a treatment regime more extensive than 24 treatments per year may obtain prior authorization if the chiropractor documents the medical necessity of the recipient's having additional treatments.

B. 42 CFR 440.230 (d) permits a state to place appropriate limits on a service based on the criterion of medical necessity. Minnesota Statutes, section 256B.04, subd.12 states that the department shall limit the types of covered services. The x-rays specified in item D are those that are necessary to diagnose a condition of subluxation of the spine, which in the human consists of cervical, thoracic, lumbar, and lumbarsacral vertebrae and articulates with the pelvis and the ilium of the pelvis. Therefore, the item is reasonable because all areas involved in a subluxation of the spine are included in the x-ray limitation.

Subp. 3. Excluded services. It is necessary to clarify the services that are not eligible for medical service payment in order to inform affected persons of the payment limitations. Because 42 CFR 440.60 (b) specifies that only treatment by means of manual manipulation of the spine and within the scope of chiropractic practice under state law is eligible, it is reasonable to exclude all services which do not meet both conditions. Thus, some services often provided by chiropractors such as laboratory service, the provision of vitamins, diathermy, medical supplies and equipment, ultrasound treatment and x-rays not related to a diagnosis of subluxation are not eligible for payment as they are not necessary for manual manipulation of the spine. These services are examples of non-covered services which nonetheless have been submitted to the department on billing invoices in the past.

because it balances the chiropractor's information about the recipient's condition and response to treatment and the responsibility of the department to safeguard against unnecessary and inappropriate services as required under Minnesota Statutes, section 256B.04, subd. 15. Thus the chiropractor who judges that additional treatment is necessary may obtain prior authorization of the additional treatments by submitting to the department information about the recipient's medical condition that documents the medical necessity of continued treatment. Furthermore, the limit of 6 treatments provides an interval long enough for the chiropractor to obtain the necessary information, submit it to the department, and obtain prior authorization without interrupting the course of treatment. In like manner, a treatment regime more extensive than 24 treatments per year may obtain prior authorization if the chiropractor documents the medical necessity of the recipient's having additional treatments.

B. 42 CFR 440.230 (d) permits a state to place appropriate limits on a service based on the criterion of medical necessity. Minnesota Statutes, section 256B.04, subd.12 states that the department shall limit the types of covered services. The x-rays specified in item D are those that are necessary to diagnose a condition of subluxation of the spine, which in the human consists of cervical, thoracic, lumbar, and lumbarsacral vertebrae and articulates with the pelvis and the ilium of the pelvis. Therefore, the item is reasonable because all areas involved in a subluxation of the spine are included in the x-ray limitation.

Subp. 3. Excluded services. It is necessary to clarify the services that are not eligible for medical service payment in order to inform affected persons of the payment limitations. Because 42 CFR 440.60 (b) specifies that only treatment by means of manual manipulation of the spine and within the scope of chiropractic practice under state law is eligible, it is reasonable to exclude all services which do not meet both conditions. Thus, some services often provided by chiropractors such as laboratory service, the provision of vitamins, diathermy, medical supplies and equipment, ultrasound treatment and x-rays not related to a diagnosis of subluxation are not eligible for payment as they are not necessary for manual manipulation of the spine. These services are examples of non-covered services which nonetheless have been submitted to the department on billing invoices in the past.

9505.0250 CLINIC SERVICES

This part is necessary to specify the standards for clinic services which are eligible for medical assistance payment under Minnesota Statutes, section 256B.02, subd. 8(4).

Subpart 1. Definition. A definition is necessary to clarify the meaning of the term "clinic services" and set a standard concerning services eligible for medical assistance payment. 42 CFR 440.90 defines the meaning of "clinic services" for purposes of the medical assistance program. The proposed definition is consistent with the federal regulation.

Subp. 2. Eligible provider. This subpart is necessary to specify the conditions that a clinic must meet in order to be eligible for medical assistance payments for clinic services to recipients.
A. The department must give data about payments made to a provider to the United States Internal Revenue Service and the Minnesota Department of Finance. The federal government also requires certain employers to obtain a federal employer's identification number. Therefore, it is reasonable to require the clinic to have a federal employer's identification number because the number permits accurate identification of the provider receiving the payments without placing an added burden on the provider.
B. Minnesota Statutes, section 256B.02, subd. 8(4) requires that all clinic services must be "provided under the direct supervision of the physician who is on the premises" and further that the staff shall "include at least two physicians, one of whom is on the premises whenever the clinic is open." The item is consistent with the statute.
C. This item is consistent with the principle established in Minnesota Statutes, section 256B.02, subd. 8(4) with regard to the provision of physician services in a clinic under the direction of a physician. The item is reasonable because it assures that a person licensed to provide the dental service, a dentist, will give or supervise the giving of a dental service.

Subp. 3. Exemption from requirements. Staffing requirements for certain types of clinics are established in federal regulations and statutes other than the one cited in subpart 2. Therefore, subpart 3 is necessary to clarify that certain clinics providing physician and dental services are exempt from the requirements of subpart 2. The clinics exempted under subpart 3 have certain characteristics in common: they are non-profit or without a direct profit incentive; they normally operate with primary caregivers other than a licensed physician or dentist; they serve a clientele having a low income or an area having a paucity of licensed health professionals; and they are unable to acquire or to afford to pay two physicians or two dentists. Thus this subpart is reasonable because it allows exceptions that are necessary to permit non-traditional facilities to provide health services to populations that might otherwise not be served. The subpart is consistent with 42 CFR 491.8 (a) and Minnesota Statutes, section 256B.02 (4) and Chapter 145.

9505.0255 COMMUNITY HEALTH CLINIC SERVICES

Subpart 1. Definition. Minnesota Statutes, section 256B.02, subdivision 8 (4) specifies that non-profit community health clinic services to a recipient are eligible for medical assistance payment but the statutes do not define the term. A definition of community health clinic service is necessary to clarify the standard of eligibility for payment.
A. Minnesota Statutes, chapter 317, specifies the requirements an organization must meet to be incorporated in Minnesota as a non-profit organization. This item is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (4) which requires the clinic to have non-profit status.
B. Similarly this item is consistent with the statutory requirement that such a clinic be non-profit. Under section 501(c)(3) of the Internal Revenue Code, tax exempt status is available only to organizations that have validated their non-profit nature.
C. Persons with a low income have difficulty in paying for health services and are often unable to obtain necessary health care. They are therefore an underserved population group. Restricting eligibility as a community health clinic to one established to serve a low income population group is consistent with Minnesota Statutes, section 317.05, which specifies the purposes for which a non-profit corporation may be formed.
D. Community health clinics are the urban counterparts of rural health clinics which provide alternative primary care services for a low income population living in an area with a paucity of health services. 42 CFR 491.9 (b) requires rural health clinics to have written policies about the health services they provide. This item is reasonable because it is consistent with a federal requirement placed on a clinic providing similar services to a similar population group.

Subp. 2. Eligible health services. This subpart is necessary in order to specify the categories of clinic-provided health services that are eligible for medical assistance payment. The services listed in items A to D are all primary care services that can be given in an alternative care setting and that are necessary to maintain good health (item A), prevent health problems (item B), or to meet the health needs of a special clientele (items C and D). Therefore the subpart is reasonable because it limits the eligible services to those medically necessary services that can be appropriately given as a first level of care in an alternative care setting.

Subp. 3. Eligible vendors of community health clinic services. As discussed in subpart 1, item D, community health clinics are the urban counterparts of rural health clinics. 42 CFR 491.8(a) permits medical assistance payment for health services provided by a physician assistant or nurse practitioner in the rural health clinic under physician supervision. This item is reasonable because it is consistent with a federal regulation, 42 CFR 491.8(a), applicable to non-profit clinics providing similar services to a similar population group. Because community health clinics attempt to provide necessary health services at

low cost, the clinics sometimes rely on qualified volunteers who are not compensated for their professional services. Therefore permitting the service to be eligible whether it is provided by a qualified volunteer or employee is reasonable as a means to control the costs of serving a low-income population area.

Subp. 4. Written patient care policies. 42 CFR 491.9(b) requires rural health clinics, the rural counterpart of community health clinics, to have written patient care policies as in items A to C. Therefore, this item is reasonable because it is consistent with a federal requirement applicable to non-profit clinics providing similar services to a similar population group.

9505.0270 DENTAL SERVICES

Subpart 1. Definition. This subpart is necessary to clarify the meaning of the terms used in this part.
A. The term "dental service" is used in this part to set a standard for eligibility for medical assistance payment. The definition is consistent with 42 CFR 440.100 (a) and Minnesota Statutes, sections 150A.01 to 150A.12 which specify the scope of the practice of dentistry and the supervision of non-licensed dental personnel by a dentist.
B. The term "oral hygiene instruction" is used in this part to set a standard for eligibility for medical assistance payment. It falls within the scope of practice of a dentist as established in Minnesota Statutes, sections 150A.01 to 150A.12. The definition is consistent with Minnesota Statutes, section 150A.10 which permits dentists to delegate certain acts as authorized by the board of dentistry to dental assistants and dental hygienists who perform these acts under the supervision of the dentist.
C. The term "rebase" is a term used to set a standard for eligibility for payment. The definition is reasonable because it is consistent with prevailing peer usage as reflected in Dorland's Illustrated Medical Dictionary, (24th edition, W. B. Saunders Company.)
D. The term "reline" is a term used in this part to set a standard for eligibility for payment. The definition is reasonable because it is consistent with prevailing peer usage as reflected in Dorland's Illustrated Medical Dictionary.
E. The term "removable prosthesis" is used in this part to set a standard for eligibility for medical assistance payment. Prescription of this device falls within the scope of practice of a dentist as set out in Minnesota Statutes, section 150A.05. Thus, the definition is consistent with statute. Furthermore, it is consistent with Minnesota Statutes, section 150A.10, subd 3 which requires a dentist to provide a written work order to the dental technician who constructs or repairs a dental device.

Subp. 2. Eligible dental services. This subpart clarifies the application of the principle of "medically necessary" to a dental service in the determination of the dental service's eligibility for medical assistance payment. The subpart is consistent with Minnesota Statutes, sections 256B.02, subdivision 8(9) and 256B.04, subdivisions 12 and 15, 42 CFR 440.100 (a)(2), and 42 CFR 440.230 (d).

Subp. 3. Payment limitations. Minnesota Statutes, 256B.04, subd. 12 requires the department to place limits on the types and frequency of services covered by medical assistance for an individual recipient. This subpart is necessary to specify the limits. See also subpart 6, item F and its SNR, which discuss service in excess of the limits if prior authorization is obtained.
A. Oral hygiene instruction is necessary to teach the recipient proper methods of dental self-care. This instruction is given once in a visit specifically for this purpose and then reinforced by the dentist at subsequent visits for other purposes such as examination under item E and prophylaxis under item F. Therefore, additional separate periods of instruction would be duplicative and unnecessary. The limitation is reasonable as the recipient has the responsibiilty to follow the professional instructions which will benefit his health. The limitation

is consistent with the reimbursement policy of major third party payers such as Delta Dental.

B. This criterion limits a denture modification that should not require repetition more often than once every three years. The department's Dental Advisory Committee has stated that the procedure and materials used to reline or rebase a denture should enable the denture to last at least three years. More frequently required relines or rebases are often indicative of the recipient's general oral or physical health and thus may require a different procedure. An example of such a condition of general physical health affecting the fit of dentures occurs in the recipient who experiences an extreme weight loss of 100 pounds or more. Thus, the limitation is reasonable because it is based on the current standard of the professional peer group.

C. The standard set in this item is the same as the professional standard recommended in A Guide to the Use of Fluorides, Journal of the American Dental Association, September 1983, 113: 532-533. The standard is reasonable because it is the recommended practice of the professional peer group. It is reasonable to permit more frequent or later application with prior authorization because special circumstances evaluated by prior authorization may justify an exception.

D. This standard is comparable to the limitation set by major third party payers such as Delta Dental. To reduce the possibility of unnecessary expenditures, item E requires 5 years between surveys but, as recommended by the Dental Advisory Committee, permits a medically necessary additional survey if the dentist submits supporting documentation and obtains prior authorization. The standard is reasonable as it is consistent with accepted practice of the professional peer group.

E. This standard is reasonable because it limits a service that may be subject to unnecessary use to the prevailing standard of practice of the providers' professional peers. Furthermore, it is reasonable to allow an exception for an emergency because an emergency requires immediate treatment. See the definition of emergency in part 9505.0175, subpart 11.

F. This standard is reasonable because it limits a service to the prevailing standard of practice of the provider's professional peers.

G. This item permits a dentist to examine the entire mouth through the use of x-rays. Both the bitewing series and periapical series are necessary to completely investigate the teeth and supporting dental structures of the recipient. The limitation is reasonable as it protects the recipient from unnecessary radiation and also provides the dentist the information necessary for treatment. Allowing an exception for an emergency situation requiring medically necessary x-rays is reasonable to ensure the recipient will receive the proper care in an emergency.

H. A root canal problem requires palliative treatment to relieve the symptoms of the problem. Relieving the symptoms provides the dentist an opportunity to investigate more fully the nature of the problem and determine the best course of action. The item is consistent with the prevailing standard of practice of the provider's professional peers. See also subpart 6, item C, and its SNR concerning prior authorization of root canal treatment.

I. The application of sealants to molars is a measure recommended by the Surgeon General of the Public Health Service and the National Institute of Dental Research of the United States Department of Health and Human Services. (See Exhibits). Both Group Health of Minnesota and Delta Dental also cover the use of sealants. The standards for times of application and the ages of application are reasonable because they are

consistent with the prevailing standards of practice of the providers' peer group.

Subp. 4. Criteria for prior authorization of removable prostheses. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types and frequency of services covered by medical assistance. Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against unnecessary or inappropriate use of medical assistance services and against excess payments. This subpart is consistent with the statutory requirement and is necessary to specify the limits applicable to a removable prothesis, which may be either a partial or a full one. Prior authorization provides the department an opportunity to determine whether the removable prothesis is medically necessary for the recipent, whether it is the appropriate alternative to relieve the recipient's dental problem, or whether, in the case of a recipient who has a removable prosthesis, the existing device would be usable if it were relined. Thus, the requirement of prior authorization for all removable dental prostheses is reasonable because it enables the department to fulfill its statutory obligation to provide.medically necessary service at the lowest price.

A. Limiting purchase or replacement to once every five years is a standard adopted by major dental insurance carriers such as Delta Dental. It is based on the fact that, if the recipient exercises due care in using the prosthesis, its materials can be expected to last at least 10 years. Thus the limitation is reasonable because it is based on the life expectancy of the components of the prosthesis. However, it is also necessary to provide for frequent replacement as it is impossible to forsee all events that may affect the prosthesis itself or its continued appropriateness for the recipient. It is reasonable to require prior authorization of more freqent purchase or replacement as prior authorization protects the right of a recipient to receive medical assistance for a necessary service while at the same time enabling the department to carry out its statutory obligation to guard against unnecessary or inappropriate services.

B. Even if a recipient exercises care in using a prosthesis, the recipient may not be able to prevent damage to or loss of the prosthesis. For example, a recipient's prothesis may be damaged in a car accident or an elderly recipient who is confused may misplace it and be unable to find it even after a diligent search. Thus, this item is reasonable because it ensures the recipient will be able to obtain a medically necessary service for which a need arose in a manner beyond the recipient's control. Furthermore, it is reasonable to require consideration of the recipient's degree of physical and mental impairment in determining whether the recipient could control the circumstances because such impairment may limit the recipient's ability to care for the prosthesis in a customary way.

C. A recipient who has a partial prosthesis may lose additional teeth within the five year limitation in item A. A replacement of the prosthesis may be medically necessary so that the recipient's teeth occlude appropriate to their chewing and biting functions. This item is necessary to set the standards for replacement of a partial prosthesis during the five year limitation. Subitem (1) is reasonable because replacement of a front tooth aids assist the recipient's other teeth to remain in their proper positions. Subitem (2) is reasonable because it is the prevailing standard of practice of the provider's peer group that four

upper and four lower back teeth in biting function are medically necessary to chew food properly. Subitem (3) is reasonable because a partial prosthesis needs to be secure at both ends so that it will remain in place and be beneficial to the recipient. Thus if the anchoring tooth is lost, it is necessary and reasonable to provide a new prosthesis if there is another tooth that can be used to anchor it. However, if the teeth proposed to anchor the new prosthesis can not support it, a new partial prosthesis would not be an appropriate dental service. A standard of prosthesis support is necessary because there are identifiable conditions in which support would not be available or would be available for only a limited time. Insufficient bone in the area of the anchoring teeth will lead to their becoming loose and thus unable to support the prosthesis. If an anchoring tooth is not expected to support the prosthesis for at least one year, the recipient will obtain only a very brief benefit and another service is more more appropriate and cost effective.

Subp. 5. Other services requiring prior authorization. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types of service covered by medical assistance. Furthermore, Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against unnecessary or inappropriate use of medical assistance services. This subpart is necessary to set the standards as required by the statutes.

A. Hospitalization for dental services may be solely for the convenience of the recipient who fears dental services. Hospitalization for this reason is not medically necessary. On the other hand, because some dental procedures involving oral surgery do require hospital admission, requiring prior authorization is reasonable to permit an evaluation of the medical necessity of hospitalization. Therefore, the limitation is reasonable because it is consistent with the requirement of providing medically necessary service.

B. Periodontics is the branch of dentistry that specializes in treating conditions of the tissues supporting the teeth. Requiring prior authorization is reasonable because it permits the department's advisers to review the recipient's dental record and to determine whether a more aggressive or effective treatment is appropriate to the condition of the recipient's gingival tissue and its supporting bony structure.

C. Caries affecting the root canal of a tooth may have advanced to a stage where an attempt to save the tooth through root canal therapy is not feasible. Another service such as fitting of a prosthesis may be a more effective treatment. Thus requiring prior authorization is reasonable because it permits a review of the recipient's condition and a determination of an effective treatment. A root canal therapy used to relieve severe pain is an emergency treament and therefore exempt from the prior authorization requirement.

D. Almost everyone could benefit in some way from orthodontia. However, the purpose of the medical assistance program is to provide medically necessary services. Requiring prior authorization is reasonable because it permits a review to determine whether the recipient has an acute dental condition that would lead to irreversible damage to the teeth or their supporting structures. Treatment of such an acute dental condition is medically necessary.

E. Except for emergencies and alveolectomies, most surgical procedures related to dental services are elective. Therefore, it is reasonable to

require prior authorization for elective procedures because the prior authorization review permits a determination of whether the procedure is medically necessary.
F. This item is necessary and reasonable because it is impossible to forsee all situations that might require medically necessary dental services in excess of the limitations in subpart 3.
G. An impacted tooth is one that is embedded in the jaw so that its eruption is prevented or is locked in position in some way that prevents either its normal occlusion or its routine removal. (Adapted from Dorland's Medical Dictionary, page 727.) Many persons have impacted teeth that never cause them pain or adversely affect other teeth. Unless the impacted tooth is causing pain or adversely affecting another tooth, its removal is not a medical necessity but rather an elective procedure. Thus, prior authorization is a reasonable requirement because it permits a determination of whether the procedure is medically necessary.

Subp. 6. Criteria for prior authorization of orthodontic treatment. Minnesota Statutes, section 256B.04, subd. 2 requires the department to administer the medical assistance program in a uniform manner. Minnesota Statutes, sectionn 256B.04, subd. 12 requires the department to place limits on the types of services covered by medical assistance. Therefore, this subpart is necessary to establish the criteria that will be used to determine whether orthodontic treatment is a medical necessity and, thus, eligible for prior authorization. All of the conditions in items A to E are related and affect each other. Any one condition may be sufficient to warrant orthodontia. Most, if not every, case submitted as a request for prior authorization has a less than perfect oral condition in one or more of the areas specified in items A to E. However, professional judgment is required to determine whether one or more of these conditions is causing a significant functional problem for the recipient. The significance of some conditions is readily apparent as for example in cases where biting or chewing functions are impaired as a result of an overbite, spacing of teeth, or positioning of jaws or teeth, items B, C, and D. Any one of these conditions may cause the recipient's facial appearance to be disfigured. Therefore, the prior authorization requirement permits the department's dental consultants to review the documentation submitted by the recipient's dentist and determine whether orthodontia is medically necessary.to correct a condition specified in items A to E. Submitted documentation includes not only dental records but photographs of the recipient which display the degree of the recipient's facial disfugurement. Thus items A to B are reasonable because they identify conditions impairing a medically necessary function.

Subp. 7. Payment limitation; removable prosthesis. As discussed in relation to items A and B under subpart 4, it is expected that a recipient will exercise due care in using a removable prosthesis. However, a recipient receiving such a device may lack the knowledge necessary to carry out this obligation. Thus, the recipient needs to be instructed about proper care of the prosthesis. The dentist is the professional with the knowledge and experience necessary to instruct the recipient. Thus, it is necessary and reasonable to require the dentist to provide this instruction as part of a medically necessary dental service. A removable prosthesis that does not fit properly is an inappropriate service and, additionally, may seriously damage the soft supporting mouth parts, or may

decrease the recipient's ability to bite or chew even further than the impairment the device is supposed to correct. Thus, it is necessary and reasonable to require adjustment of the prosthesis as part of the service of prescribing and ordering the prosthesis. However, limiting the period in which the dentist must make adjustments without further charge is necessary to ensure that the recipient's request for adjustment is based on necessity rather than the recipient's unwillingness or inability to adapt to the prosthesis. The department's dental consultants identified a six month period as the prevailing standard of practice for achieving a satisfactory adjustment of a removable prosthesis. Requiring documentation of the instruction and necessary adjustments is reasonable because it provides a record that shows the provider's compliance with these rules and, also, enables the department to carry out its obligation under Minnesota Statutes, section 256B.064 to seek monetary recovery from a provider who presents a pattern of claims for services that are not in compliance with these rules.

Subp. 8. Payment limitation; more than one recipient on same day in same long-term care facility. This subpart is consistent with the requirement of Minnesota Statutes, section 256B.04, subd.15 to safeguard against excess payments. The payment amount set for a procedure code under part 9505.0445, item E, includes an amount for administrative overhead and other nonrepetitive costs a dentist may incur in coming to a long-term care facility. The multiple visit code prorates the payment for administrative and nonrepetitive costs and permits billings to be made according to the number of multiple visits in the same facility on the same day. Thus the limitation is reasonable because the limitation affects nonrepetitive and administrative costs but allows for payment of actual dental services to the residents of the long-term care facility. A similar provision is found in part 9505.0404, subpart 3, concerning vision care services of a provider who furnishes the service in a long term care facility.

Subp. 9. Excluded dental services. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types and frequency of covered services. Furthermore, Minnesota Statutes, section 256B.04, subd.15 requires the department to safeguard against unnecessary or inappropriate use of medical assistance services and against excess payments. This subpart is necessary to specify the services that are not covered services.

A. A partial prosthesis is a custom designed denture that is fabricated according to the dentist's instructions for a particular recipient. The number of clasps depends on the recipient's dental condition but usually varies between two and four. Additional clasps would only raise the cost but would have no medical benefit to the recipient. The item is consistent with the recently adopted coding standard of the American Dental Association which specifies ,"including any conventional clasps and rests." However, even if more are necessary, another clasp added at the time of the denture's fabrication does not add significantly to the cost of the denture. Therefore, it is reasonable to establish a single maximum fee based on the average number of clasps on a denture as the average cost will balance out and the right of the dentist and the laboratory to a fair return for their work will be protected. Furthermore, the item is reasonable because the dentist and the laboratory fabricating the denture are able to choose the design and number of clasps that are medically

necessary. Therefore, the exclusion is reasonable as it is consistent with Minnesota Statutes, section 256B.04, subd.15 to safeguard against inappropriate services and unnecessary expenditures. The department's two dental advisors recommend this exclusion.

B, C, F. These services are components of a procedure that is eligible for medical assistance payment. The costs of these services are included in the medical assistance payment allowed for the procedure. For example, bases and pulp caps are components of fillings and are reimbursed as part of the cost that service. Thus, their exclusion is reasonable because it prevents duplicate payments.

D. Hygiene aids are the responsibility of the recipient. It is customary practice for a person to purchase his or her own choice of a dentifrice or a toothbrush. Similarly, it is customary for a person to purchase his or her own soap and bath utensils. Therefore, their exclusion is reasonable because it is consistent with the prevailing community standard.

E. Part 9505.0340 sets the eligibility requirements for pharmacy services. Compliance with part 9505.0340 ensures a drug dispensed to a recipient will be properly labeled and dispensed according to the drug formulary required under Minnesota Statutes, section 256B.02,subd.8 (11). Compliance with part 9505.0340 protects the safety of the recipient. Therefore, it is reasonable to prohibit payment of medication dispensed by a dentist if the recipient can obtain it from a pharmacy because this prohibition is consistent with ensuring a degree of safety of the recipient.

H. Prosthesis cleaning is a hygiene measure in the same manner as bathing or brushing teeth. The recipient may choose from among the many preparations on the market. It is the prevailing community standard for a person to assume responsibilty for choosing and purchasing hygiene aids. Therefore, its exclusion is reasonable because it is not a medically necessary service.

I. A unilateral partial prosthesis involving posterior teeth is used to replace the loss of one or two posterior teeth on a one side of a mouth. The department's dental consultants have stated that such a loss does not impede the recipient's chewing and therefore has no adverse affect on the recipient's digestion. Therefore, the exclusion is reasonable because the unilateral partial prosthesis is not medically necessary. The exclusion only applies to a unilateral loss of posterior teeth; there is no prohibition of payment in the case of a bilateral loss of posterior teeth.

J. This exclusion from payment is required by Minnesota Statutes, 256B.02, subd.8(9).

K. A fixed prosthodontic is an artificial device made to replace missing teeth. Its use requires a cast metal restoration of adjacent teeth. A cast metal restoration is excluded from payment by Minnesota Statutes, section 256B.02, subd.8(9). Therefore, the exclusion from payment is consistent with statute. However, the program does pay for a removable prosthesis as an alternative to a bridge. Thus, the recipient's health is protected.

L. Minnesota Statutes, section 256B.04, subd.15 requires the department to safeguard against unnecessary use of medical assistance services and against excess payments. Relining and rebasing a denture are less costly items than replacement of a denture. Therefore if relining or rebasing a denture would correct the problem, it is reasonable to do this because replacement of the denture would not be medically necessary and would be an excessive cost.

M. Minnesota Statutes, section 256B.02, subd.8(9) prohibits payment for cast metal restorations. This item is consistent with statute.
N. The department's dental consultants have advised the department that full mouth or panoramic x-rays are not an effective diagnostic tool for most dental conditions affecting children under 8 years of age. Furthermore, inappropriate use of x-rays unnecessarily exposes the children to radiation. Therefore, it is reasonable to exclude these items from payment as they do not satisfy the conditions of being medically necessary and appropriate. However, in some conditions such as those requiring orthodontia or pedodontics, full mouth or panoramic x-rays are appropriate and medically necessary to identify and remedy the underlying problem. Therefore providing an exception through prior authorization is necessary and reasonable because it permits a review to determine whether the x-rays are appropriate and medically necessary.

9505.0275 EARLY PERIODIC SCREENING, DIAGNOSIS AND TREATMENT

Subpart 1. Definition. This subpart is necessary to clarify the meaning of the term "early and periodic screening, diagnosis, and treatment services" (EPSDT) and set a standard under these rules for eligibility for medical assistance payment. The definition is consistent with 42 CFR 440.40 (b) and 42 CFR 441.50. Its inclusion is reasonable to inform affected persons.

Subp. 2. Duties of provider. This subpart is necessary to clarify the duties that a provider of early and periodic screening, diagnosis, and treatment service must perform in order to be eligible for medical assistance payment. 42 CFR 441.55 prescribes the EPSDT services required to qualify the program for federal financial participation. Under Minnesota Statutes, section 256B.04, subdivision 4 the department must cooperate with federal requirements in any reasonable manner necessary to qualify for federal financial aid in the medical assistance program. Further, under Minnesota Statutes, section 256B.04, subdivision 2 the department promulgated parts 9505.1500 to 9505.1690 to govern the administration of EPSDT. Therefore, requiring an EPSDT provider to comply with applicable federal regulations and state rules is reasonable because the compliance will ensure federal financial participation.

9505.0280 FAMILY PLANNING SERVICES

Subpart 1. Definitions. "Family planning service" and "family planning supply" are eligible for medical assistance payment under 42 CFR 440.40 (c). However, the federal regulations do not define the terms. Thus a definition is necessary to clarify their meaning and set a standard for this part.

A. Minnesota Statutes, section 145.912, subd. 9 defines "family planning services" to mean "counseling by trained personnel regarding family planning; distribution of information relating to family planning; and referral to licensed physicians or local health agencies for consultation, examination, medical treatment, genetic counseling, for the purpose of family planning; and the distribution of family planning products...." The statute specifies the voluntary nature of family planning. Thus, the definition is consistent with statute. The definition includes voluntary sterilizations that meet the requirements of 42 CFR 441.250 to 441.259 as is necessary to qualify this procedure for federal financial participation.

B. Various drugs and contraceptive devices are used to treat health conditions related to family planning. Skill and knowledge are required to determine the appropriate drug or device. Thus limiting the definition of family planning supply to a drug or contraceptive device prescribed by a physician is reasonable because it will ensure the device or drug is ordered by a person whose scope of practice includes treatment of health conditions related to fertility.

Subp. 2. Conditions for payment. The subpart is necessary to set the standards a service must meet in order to be eligible for medical assistance payment. Items A to C are reasonable because they protect the recipient's due process rights and support the voluntary nature of family planning. They are consistent with the voluntary nature of family planning prescribed in Minnesota Statutes, section 145.912, subd.9. Item C is required by 42 CFR 441.252.

Subp. 3. Eligible provider. This subpart is necessary to specify the providers who are eligible to receive medical assistance payments for family planning services to recipients. Services in all of the specified agencies are furnished either by or under the supervision of a physician. The subpart is reasonable because it limits eligibility for payment as a family planning service provider to a physician or to an agency that has staff members whose scope of practice includes treatment of health conditions related to fertility.

9505.0285 HEALTH CARE PREPAYMENT PLANS OR PREPAID HEALTH PLANS

Subpart 1. Eligible provider. This subpart is necessary to set the requirements that a health care prepayment plan or prepaid health plan must meet to be eligible for medical assistance payments.
A. One type of prepaid health plan is a health maintenance organization. As specified in Minnesota Statutes 62D.02, subd.7, a health maintenance organization provides "a set of comprehensive health services which the enrollees might reasonably require to be maintained in good health including as a minimum..... emergency care, inpatient hospital and physician care, outpatient health services and preventive health services." It is reasonable to require a prepaid health plan to sign an agreement with the department because the agreement will specify the services to be furnished by the plan and provide a means to ensure a uniform standard applicable to all types of prepaid health plans.
B. Some prepaid health plans have a diversity of qualified staff great enough to furnish all health services eligible for payment under parts 9505.0170 to 9505.0475; others do not. However, a recipient who enrolls in a prepaid health plan is entitled to receive all medically necessary health services under 42 CFR 440, Subpart A. Thus, it is reasonable to permit a plan to choose whether to provide a service directly or through an arrangement with another provider because such a choice will be consistent with federal regulation. The provision is also consistent with Minnesota Statutes, section 256B.71, subdivision 2, which requires the participating plan to arrange for the provision of all needed health services including those listed in Minnesota Statutes, section 256B.02, subdivision 8.
The requirements of items A and B are consistent with 42 CFR 434.20, which specifies the general requirements for a contract with a HMO and 42 CFR 434.65 concerning referrals to other providers.

Subp. 2. Limitations on services and prior authorization requirements. This subpart is necessary to clarify the obligation of the prepaid health plan about comparability of service. The subpart is consistent with 42 CFR 434.52 and 440.240. Under the contract between the department and the prepaid health plan, the plan receives medical assistance payments on a capitation basis for each enrolled recipient. Therefore it is reasonable to exempt the plan's staff from having to comply with the procedures required by rules related to prior authorization, second surgical opinion, and hospital admission certification programs which are based on medical necessity as the HMO's contract specifies the per capita payment and what is medically necessary. However, the plan has the right to provide services in addition to those specified in the contract but will receive only the agreed upon capitation payments. These three programs are established pursuant to Minnesota Statutes, section 256B.04, subd. 15, which requires the department to safeguard against excess payments, unnecessary or inappropriate services, and unnecessary or inappropriate hospital admissions or lengths of stay. Thus it is reasonable to permit the prepaid health plan to establish its own programs because such programs may assist the plan in safeguarding against similar concerns.

9505.0290 HOME HEALTH AGENCY SERVICES

Subpart 1. Definition. "Home health agency service" is a term used in this part. A definition is necessary to clarify the meaning of the term and set a standard. The definition is consistent with 42 CFR 440.70 (a) which requires a home health service to be provided at the recipient's place of residence and on written orders of a physician. It is also consistent with 42 CFR 440.70 (b) which mandates nursing services to be provided by a home health agency. 42 CFR 440.70 (c) excludes a hospital or long term care facility from being considered a residence for home health services.

Subp. 2. Eligible providers. This subpart is necessary to set the standard of eligibility to participate in the medical assistance program as a home health agency. 42 CFR 440.70 (d) defines a home health agency as one that meets the requirements of participation under Medicare. The Medicare requirements are established in 42 CFR 405.1201 to 405.1230. The subpart is consistent with federal regulations.

Subp. 3. Eligible home health agency services. This subpart is necessary to set the standards the services of the agency must meet to be eligible for payment.

A. 42 CFR 440.70 (b)(1) requires home health services to include "nursing services, as defined in the State Nurse Practice Act,.....". Minnesota Statutes, section 148.171 is the statute defining the practice of professional nursing. Thus the item is consistent with the federal regulation.

B. 42 CFR 440.70 (b)(2) requires a home health agency to provide home health aide service. It is reasonable to require the service to be under the direction of a registered nurse as the scope of practice of a registered nurse includes the supervision and teaching of less qualified health team members such as home health aides. Because "home health aide" is a term used in this part, a definition is necessary to clarify its meaning. Requiring the directing nurse's approval of a health aide to perform physician-prescribed "medically-oriented tasks" is reasonable because the approval signifies that the professional nurse through direct training or observation of the aide is satisfied with the ability of the non-licensed aide to perform the medically-oriented tasks. HCFA's Medicaid Manual, as published in the Medicare and Medicaid Guide, Commerce Clearing House, 411, 12-83, page 6303-2 defines services performed by home health aides as medically-oriented tasks having to do with the recipient's physical requirements as opposed to housekeeping requirements and that may encompass a higher level of skill than those designated as personal care services. The Guide further specifies that home health services must be provided through a home health agency.

C. 42 CFR 440.70 (b)(3) requires home health service to include "medical supplies, equipment, and appliances suitable for use in the home....". Thus it is reasonable to specify that such supplies ordered by a licensed practitioner are eligible for payment because they are a required service and prescribed as necessary for the recipient's health care.

D. 42 CFR 440.70 (b)(4) requires these services to be includded as home health services. The item is consistent with the regulation.

Subp. 4. Payment limitation. This subpart is necessary to specify the conditions that a covered service must meet to be eligible for payment.

The documentation is required by 42 CFR 440.70 (b)(1)(iii). A written record is reasonable because it provides the information that can be used for billing and surveillance purposes. Review of service by the physician every 60 days is required under 42 CFR 440.70 (a)(2). However, a change in the recipient's health condition may cause a need to revise the physician's order before the end of the 60 day period. Thus, permitting more frequent review is reasonable because such a review is consistent with providing health service based on the recipient's health condition.

Subp. 5. Excluded home health agency services. This subpart is necessary to clarify other services of a home health agency that are not covered services and, thus,to prevent misunderstanding about eligibility for payment. Homemaker services, social services, and educational services do not meet the medical assistance payment criterion of being medically necessary. Therefore, their exclusion is reasonable because it is consistent with a payment criterion. See part 9505.0220, item S and its SNR.

9505.0295 HOME HEALTH SERVICE

Subpart 1. Definition. "Home health service" is a term used in this part. A definition is necessary to clarify the meaning of the term and set a standard. The definition is consistent with 42 CFR 440.70 (a) (1) and (2) and 42 CFR 440.70 (c).

Subp. 2. Covered services. This subpart is necessary to specify the health care which is eligible for payment as a home health service. The services listed in items A to G are consistent with the requirements of 42 CFR 440.70. Requiring respiratory therapy services to be given by a registered respiratory therapist or a certified respiratory therapist working under the direction of a registered nurse is reasonable because these persons have the specialized training required to competently perform these services. Neither the federal regulations nor state statutes specify who is qualified to provide respiratory therapy. However, The National Board for Respiratory Care is the professional organization that sets the professional standards for respiratory therapy and registers those applicants who are qualified to provide this therapy. Therefore, it is reasonable to limit payment for the service to a person who is registered as a therapist by the Board because such registration ensures that the recipient will receive the prevailing standard of professional respiratory therapy care from a qualified person. Also see the SNR for part 9505.0290, subpart 3.

Subp. 3. Payment limitation; general. 42 CFR 440.230 (d) permits a state to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the types of service, the frequency with which the same or similar services may be covered by medical assistance, and the amount paid for a covered service. Furthermore, Minnesota Statutes, section 256B.04, subdivision 2 requires the department to carry out the medical assistance program in an efficient and economical manner. This subpart is necessary to specify the limits placed on home health services in order to comply with statutory and federal requirements. Finally, it should be noted that not all health services are classified as home health services and, therefore, do not fall within the limits that are in items A to C. For example, dental and vision care services are not home health services and, thus, costs to provide them are in addition to the limits in this subpart.
A. A recipient whose home health services began before and are continued without increase on or after the effective date of this part has become accustomed to his or her situation and is used to living independently. The rule would place a harsh burden on such a recipient if he or she would be required to be assessed for continuation of the services without any change. Furthermore, it would be inconsistent with the recipient's demonstrated ability to live independently if services to such a recipient were to be subject to a decrease resulting from a limitation within this proposed rule. Therefore, this item is reasonable because it supports continuation of present services to recipients who have shown their ability to live independently.
B. Minnesota Statutes, section 256B.04, subd. 2 requires the department to implement the medical assistance program in an efficient and economical manner. Minnesota Statutes, section 256B.04, subd. 15 requires the

department to safeguard against inappropriate use of medical assistance services. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types and frequency of covered services. This item is consistent with the statutes. Minnesota Statutes, section 256B.091 requires all applicants seeking admission to a licensed nursing home to be screened by a screening team for the purpose of preventing inappropriate placement in a nurisn home. A screening team is comprised of health care professionals who are qualified by training and experience to make judgments about the most appropriate setting for an individual's ongoing health care. Members of a team include a public health nurse from the local public health nursing service and a social worker from the local community welfare agency. The team is required to have a physician available for consultation and to use any assessment information available from the recipient's attending physician. Thus,it is reasonable to require the determination of a screening team because the screening team is qualified to review the recipient's needs and judge the most appropriate, cost effective setting. See the definition of "screening team" in part 9505.0175, subpart 45. The period of two consecutive months provides a reasonable amount of time for a recipient's physician to assess the level of care the recipient needs on a continuing basis and for a recipient's needs to stabilize. Furthermore, the consecutiveness is reasonable because it makes allowance for significant increases in health care costs incurred as a result of a short-term acute illness or non-recurring surgical procedure. The limit of $1200 represents 197 hours of private personal care service per month at $6.08 per hour, the present rate of pay of a personal care assistant. Furthermore, it is reasonable to adjust the limit annually to reflect CPI increases as the rate of pay of personal care assistants also is adjusted according to increases in this index.

C. This item is necessary to set the standard for determining the most appropriate and cost effective setting for a recipient whose eligibility for home health services is being assessed by a screening team. The persons being screened under this item belong to one of two groups: persons who are physically handicapped but are fully able to control decisions about their own lives and persons who have suffered brain impairment. The service needs of these groups are different from each other. Subitems (1) and (2) are necessary and reasonable because the facilities and their cost are related to the diagnoses of and services appropriate to the recipients. Determination of the case mix classification will be a duty of the screening team. This determination is consistent with Minnesota Statutes, section 256B.091. Neither a long-term care facility nor a residential facility for the handicapped provides an appropriate comparison for a recipient who is ventilator dependent because the care needs of the recipient exceed those offered in these facilities. For a ventilator dependent recipient, the choice may be between a hospital and the recipient's residence. Furthermore, in making the comparison for the purposes of limitation, it is necessary to ensure that the hospital being compared to the recipient's residence has qualified staff who are able to provide all the health services required by the recipient because the recipient is entitled to receive the services that are medically necessary for treatment of his or her condition. Thus, subitem (3) is necessary to specify the standard for the payment limitation applicable to home health services for ventilator dependent recipients. Requiring the hospital to be the least expensive one in the

recipient's local trade area that can provide the services is consistent with the requirement of administering the medical assistance program in an economical manner under Minnesota Statutes, section 256B.04, subd.2 and of safeguarding against excess payments under Minnesota Statutes, section 256B.04, subd.15. It is reasonable to use the hospital's projected monthly cost of services to the ventilator dependent recipient rather than the payment under the diagnostic category as in parts 9500.1090 to 9500.1155 as the system of DRG payments is based on statistical averages of the costs of acute illnesses. A ventilator dependent recipient is not experiencing an acute illness but rather a chronic condition that requires intensive maintenance treatment for an unpredictable length of time. Such persons who are being cared for in the hospital are in effect residents of the hospital. The needs of ventilator dependent persons were never contemplated when the system of DRG payments was devised. Thus, the system of DRG payments does not meet the burden of costs that a hospital incurs in providing necessary services to a ventilator dependent recipient. Therefore, it is unreasonable to pass the burden of the costs of the recipient's services to the hospital if the necessary services can be provided at lesser cost outside of the hospital. Furthermore, providing the services in the recipient's residence is consistent with the concept of encouraging the recipient to live in the least restrictive environment. Therefore, this subitem is reasonable because it will benefit both the hospital and the recipient. The subitem is consistent with Minnesota Statutes, section 256B. 04, subd. 12 which requires the department to place limits on the types of services covered by medical assistance.

Subp. 4. Review of screening team determinations of eligibility. This subpart provides a way for persons who have unresolved concerns about personal care services to have their concerns reviewed. Such a review is necessary to ensure that the personal care services program is implemented in the best interests of the recipients while at the same time protecting the rights of the providers and their employees or contractors. It is reasonable to permit the commissioner to appoint an advisory committee either on her own initiative or on the request of a recipient as the commissioner has the responsibility under Minnesota Statutes, section 256.01 of administering and supervising the medical assistance program. Establishing a grievance committee comprised of persons familiar with the program is reasonable so that the committee will have the knowledge necessary to weigh the goals of the program and the need of the disabled recipient. A seven member committee is reasonable as it balances representation of diverse points of view and knowledge with a size that encourages all members to participate in the discussion. Requiring the majority of the committee to be qualified recipients is reasonable because the recipients have first-hand knowledge of how the program actually works and because it is consistent with the program's goal of supporting the ability of recipients to live independently.

Subp. 5. Payment limitation; screening team. This subpart is necessary to ensure that members of the screening team do not have a conflict of interest growing out of a common financial interest with a provider that would affect their ability to make impartial recommendations concerning appropriate care for a recipient. Thus, it is reasonable to prohibit medical assistance payment to a team which has such a financial interest

because the ability of the team to render the required service, an impartial recommendation based on the facts of the situation, is open to question. On the other hand, there are circumstances that justify exceptions to this prohibition. One example is a screening team in a rural area where no other person having knowledge and experience comparable to that of the member having a conflict of interest is available to serve on the team or a screening team composed of members of a county agency that also is a provider of personal care services. In these circumstances, it is resonable to require the department's review and approval of the exception as the department has the responsibility to monitor the program's implementation to assure compliance with these rules. Furthermore, it is reasonable to permit an exception if the team members and the provider are part of a government personnel system as such team members would not have a direct financial interest in the services and the persons providing the services would be subject to scrutiny under the personnel procedures of the governmental unit.

9505.0300 INPATIENT HOSPITAL SERVICES

Subpart 1. Definition. "Inpatient hospital service" is a term used in this part. A definition is necessary to clarify its meaning and set a standard. The definition is consistent with 42 CFR 440.10 and the definition of "hospital" in part 9505.0175, subpart 16, and the definition of "inpatient" in part 9505.0175 subpart 17.

Subp. 2. Eligibility for participation in medical assistance program; general. This subpart is necessary to set the requirements that a hospital must meet in order to participate in the medical assistance program. It is reasonable to require a hospital to comply with items A to C so that the state complies with its obligation under Minnesota Statutes, section 256B.04, subd. 4 to obtain federal financial aid. It is reasonable to include these items in order to inform affected parties and encourage compliance.
A. This item is required under 42 CFR 440.10 (a)(3)(iii).
B. This item is required under 42 CFR 440.10 (a)(3)(iv). The timely review of the specified items is required under 42 CFR 405.1035 (a).
C. To qualify for federal financial participation, inpatient hospital services for sterilization, hysterectomy, and abortion must comply with the federal regulations cited in this item.

Subp. 3. Payment limitation. Minnesota Statutes, section 256B.04, subd. 2 requires the department to carry out the medical assistance program in an economical manner. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the types of services covered by medical assistance. Parts 9500.1090 to 9500.1155 are the rules that establish hospital payment rates as authorized in Minnesota Statutes, section 256.969. Under these rules, hospitals are paid a cost per admission based on the recipient's diagnosis category. The cost per admission is reimbursement for all services that are medically necessary for the recipient's diagnosis category. Thus costs for medically necessary treatment of the patient's diagnois category are not eligible for separate payment but are included within the payment rate. The provision is consistent with statute and rules of the department. A recipient may require a medically necessary service such as a private room. This possible need is considered as a service to be provided within the categorical payment rate for the admission. The physician's certification of the need for the private room is reasonable as the physician is the person qualified by training and licensure to make such a determination.

Subp. 4. Eligibility for participation in medical assistance; emergency. Because a recipient who has a medical emergency may need immediate inpatient hospital service, the recipient's physician may be unable to delay long enough to admit the recipient to a Medicare certified hospital. This provision is necessary to ensure that the recipient will be able to obtain the necessary care without incurring an unreasonable financial obligation. Thus, providing an exception to the requirement that the hospital must be Medicare certified is reasonable because it ensures the hospital, regardless of certification, will be eligible for payment for emergency health services to a recipient and thus will be

encouraged to care for the recipient in an emergency. On the other hand, urgent care is not care given in response to a life-threatening situation and, even though urgent care is medically necessary, its provision can be delayed sufficiently to plan and schedule it at a hospital that is qualified under Medicare. This limiting the exception from using a hospital qualified to participate in Medicare to an emergency is reasonable because there is a difference between emergency and urgent care concerning the need for immediate treatment.

Subp. 5. Excluded services. This subpart is necessary to inform persons affected by the rule of those inpatient hospital services that are not eligible for medical assistance payment. Parts 9505.0500 to 9505.0540 require the certification of the medical necessity of inpatient hospital service for a recipient as a condition of the hospital's eligibility for payment for the service. Exclusion of alcohol treatment that is not a medical necessity is consistent with parts 9505.0500 to 9505.0540. Further, because rules requiring prior authorization of services meeting certain criteria and a second opinion before surgery have been promulgated under Minnesota Statutes, section 256B.04, subdivision 15, this subpart reasonably excludes these services from medical assistance coverage in order to encourage compliance and consistency with the other rules.

9505.0305 LABORATORY AND X-RAY SERVICES

Subpart 1. Definition. "Laboratory and x-ray service" is a term used in this part. These services are specified in Minnesota Statutes, section 256B.02, subdivision 8(10) as available under the medical assistance program. However, the statute does not define the term. Thus, a definition is necessary to clarify its meaning and set a standard for these rules. The definition is consistent with 42 CFR 440.30. Specifying that the service must be directly related to the diagnosis and treatment of a recipient's health status is reasonable because it applies the concept of the medical necessity of a service to the determination of the service's eligibility for medical assistance payment. (See part 9505.0210, item A.)

Subp. 2. Covered service. This subpart specifies the conditions that a laboratory or x-ray service must meet in order to be eligible for medical assistance payment. Such a standard is necessary in order to ensure uniform administration of the medical assistance program as required in Minnesota Statutes, section 256B.04, subdivision 2. The standard chosen is consistent with the requirements of 42 CFR 440.30 that must be met for federal financial participation.

Subp. 3. Eligible provider. This subpart is necessary to inform affected vendors of the standards they must meet to qualify as a provider whose service is eligible under these rules for federal financial participation. The cited regulations, 42 CFR 405.1310 to 405.1317, specify the conditions for Medicare coverage as a provider of independent laboratory services and 42 CFR 405.1411 to 405.1416 specify the conditions for Medicare coverage as a provider of x-ray service. Meeting the Medicare standards is consistent with the requirements of 42 CFR 440.30 (c).

Subp. 4. Payment limitation. This subpart is necessary to set the payment limitations on laboratory and x-ray services and to inform affected persons of the requirements for medical assistance payment. The subpart is consistent with Minnesota Statutes, section 256B.03, subdivision 1 which requires medical assistance payment to be made to the service vendor. Requiring the provider to submit the claim to the department is reasonable because the provider has the information about the services to the recipient and, thus, is best able to complete the claim in a cost effective and efficient manner. Eligibility to be a provider of these services requires certification according to Medicare standards. (See subparts 2 and 3.) The Medicare established payment rates for these services are based on the costs the providers incur in complying with the Medicare certification requirements. Thus, setting the maximum payment at the amount established by Medicare is reasonable because it ensures that the costs of the provider will be covered.

9505.0310 MEDICAL SUPPLIES AND EQUIPMENT.

Subpart 1. Conditions for payment. This subpart specifies the eligibility of medical supplies and equipment for medical assistance payment. It is consistent with Minnesota Statutes, section 256B.02, subd.7, and with 42 CFR 440.70 which requires the state plan to provide for medical equipment services and supplies suitable for use in the home. Minnesota Statutes, section 256B.04, subd. 2 requires the department to carry out the medical assistance program in an efficient and economical manner. Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against excess payments for medical assistance services. The subpart is necessary to set the standard and inform affected persons.

A. The majority of nondurable medical supplies are medically necessary for a recipient during a short period. An example of such nondurable medical supply would be dressings for surgical wounds. Requiring prior authorization of nondurable supplies which are used on an ongoing basis for more than a short time is reasonable because it permits the department to determine the medical necessity and appropriateness of the supply and the quantity being purchased. For example, dressings for ulcers and other slow-to-heal wounds are nondurable supplies that might be used on an ongoing basis for more than a short time, require frequent changes, and are very costly. Prior authorization provides an opportunity to determine the appropriate amount without placing an undue burden on the provider or the recipient. The limit of a one-month supply is consistent with a recipient's month-to-month eligibility status under parts 9505.0010 to 9505.0150.

B. To pay for a repair of an item that is under warranty would be unreasonable because the cost of the repair is part of the rental or purchase price. Guarding against duplicative payments is consistent with the statutes cited above.

C. This item is consistent with Minnesota Statutes, section 256B.04, subd. 2. It is cost effective to rent an item with an option to purchase if there is uncertainty about the length of time the item will be needed. Applying rental payments toward the purchase price is an accepted business practice that is cost effective for the purchaser.

Subp. 2. Payment limitation on durable medical equipment in hospitals and long-term care facilities. This subpart is necessary to set limits as required under Minnesota Statutes, section 256B.04, subdivisions 4, 12, and 15.

A. Durable medical equipment that can be interchangeably used by many persons must be provided by hospitals and long-term care facilities as part of their routine service. Reimbursement for such equipment is a component of the per diem payment to long-term care facilities and a hospital's categorical rate payment. However, if the item cannot be used by other persons either because of the item's modification or dedicated use, then it is no longer a routine service. Thus it is reasonable to permit a spearate claim for payment for equipment modified for or dedicated to the use of a particular recipient as such equipment is not available to other persons. Requiring a physician's written order to document the recipient's unusual medical need is reasonable as the physician is the person licensed to diagnose the recipient's condition and order treatment. If an item is paid for on a separate claim for payment

because of a recipient's medical needs, it is reasonable to permit the recipient to retain it as the purpose of the medical assistance program is to assist medically needy persons.
A definition of the term "modified" is necessary to set a standard applicable to equipment for which a separate payment claim is made. The definition is reasonable because, if specially ordered modifications permanently alter the equipment or cannot be removed without damaging the equipment, the equipment is not available for use by other persons and requiring the facility to pay for it as a routine service would place an unreasonable burden on the facility.
Specifying that equipment that is not for the continuous care and exclusive use of the recipient is included within the payment rate is necessary and reasonable to inform affected persons and avoid confusion. The provision is consistent with the cited rules, parts 9500.1090 to 9500.1155 and 9549.0070.
B. This item is reasonable because it informs affected persons of services that are components of services subject to a fixed reimbursement. Subitem (1) specifies the equipment that the Minnesota Department of Health requires as a condition of licensure as a long-term care facility. Subitem (2) also specifies equipment that is required for licensure, is medically necessary to care for the elderly and physically frail population served by nursing homes, and can be used interchangeably by the facility's residents. Equipment listed in subitem (3) is used to treat conditions that result from less than adequate or appropriate care. Thus, if the facility meets the nursing service and patient care standards required for licensure which are reimbursed as components of the hospital's or facility's payment rate, the conditions will not occur and the hospital or facility will not incur unnecessary expense. Subitem (4) falls in the category of nursing service under part 9549.0040, subpart 5 and is reimbursed as a component of the per diem payment rate. A hospital and a long-term care facility have an obligation to provide equipment that can reasonably be expected to be medically necessary for the expected resident population. Thus, subitem (5) is reasonable because it is an obligation of the provider and its cost can be a component of the provider's payment rate.
C. It is necessary and reasonable to coordinate covered services with medical assistance payments specified in other rules. This item provides consistency with per diem payment rates established in parts 9549.0010 to 9549.0080.

Subp. 3. Payment limitation; prior authorization. Minnesota Statutes, section 256B.04, subdivision 15 requires the department to safeguard against the unnecessary or inappropriate use of medical assistance services. This subpart is consistent with that requirement and is necessary to specify the criteria.
A. The present cost limit applied to the purchase of a nondurable medical supply is $150. Requiring prior authorization to exceed that limit is reasonable as it permits the department to determine the medical necessity of the supply and whether a less costly approach to care is appropriate. Examples of equipment that would require prior authorization include equipment for the administration of enteral and parenteral nutritive products and some types of wound dressings.
B. All these limitations are consistent with the obligation of the department to determine the medical necessity and cost effectiveness of the medical equipment. Requiring prior authorization is reasonable

because it permits the department to determine whether a more cost effective alternative will meet the medical necessity of the recipient. Examples of equipment that might require prior authorization under this item include wheel chairs, hospital beds, respiratory therapy equipment, and hearing aids.

C. An item of durable medical equipment used daily by a recipient shows evidence of wear although its effectiveness remains unimpaired. Thus, department experience shows that a dealer who is less than scrupulous can find an excuse to charge medical assistance for maintaining equipment even though the maintenance is not a medical necessity. Therefore, it is reasonable to require prior authorization of maintenance of durable medical equipment because the prior authorization review permits the department to determine the medical necessity of the request based on the projected use, length of time in service, and the expected life and appropriateness of the equipment.

The definitions of the terms "maintenance" and "repair" are necessary and reasonable to clarify terms used in this subpart and set a standard to use in implementing the subpart. They are consistent with common usage among persons responsible for providing equipment in working order. See The American Heritage Dictionary of the English Language, pages, 787 and 1102.

Subp. 4. Excluded medical supplies and equipment. This subpart is necessary to comply with Minnesota Statutes, section 256B.04, subdivisions 12 and 15.

A. Medicare standards are based on cost containment efforts. Such measures are consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 2. However, because not all recipients are Medicare eligible and, thus, services to non-Medicare eligible recipients would not be reviewed against Medicare criteria, it is necessary to establish the criterion of medical necessity. 42 CFR 440.240 (d) authorizes the department to set service limits based on medical necessity. This item is consistent with the regulation. However, Medicare regulations are interpreted differently by different Medicare intermediaries. Furthermore, Medicare standards may not always reflect the prevailing standard of practice in a given community. Therefore, it is reasonable to pay for some items that are not covered by Medicare. The exceptions specified in this item are reasonable because these items do meet the general requirements to be a covered service under these proposed rules.

B. This item is reasonable because the cost of maintaining equipment owned by a long-term care facility is a component of the facility's per diem payment rate. Therefore a separate fee schedule would be duplicative.

C. This item is reasonable because it safeguards against purchases of duplicate equipment to serve the same medical necessity.

D. 42 CFR 440.230 (d) permits the agency to limit services based on the criterion of medical necessity. If Medicare has denied a claim as not medically necessary, applying that determination to the medical assistance program is reasonable because it prevents duplicate determinations and is cost effective and administratively efficient. Furthermore, the item is consistent with the cited federal regulation.

E. The item is reasonable because it ensures consistency with another rule which sets criteria for determining need and appropriateness.

F. Dental hygiene supplies include items such as toothbrushes, dentifrices, and water picks. A recipient is able to choose from among a

wide variety of these items according to the recipient's personsal preference. Recipients are expected to pay for these items from their own funds as it would not be cost effective or administratively possible to monitor the medical necessity of the items they choose. However, dental equipment that is medically necessary is provided as a dental service under part 9505.0270. The item is reasonable because it is consistent with the requirement of Minnesota Statutes, section 256B.04, subd.2, of administering the program in an efficient, economical, and impartial manner.

G. Shoes are an item that can withstand repeated use and thus are durable equipment. The definition of durable medical equipment in part 9505.0175, subpart 10, requires the item to be provided to correct or accommodate a physiological disorder or physical condition. The definition implies that an item such as shoes must be designed for the recipient's particular medical need and thus be for the recipient's exclusive use. Stock orthopedic shoes do not meet these criteria and are therefore not medically necessary. This exclusion is consistent with Medicare regulations.

9505.0315 MEDICAL TRANSPORTATION

Subpart 1. Definitions. This subpart is necessary to define terms which are used in this rule and to inform affected persons.
A. "Ancillary services" is a term used by the medical transportation industry to refer to services that are not medically necessary for all transported recipients. Thus, these services are supplied when and if a recipient needs them. Examples of such services include oxygen, injectable medications and the equipment necessary to administer them, and MAST trousers used to maintain blood flow to a person's extremities. Thus these services are not included in the base rate for life support transportation but are paid on a separate claim for service to a specific recipient. The definition is reasonable because it is consistent with the requirement of Minnesota Statutes, section 256B.04, subd.15 of safeguarding against excessive payment.
B. "Common carrier transportation" is a term used in these rules for reimbursement purposes. 42 CFR 431.53 states that the department must assure necessary transportation for recipients to and from providers. 42 CFR 440.170 permits payment of transportation expenses to obtain necessary medical care but requires the transportation to be furnished by a provider to whom a direct vendor payment can be made or, "if other arrangements are made to assure transportation," then federal financial participation is assured for administrative costs. Many recipients who do not require transportation designed for persons with health related conditions or provided by an enrolled vendor need transportation to the site of medical care. Such recipients commonly use the same types of transportation as the general public: private cars, buses, taxicabs, or commercial carriers that are not medical assistance providers. Reimbursement for the expense of this type of transportation is made by the local agency directly to the recipient as provided in part 9505.0140, subpart 1, item B based on receipts and claims submitted by the recipients. The local agency in turn bills the department for these costs. The definition is reasonable because it groups together forms of transportation commonly accepted as non-emergency transportation that are all reimbursed in a similar manner. It is consistent with Minnesota Statutes, sections 256B.02, subdivision 8 (15) and 256B.04, subdivision 12.
C. This definition is consistent with Minnesota Statutes, section 144.801, subdivision 4.
D. This definition is consistent with Minnesota Statutes, section 256B.02, subdivision 15 and 42 CFR 440.170.
E. The term "no load transportation" is commonly used by medical transportation providers to refer to movement of an empty ambulance. For medical assistance payment purposes, an ambulance that does not carry a recipient is consisdered to be empty. Minnesota Statutes, section 256B.02, subd. 8 limits medical assistance payments to services given to recipients. The definition is consistent with statute. See also subpart 5, item C and subpart 6, item E and the SNR for these items.
F. This item ,including the definition of "physical or mental impairment," is consistent with parts 8840.0100, subpart 10, which defines "physical and mental impairment" and part 8840.0300, which establishes eligibility criteria for a handicapped person's use of special transportation service through the Metro Mobility project established under Minnesota Statutes, section 174.31, subd. 1. Special transportation differs from life support transportation as its clientele do not require medically necessary services during transport and therefore specially trained personnel and

special equipment are not in the transporting vehicle.

Subp. 2. Payment limitations; general. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the types of services covered by medical assistance. This subpart is necessary to specify the limits applicable to medical transportation. The requirement that the transportation be to a place where the recipient receives a covered service is consistent with the criterion of medical necessity authorized in 42 CFR 440.230 (d). It is reasonable to provide for returning a recipient to his or her residence after receiving a covered service because the recipient's residence is where the recipient lives. See also Medicare and Medicaid Guide (Part B Coverage), Commerce Clearing House, Inc., 9-16-86, No. 3148, page 1141, Ambulance Service.

Subp. 3. Payment limitation; transportation between providers of covered services. This subpart is a related to the services covered under subpart 2. However, because the transportation is between two providers of covered services rather than between the provider and the recipient's residence, this subpart is necessary and reasonable to inform affected persons and avoid confusion about what is eligible for medical assistance payment.

A. This item is consistent with the provision in the Medicare and Medicaid Guide (Part B Coverage), ibid., page 1143. The level of care a recipient requires depends on the recipient's diagnosis and condition as detailed in the recipient's plan of care. Thus, transportation between two facilities to obtain care based on the recipient's plan of care is reasonable because it is consistent with the criterion of medical necessity authorized in 42 CFR 440.230 (d) and required by Minnesota Statutes, section 256B.04, subdivision 15.

B. This item is consistent with the criterion of medical necessity authorized in 42 CFR 440.230 (d) and required by Minnesota Statutes, section 256B.04, subdivision 15.

C. This item is reasonable because it provides an equitable standard for department use in monitoring claims for transportation. It is consistent with the criterion of medical necessity authorized in 42 CFR 440.230 (d) and required by Minnesota Statutes, section 256B.04, subdivision 15. It also is consistent with the Medicare and Medicaid Guide (Part B Coverage), ibid., Ambulance Service, page 1145.

Subp. 4. Payment limitation; transportation of deceased person. A recipient's medical assistance eligibility ends when the recipient dies. See 9505.0110, subpart 3, item A and part 9505.0125, subpart 2, item B (1). Furthermore, other modes of transporting a dead person are more appropriate than medical transportation. However, circumstances arise in which medical transportation is requested for or used by a recipient who dies either before the transportation arrives or during the transportation. This subpart is necessary to specify the circumstances which justify the medical assistance payment for medical transportation service to a dead recipient.

A. This item is consistent with the Medicare and Medicaid Guide (Part B Coverage), ibid., page 1144. A provider usually has no knowledge of or control over the recipient's status before arriving at the point of pickup. Thus, it would be unreasonable to deny payment to a provider who responds in good faith to a call to pickup a recipient whose transportation needs meet the requirements of this part. The item is

reasonable because it ensures that a provider who is called to transport a living person will be paid for carrying out his obligation of responding to the call. Limiting the payment to the point of pickup is reasonable because the provider is then under no further obligation concerning the service call and is free to respond to another request for service.
B. This item is consistent with Medicare and Medicaid Guide (Part B Coverage), ibid., page 1144. As in item A, the provider is responding to a request to provide a recipient a covered service. The provider is required by licensure to be trained in certain areas of emergency medical services and to carry certain kinds of equipment. However, maintaining the recipient alive may be beyond the provider's ability and the recipient may die before reaching the site of the medically necessary service. Therefore, the item is reasonable because it ensures that a provider who is giving an otherwise covered service in good faith of receiving payment will be paid for carrying out his service obligation.
C. This item is consistent with the criterion of medical necessity authorized in 42 CFR 440.230 (d) and required by Minnesota Statutes, section 256B.04, subdivision 15. It is reasonable because medical transportation of a dead person is not medically necessary.

Subp. 5. Excluded costs related to transportation; general. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on services covered by medical assistance, and Minnesota Statutes, section 256B.04, subdivision 15 requires the department to safeguard against unnecessary or inappropriate use of medical assistance services. This subpart is necessary to specify transportation services that do not meet the criterion of medical necessity.
A. The medical assistance program is designed to provide medically necessary services. It is not responsible for paying for transportation required to carry out an order of a court or law enforcement agency unless medical transportation services for the person are a medical necessity. The use of life support transportation is based on the determination that the transported person requires medically necessary services. Therefore, this item is consistent with the criterion of medical necessity authorized in 42 CFR 440.230 (d) and required by Minnesota Statutes, section 256B.04, subdivision 15.
B. This item is consistent with the criterion of medical necessity.
C. No load transportation is a "term of art" used by medical transportation providers to refer to ambulance travel with an empty ambulance. Thus, the vehicle has "no load." "The dispatch or return of an empty ambulance does not constitute the transportation of a recipient." (Red Lake Comprehensive Health Services v. Department of Public Welfare, Exhibit .) Such transportation is not consistent with the requirement of medical necessity. However, it is reasonable to permit payment for the circumstances specified in subpart 4 and also in item E below as medically necessary service is provided even though a recipient is not picked up. The item is consistent with 42 CFR 431.53.
D to F. The services in these items are not medical in nature. A provider who chooses to incur these costs must meet them from the payment made according to the schedule for medical transportation services. Therefore, the exclusions are reasonable because they are consistent with the criterion of medical necessity and they prevent duplicate payments.

Subp. 6. Payment limitations; life support transportation. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to set limits on the types and frequency of services that are eligible for medical assistance payments. This subpart is necessary to set limits on the payment eligibility of life support transportation.

A. Minnesota Statutes, section 256B.02, subd.8 (15) states that a recipient's transportation costs for obtaining medical care are eligible for payment when paid "directly to an ambulance company, common carrier, or other recognized providers of transportation services." Some recipients are unable to use common carriers and thus require specialized transportation that suits their need. One form of specialized transportation is life support transportation. Minnesota Statutes, sections 144.802 and 144.804 require entities providing life support transportation to be licensed by the commissioner of health. This item is consistent with the cited statutes.

B. This item is consistent with the statutory requirements. It is reasonable to require the provider to identify the types of service so that the department will know whether the provider has been determined able to provide the service for which payment is being claimed and thus the department will be able to monitor the appropriateness of the service and the requested payment.

C. Minnesota Statutes, section 144.807 requires the provider of life support transportation to report data about the service to the commissioner of health. Requiring the provider's report to document medical necessity is reasonable because the report can be used as an audit trail in establishing medical necessity, use of the same report is cost effective and does not impose an additional burden on the provider, and the assumption can be made that the report is reliable, as the provider's licensure depends on the accuracy of reporting.

D. This item addresses part of an issue raised by the Minnesota Ambulance Association in January 1985. The item is reasonable because it compensates a provider who is required by licensure to answer to a 911 emergency call. The item is consistent with federal regulation and state statutes that an immediate response to an emergency requiring life support transportation is medically necessary. Furthermore, it is consistent with the requirement that medical assistance funds may be used only to pay for services actually given to a recipient. See also item E.

E. This item addresses an issue raised by the Minnesota Ambulance Association and is a necessary companion to item D in order to compensate the transportation provider who responds to an emergency call in good faith and renders medically necessary ancillary treatment at the pickup point but does not transport the recipient. Because the provider has responded to an emergency situation and provided ancillary services to the recipient at the site of the recipient's emergency, it is reasonable to compensate the provider for the provider's cost of sending the staffed ambulance to the site and of providing the medically necessary ancillary service. The language was suggested by the Minnesota Ambulance Association.

Subp. 7. Payment limitation; special transportation. This subpart is necessary to set a uniform standard of eligibility for payment of special transportation services. The subpart is reasonable because it requires the special transportation provider to be certified by the Department of

Transportation as specified in Minnesota Statutes, section 256B.04, subdivision 12.

A. Requiring the recipient's eligibility for special transportation to be based on certification of need by the recipient's attending physician is necessary and reasonable because it is consistent with the requirement of Minnesota Statutes, section 256.B.04, subdivision 15 of safeguarding against unnecessary and inappropriate services and because the recipient's attending physician is licensed to make decisions about medically necessary services.

B. It is reasonable to require payment eligibility of special transportation to be based on the order of the recipient's attending physician because the physician is licensed to make decisions related to medical necessity and is familiar with the recipient's impairments and health status. It is also reasonable to require payment eligibility to be based on local agency approval of the service as the local agency is knowledgeable about community resources and can review the physician's order to determine how best to provide appropriate service.

C. This item is necessary to clarify what may be reimbursed as a separate claim. When limits on equipment allowances were developed for long-term care facilities under parts 9549.0010 to 9549.0080, the base included an allowable amount for equipment including vehicles used for transportation for the reporting year ending September 30, 1984. If the long-term care facility reported these costs at that time, they were included in the facility's rate determination. If the facility's costs for equipment exceeded the limit, the excess costs were disallowed. The facility is able to choose how to spend its equipment allowance in regard to transportation; it may spend it to own or to rent a vehicle. The item is reasonable because it prevents duplicate or excessive payments as required by Minnesota Statutes, section 256B.04, subd.15. It is consistent with parts 9549.0010 to 9549.0080.

D. This item is necessary to clarify how reimbursement of the cost of special transportation is made in the case of a resident of an intermediate care facility for the mentally retarded who participates in a training and rehabilitation program. The item is reasonable because it ensures that the facility will be paid for the transportation either through the per diem, under parts 99525.1200 to 9525.1230, or as a separate claim.

E. Minnesota Statutes, section 256B.04, subdivision 2 requires the department to carry out the program in an "efficient, economical, and impartial manner..." Minnesota Statutes, section 256B.04, subdivision 15 requires the department to safeguard against unnecessary and inappropriate services. It is consistent with these statutes to limit the distance that a recipient may be transported to receive a medically necessary service. Neither federal regulations nor the Medicare and Medicaid Guide (Part B Benefits) specify a mile limit. However, the Medicare and Medicaid Guide (Part B Benefits), ibid., page 1143 does limit coverage to "local transportation" and defines "locality" as the "service area surrounding the institution from which individuals normally come or are expected to come for hospital or skilled nursing facility services." In the metropolitan area, most services can be found within 20 miles of the recipient's residence. A greater distance outside the metropolitan area is consistent with the greater distances between population and service centers in greater Minnesota. The limits chosen are reasonable because

they are consistent with ensuring the recipient's ability to reach the site of a medically necessary service. Likewise, it is necessary and reasonable to apply the limit only to localities where service is available so that the recipient may be assured of eligibility for transportation to medically necessary services. In less populated areas of Minnesota, necessary health services may not be readily available in the locality. Furthermore, the emergency may require the recipient's transportation to a specialized center although a less specialized level of care is available in the locality. Thus it is reasonable to allow a greater mileage to ensure the recipient has access to medically necessary services.
It is necessary to clarify the term "seven county metropolitan area" to avoid misunderstanding. The definition is reasonable because it is the one in common use in Minnesota. See Minnesota Statutes, section 473.121, subd. 2. However, the definition in this item includes all portions of the specified counties.

Subp. 8. Payment limitation; common carrier. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to provide an opportunity for all recognized transportation providers of nonemergency transportation to be reimbursed at maximum rates established by the department. This subpart is necessary to specify the payment limitations required by statute. A business that presents a claim for payment usually includes with the claim sufficient information about the service so the payer can identify the service and its cost and thereby decide whether the claim is accurate. This item is reasonable because the required information is customarily given in billing for a service and assists the local agency to make a financially responsible decision about paying the claim. Furthermore, it is reasonable because the information will leave an audit trail the department can use in monitoring compliance with this part.

Subp. 9. Payment limitation ; air ambulance. Under some circumstances, a recipient may need health services that can not be reached quickly enough to reduce or remove the threat to the recipient's life if a form of surface transportation is used. For example, a badly burned recipient who lives outside of the metropolitan area may require the highly specialized services of the burn unit at St. Paul Ramsey Hospital or a person who lives in a wilderness or remote area of the state may suffer a heart attack and require immediate treatment in a hospital coronary unit. The recipient's transportation by air ambulance may be required to reach the site of the necessary health service. This item is necessary to specify the standard for payment eligibility of transportation by air ambulance. Limiting the use of this expensive form of transportation to life threatening situations is reasonable because it guards against excess payment as required under Minnesota Statutes, section 256B.04, subd. 15 while at the same time it protects the right of the recipient to receive treatment that is medically necessary as quickly as possible to respond to a life threatening condition.

9505.0320 NURSE-MIDWIFE SERVICES

Subpart 1. The terms in items A to C are used in this part. The definitions are necessary to clarify their meanings and set standards for eligibility for federal financial participation as required under Minnesota Statutes, section 256B.04, subdivision 4.

A. The definition of "maternity period" is consistent with the standard specified in 42 CFR 440.165 (c).

B. Part 9505.0175, subpart 42 defines the term "registered nurse." Item B is consistent with 42 CFR 440.165 (b).

C. This item is consistent with the standard specified in 42 CFR.440.165 (a).

Subp. 2. This subpart is necessary to specify the type and duration of covered service as required under Minnesota Statutes, section 256B.04, subdivision 12. Its provisions are consistent with 42 CFR 440.165 (a). Consistency with federal regulations is reasonable because it complies with Minnesota Statutes, section 256B.04, subdivision 4 in regard to qualifying for federal aid.

9505.0325 NUTRITIONAL PRODUCTS

Subpart 1. Definition. Some recipients are unable to receive nourishment from the usual food sources because of health conditions such as allergies and metabolic diseases. Their conditions require the use of special nutritive substances which this rule calls nutritional products. This definition is necessary to define a term used in this part. A commercially formulated source of nutrition is subject to review by the Food and Drug Administration of the United States. It is the responsibility of the FDA to determine the medical or remedial or nutritive value of commercially manufactured preparations. Limiting the definition to a commercially formulated one is reasonable because it ensures the FDA will have evaluated its safety and efficacy in treating health conditions leading to special nutritional needs.

Subp. 2. Eligible provider. A parenteral drug is not administered orally but may be administered subcutaneously, intramuscularly, intrasternally, intravenously, or by way of the intestines. It is a legend drug which under federal and state law can be dispensed only on the written order of a physician. (See Minnesota Statutes, section 151.01, subd.17.) Furthermore, the dispensing of a legend drug is subject to Minnesota Statutes, sections 151.36 and 151.37. Therefore, requiring the dispensing of parenteral drugs as a pharmacy service is consistent with statute and this rule to ensure full compliance with requirements for handling, selling, labelling, or distributing a legend drug. It is also reasonable to require parenteral drugs to be prescribed by a physician as these drugs fall within the definition of "drug" in Minnesota Statutes, section 151.01, subd. 5. See also part 9505.0340, subpart 1, item H and its SNR. An enteral nutritional product is administered orally and is not a legend drug. However, the customary source of an enteral nutritional product is a pharmacy or medical supplier. Many of these products can be purchased over the counter without a physician's prescription and, thus, may or may not be medically necessary for the recipient. Requiring an enteral nutritional product to be prescribed by a physician as a condition of eligibility for medical assistance payment is reasonable because the physician is able to evaluate the recipient's health status and determine what is medically necessary. The determination of medical necessity is consistent with the requirements of Minnesota Statutes, section 256B.04, subd. 15, and 42 CFR 440.230 (d). It is reasonable to require an enteral nutritional product to be obtained from a source that has a provider agreement with the department as the agreement sets the conditions for participation in the medical assistance program, enables the department to monitor the provider's compliance, and thus safeguards recipients against inappropriate treatments.

Subp. 3. Payment limitation; enteral nutritional products. This subpart is necessary to establish a limit on the service as required by Minnesota Statutes, section 256B.04, subd. 12. Some enteral products are readily available and can be bought across the counter without prescription. Thus, the purchase of these products may not be medically necessary but rather a convenience of the purchaser. Therefore, requiring prior authorization is necessary and reasonable because it enables the

department to determine whether the use of such a product is medically necessary. This determination is consistent with the 42 CFR 440.230 (d). See the SNR for subparts 4 and 5 for discussion of the exceptions to this payment limitation.

Subp. 4. Covered services; enteral nutritional products for designated health conditions. This subpart establishes the eligibility of enteral products which are medically necessary for persons with certain health-related conditions and are not used by other persons. Therefore requiring their prior authorization would be unreasonable. Furthermore, Minnesota Statutes, section 256B.02, subd.8 (11) specifies that nutritional products needed to treat the conditions in items A to D are not included in the drug formulary. The subpart is consistent with statute.

Subp. 5. Covered services; enteral nutritional product for recipient discharged from a hospital. This subpart is necessary to establish a limit as required by Minnesota Statutes, section 256B.04, subd. 12. The subpart is consistent with Minnesota Statutes, section 256B.02, subd. 8(11) which authorizes the commissioner to identify conditions requiring medically necessary nutritional products. A hospital and attending physician preparing an inpatient for discharge advise and assist the patient to obtain services that are medically necessary after discharge. The assistance includes furnishing the person being discharged the medications necessary for the discharge to be successful. It is reasonable, therefore, to make these medications eligible for medical assistance payment as the hospital staff has determined them to be medically necessary. A 30 day supply is a reasonable limitation as it is consistent with the requirements of part 9505.0340, subpart 3.

Subp. 6. Payment limitations; long-term care facilities and hospitals. This subpart is necessary to inform affected persons and providers about the eligibility of enteral products for medical assistance payment. The subpart is consistent with Minnesota Statutes, section 256B.02, subd. 8 (11) which states, "Separate payment shall not be made for nutritional products for residents of long-term care facilities; payment for dietary requirements is a component of the per diem rate paid to these facilities." Similarly, payment for dietary requirements during an inpatient admission is a component of hospital reimbursement rates and payment of a separate claim would be duplicative.

Subp. 7. Payment limitation; parenteral nutritional products. This subpart is necessary to establish a payment limitation as required by Minnesota Statutes, section 256B.04, subd.12. Because a parenteral nutritional product is a legend drug prescribed and dispensed as a pharmacy service under Minnesota Statutes, sections 151.36 and 151.37, it is reasonable to subject it to the same payment limitations as other drugs provided as pharmacy services.

9505.0330 OUTPATIENT HOSPITAL SERVICES

Subpart 1. Definition. Minnesota Statutes, section 256B.02, subdivision 8(4) authorizes medical assistance payment for outpatient hospital services to a recipient but does not define the term "outpatient hospital service." A definition is necessary to set a standard for this part. 42 CFR 440.20 (a) defines outpatient hospital services and requires them to be furnished by or under the direction of a physician or dentist (except in the case of nurse-midwife services) in a hospital licensed by the state. The definition is consistent with the requirement for federal financial participation.

Subp. 2. Eligibility for participation in medical assistance program. 42 CFR 440.20 (a)(3)(ii) requires an institution furnishing outpatient hospital services to meet the requirements for participation in Medicare. Part 9505.0300, subparts 2 and 4 state the requirement that a hospital's eligibility for MA payment depends on its qualification for participation in Medicare except that a hospital furnishing emergency health services to a recipient may receive MA payment regardless of its Medicare status. (See 42 CFR 405.1011 and 42 CFR 440.170(e).) This subpart is necessary to clarify the eligibility standard. It complies with the requirement for federal financial particpation.

Subp. 3. Payment limitations; general. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on services covered by medical assistance. This subpart is necessary to clarify the payment limitations applicable to outpatient hospital services. Several types of health services may be available as outpatient hospital services. They include physician, dental, vision care, and emergency services. Payment limitations under parts 9505.0170 to 9505.0475 apply to these health services when they are provided at a site other than an outpatient hospital facility. These limitations are based on the type and frequency of the service that is medically necessary. Minnesota Statutes, section 256B.02, subdivision 8(4) requires hospital outpatient departments to be subject to the same limitations and payments as other providers except for emergency services and services not available elsewhere. Applying the same limitations to outpatient hospital services is reasonable because it is consistent with statute and sets uniform standards based on medical necessity. Likewise, subjecting outpatient hospital services to prior authorization requirements applicable to similar health services furnished at a site other than an outpatient hospital facility is reasonable in order to insure a uniform standard.

Subp. 4. Payment limitation; emergency outpatient hospital service. This subpart is necessary to clarify the payment limitations applicable to emergency outpatient hospital services. 42 CFR 447.325 states that MA "may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances." Items A to C are reasonable because they insure the facility will receive its usual and customary charge for an emergency service and that MA payment will also be made for covered

services whose cost is not included in the usual and customary charge for the emergency service. The items are consistent with the federal regulation. A definition of "emergency outpatient hospital service" is necessary to clarify its meaning and set a standard for this subpart. The definition is consistent with 42 CFR 440.170 (e)(2) which specifies a hospital that is "equipped to furnish the (emergency hospital) services" and with 42 CFR 440.20 which specifies that outpatient hospital services must be furnished in a facility approved by the state.

Subp. 5. Payment limitation; laboratory and x-ray services. Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against excess payments. Admission to a hospital for other than emergency purposes must be scheduled in advance of the admission because medical assistance pays for hospital services only if the admission has been certifed by the medical review agent as medically necessary. (See parts 9505.0540 to 9505.0540.) This determination is based on the recipient's condition and diagnosis. Physician and other health services including laboratory and x-ray services necessary to diagnose the recipient's condition and assist the physician's decision that hospitalization is necessary are, thus, necessarily performed before admission is planned. These services are eligible for medical assistance payment. Additional laboratory and x-rays may be necessary because of the recipient's condition to further establish the recipient's diagnosis or the most appropriate treatment or to monitor the recipient's condition. These services are customarily provided after the patient's admission. Payment for such laboratory and x-ray services is included in the categorical payment rate for the hospital established for the recipient's diagnostic category under parts 9500.1090 to 9500.1150. Therefore, it is reasonable to exclude laboratory and x-ray services that occur in an outpatient setting immediately before a recipient's scheduled hospital admission because such services would duplicate those that are customarily provided after admission and the payment for these services is included within the hospital's categorical payment rate for the recipient's diagnostic category. The limitation is consistent with the statutory requirement of safeguarding aginst excess payment and unnecessary use of services as specified in Minnesota Statutes, section 256B.04, subd.15.

Subp. 6. Excluded services. This subpart is necessary to clarify which items are not eligible for medical assistance payment as outpatient hospital services. Exclusion of payment for diapers (Item A) furnished by the facility to the recipient is reasonable because diapers do not fall within the definition of outpatient hospital service given in 42 CFR 440.20 (a). Exclusion of payment of separate claim for the services of a hospital employee is reasonable because the salaries of such employees assigned to the hospital's outpatient facility are customarily included in the facility's calculation of its charge for usage of the emergency outpatient service. The exclusion in item C is reasonable because medical assistance payment is limited to medically necessary services in order to obtain federal financial particpation as required by Minnesota Statutes, section 256B.04, subdivision 4.

Subp. 7. Payment limitations; non-emergency outpatient hospital services. Minnesota Statutes, section 256B. 04, subd. 12,requires the department to place limits on the types of services coverecd by medical assistance. An

outpatient hospital area that is designated, equipped, and staffed for emergency services receives a facility usage payment based on the special equipment and staffing that it must have in order to respond to many different types of emergency. Non-emergency services do not require such staffing and equipment and can be appropriately provided in another setting. Therefore, it is reasonable that a facility usage charge for an emergency service area not be eligible for payment when outpatient hospital services of a non-emergency nature are provided in a designated emergency area as non-emergency services are not expected to require the special staffing and equipment but can be appropriately provided elsewhere. This subpart is consistent with Minnesota Statutes, section 256B.04, subd. 15, which requires the department to safeguard against excess payments.

9505.0335 PERSONAL CARE SERVICES

Introduction

Services provided by personal care attendants became eligible for medical assistance reimbursement beginning July 1, 1977. Under Minnesota Statutes, section 256B.02, subd.8 (17), personal care services can be provided by qualified individuals, other than relatives, according to a plan of care approved by a physician and supervised by a registered nurse. Since its inception, the program has grown beyond the original projections of both the number of persons needing personal care services and the scope of the services because of Minnesota's increased effort to assist recipients to live independently in the community as an alternative to residence in a long-term care facility. The result of this growth is the development of numerous issues such as the identification of persons for whom such services are an appropriate alternative care method, the number of hours of service, and the qualifications necessary to provide or to supervise such services.

The State currently limits the services in the State plan to bowel program, ileo change, urethral sheath change, bladder care, skin care, range of motion, home dialysis, sterilizing equipment, bathing, turning and positioning, administering medications, inserting prostheses, and heat lamp treatment.

From the program's inception through August 1978, specific reimbursements for specific procedures were allowed to a maximum of $500 per month per recipient. Effective September 1, 1978, the maximum monthy amount per recipient was increased to $800 and reimbursement was based on the number of hours worked and whether the attendant lived with the recipient rather than specific procedures performed by the attendant. As of July 1981, the maximum for PCA services per recipient was raised to $1000 per month and the hourly rate was increased to $5.00. The current rate of pay is $6.08 per hour.

The number of persons receiving PCA services has increased from 21 in March 1978 to approximately 530 in 1986. A majority of these persons reside in communities having a population over 10,000.

Under current State rules, the recipient must select, train, and enroll the PCA in the program. The recipient must also review the billing records the PCA submits to the department. Because a PCA is self-employed, any agreement concerning services is made directly between the recipient and the PCA.

In July 1985, the department entered into its first contract with a non-profit corporation for personal care services. The corporation provides personal care services to disabled adults in residential facilities. The contract allows a PCA to serve more than one individual and allows for maximization of services at the least Medicaid cost.

Subpart 1. Definitions. This subpart is necessary to define the terms used in the rule for purposes of clarity and understanding by clients, recipients, providers, and local agency personnel. Terms that are not common to everyday usage have been defined in context of this rule.

A. It is necessary to define when a person is capable of directing his or her own care in order to have a uniform standard. It is reasonable to base the definition on the degree of the person's functional impairment because the concept underlying the program is that the recipient has the acumen and desire to be responsible for himself or herself. However, a person may have both the skill and the desire to be responsible but be unable to communicate with other individuals. A recipient must be able to communicate his or her needs and directions to his or her personal care assistant in order to live independently. Although a recipient may not be able to orally communicate, the recipient may be able to express himself or herself through other means such as interpreters, Bliss Boards, and electronic devices. For example, see part

9505.0140, subp. 1 which requires a local agency to provide a recipient access to health services. Therefore, it is reasonable to relate this acumen and desire to the person's ability to communicate in a two-way process in which the person can express his or her needs and can also show an awareness of the environment including appropriate responses to the speech and actions of other individuals in that environment. It is necessary to clarify how the individual's functional impairment status shall be assessed in order to have a standard that can be equitably and consistently applied to recipients. It is reasonable to include these four areas as they are commonly accepted as the capabilities a person needs to be responsible for directing or carrying out measures to ensure his or her own safety, health, and welfare. Other programs support this notion. For example, the state of Ohio includes the requirement that recipients of the PCA program in the state of Ohio must be able to direct their own care. Likewise, Minnesota's Home and Community Based Waiver for Chronically Ill Children includes an assessment of the child's orientation in order to determine the plan of care for the child. This assessment is particularly important for brain impaired recipients, who currently have not had access to the program because of the concerns for their vulnerability. As the types of services are limited, it is reasonable to determine whether the recipient is able to control the aspects of his needs that are not provided under the PCA program.

B. The terms "independent living" and "live independently" are used in this part to define when PCA services should be offered. A definition is necessary to clarify its meaning and set a standard. Minnesota Medical Assistance Manual, Part 5, (HCFA-AT-79-33), 5-140-00, a guide from HCFA on Medicaid programs, authorizes the provision of personal care services in a recipient's home. The definition is reasonable because it is consistent with the established goal of the program of assisting individuals to reside in the community as an alternative to nursing home placement. The program is also established under Medicaid (Minnesota Medical Assistance Manual, Part 5, 5-140-00 C) as an alternative to funding inappropriate placements in nursing homes due to insufficient alternatives. It is reasonable to use this terminology as it is the language provided by the PCA Advisory Committee and accepted by the advocacy groups on the Committee. The special meaning of the term "residence" as used in this item is required by 42 CFR 440.70 (c).

C. "Personal care assistant" is a term used throughout this part. A definition is necessary to clarify its meaning. The language is similar to that proposed by recipient advocacy groups during the 1985 legislative session. The definition was also proposed by the PCA Advisory Committee. The definition is reasonable because standards related to training, experience, employment, and job responsibility are commonly used by business, industry, and government agencies in posting, and screening applicants for, jobs. The definition is consistent with 42 CFR 440.170(f) which defines personal care services in a recipient's home as provided by an individual who is qualified to provide the services. A federal review of Minnesota's PCA program in 1986 specifically recommended that the state establish standards for PCA requirements and training in areas such as personal care services. Minnesota Statutes, section 256B.02, subd. 8, item 17, also requires that personal care attendant services be provided by an individual who is qualified to provide the services. The definition is also consistent with Minnesota Statutes, section 268.04, subdivision 9 which states that "any agency providing or authorizing the hiring of homeworkers, personal care attendants, or other individuals performing similar services in the private home of an individual is the employing unit of the (attendant) whether the agency pays the employee directly or provides funds to the recipient to pay for the services."

Including a person who is under contract to a personal care provider within the definition allows a recipient to retain his or her independence through identifying or recruiting an individual qualified to provide his or her personal care services and yet at the same time the definition removes the state from liability issues, such as workers' compensation, by making the person a subcontractor of the personal care provider rather than an employee or contractor of the state. Minnesota Statutes, section 176.011 (15) requires a worker who renders in-home attendant care services to a physically handicapped person and who is paid directly for those services to be an employee of the state for purposes of workers' compensation. Thus, the definition is reasonable because it is consistent with the program's goal of supporting the recipient's ability to live independently while at the same time it protects the state from possible liability for workers' compensation claims and provides a financial incentive for the provider to ensure that assistants are properly trained and responsible.

D. "Personal care provider" is a term used in these rules. A definition is necessary to clarify its meaning. The concept of personal care providers is the department's response to the concerns of recipients and their advocates about hiring a PCA or finding a substitute. More than half of the present recipients have had their PCAs for four years or less. (Metropolitan Center for Independent Living Report: Living Independently). 49 percent of the recipients responding to a questionnaire of the Metropolitan Center for Independent Living indicated that they had problems with the care they were receiving. Their problems included scheduling the PCAs and the absence or illness of the PCA. 43% of the respondents indicated that their PCAs had been more than one hour late on at least one occasion. Respondents also reported that they had problems locating competent, trustworthy attendants who do quality work. Minnesota currently has two types of contracts with non-profit agencies that provide personal care services. The non-profit corporations are located in the metropolitan area and Rochester and provide services to disabled adults. The current contracts allow PCA services to be provided to more than one individual in an effort to maximize services at the least Medicaid cost. This definition is similar to language proposed in the Minnesota Senate during the 1986 legislative session. The agency concept was reviewed in a department study, Needs of the Adult Physically Disabled Population in Minnesota in Relationship to the Use of a Home and Community Based Waiver Option. The concept was also reviewed by the PCA Advisory Committee and the Task Force on the Needs of Individuals with Brain Impairment as an alternative to placement in nursing home facilities.

E. This definition is needed to define a term that is used in this rule. The definition was reviewed and accepted by the PCA Advisory Committee. This definition is consistent with federal and state requirements. Minnesota Medical Assistance Manual (5-140-00 pg. 1) states "services must be prescribed by a physician" and authorizes the provision of PCA services in a recipient's home. PCA services are health oriented tasks related to a recipient's health condition which enable a patient to be treated by her or his physician on an out-patient rather than in-patient or institutionalized basis. Minnesota Statutes, section 256B.02, subd. 8, item 17 mandates personal care services to be prescribed by a physician in accordance with a plan of treatment. Furthermore, 42 CRF 440.170 (f) states ' "personal care services in a recipient's home" means services by a physician in accordance with the recipient's plan of treatment.....'

F. "Plan of personal care services" is a term used in this subpart. A definition is necessary to distinguish it from the broader term, "plan of

care", which is defined in part 9505.0175, subpart 35. The definition is reasonable because it makes this plan specific to personal care services, informs affected persons, and, thus, reduces the possibility of confusion.
G. "Private personal care service" is a term used in this rule. A definition is necessary to clarify its meaning and to differentiate it from "shared personal care service", another term used in this rule. The definition is consistent with that found in Independent Living with Attendant Care: A Guide for the Person with a Disability. The definition is reasonable because it is familiar to affected persons, including recipients and local agencies, and because it does differentiate between the two types of service.
H. This definition is necessary to clarify a term used in this rule. The definition is consistent with 42 CFR 440.170 (f).
I. "Responsible party" is a term used in this part. A definition is necessary to clarify its meaning. The PCA Advisory Committee reviewed and accepted this definition. Eighteen years is the age at which a person usually begins to be held accountable for his or her actions and is treated as an adult under state law. Therefore, it is reasonable to limit a responsible person to someone who is at least 18 years of age because he or she is considered adult and can be held accountable. Requiring the responsible party to be someone other than the PCA is reasonable because the action required of the responsible party on behalf of the recipient may conflict with the interests of the PCA.
J. The term "shared personal care service" is a term used in this part. A definition is necessary to clarify its meaning. The definition is consistent with the department's current practice of providing personal care services to recipient's living in group housing at the least Medicaid cost. The definition is reasonable because the model is consistent with the one proposed by the Institute for Rehabilitation and Research in Independent Living with Attendant Care. Other states such as Michigan, Massachusetts, and Arkansas also include personal care services provided in group settings within their medical assistance programs. The concept is supported by the Task Force on the Needs of Individuals with Brain Impairments, by Courage Center, by the Rochester Independent Living Center, and by the MA Advisory Comittee on the PCA rule. Medical assistance funds to purchase personal care services are limited by legislative appropriation. Because the department supports the independent living of recipients who require continuous availability but only intermittent use of these services on a 24-hour basis, the department developed a plan for shared services. A minimum of four persons is necessary to place continuously available service on a cost effective basis within the legislative appropriation. If more than four persons were sharing a residence, the residential facility would have to be licensed under part 4665.0200 as a supervised living facility. Therefore, the definition is reasonable as it permits recipients to receive the care they need to live together in an independent manner and yet does not burden them with having to obtain a license for their residence or with having to live in a licensed facility.

Subp. 2. Covered services. This subpart is necessary to specify the general requirements a personal care service must meet to qualify for medical assistance payment. The requirements are consistent with Minnesota Statutes, section 256B.02, subdivision 8 (17) and with 42 CFR 440.170 (f)(2). See also part 9505.0295, subpart 3 and its SNR.
A. The inclusion of this item is necessary and reasonable to inform affected persons and, thereby, coordinate two rules.
B. This item is reasonable because it ensures that only persons who are capable of "independent living" will receive the service as a covered service. See the

definition of "independent living" in subpart 1, item B and the definition of "qualified recipient" in subpart 1, item H.
C. This item is reasonable because it is consistent with the purpose of the program to provide health services in the least restrictive environment appropriate to the recipient's diagnosis and condition.
D. A plan of personal care services details the specific services that are required by the recipient to live independently. All the affected persons require a common understanding of the recipient's service needs. It is reasonable to require such a plan as a condition of payment eligibility because the plan ensures coordination of the services, reduces the possibility of misunderstanding between the recipient, the personal care assistant, the supervising registered nurse, and the provider, and enables all affected persons, including the department, to monitor the provision of the services. It is reasonable to require the supervising registered nurse to develop the plan as she or he has the training and experience necessary to perform the function and will also be responsible for supervising the plan's implementation. Furthermore, requiring the plan to be developed in consultation with the recipient is consistent with the program's goal of providing the recipient an opportunity to control basic decisions about his or her own life to the fullest extent possible.

Subp. 3. Training requirements. Minnesota Statutes, section 256B.02, subdivision 8 (17) and 42 CFR 440.170 (f) require personal care services to be provided by an individual who is qualified to provide the services. Therefore, this subpart is necessary to establish when a personal care assistant is qualified. However, although neither the regulations nor the statute specifies the qualifications, HCFA recommended in its review of Minnesota's program that minimum training requirements should be established. This recommendation is also supported by the Metropolitan Center for Independent Living Report: Living Independently. The federal guidelines given in the Medical Assistance Manual, Part 5 (5-140-00) at present set a minimum requirement of completion of a course of 40 hours of training in basic personal care procedures such as grooming, bowel and bladder care, food, nutrition, diet planning, etc., methods of making patients comfortable, care of the aged, care of the confused, first aid and health-oriented record keeping. Minnesota currently has no training requirements. However, there are differences among the states that do have training requirements. New Jersey requires 60 hours of home health training. South Carolina and Virginia require the PCA to be able to read and write, be physically able to do the work, be capable of following a care plan, have a satisfactory work record, and have completed some training. Rhode Island requires skills in bowel and bladder management, proper nutrition, medical emergencies, skin care, medications, transfers, home safety, home making skills, bathing and equipment use. Massachusetts requires training by the consumer and four hours of training by the state. Virginia requires completion of 40 hours of training by the Department of Medical Assistance. Oklahoma requires completion of 20 hours of training which includes 12 hours of basic home nursing. Oregon requires completion of 60 hours of training by the Oregon State Board of Nursing. South Carolina requires 40 hours of training in various areas. Courage Center, a Minnesota organization which specializes in rehabilitation of physically disabled individuals, has a training manual that provides training on urinary system care, bowel care, positioning, transfers, the avoidance and care of pressure sores, range of motion, sexuality, adjustment to the disability, nursing care procedures, exercise, first aid, and disabilities. Although the training is not now being given, this manual does

provide a training model developed out of Courage Center's experience of serving a physically handicapped population of children and adults. Therefore, allowing persons a choice of how to qualify is reasonable because it reflects the diversity of present state requirements, provides flexibility for providers and recipients to meet their needs, and allows persons now serving as PCAs to receive credit for training or skills acquired previous to the adoption of this subpart. The minimum standards set out in items A to E reflect views expressed to the department by recipients, advocacy groups, potential providers, the medical community, and local agency staff.

Item B follows the requirement used by the Ramsey County Nursing Service in determining certification of home health aides. As many of the responsibilities of the PCA and Home Health Aide are the same and as the experience of Ramsey County has shown that persons fulfilling the requirement are capable of giving satisfactory health care to persons living at home, it is reasonable to specify this program as a training alternative.

Items A and C are programs that qualify individuals at a higher level of skill and knowledge than is necessary for personal care service. Thus, their inclusion as a training option is reasonable as the individual meeting the requirement will have at least the minimum necessary qualifications.

Item D is reasonable because it provides the option of using the programs developed through experience by agencies such as Courage Center and Accessible Space, Inc., which also is a Minnesota organization. These quality programs are specific to a clientele of disabled persons who constitute a large part of the population that is eligible for personal care services. Therefore, it is reasonable to accept these programs in lieu of requiring additional training.

Item E allows the provider to determine whether the assistant has the skills required to perform the personal care services. An example of such a provider is Accessible Space, Inc., which hires personal care assistants to assist recipients to live independently. The department has received much testimony from present users of personal care services who want the opportunity to select their personal care assistants themselves. This item would enable a recipient to do so but at the same time place the responsibility for determining whether the person meets minimum qualifications in the hands of the provider who must have a contract with the department. Thus, this item is reasonable because it balances the desire of the recipient to live independently against the department's responsibility to set minimum qualifications.

Furthermore, items A to E are reasonable as they meet the minimum standards for training required in the federal guidelines in the Medical Assistance Manual, Part 5, 5-140-00 which allows sources of PCA training to include community colleges, vocational technical programs, health-oriented organizations, clinics, hospitals, licensed health facilities, and special courses developed and/or conducted by a registered nurse or nurse practitioner for the specific purpose of training personal care attendants.

Subp. 4. Supervision of personal care services. 42 CFR 440.170 (f) and Minnesota Statutes, section 256B.02, subdivision 8 (17), require a personal care service to be supervised by a registered nurse. Therefore, this subpart is consistent with the federal regulations and state law. This subpart is necessary to establish the components of supervision, thereby setting a standard and informing affected persons of what is expected. The federal guidelines in the Medical Assistance Manual part 5 (5-140-00-p.9) lists some tasks and responsibilities that the supervising nurse should perform. They include providing the personal care assistance and the provider a listing of the services required by the recipient, making periodic visits to assess the

patient's health condition and the quality of personal care being given, reviewing the plan of care, reviewing the PCA's observations and notes, assessing the patient's health, and evaluating the interactions and relationship between the patient and assistant. Items A to G specify the responsibilities and tasks of the supervising registered nurse.

Item A is necessary to establish the registered nurse's role in determining if the PCA is capable of providing the required personal care services. It is reasonable to require direct observation or consultation with the qualified recipient to determine this capability because the supervising nurse has the professional knowledge and judgment to ascertain the capability of the PCA and further, to decide whether to obtain the information through first hand observation or to rely on the ability of the recipient to make a full and accurate report. Reliance on the report of the recipient is consistent with the intent of the PCA program to foster independent living to the extent of the recipient's ability.

Item B is necessary and reasonable to establish the responsibility and authority of the supervising nurse to ensure that the PCA is knowledgeable about the plan of personal care services before the PCA performs personal care services and, thus, ensure the recipient appropriate care. The department considered allowing a 72 hour delay in the instruction of the PCA about the plan of care, but concluded that allowing a PCA to perform a service without knowledge of the plan of personal care services might be detrimental to the recipient's health. Additionally, the department considers that requiring assurance of the PCA's knowledge about that plan of personal care services before care is given provides an opportunity for the supervising nurse to include the recipient in the instruction of the PCA.

Item C is necessary and reasonable to be sure that the PCA understands what is necessary to protect the health of the recipient. A recipient's health condition may change from time to time. Thus a procedure that is appropriate one day might not be the procedure of choice on another day. The recipient's health condition might improve and require less care or might worsen and require an immediate change in the plan of care. Thus it is necessary and reasonable to require the supervising nurse to ensure that the PCA knows how to observe and what must be reported immediately to assure that professional medical assistance is obtained as needed.

Item D is necessary to specify the frequency of evaluations by the supervising nurse. HCFA recommended in its review that a definite schedule be determined and followed. Although the federal guidelines follow a 60 day evaluation pattern, the Advisory Committee believed that the need for evaluation is greatest when a PCA is first placed with a recipient and that evaluation is less necessary once a pattern of care has been established and the caregiver is experienced. An immediate evaluation, although desirable, is not feasible in all cases. Therefore, a requirement of "within 14 days after the placement" is allowed, in recognition of the possible workload of the supervising registered nurse. The pattern specified in subitems (1) to (3) is reasonable because it reflects the need for different amounts of supervisory evaluation according to the on-the-job experience of the person being evaluated. The advisory committee recommended allowing the evaluation to be through direct observation or consultation with the recipient to assure recipient involvement to the fullest extent possible, without limiting the supervisory responsibility of the registered nurse. Requiring the supervising nurse to make a written record of the evaluation is consistent with the requirements of 42 CFR 440.170 (f). It is also reasonable to require the supervising nurse to record actions taken to correct deficiencies in the PCA's work because such a record provides a means

to determine whether the supervising nurse is carrying out her or his supervisory responsibilities.
Item E is necessary to establish the minimum frequency of reviewing the plan of care. Many recipients have an ongoing need for personal care services over a period of many months or even years. During this time a recipient's health condition may change or remain the same. A review schedule is reasonable because it provides a systematic means to review a recipient's condition and the efficacy of the services. This subitem is consistent with the recommendations of Comprehensive Services for Disabled Citizens, Inc., a PCA referral group for disabled individuals. Comprehensive Services believes that the supervising nurse, in cooperation with the recipient, should determine the level of care. The 120 day review requirement is consistent with the evaluation schedule specified in item D.
Item F is necessary and reasonable because it ensures the PCA is following the plan of care. It is consistent with the requirement of item B.
Item G.is necessary and reasonable because it provides both the department and the provider a means to monitor the work performed by the PCA whose work is observed on a daily basis only by the recipient receiving the services. The item is consistent with item D.
Item H is consistent with the intent of the program to encourage independent living to the fullest extent possible for the recipient. It is also consistent with that fact that certain recipients will need support care by a third party, the "responsible party", to enable the recipient to live in his or her own residence. Thus, the item is necessary and reasonable because it is consistent with the program established under Minnesota Statutes, section 256B.02 Subd. 8(17).
Item I. This item is necessary to specify who makes the decision that a recipient is a "qualified recipient." It is reasonable that the determination be made by the supervising nurse in consultation with the physician as these two persons are qualified by licensure to make medical judgments.

Subp. 5. Personal care provider; eligibility. This part is necessary to establish uniform criteria for determining who may be a provider of personal care services to recipients. The department considered two means of selecting entities to be personal care providers: by competitive bids or under contracts with the department. The department accepted the recommendation of the PCA Advisory Committee that the contractual method be used. The use of contracts is reasonable because it allows the department to review the contracts, choose between the contracts based on quality and types of services provided, as well as cost effectiveness, and is consistent with HCFA's recommendation that the state establish minimum standards for personal care service providers.
A. A provider must be able to enter into a legally binding contract as that is a criterion to be used to determine PCA providers. Therefore, it is reasonable to require the agency to illustrate the ability to enter into a legally binding contract prior to qualifying as a PCA provider.
B. A provider must fulfill the responsibilities of the contract once it is signed. Therefore, it is reasonable to require a provider to demonstrate the ability to do so because such demonstration will be consistent with the purpose of the contract of providing personal care services to a recipient.
C. A provider must be able to show that its proposal is cost effective. To require cost effectiveness is consistent Minnesota Statutes, section 256B.04, subdivision 3, and the goal of maximizing the use of avaiable program funds.
D. Compliance with part 9505.0210 is reasonable because such compliance ensures that the services meet the criteria for payment under the medical assistance

program.
E. The goal of the PCA program is to assist recipients to live independently in the community in the least restrictive setting. Meeting the goal requires persons assisting the recipients to know, be sensitive to,and have experience in meeting the needs to enable independent living. Therefore, this item is reasonable because it ensures the provider will have the knowledge and experience necessary to implement the contract.
F. As the PCA program is established to assist recipients to live independently in the community in the least restrictive environment, it is reasonable to require the provider to provide the services in a manner consistent with the recipient's ability to live independently. The recipients' health care needs and consequent abilities to live independently differ greatly. For example, the needs and abilities of a person who is brain impaired are different from the needs and abilities of one who is a quadraplegic; the needs and abilities of an assertive young adult are different from those of a frail, elderly Alzheimer patient. The provider must be flexible enough to recognize the needs and abilities of the various populations qualifying for the program. Therefore, it is reasonable to require the provider to provide service in a manner consistent with the recipient's ability to live independently.
G. This item is consistent with 42 CFR 440.260 which requires methods and standards used to assure that services are of high quality.
H. The medical assistance program uses a billing system that allows payment on a 30 day cycle. A provider who does not have a cash flow sufficient to cover operating expenses during this cycle might be in danger of financial difficulties and, thus, find it difficult or impossible to provide the services required in the contract. Therefore, it is reasonable to require the provider at contract time to demonstrate the financial ability to produce a 30 day cash flow because such ability will help ensure the provision of uninterrupted services to recipients.
I. This item is consistent with the requirements of 42 CFR 455.104 to 455.106.
J. A provider of personal care services will receive payment according to the provider's contract with the department. It is reasonable to require a provider to use an accounting system that can be reviewed to determine whether procedures required by these rules and the terms of the contract are being followed. Requiring the system to comply with generally accepted accounting principles is reasonable as adherence to such principles is a standard in current use by both business and government.
K. A system of personnel management describes the employment procedures and criteria used by an organization. Requiring such a system is reasonable as a means to ensure the provider complies with subparts 7 and 15. It is also a reasonable safeguard to protect personal care assistants against possible arbitrary and capricious actions of the provider and to ensure a recipient of continuity of personnel.
L. This item is necessary and reasonable because it ensures that the special qualifications required to supervise services to a ventilator-dependent recipient will be available if such services are a part of the contract.

Subp. 6. Personal care provider responsibilities. It is necessary to specify the personal care provider responsibilities for understanding by providers, recipients, local agencies, and the department.
A. This item states the responsibility of the provider for employing or contracting for staff to give and to supervise personal care services. It is reasonable to allow the options of employing or contracting staff to provide the PCA service because this choice allows those entities that are structured to provide services to independent, disabled adult populations to continue to

program.
E. The goal of the PCA program is to assist recipients to live independently in the community in the least restrictive setting. Meeting the goal requires persons assisting the recipients to know, be sensitive to,and have experience in meeting the needs to enable independent living. Therefore, this item is reasonable because it ensures the provider will have the knowledge and experience necessary to implement the contract.
F. As the PCA program is established to assist recipients to live independently in the community in the least restrictive environment, it is reasonable to require the provider to provide the services in a manner consistent with the recipient's ability to live independently. The recipients' health care needs and consequent abilities to live independently differ greatly. For example, the needs and abilities of a person who is brain impaired are different from the needs and abilities of one who is a quadraplegic; the needs and abilities of an assertive young adult are different from those of a frail, elderly Alzheimer patient. The provider must be flexible enough to recognize the needs and abilities of the various populations qualifying for the program. Therefore, it is reasonable to require the provider to provide service in a manner consistent with the recipient's ability to live independently.
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L. This item is necessary and reasonable because it ensures that the special qualifications required to supervise services to a ventilator-dependent recipient will be available if such services are a part of the contract.

Subp. 6. Personal care provider responsibilities. It is necessary to specify the personal care provider responsibilities for understanding by providers, recipients, local agencies, and the department.
A. This item states the responsibility of the provider for employing or contracting for staff to give and to supervise personal care services. It is reasonable to allow the options of employing or contracting staff to provide the PCA service because this choice allows those entities that are structured to provide services to independent, disabled adult populations to continue to

operate in the manner most familiar to the independent, disabled adult and the entity. This choice also requires the agency to retain responsibility for liability and workers' compensation of the contractors and to ensure benefits for the personal care assistants. The provision is similar to the PCA program of South Carolina which permits the PCA contractor to subcontract for registered nurses as supervisors, personal care assistants, and personnel to train these workers. The provision is also similar to the PCA program of Alabama in which the Home Health Agency is the employer. As training is a requirement for an individual to qualify as a personal care assistant, it is reasonable to require the provider to train services staff because the provider has the responsibility of ensuring that individuals have the skills necessary to carry out their job assignments, is able to review the evaluations of the personal care assistants' work, and thus determine the training needs.

B. The rule requires the personal care assistant to be supervised by a registered nurse. It is common personnel administration practice for the entity that employs or contracts with an individual to perform work also to supervise the worker. Thus it is reasonable to require the provider to supervise the personal care services staff. Furthermore, such supervision will enable the provider to carry out the responsibility of providing a quality assurance mechanism as specified in subpart 5, item G.

C. This item responds to the recommendation of the Metropolitan Center for Independent Living report that the PCA program be structured to ensure the greatest possible control by the recipient and yet address the concern for quality of care. The item is reasonable because it is consistent with the program's goals of supporting independent living and providing quality care. It is reasonable to require that the applicant chosen by the recipient be qualified and meet the conditions of subpart 7 because these requirements protect the safety of the recipient and ensure the applicant has the skills necessary to do the work. However, it is necessary and reasonable to exempt from this requirement those providers who must comply with a governmental personnel administration system because such a system sets specific qualifications for each job, has specific hiring procedures, and hires only those persons who have been determined qualified under these procedures. An example of such a system is a county civil service system which has defined hiring practices that cannot be superseded by requirements established in this rule.

D. Minnesota Statutes, section 256B.03 requires all payments for medical assistance to be made to the vendor. Therefore, it is necessary for the vendor to bill medical assistance for the services of the personal care assistant and the supervising registered nurse and, in turn, pay them according to their terms of employment or contracts. It is reasonable to include this item in the rule in order to inform affected persons.

E. Under subpart 5, the provider must ensure that personal care services are provided in a manner consistent with the recipient's ability to live independently and must provide a quality assurance mechanism. It is necessary, therefore, to have a procedure which will assist recipients to resolve their concerns about the personal care services of the provider. A grievance procedure is the customary means used to resolve disputes. Therefore, to safeguard quality of care and resolve recipient concerns, it is reasonable to require the provider to estabish a grievance mechanism to resolve recipient complaints.

F. 42 CFR 431.17 requires the state to maintain or to supervise the maintenance of records related to the provision of medical assistance. Minnesota Statutes, section 256B.27 requires providers to keep records documenting payment claims for medical assistance services to recipients. This item is consistent with the federal regulation and the state statute. Parts 9505.1750 to 9505.1880 are the rules which specify the required records. It is reasonable to include the citation in this rule to inform affected persons and encourage compliance.
G. This item is necessary and reasonable to inform providers affected by this rule of their service and function responsibilities and thus encourage compliance with these rules.
H. Minnesota Statutes, section 256B.04, subdivision 2 authorizes the commissioner to make, carry out and enforce rules in an "efficient, economical, and impartial manner" so that the medical assistance program is uniformly administered. This item is consistent with statute. It is reasonable to include it in the rule in order to inform affected persons and encourage their compliance.
I. Because a list may inadvertently fail to include all functions necessary to perform mandated responsibilities, it is reasonable to include this item as a safeguard and continuation of the previously listed items A to I.

Subp. 7. Personal care provider; employment prohibition. Personal care service involves direct contact between the personal care assistant and the recipient within the recipient's residence. Sometimes no other person is in the residence while the service is being given. Some recipients may be vulnerable adults or minors who are potential victims of physical or mental abuse. Thus the potential exists for the occurrence of abusive situations. In the past, the department has been made aware of and has had to address abusive situations involving recipients and personal care assistants. Therefore, this subpart is necessary to protect vulnerable adults and children from potentially abusive situations. It is reasonable because it prohibits the employment or contracting of persons who have been identified as abusive, (items B and C), or as not fully in control of their actions, (item D), or as not meeting all the requirements of subpart 12, (item A). Furthermore, it is reasonable to allow the state agency to have a means to prohibit employment of persons who are abusive or neglectful because such action is necessary to protect the safety of the vulnerable persons.

Subp. 8. Payment limitation; general. Minnesota Statutes, section 256B.02, subd. 8 (17) authorizes medical assistance payments for personal care services. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types of services covered by medical assistance. Minnesota Statutes, section 256B.04, subdivision 15, requires the department to safeguard against the unnecessary or inappropriate use of medical assistance services. Thus, this subpart is consistent with statute and is necessary to establish the required limits. The federal guidelines in the Medical Assistance Manual part 5, 5-140-00, page 2, suggest that personal care assistants perform such tasks as basic personal care and grooming including bathing, care of hair, and dressing; assisting with bladder and bowel requirements; assisting with medications which are ordinarily self-administered; assisting with food, nutrition, and diet activities, including meal preparation; performing such household tasks as are essential to the recipient's health and comfort in his residence; accompanying the recipient

to a clinic, physician's office, or other site for the purpose of obtaining medical diagnosis or treatment. The department at present pays for the services of the bowel program; bladder care; skin care; range of motion; home dialysis; equipment sterilization; respiratory assistance; transferring, turning and positioning; applying and maintaining prosthetic and orthotic devices; heat lamp treatments; and feeding but not meal preparation.

A. This service is required by persons who are quadraplegics. It is reasonable to specify it as a covered service because bowel and bladder care are necessary and assistance must be provided to ensure a person's ability to live independently. Other states that include bowel and bladder care in the program are Massachusetts, Oregon, Alabama, Colorado, and Kentucky.

B. Skin care is a presently covered service. New York pays for assistance with routine skin care including the application of nonprescription skin care products. Heat lamp treatments are a component of skin care.

C. "Range of motion" is a term of art applied by rehabilitation personnel to describe certain exercises and procedures that are necessary to maintain or improve a person's ability to move a part or parts of the body after the functionning of the part or parts has been impaired. These exercises are a presently covered service. Oregon and Colorado also include it in their programs.

D. Respiratory assistance other than ventilator operation and maintenance is a presently covered service. Home health aides at present assist many qualified recipients with ventilator operation and maintenance. The skill level of such aides may be less than that of a personal care assistant. Under these proposed rules, the services of both personal care assistants and home health aides will be supervised by a registered nurse and will be obtained through a home health agency. (See part 9505.0290, subpart 3, item B.) Thus, it will be possible for the same health professional, the registered nurse, to supervise the work of the person who furnsihes the respiratory assistance. It is reasonable to allow respiratory assistance include ventilator operation and maintenance as a personal care service to ensure that the home health services including personal care services are provided in a coordinated, efficient manner.

E, F, and G. These items are presently covered services.

H. This item is a presently covered service. The wording is consistent with the language in the HCFA manual cited above.

I. This item is a presently covered service.

J. The Medicare Intermediary Care Manual suggests the inclusion of sterilizing procedures. However, because sterilizing is impossible in most home settings, it is reasonable to include cleaning equipment as a covered service.

K. This item is a presently covered service.

L. New York includes meal preparation, shopping and marketing within its covered personal care services (Personal Care Services in New York State Report #1, New York Department of Social Services.) Kansas also allows meal preparation, feeding, and cleaning activities after meals. The intent of the wording of this item is to continue current Minnesota practice but the language has been revised to more accurately reflect the requirements of HCFA's Medicaid Manual. Other states including this service are Massachusetts, Virginia, Oregon, Alabama, South Carolina, Michigan, North Dakota, and Colorado.

M. This item is not in the current Minnesota PCA program. However, in practice Minnesota has allowed recipients to accompany recipients on vacations and to other places consistent with the recipient's ability to live independently. Missouri allows personal care service to assist recipients' traveling ; the only restriction is that the accompanying person must be needed for the recipient to be independent. Kansas and Idaho allow personal care assistants

to accompany the recipient to the site of therapy, school, shops, and a physician's office. This item is reasonable because it enables recipients to obtain medically necessary services and also lead as normal a daily life as possible. Two examples of activities that would be covered are attendance at church and at school.
N. This item is not in the current Minnesota PCA program. However, there are small tasks that become necessary because of the recipient's physical condition. Listing all these tasks would be difficult. An example is the need to change the recipient's linen after a bladder accident. Thus the item is reasonable because it facilitates payment for services that are necessary to maintain the recipient's healthy environment.

NOTE TO READER: The department wants to call attention to the fact that home dialysis is now reimbursable under Medicare. Therefore, it is no longer a covered service under medical assistance.

Subp. 9. Shared personal care services. This subpart is necessary to specify which shared personal care services are covered services. The services listed in items A to D are in addition to the private personal care services and are allowed under the contract to meet the additional needs of certain types of recipients. For example, recipients who are "brain-impaired" require more service than other recipients in order to remain in the community. Therefore, it is reasonable to include assistance with tasks related to the recipient's self-care because such assistance provides a cost effective alternative to nursing home placement. Items A and D are reasonable because they ensure all recipients the same standards for care, whether they receive personal care as a shared or individual service. Items B and C are reasonable because they address services for which brain-impaired persons have a special need. Thus, items A to D include the services that increase or maintain the physical, intellectual, and emotional functioning of the recipient.

Subp. 10. Excluded services. This subpart identifies those services that are not covered services in Minnesota's personal care service program. This subpart is necessary and reasonable to inform affected persons, including recipients, providers, personal care service staff, and local agencies and thereby to avoid misunderstanding.
A. This item is consistent with current practice. A provider agreement specifies the conditions a provider must meet to receive medical assistance payment. (See part 9505.0210, item D and its SNR.) Therefore, it is reasonable to exclude services provided by an entity that does not have an approved provider agreement for personal care services because the exclusion ensures consistency with part 9505.0210 and encourages compliance with the rule.
B. Under Minnesota Statutes, section 256B.04, subd. 15, the department must determine whether a service is health related and therefore necessary for the recipient's well being. HCFA's MA Manual, part 5, 5-140-00, page 2, states that household tasks are covered only if they are incidental to the patient's health care needs. The present guide for Minnesota's PCA program, issued March 1985, also states that homemaking services must be paid for through the county agency. Nonetheless, subpart 8, item N and subpart 9 do permit payment for certain homemaking services that are essential to the recipient's health care or the effective performance of the personal care assistant. Thus homemaking services that are not essential to the recipient's health care are not

reimbursable under medical assistance because they are not medically necessary. Thus the exclusion is reasonable because it is consistent with statute. Similarly, the exclusion of social services not related to health care is consistent with statute.
C. A plan of personal care services specifies the personal care services that are medically necessary. Personal care services included in a plan of care have been identified by an attending physician and/or the supervising nurse and the recipient as health related services that are medically necessary. Therefore, exclusion of services that are not in the plan of care is reasonable because these services have not been identified as medically necessary. This item is consistent with Minnesota Statutes, section 256B.04, subd. 15.
D. As stated in the SNR for subpart 4, a registered nurse must supervise the delivery of personal care services in order to ensure quality care. Therefore, this item is necessary and reasonable because it is consistent with the requirement of subpart 4, informs affected persons, and encourages compliance with the supervisory requirement.
E. Minnesota Statutes, section 256B.02, subd.8 (17) requires, as a condition of medical assistance payment, that personal care services be provided by an individual who is not a relative. 42 CFR 440.170 (f) also states that to be eligible for payment a personal care service must be provided by someone who is not a member of the recipient's family. Therefore, this item is consistent with statute and the federal regulation. However, because neither the statute nor the regulation defines relative or family, the definition in this item is necessary to clarify the term. The exclusion of the relatives listed in this item, spouse, parent, brother, sister, and child is consistent with Minnesota's current practice. It is reasonable because it excludes only individuals who either by statute or custom are considered to have some financial responsibility toward the recipient. (See Minnesota Statutes, section 256B.14.)
F. It is reasonable to exclude sterile procedures because personal care assistants are not expected to have the knowledge and skill necessary to perform these procedures. Such procedures are properly carried out by registered nurses or in a setting other than the recipient's home. HCFA's Medicaid Manual, 5-140-00, page 2, specifies the exclusion of sterile procedures such as the sterile irrigation of any body cavity.
G. Injecting fluids intravenously, intramuscularly, or subcutaneously is a procedure requiring the knowledge and skill of a registered nurse, a licensed practical nurse, or a therapist. HCFA's Medicaid Manual, 5-140-00, page 2 specifies these procedures as inappropriate duties of a personal care assistant. Therefore, the item is reasonable because it is consistent with current medical practice and federal guidelines.

Subp. 11. Maximum payment. This subpart establishes the maximum payment for personal care services and is, therefore, consistent with Minnesota Statutes, section 256B.04, subd. 12. The subpart is necessary to inform persons affected by the limit. Minnesota Statutes, section 256B.04, subd. 2 requires medical assistance to be carried out in an efficient and economical manner. (See also part 9505.0295, subpart 3 and its SNR.) This subpart is necessary and reasonable to ensure coordination of the rule parts affecting personal care services and, thereby, inform affected persons.

Subp. 12. Preemployment check of criminal history. The department's experience with the personal care services program includes circumstances where an individual previously convicted of abusive behavior while providing personal

care services obtains further employment as a personal care assistant. Such further employment as a personal care assistant may subject another recipient to abusive behavior. Therefore, this subpart is necessary to protect recipients from possible abuse. The subpart is reasonable as it limits the prohibition to persons who have been convicted. Furthermore, the subpart is necessary and reasonable because the disclosure requirement protects the hiring agency, the personal care provider, from having to hire anyone who fails to disclose and, thus, places the burden of disclosure on the applicant. The subpart is also reasonable because it supports the requirement placed on the provider in subpart 5 to assure quality of care.

Subp. 13. Overutilization of personal care services. Minnesota Statutes, section 256B.064, subd. 1a authorizes the commissioner to impose sanctions against a provider for providing services that are not medically necessary. This subpart is necessary to establish that personal care providers, who knowingly or unknowingl;y, abuse the medical assistance progam will be subject to the the provisions of the cited statute and, thereby, will not be allowed to participate in the medical assistance program. It is reasonable to require the determination of medical necessity to be made by a screening team because, under Minnesota Statutes, section 256B.091, subd. 3, these teams are responsible for assessing an individual's health and social needs and also for identifying the services necessary to maintain the individual in the least restrictive environment. Thus, the provision is consistent with statutes and also with the cited rules, parts 9505.1750 to 9505.2150. Requiring that the exclusion process (termination) be consistent with the contract between the provider and the department is reasonable because the provider accepted the terms and conditions of the contract as a condition of eligibility for payment as a medical assistance provider.

9505.0340 PHARMACY SERVICES.

Subpart 1. Definitions. This subpart is necessary to clarify the meanings of terms used in this rule and set a standard.
A. This definition is consistent with Minnesota Statutes, section 256B.02, subdivision 8(11). Its inclusion is necessary and reasonable to inform persons affected by the rule and, thus, to avoid misunderstanding.
B, E, F, G, H, and I. These items are consistent with definitions found in Minnesota Statutes, Chapter 151 and 42 CFR 440.120 (a). Item H is also consistent with Minnesota Statutes, sections 151.01, subdivision 23 and 152.12, subdivision 1 concerning the prescribing and administering of drugs by a licensed physician, a licensed osteopath, or a licensed podiatrist.
C. The term "dispensing fee" is used in Minnesota Statutes, section 256B.02, subdivision 8 (11) which specifies the basis for determining the payment for drugs as including "a fixed dispensing fee established by the commissioner." The definition is reasonable because it is based on the customary practice of the pharmacy industry and third party payers to allow a charge for the work involved in dispensing the drug. The definition is consistent with statute.
D. The term "maintenance drug" is a term in common use by the medical and pharmaceutical professions to describe a drug used to relieve other than an acute or temporary condition. The period of two months was recommended by the department's pharmacy consultants as the period after which continued use of a drug becomes an ongoing pattern with stable dose, usage and refill patterns. Therefore, the definition is reasonable because it is based on the standard recommended by professional peers.
J. See part 9505.0175, subpart 49 which defines the phrase "usual and customary" and its SNR. Grouping within the definition the different modes of purchase that are specific to pharmacy services is reasonable because these are related to the type and amount of purchase rather than the price or purchaser.
HCFA's Regional Administrator advised the department that the term"general public" used in 42 CFR 447.331 (a) is "defined as a patient group accounting for the largest number of non-Medicaid prescriptions from the individual pharmacy, but not including patients who purchase or receive their prescriptions through other third party payors. No distinction has been made nor authority given in 42 CFR 447.331 to establish separate categories of usual and customary charges for cash customers and charge customers." See Exhibit . The item is consistent with the federal regulation.
A large number of pharmacy providers in Minnesota's medical assistance program serve long-term care recipients only. Customarily, such a pharmacy provider serves all the residents in a particular long-term care facility and may serve more than one facility. These providers do not serve a walk-in clientele comprised of members of the general public. Thus, these providers do not have shelf prices that are affected by competitive pricing practices. Thisd non-competitive pricing practice may result in drug prices that are higher than the market price. Therefore,it is reasonable to include within the definition the special condition applicable to the determination of a usual and customary charge of a provider who does not serve the general public. Basing the markup on the actual acquisition cost incurred by such a provider is reasonable because it ensures the provider will make a profit. Furthermore, allowing a 50

percent markup is reasonable because it is an amount often used by the provider's peer group and yet implements the requirement under Minnesota Statutes, section 256B.04, subd. 15 of safeguarding against excess payments.
Finally, if 51 percent or more of the pharmacy's business comes from third party payers, including it in the calculation is reasonable because it alone is the majority of the business.

Subp. 2. Eligible providers. This subpart is necessary to set the standard for payment. Items A, B,and C are consistent with Minnesota Statutes, Chapters 151 and 152. They are necessary to clarify the standard and inform persons affected by the rule. Under Minnesota Statutes, section 151.37, a physician is permitted to dispense drugs. A rural area may have a licensed physician but not a pharmacist. Thus to ensure that recipients in a rural area have access to pharmacy services, it is reasonable to specify that physician dispensed drugs are eligible for medical assistance payment. It is also reasonable to require the physician to adhere to the labeling requirements of the Minnesota Board of Pharmacy as Minnesota Statutes, section 151.06 authorizes the Board of Pharmacy to set the labeling standards of all drugs and medicines. Physicians will then have to meet the same requirements as pharmacists. Furthermore, meeting the labeling requirements protects the recipients from possible misunderstandings about the contents and administration of the drugs.

Subp. 3. Payment limitations. Minnesota Statutes, section 256B.04,subdivision 12 requires the department to place limits on the types and frequency of service covered by medical assistance. This subpart is necessary to set the standards for these limits.
A. This item is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (11). Because pharmaceutical research develops new efficacious drugs or shows customarily used drugs to be ineffective or damaging, a method is needed to modify the drug formulary to be consistent with the research. Permitting a provider, recipient, or seller to apply to the department for the addition or deletion of a drug from the drug formulary is reasonable because these persons are the ones who would be affected by research findings.
B. A pharmacist who fills a prescription is entitled to receive a dispensing fee. This item ensures that the pharmacist will provide the recipient the amount prescribed by the physician as medically necessary and that the pharmacist will not attempt to obtain two dispensing fees by splitting the prescription. Thus the item is reasonable as it ensures the provision of what is medically necessary and safeguards against unnecessary payments in the form of extra dispensing fees. The dispensing fee paid under the Minnesota medical assistance program, $4.30, is the highest in the nation. An exception to the requirement of dispensing the specified on the label is reasonable in the case of a pharmacy using unit dose dispensing as such a method is permitted under part 6800.3750. A unit dose system is a method commonly used in hospitals and long term care facilities to control the administration of medication. A further exception to the requirement of dispensing the prescribed quantity is reasonable and necessary if the quantity is not available because the exception allows the recipient to receive some of the drug without the delay that might result from waiting until the pharmacist had the

prescribed quantity. Furthermore, the exception is reasonable because it relieves the recipient of the burden of locating and going to another pharmacy which has the prescribed quantity.

C. Minnesota Statutes, section 256B.04, subd, 15 requires the department to safeguard against unnecessary and inappropriate use of medical assistance services. Thus it is necessary to limit the dispensed quantity to an amount which is expected to be used. The quantity for a three month period is a reasonable limit because it balances economies obtained in dispensing a large quantity at one time and possible waste because the recipient's medication is changed during the three month period or the recipient dies. Furthermore, it prevents a recipient who anticipates loss of medical assistance eligibility from acquiring a large supply through medical assistance at taxpayer expense prior to going off medical assistance. It is reasonable to permit a dispensing of a larger supply by prior authorization as prior authorization permits the department to review the need for exceeding a three month supply.

D. By definition, a maintenance drug is expected to be used by the recipient for a period greater than two months. (See subpart 1, item C and its SNR.) Therefore, it is reasonable to require the dispensing of a maintenance drug in a 30 day supply as this amount balances the projected need of the recipient and the possibility that the recipient's need may change. However, allowing an exception if the pharmacy is using unit dose dispensing is consistent with part 6800.3750 and the customary practice of many hospitals and long-term care facilities of administering medications in unit doses Furthermore, prohibition of payment of an additional dispensing fee until the quantity is used is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 2 which requires the program to be administered in an efficient and economical manner.

E. A physician prescribing a maintenance drug anticipates the recipient will need the drug for more than two months. (See subpart 1, item C.) Because its continued use is anticipated, it is reasonable to limit the number of dispensing fees in order to safeguard against unnecessary payment as required by Minnesota Statutes, section 256B.04, subdivision 15. One dispensing fee per month is a reasonable number because it is consistent with professional pharmaceutical practice of filling such prescriptions with a 30 day supply.

F. This item specifies circumstances which make it necessary to limit the quantity of drug given to a recipient in order to protect the recipient's health, safety, and general welfare. Such a recipient may have to return to the pharmacy more than once a month to refill the same prescription. Thus, it is necessary and reasonable to permit payment of more than one dispensing fee per calendar month in order pay the pharmacist for a medically necessary service. It is reasonable to require records to be kept concerning the reasons because these records are evidence of the medical necessity for the limited quantity.

G. This item is consistent with Minnesota Statutes.

H. Minnesota Statutes, section 256B.04, subd.15 requires the department to safeguard against excess payments. Generically equivalent drugs have the same compositions as proprietary drugs and usually cost less. Therefore, this item is necessary and reasonable to contain costs and to set the parameters of the process. The United States Food and Drug Administration has the responsibility to determine whether drugs are safe and effective. Furthermore, medical assistance payment is not permitted for drugs found

by the FDA to be less than effective under the Omnibus Budget Reconciliation Act of 1981, as implemented by the Tax Equity and Fiscal Responsibility Act of 1982. (State Medicaid Manual, Part 4, Transmittal 18, May 1986.) Subitem (1) therefore is reasonable because it is consistent with law and protects the right of the recipient to receive a therapeutically effective drug. Subitem (2) relies on the judgment of the pharmacist's professional peer group. It is consistent with Minnesota tatutes, section 151.21, subdivision 2. Subitem (3) is a cost containment measure that is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 15. Subitem (3) is also consistent with Minnesota Statutes, section 256B.02 (11). Finally, subitem (3) is consistent with Minnesota Statutes, section 151.21, concerning notice to the purchaser if a generic drug is substituted and the prohibition from substituting a generic drug if the practitioner has specified "Dispense as Written." It is reasonable to require the notice to the recipient to be placed on the label as the label's contents are designed to inform the recipient about the drug and its proper use. Notice to the department by using an appropriate billing code is also necesssary and reasonable because it ensures that the department will have the information required to make the proper payment.

H. This item is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (11).

I. Delivering a drug is not eligible for a separate fee but rather is included in the administrative costs of the pharmacy. It is a cost containment measure. It is reasonable because the pharmacy can choose whether to deliver the drug, send it through the mail, or require the recipient or his representative to pick it up at the pharmacy. Thus, the pharmacy chooses what the pharmacy's cost will be.

Subp. 4. Payment limitations; unit dose dispensing. This subpart is necessary to establish payment limitations which apply to pharmacy services using a unit dose dispensing system. Establishing a unit dose dispensing system as a covered service is consistent with rules of the Minnesota Board of Pharmacy which regulate unit dose dispensing systems. See part 6800.3750. It is reasonable to permit incremental dispensing because it enables the pharmacist to make professional judgments about appropriate service to providers and recipients.

A. As stated for subpart 3, it is reasonable to limit the number of dispensing fees paid by medical assistance because the limitation enables the department to safeguard against unnecessary payments as required by Minnesota Statutes, section 256B.04, subd. 15. This provision is necessary because the frequency of dispensing under this system depends on the particular system being used. Some unit dose systems dispense less than a 30 day supply and therefore require multiple refills during a month. For example, a 7-day unit dose system would be refilled at least four times in a calendar month. The limitation of one dispensing fee a calendar month or after the usage of 30 dosage units is consistent with current community practice and the purchasing decisions of a prudent buyer. It is also reasonable to require a record of dispensing because the record provides an audit trail for the department's monitoring efforts as required by Minnesota Statutes, section 256B.04, subd. 15.

B. This item is necessary to provide notice of payment limitations applying specifically to maintenance drugs. The limitation is consistent

with current professional billing practices and with the limit in item A. It is consistent with Minnesota Statutes, section 256B.04, subd. 2 which requires the department to administer the medical assistance program in an efficient and impartial manner.
C. Requiring that the date of dispensing be reported as the date of service is reasonable because it sets a uniform standard which can be used as an audit trail . However, as shown in the example item A, increments smaller than a calendar month's supply may be dispensed several times during the month. Thus, there may be several dispensing dates in a month. An exception is necessary to provide a uniform ddispensing date for the purpose of payment of the dispensing fee. It is reasonable to require that the cumulative total for the calendar month or a total of 30 dispensed unit must be reported on the claim because these limits are consistent with administering the program in an efficient manner as required by Minnesota Statutes, section 256B.04, subd. 2 and with safeguarding against excess payments as required by Minnesota Statutes, section 256B.04, subd. 15. Furthermore, this limit is consistent with cost saving practices that would be anticipated by the prudent buyer.

Subp. 5. Return of drugs. This provision is necessary to set forth provisions governing the use of unit dose systems and the provisions governing the return of unused drugs. The Board of Pharmacy is the agency established by statute to regulate pharmacies and the dispensing of drugs. Therefore, it is reasonable to require that a unit dose system serving recipients meet the permeability and packaging standards of the Board of Pharmacy as adopted in its rules. Only drugs packaged according to part 6800.3750 may be returned. All other drugs no longer in use or needed by the recipient must be destroyed. If unused drugs can be safely returned and reused in compliance with the rules of the Board of Pharmacy, then it is reasonable to require a pharmacy to do so because the return prevents the waste of a usable product or prevents the pharmacy from possibly selling the same product to a second buyer. Thus, the requirement is consistent with administering the program in an economical manner as required by Minnesota Statutes, section 256B. 04, subd.2 and with safeguarding against unnecessary payments as required by Minnesota Statutes, section 256B.04, subd. 15.

Subp. 6. Billing procedure. This subpart is necessary to specify the information the department requires on the claim for payment for a drug. The required information is reasonable because it is necessary to permit the department to comply with 42 CFR 447.332. Specifying the date to be reported as the dispensing date is necessary to set a uniform standard. The use of the date on which the drug was actually dispensed is reasonable as it provides consistency with the pharmacy's record and thereby provides an accurate audit trail for departmental monitoring. The exception from the reporting date requirement is necessary and reasonable because it gives consideration to the circumstances unique to unit dose dispensing.

Subp. 7. Maximum payment for prescribed drugs. Minnesota Statutes, section 256B.02, subdivision 8 (11) permits medical assistance payment for

the costs of drugs provided to recipients. This subpart is necessary to specify the payment limits for drugs eligible for medical assistance payment so that the program can be carried out in an efficient, economical, and impartial manner as required under Minnesota Statutes, s ction 256B.04, subdivision 2. It is reasonable to specify the lowest payment among the available choices as this amount is consistent with the statutory requirement.
Items A, B, and C are consistent with 42 CFR 477 332.

9505.0345 PHYSICIAN SERVICES.

Subpart 1. Definitions. This subpart is necessary to clarify the meaning of terms that are used in this rule and to set a standard.
A. Minnesota Statutes, section 256B.02, subdivision 8 (4) requires a physician-directed clinic staff to "include at least two physicians, one of whom is on the premises whenever the clinic is open, and all services shall be provided under the direct supervision of the physician who is on the premises." The definition of physician-directed clinic is consistent with statute. Its inclusion is reasonable because it informs affected persons of the standard required to be eligible for medical assistance payment. The definition also is consistent with 42 CFR 440.50.
B. 42 CFR 440.50 (b) permits the provision of services provided under the supervision of a physician. Such a person may be an employee of the physician. It is reasonable to require such an employee to have the appropriate credential because the credential ensures the employee has the training and knowledge necessary to provide the health service with an element of independence. The two occupations included in this item are recognized by the physicians' peer group as having the credentials necessary to perform physician services under the supervision of a physician. (See the SNR for part 9505.0175, subpart 30, "Nurse practitioner" and subpart 34, "Physician assistant.") The item is consistent with 42 CFR 440.20 (b) and 42 CFR 491.8.
C. This definition is consistent with the requirements of 42 CFR 440.50 (b) and Minnesota Statutes, section 256.02, subdivision 7.

Subp. 2. Supervision of nonenrolled vendor. This subpart is necessary to clarify the standard to determine eligibility for payment applicable to physician services provided by a physician's employee. The subpart is consistent with 42 CFR 440.50 (b) which authorizes payment eligibility of physician's services provided "by or under the personal supervision of an individual licensed under State law to practice medicine..."
The term "on the premises" is defined in part 9505.0175, subpart 31; the term "supervision " is defined in part 9505.0175, subpart 46. (See the corresponding SNRs.)

Subp. 3. Physician service in long-term care facility. This subpart is necessary to set the standard for eligibility for medical assistance payment for a physician service in a long-term care facility. Minnesota Statutes, section 256B.04, subdivision 4 requires the department to cooperate in any reasonable manner as may be necessary to qualify for federal aid in the medical assistance program. Items A to C are requirements that a physician service in a long-term care facility must meet to qualify for federal financial participation. The items are consistent with 42 CFR 405.1123, 42 CFR 442.346, and 42 CFR 456.260. Their inclusion is reasonable because they inform affected persons of the standard required for the service to be eligible for medical assistance payment.
A definition of the phrase "under the direction of a physician who is a provider" is necessary to set a standard. Requiring the physician to be a provider is reasonable because it is consistent with Minnesota Statutes, section 256B.03. Requiring the physician to review and sign the record of service no more than five days after the service was performed is

reasonable because the timely review is consistent with the physician's responsibility for the plan of care required in 42 CFR 442.202 and 42 CFR 442.319. The five-day period balances the need to inform the responsible physician as soon as possible of the outcome of the treatment and the availability of the physician to carry out the review.

Subp. 4. Payment limitation on medically directed weight reduction program. Many persons are overweight but only a few of them have a condition for which weight reduction is a medical necessity. Examples of such conditions are diabetes and cardiac rehabilitation. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the types of services eligible for medical assistance payment. 42 CFR 440.230 (d) permits medical necessity to be a criterion for limiting a service. This subpart is necessary to specify the standard. It is consistent with the cited statute and federal regulation. That the program must be prescribed and administered by a physician is reasonable because a physician is the professional licensed to diagnose and treat health related conditions.

Subp. 5. Payment limitation on service to evaluate prescribed drugs. Antipsychotic and antidepressant drugs are commonly used by a recipient over a long period. Medical management is necessary to ensure that the dose is adjusted as necessary to alleviate the recipient's condition. Titration, which is the usual method of evaluating the drug's effectiveness and establishing the correct dosage, is a physician service. This subpart is necessary to set the limit for frequency of the covered service as required in Minnesota Statutes, section 256B.04, subdivision 12. The current practice of one service per week is reasonable because it allows time, if the dosage is adjusted, for the recipient's titer to stabilize at the new level.

Subp. 6. Payment limitation on podiatry service furnished by a physician. This subpart is necessary to set the limit on the frequency and type of service eligible for medical assistance payment as required under Minnesota Statutes, section 256B.04, subdivision 12. The limits set in part 9505.0350, subparts 2, 3, and 4 are based on the medical necessity of the service. Therefore specifying the same limits for similar services provided by a physician is reasonable because it treats providers equitably and is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 2 that the program be carried out in an impartial manner.

Subp. 7. Payment limitations on visits to long-term care facilities. Minnesota Statutes, section 256B.04, subd. 15, requires the department to safeguard against unnecessary use of medical assistance services. 42 CFR 442.346 (b) requires physician visits to a recipient in an ICF "whenever necessary but at least once every 60 days unless this frequency is unnecessary...." 42 CFR 405.1123 (b) requires physician visits to a recipient in a SNF at least once every 30 days but permits use of an alternate schedule of 60 days when the recipient is in a stable medical condition. This subpart is consistent with the federal regulations. Requiring documentation of the medical necessity of additional visits is reasonable because it provides a record that the department can review to determine the provider's compliance with the rule.

Subp. 8. Payment limitation on laboratory service. Part 9505.0305, subpart 4 sets the payment limitation for laboratory service. Minnesota Statutes, section 256B.04, subdivision 2 requires the department to carry out the medical assistance program in an impartial manner. Placing the same payment limitations on physician ordered laboratory services as specified in part 9505.0305, subpart 4 is reasonable because it ensures equitable treatment of providers of similar services.

Subp. 9. Payment limitation; more than one recipient on same day in same long-term facility. This subpart is similar to part 9505.0270, subpart 5, concerning dental services, part 9505.0350, subpart 5 concerning podiatry services, and part 9505.0405, subpart 3, concerning vision care services. See the SNR for these subparts. The subpart is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 2 concerning the carrying out of the program in an efficient, economical, and impartial manner. The subpart is necessary to inform affected providers of the payment limitation.

Subp. 10. Excluded physician services. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the frequency and types of services eligible for medical assistance payment. 42 CFR 440.230 (d) permits the limits to be based on the citerion of medical necessity. This subpart is necessary to specify services that are not eligible for medical assistance payment.

A. Artificial insemination is a health service that is used to achieve pregnancy in women who have difficulty conceiving. However, the bearing of children is not a medical necessity. Therefore, the exclusion is reasonable.

B. A procedure to reverse voluntary sterilization is carried out to enable impregnation. However, fathering children is not a medical necessity. Therefore, the exclusion is reasonable.

C. Surgery primarily for cosmetic purposes is not consistent with the criterion of medical necessity. Therefore, the exclusion is reasonable.

D. A surgical assistant is not eligible to be a provider or a vendor. See the definition in part 9505.0175, subpart 46. Payment for the services of a surgical assistant is part of the payment to the physician, dentist, or podiatrist who is the provider. Therefore exclusion of the services of a surgical assistant is reasonable because it is consistent with Minnesota Statutes, section 256B.02, subdivision 7 and section 256B.03, subdivision 1.

E. Statutes and federal regulations restrict medical assistance payment to those health services given to a recipient. A physician visiting a hospital who does not have face to face contact with the recipient does not provide services to the recipient. Thus the exclusion is reasonable because the physician has not provided a medically necessary service to the recipient. Medicare has a similar payment prohibition.

9505.0350 PODIATRY SERVICES.

Subpart 1. Definitions. The terms in items A and B are used in this part. Their definitions are necessary to clarify their meaning and set a standard.
A. The definition of "foot hygiene" was recommended by the podiatrist who served on the Provider Services Rule Advisory Committee. It is consistent with the definition of "hygiene" and "hygienic" in the American Heritage Dictionary of the English Language.
B. This definition is consistent with Minnesota Statutes, chapter 153.

Subp. 2. Payment for debridement or reduction of nails, corns, and calluses. This subpart is necessary to set a payment standard. Pathological toenails and infected or eczematized corns or calluses are pathological or diseased conditions. Appropriate treatment of these conditions is medically necessary. Thus their eligibility for medical assistance payment is consistent with 42 CFR 440.230 (d) and Minnesota Statutes, section 256B.04, subd. 15. Treatment at intervals of every 60 days is consistent with the current accepted professional practice

Subp. 3. Limitation on payment for debridement or reduction of nails, corns, and calluses. Medical necessity is a condition for payment of service under the medical assistance program. See 42 CFR. 440.230 (d) and Minnesota Statutes, section 256B.04, subd. 15. Although the service need itself may not result from a pathological condition, it may be medically necessary because another health related condition of the recipient interferes with the recipient's performing a routine task or requires a routine task to be carried out under special conditions. This subpart is necessary to set the standard for podiatry services that do not treat pathological conditions but are necessary as preventive services.
A. Appropriate foot care of a person suffering from one of the listed conditions is essential to minimize the occurrence of ulcerations, infection, abcesses, and serious complications that may result from these conditions. The item is reasonable as it is consistent with accepted professional practice.
B. Persons who are physically unable to care for their feet are at risk of ingrown toenails, infections, and other foot conditions which might adversely affect foot health. This item is reasonable because it allows the eligibility for payment of a medically necessary health related service to persons who are physically unable to carry it out.
C. This item is reasonable because it safegaurds against duplicative payments as required under Minnesota Statutes, section 256B.04, subd. 15.

Subp. 4. Limitation on payment for podiatry service provided to a resident of a long-term care facility. Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against unnecessary or inappropriate use of medical assistance services. 42 CFR 440.230 (d) permits the department to place limits on services based on medical necessity. This subpart is necessary to ensure that the podiatry service to the recipient is medically necessary and not just a routine service customarily performed by the recipient or nursing home staff. It is reasonable because it is the attending physician and nursing staff who are knowledgeable of medically necessary conditions and it is the recipient's family or guardian who is responsible for requesting care for a recipient

who is unable to do so.

Subp. 5. Payment limitation; more than one recipient on same day in same long-term care facility. This limitation in this subpart is similar to those in part 9505.0270, subpart 8 for dental services and part 9505.0405, subpart 3 for vision care services. This subpart is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 15 to safeguard against excess payments. The maximum amount for a procedure code includes an amount for administrative overhead, travel, and other nonrepetitive costs a podiatrist may incur in coming to a long-term care facility. The multiple visit code prorates the payment for administrative and nonrepetitive costs and permits billings to be made according to the number of visits in the same facility on the same day. Therefore, the subpart is reasonable because it safeguards against excess payment and reimburses the provider on a pro rata basis according to the number of recipients visited in the same facility on the same day.

Subp. 6. Excluded services. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types of services covered by medical assistance. 42 CFR 440.230 (d) permits the department to set limits based on criteria such as medical necessity or utilization control procedures. This subpart is necessary to specify which services are not eligible for medical assistance payment. It is consistent with statute and federal regulation.

A. A pair of orthopedic shoes is not medically necessary unless it has been built to the specifications required for the continuous and exclusive use of an individual recipient. Stock orthopedic shoes have not been built to an individual's specific requirement but are made according to general specifications which may or may not meet the medical needs of the purchaser. Therefore, excluding stock orthopedic shoes from eligibility for medical assistance payment is reasonable because the shoes do not meet the criterion of medical necessity.

B, C, and D. Payments for these items, a surgical assistant, local anesthetics, and use of an operating room, are components of the reimbursement to a podiatrist performing a surgical procedure. Therefore, their exclusion is reasonable because it prevents duplicate payment for the same service.

E. Foot hygiene in the same manner as other personal hygiene practices is the responsibility of the recipient unless the recipient is physically or mentally unable to carry it out. If the recipient is incapable, then foot hygiene is the responsibility of the nursing staff of the long-term care facility. The nursing services of facility personnel are reimbursed as a component of the facility's per diem payment rate. Therefore, their exclusion from separate payment is reasonable as it prevents duplicate payments for the same service.

F. Whether to use skin cream depends on the recipient's personal preference. It is not a medically necessary item. Therefore, its exclusion from payment is reasonable.

G. Medicare has determined that certain services are not medically necessary and denies payment for them. These services are listed in the Medicare Guide put in the correct citation. These services have been determined to be not medically necessary. Furthermore, certain other

services are not covered under Medicare because HCFA or the Medicare intermediary has determined that the service is not appropriate for a condition, is obsolete, is not cost effective, or is still investigative and experimental. These decisions of Medicare are based on the prevailing standard of practice of the group of providers furnishing the service. Therefore, their exclusion from payment is reasonable.

H. As stated in the SNR for subparts 2 and 4, this procedure is the recipient's responsibility unless the recipient has an overlying medical condition that prevents proper foot care or requires special foot care. The exclusion applies to a service that would be a convenience and not a medical necessity. Therefore, the exclusion from payment is reasonable because the rule does allow payment for the service when it is medically necessary.

I. The duties specified in this item are clearly the duties of nursing staff and do not require the skill and training of a licensed podiatrist. Payment for nursing services in a long-term care facility is a component of the per diem payment rate. Therefore, their exclusion from separate payment is reasonable.

9505.0353 PRENATAL CARE SERVICES

This part addresses the need of certain pregnant women for services that are not available to the entire population of pregnant women who are medical assistance recipients. Public Law 99-272, Section 9501 (b) permits states to offer services to pregnant women without regard to whether these services are availble to the entire population of pregnant medical assistance recipients in the same amount, duration, and scope. Improved prenatal care is accepted by the medical profession as an important factor in achieving positive pregnancy outcomes and reducing both short-term (during the infant's first year after birth) and longer term expenditures for services to treat significant handicaps which prevent normal functionning. The Minnesota Coalition on Health pointed out in its report Investing in Healthy Babies: Preventing Immaturity and Low Birthweight (Minneapolis, March 1986, page 42) that approximately 13 percent of women whose prenatal care is provided through state funded programs is at risk of delivering preterm or low birth weight infants because of the same factors which contributed to their eligibility for the state funded programs. The study of the Institute of Medicine (Preventing Low Birthweight, Summary page 9, National Academy Press, Washington, D. C., 1985) indicated that the effect of socioeconomic status may represent a proxy for a number of other factors which increase the risk of poor pregnancy outcomes. The result is that pregnant women who are eligible for medical assistance are at higher risk of delivering low birth weight infants than the general population. In fiscal year 1986, more than 1,300 infants whose deliveries were paid by medical assistance were diagnosed as having low birth weights. Therefore, this part is necessary and reasonable because it specifies the additional services needed by women who are at risk and eligible for medical assistance so that the probability of their having positive pregnancy outcomes will be increased.

Subpart 1. Definitions. This subpart is necessary to define words and phrases used in this part.

A. "At risk" is an abbreviation used in this part to identify a woman whose pregnancy has a high probability of ending in a preterm delivery or in the delivery of a child with a low birth weight. It is reasonable to use an abbreviation because the abbreviation will shorten the rule and is used by health care professionals who care for pregnant women. Although the terms "at risk of poor pregnancy outcome" and "at high risk of poor pregnancy outcome" are not used in this part, they are used by the general public and the providers' peer group in referring to a pregnant woman whose is at risk. Therefore, it is reasonable to include them within the definition because including them clarifies their meaning and, thus, reduces the possibility of confusing affected persons.

B. The term "prenatal care menangement" is used in this part to refer to certain additional services whch may be provided to a pregnant woman determined to be at risk. A definition is necessary to set a standard. It is reasonable that these services be in a plan of care because a plan reduces confusion and fosters the provision of services in an orderly manner. It also is reasonable to require the plan to be developed, coordinated, and evaluated by a physician or registerd nurse because these persons are licensed under Minnesota Statutes to provide such services within their scope of practice and are professionally knowledgeable about the need of at risk women. The definition was developed by a group of

medical and public health professionals who were part of the department's Prenatal Care Initiatives Task Force. The Task Force also expressed the belief that prenatal care management must be on a one-to-one basis because such a relationship between the woman and the health professional will encourage the woman to schedule and attend appointments, understand and accept needed services, and participate knowledgeably in planning for these services.

C. "Prenatal care services" is a general term that encompasses all services associated with the care of a pregnant woman, whether or not the woman is at risk. It is reasonable to include within the definition the services necessary for any pregnancy as well as those specific services identified in this part as necessary for the woman who is at risk in order to ensure that all these services will be provided to an at risk woman as covered services. Including within the definition services not generally available to the population of pregnant women who are medical assistance recipients is authorized in Public Law 99-272, section 9501 (b). Thus, the definition is consistent with federal law.

D. Nutrition counseling is one prenatal care service provided to improve the health status of the at risk pregnant woman and therby increase the probability of a positive pregnancy outcome. The definition was approved by a subcommittee of the department's Prenatal Care Initiatives Task Force. Requiring the counseling to be provided by a person with specialized training in prenatal nutrition education is reasonable because the training will ensure the person has knowledge about the normal and special needs of pregnant women.

E. "Prenatal education" is a term used in this part. The definition was developed by a subcommitte of the department's Prenatal Care Initiatives Task Force. Requiring the counseling to be provided by a person with specialized training related to pregnancy, delivery, and parenting is reasonable because the training will ensure the person has knowledge about measures related to increasing the probability of a positive outcome of the recipient's pregnancy.

F. "Risk assessment" is a term used as an abbreviation for the process and factors that must be considered in determining whether a pregnant woman is at risk. The factors included in this definition were recommended by the department's Prenatal Care Initiatives Task Force, by the Minnesota Deprtment of Health in its publication Health Plan for the Mothers and Children of Minnesota (1985, page 36) and by the Minnesota Coalition on Health in its report cited above (page 41.) The definition is reasonable because it is consistent with standards accepted by health care professionals who are knowledgeable about health services to pregnant women who are at risk.

Subp. 2. Risk assessment. Minnesota Statutes, section 256B.04, subd.2 requires the department to administer the medical assistance program in a uniform manner. This subpart is necessary to set a payment eligibility standard that must be met by a provider of prenatal care services. Prenatal care services provided under this part are limited to pregnant medical assistance recipients who are at risk. An assessment of the pregnant woman's condition is necessary and reasonable because such an assessment identifies whether a pregnant woman is at risk and which services, if any, are necessary to reduce the risk. Therefore, requiring the risk assessment to be completed at the recipient's first prenatal visit is reasonable because the assessment is the means of identifying at

risk status and the services required to reduce the risk for the particular pregnant woman. (See also subpart 3 for the additional services.) Requiring the provider to use a form supplied by the department is reasonable because it will ensure a uniform method of assessment. This is consistent with the requirement of Minnesota Statutes, section 256B.04, subd. 2. Furthermore, requiring a provider to submit the form to the department is reasonable because it enables the department to monitor whether the assessment is done in a timely manner. It also is reasonable because the department will be able to obtain consistent data about the prevalence of specific risk factors among the medical assistance population and, thus, will be able to evaluate the effectiveness of the prenatal care services in reducing preterm deliveries and the incidence of low birth weights.

Subp. 3. Additional service for at risk recipients. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types, frequency, and scope of services covered by medical assistance. This subpart is consistent with the statute and is necessary to identify the limits. Requiring prior authorization of these services is reasonable because it protects the right of the recipient to receive a medically necessary service while at the same time enabling the department to carry out its statutory obligation under Minnesota Statutes, section 256B.04, subd. 15 of safeguarding against unnecessary or inappropriate services.
A. Identifying the components of prenatal care management is necessary to set a uniform standard as required under Minnesota Statutes, section 256B.04, subd. 2. An individual plan of care is reasonable because it provides a complete plan that will address the specific needs of a particular individual in an organized manner and, thus, the plan enables close monitoring of the individual's at risk status. For a discussion of the services listed in subitems (1) to (4), see: Gregory, Maridee, M. D., Project Director, Final Evaluation of the Obstetrical Access Pilot Project, Department of Health and Human Services, Health Care Financing Administration, December, 1984; Heins, Henry C., Jr., M. D., et al., "Benefits of a Statewide High-Risk Perinatal Program", Obstet.-Gynecol., Vol. 62:3, Sept. 1983: 294-296. Finally it is reasonable to require that the services be provided in the most economical, efficient, and effective manner as the resources of the medical assistance program are finite and this requirement is consistent with Minnesota Statutes, section 256B.04, subdivisions 2 and 15.
B. Identifying the components of nutrition counseling is necessary to set a uniform standard as required by Minnesota Statutes, section 256B.04, subd. 2. It is reasonable to assess the recipient's knowledge of nutritional needs in pregnancy because the assessment will identify the areas, if any, where her knowledge is deficient and, thus, will facilitate efficient and effective instruction to remedy the deficiency. (See subitems 1 and 3.) A recipient may know what the nutritional needs of pregnancy are but may still have an insufficient diet that places her at risk. Thus, subitem 2 is reasonable because dietary insufficiency is a component of at risk status. It is reasonable to include referral to community resources in subitem (4) as the financial resources of a pregnant woman receiving medical assistance may be inadequate to purchase

items identified in her individual plan as necessary to meet her special needs during pregnancy.

C. It is necessary to identify the components of prenatal education to set a uniform standard as required by Minnesota Statutes, section 256B.04, subd.2. All components of subitems (1) to (3) were recommended by the department's Prenatal Care Initiatives Task Force which is comprised o persons knowledgeable of research findings and accepted community standards of practice in the area of prenatal education and care. Management of at risk pregnancies requires not only high quality medical care but also recognition of the signs of premature labor and lifestyles that are conducive to positive pregnancy outcomes. A pregnant woman needs this information in order to increase her possibility of delivering a full-term child having a birth weight within the normal range. Therefore, it is reasonable to require prenatal education to include instruction and information in these areas because such instruction iincreases the possibility of a positive pregnancy outcome.

9505.0355 PREVENTIVE HEALTH SERVICES

Subpart 1. Definition. The term "preventive health service" is used in this part to describe a covered service. A definition is necessary to clarify its meaning and set a standard. 42 CFR 440.130 (c) defines a preventive service as one "provided by a physician or other licensed practitioner... to (p)revent disease, disability, and other health conditions or their progression; (p)rolong life; and (p)romote physical and mental health and efficiency." The definition is consistent with the federal regulation and is reasonable because it meets the requirement of Minnesota Statutes, section 256B.04, subdivision 4 to cooperate with federal authorities as necessary to obtain federal aid. The examples in this definition do not comprise an all inclusive list of eligible preventive health services.

Subp. 2. Covered preventive health service. Minnesota Statutes, section 256B.02, subdivision 8(12) as well as the federal regulation cited in the SNR of subpart 1 authorize payment of preventive services. This subpart is necessary to specify the requirements a preventive health service must meet to be eligible for medical assistance payment.

A. 42 CFR 440 which sets the general provisions related to covered services specifies the provision of services to individuals who are receiving needed professional medical or remedial services directed by licensed practitioners of the healing arts. Requiring the service to be given to the recipient in person is reasonable because it is the accepted professional standard of practice and is consistent with the federal regulations.

B. 42 CFR 440.2 specifies professional services directed "toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain." Such services affect the recipient's health condition. The item is reasonable because it meets the standard required to qualify for federal aid and because it complies with Minnesota Statutes, section 256B.04, subdivision 15 which requires the department to safeguard against unnecessary or inappropriate use of medical assistance services.

C. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to "encourage providers to coordinate their operation with similar services that are operating in the same community" and to "encourage eligible individuals to utilize less expensive providers capable of serving their needs." Such action is a cost containment measure that enables the conservation of medical assistance program funds. A service otherwise available to a recipient without cost as part of another program is a less expensive service. The item is reasonable because it contains costs and conserves medical assistance funds.

D. This item is reasonable because it ensures medical assistance payment will not be paid more than once for the same or part of the same service.

E. Payment for service under the MA program is based on the assumption that the service is medically necessary for the well being of the recipient. Thus requiring the treatment to have an expected positive affect on the recipient's well being is reasonable because only such a treatment is medically necessary.

F. Minnesota Statutes, section 256B.04, subdivision 15 requires the department to determine whether health services are necessary and reasonable in consultation with a professional services advisory group. The advisory group is comprised of the peers of the health service providers. (See part 9505.0185 and the corresponding SNR.) A health service is reasonable if the provider's professional peer group accepts it as a safe and effective means to avoid or treat the illness. Item F is reasonable because it is consistent with the accepted standard of professional practice.

G. The requirement under this item is the same as for all other services. The physician is the person licensed to diagnose, treat, and prescribe for a patient's health condition. In carrying out these responsibilities, the physician exercises his professional judgment about the services that are medically necessary for the patient. Therefore, requiring the service to be on a written order of the physician and part of the plan of care is reasonable because it documents the physician's judgment of what is medically necessary and because the written record reduces the possibility of error and misunderstanding about the service the physician prescribes.

Subp. 3. Payment limitation. This subpart is necessary to clarify that a preventive service must directly affect the recipient's physical or mental health, even though it may serve other purposes, in order to be eligible for medical assistance payment. The service must be medically necessary. Items A and B are reasonable because they exclude from medical assistance payment services which are not health related and therefore are not medically necessary.

9505.0360 PRIVATE DUTY NURSING SERVICES.

Subpart 1. Definition. "Private duty nursing service" is a term used in this rule. A definition is necessary to clarify its meaning and set a standard. The definition is consistent with 42 CFR 440.80.

Subp. 2. Prior authorization requirement. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to set limits on the types and frequency of covered services. The limit of 50 hours per month provides service on an intermittent basis during a month. For example, it would provide private duty nursing service throughout a month at the rate of three hours per day, four days per week. The number of hours is large enough to avoid burdening the provider with paperwork. If additional service is medically necessary, a different and more suitable type of service may be required or a more economical service not requiring the skills of a registered nurse or licensed practical nurse may be a feasible supplement of the 50 hour limit of private duty nursing service. An example of a different and more suitable service might be residence in a long-term care facility rather than continued residence in the recipient's own home. Examples of less costly alternatives include home health aides and personal care assistants who provide services in the recipient's own home. Requiring prior authorization for an amount in excess of 50 hours per month is reasonable because the department can review the reason for the request and determine what is the appropriate and necessary treatment at the least cost to the program. A long-term care facility and a hospital provide nursing care to recipient. The amount of nursing care and whether the care is given by a registerd nurse or by a licensed practical nurse depends on the recipient's condition and needs. Customarily a registered nurse and a licensed nurse care for several patients at a time. Thus, a private duty nurse who only cares for one recipient is necessary only under unusual circumstances. Requiring prior authoirzation of private duty nursing service in a hospital or long-term care facility is reasonable because it enables the department to determine whether such intensive care is medically necessary. The subpart is consistent with Minnesota Statutes, section 256B.04, subdivision 15.

Subp. 3. Covered service. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to limit the types and frequency of services covered by the medical assistance program. This subpart is necessary to specify the required limits.
A. This item is consistent with 42 CFR 440.80 which defines private duty nursing services as nursing services for recipients "who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility ...."
B. A registered nurse or licensed practical nurse is not routinely employed by a medical transportation service to accompany a recipient requiring medical transportation. However, life support transportation is a specialized form of medical transportation that is used when a recipient has a medical condition or diagnosis requiring medically necessary services before and during the recipient's transportation as permitted under part 9505.0315, subpart 2. A registered nurse or licensed practical

nurse may be required to provide the service. The cost of such a private duty nursing service is not included in the medical assistance payment schedule for medical transportation. If private duty nursing service is medically necessary during life support transportation, then it is reasonable to pay for it on a separate schedule as a covered service.
C. This item is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (17).

Subp. 4. Payment limitations. Minnesota Statutes, section 256B.04, subd.12 requires the department to place limits on the types and frequency of covered services. This subpart is necessary to establish the conditions a service must meet in order to be eligible for payment.
A. This item is consistent with 42 CFR 440.80 (b) which sets an eligibility standard for federal financial participation. Requiring a written order is reasonable because a written order avoids confusion and provides a clear record.
B. The recipient's physician is the individual who has the knowledge and skill to diagnose the recipient's health condition. The recipient's physician therefore assures, directs, and coordinates the recipient's overall medical care which may include a broad array of services. The physician customarily specifies these services in a written plan of care. Private duty nursing service may be specified. Therefore, this item is reasonable because it assures the service will be coordinated with the total array and thus it promotes quality care based on the recipient's condition.
C. 42 CFR 440.70 (b) sets the standards for the provision of nursing service as a home health service. This item is consistent with the federal regulation. The department does not have the ability to coordinate private duty nursing services with the other services the recipient requires or to determine whether another service such as a personal care service or home health service is more appropriate than private duty nursing service. A home health agency located in the recipient's community knows community resources and is able to arrange the provision of health services in the recipient's home in an efficient, cost effective manner. (See the SNR for parts 9505.0290 and 9505.0295.) The quality of such coordination by the home health agency is assured because the agency must meet the standards necessary to be certified by Medicare. Therefore, it is reasonable to require the services to be coordinated by the home health agency if such agency is available in the recipient's local trade area because the agency can assure that the services are appropriate and necessary. If such an alternative is not available, then the department will pay for a possibly more expensive alternative.
D. This item is consistent with customarily accepted ethical considerations that discourage the practice of one family member giving professional health care to another member of the same family. This item is consistent with the position of the Minnesota Nurses Association. It is also consistent with part 9505.0335, subpart 10, item E. Furthermore, it is reasonable because it ensures that medical assistance will not be requested to pay for care that is a customary responsibility of family members toward each other.

9505.0365 PROSTHETIC AND ORTHOTIC DEVICES.

Subpart 1. Definitions. This subpart is necessary to clarify the meaning of terms used in this part and set a standard.
A. "Ambulatory aid" is an abbreviation commonly used by health care providers to refer to a category of prosthetic devices that assist a person to move from place to place. Examples include canes, walkers, wheelchairs, and braces. These devices substitute for the support of a defective or missing body part of the user. The abbreviation is reasonable as it is consistent with common usage and shortens the rule.
B. This definition is consistent with 42 CFR 440.110 (c)(2).
C. "Hearing aid" is an abbreviation commonly used by providers and the general public to refer to a device used to replace a missing body organ or assist a malfunctioning body organ, the ear. The abbreviation is reasonable as it consistent with common usage and shortens the rule.
D. "Hearing aid dispenser" is a recognized occupation that provides a medically necessary service to a recipient. It is reasonable to limit the term to a person who has signed a performance agreement with the department because the performance agreement sets the standards to be eligible for medical assistance payment, minimizes the possibility of misunderstandings between the provider and the department, and enables the department to monitor the compliance of the hearing aid dispenser.
E. The definition is consistent with 42 CFR 440.120 (c). Furthermore, it is consistent with 42 CFR 405.260 (f) (1) and 42 CFR 405.231 (h) in regard to prosthetic devices and to 42 CFR 405.260 (g) (1) in regard to orthotic devices.

Subp. 2. Eligible providers; medical supply agreement. This subpart is necessary to specify a condition to be eligible as a provider in the medical assistance program. It is consistent with 42 CFR 431.107 which requires an agreement between the medicaid agency and each provider furnishing services. Requiring a performance agreement is reasonable because it clarifies the terms and conditions for payment, reduces the possibility for misunderstanding between the provider and the department, and enables the department to monitor the provider's compliance with the contract terms. The subpart is also consistent with Minnesota Statutes, section 256B.04, subd.2, concerning the carrying out of the medical assistance program in an efficient and impartial manner and cooperating with the federal government to qualify for federal aid.

Subp. 3. Payment limitation; ambulatory aid. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the types of service eligible for medical assistance payment. Minnesota Statutes, section 256B.04, subdivision 15 requires the department to safeguard against the use of unnecessary or inappropriate use of medical assistance services. 42 CFR 440.230 (d) permits the department to use medical necessity as a criterion in limiting service. A physician is qualified to make determinations of medical necessity. Thus, it is reasonable to require an ambulatory aid to be prescribed by a physician so that the recipient's need for the aid is medically determined. However, prescription of ambulatory aids requires knowledge and expertise in a particular area to ensure the device is the most appropriate and effective

one at the least cost. A general practitioner may not have such knowledge. Providers who have the specialties listed in the subpart are knowledgeable and expert about ambulatory aids. Therefore, it is reasonable to limit payment eligibility to devices prescribed by or in consultation with these persons because devices so prescribed will be appropriate to the medical needs of the recipient.
Requiring prior authorization of devices that cost in excess of the limits specified in the provider's performance agreement is reasonable so that the department can review the need for the equipment and determine whether the requested device is the most appropriate and effective one at the least cost. This determination is consistent with Minnesota Statutes, section 256B.04, subdivision 15. The prior authorization requirement is similar to the one for durable medical supplies, in part 9505.0310, subpart 3, item A.

Subp. 4. Payment limitation; hearing aid. This subpart is necessary to limit the types of service that will be eligible for medical assistance payment as required by Minnesota Statutes, section 256B.04, subdivision 12. Selecting a hearing aid that will supplant the loss or correct the malfunctioning of a recipient's hearing is a task that requires specific expertise. An audiologist is a person with such expertise. (See the definition in subpart 1, item B.) Requiring the physician to consult with the audiologist is necessary and reasonable to safeguard against inappropriate and unnecessary service as required by Minnesota Statutes, section 256B.04, subdivision 15. The subpart is consistent with 42 CFR 440.230 (d) which permits a service limitation based on medical necessity.
A. Changes in hearing capacity occur slowly. Under most circumstances the prescription will remain effective for a five year period. However, if change occurs rapidly enough to require a new prescription more often than once in five years, prior authorization is a means to permit the department to determine the circumstances and authorize payment for a medically necessary new prescribed hearing aid. The item is reasonable because it safeguards against unnecessary and inappropriate services and yet provides a means , prior authorization, for a recipient to obtain a medically necessary new aid within the time limitation.
B. The recipient has a responsibility to care for equipment purchased by medical assistance for his or her individual use. Thus the item is reasonable as it safeguards against unnecessary services, as required under Minnesota Statutes, section 256B.04, subdivision 15. However, prior authorization of repairs more than once a year is reasonable because a need for repair may arise from unusual circumstances and prior authorization does permit the department to review the need for the repair and to monitor the circumstances as required under utilization control procedures. Requiring the vendor to itemize the charges is reasonable because the department needs the itemization to determine whether the billing is appropriate.
C. Minnesota Statutes, section 256B.04, subdivision 15 requires the department to safeguard against inappropriate and unnecessary services. This item is consistent with that requirement. If the dispenser can show that additional visits are medically necessary during the calendar year, then prior authorization can be obtained for medical assistance payment of the service. Thus the item is consistent with the requirement of basing service payment on medical necessity.

D. The effectiveness of a hearing aid depends on batteries in good condition. Thus replacing batteries is medically necessary to ensure that the hearing aid functions properly. This item is consistent with the criterion of medical necessity. Because the life of a battery depends on the circumstances in which it is used, it is reasonable not to specify a limit on the number supplied or length of service.
E. This item is consistent with the requirements of 42 CFR 456.280.

Subp. 5.. Payment limitation; general. This subpart is necessary to specify a payment limitation applicable to items that are rented or under warranty. The subpart is consistent with Minnesota Statutes, section 256B.04, subd. 15 which requires the department to safeguard against unnecessary payments.

Subp. 6. Excluded prosthetic and orthotic devices. Minnesota Statutes, section 256B.04, subdivision 12 requires the department to place limits on the types, and frequency of service eligible for medical assistance payment. This subpart is necessary to specify the limits.
A. If Medicare denies a claim on the grounds that service is not medically necessary, the recipient may appeal the denial to Medicare as permitted under 42 CFR, part 405. Medical assistance is the payer of last resort. It is reasonable that medical assistance accept Medicare's determination of not medically necessary.
B. This item is consistent with 42 CFR 440.230 (d) and Minnesota Statutes, section 256B.04, subdivision 15.
C. Part 9505.0310, subpart 2, specifies the payment limitations for items of durable medical equipment furnished to residents of long-term care facilities. This item is consistent with that subpart. Unless the device has been modified to meet the recipient's individual need or is necessary for the recipient's continuous care and exclusive use, the nursing home is expected to provide the device as a routine service and payment for the device is included within the per diem payment of the long-term care facility. An example of such a device is a wheelchair that can be used interchangeably by many residents. However, some devices such as hearing aids are designed according to a specific recipient's prescription. The item is reasonable because it safeguards against duplicative and unnecessary payments at the same time as it provides for payment of services to meet a recipient's unique needs.
D. and E. The cost of repairing a rented device or the cost of servicing a device owned by a long-term care facility is the responsibility of the owner. Such costs are included in setting the rental fee for the device and the per diem payment to the long-term care facility.
F. A device whose primary purpose is to serve the convenience of the owner is not medically necessary. For example, an electric hospital bed is only a convenience for the caregiver if the recipient is not capable of manipulating the controls to change his position. This item is reasonable because these devices are not medically necessary.
G. Minnesota Statutes, section 256B.02, subdivision 8 states that "'medical assistance' or 'medical care' means payment of part or all of the cost of....care and services for eligible individuals...." Part 9505.0175, subpart 42, defines a recipient as a person determined eligible for medical assistance. Therefore, this item is consistent with the purpose of the medical assistance program. An example of a device not

received by a recipient is an orthotic or prosthetic device made to a recipient's specification but not delivered before the recipient's death. See also part 9505.0125, subpart 1, item C.

H. This item is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 15 in regard to safeguarding against unnecessary use of medical assistance services and with 42 CFR 440.230 (d) authorizing limitations based on medical necessity.

I. A provider who both prescribes and supplies a device profits from both the examination necessary to prescribe and the sale. Thus, a conflict of interests exists as the provider may prescribe an unnecessary device in order to obtain the sale. A consultant who advises the physician and sells the prescribed device also has a potential conflict of interests. Thus this item is reasonable and necessary to safeguard against unnecessary or inappropriate use of medical assistance services and excess payments as required by Minnesota Statutes, section 256B.04, subdivision 15.

J. This item is similar to provisions in other medical assistance rules, including parts 9549.0010 to 9505.0080 setting standards for reimbursement of long-term care facilities. It is designed to avoid a conflict of interests that might occur when the physician receiving payment for prescribing the device also stands to profit indirectly through the sale of the device by a family member. This item is consistent with item I. It is reasonable and necessary to safeguard against unnecessary or inappropriate use of medical assistance services and to safeguard against excess payments as required by Minnesota Statutes, section 256B.04, subdivision 15.

K. Replacement batteries provided on a schedule under a medical assistance contract are paid according to the terms of the contract. Therefore, excluding them from payment on a separate schedule is necessary and reasonable to ensure compliance with Minnesota Statutes, section 256B.04, subdivision 15.

9505.0380 PUBLIC HEALTH CLINIC SERVICES

Subpart 1. Definition. " Public health clinic services" is a term applied in this part to certain health services offered by a public health agency that is responsible to a local board of health under Minnesota Statutes, sections 145.911 to 145.922. A definition of the term "public health services" is necessary to clarify its meaning and set a standard. Public health clinics are a special category of non-profit community health clinic: they are a department of or responsible to one or more governmental units such as a county or city whereas a community health clinic as defined in part 9505.0255, subpart 1 is usually operated by a private non-profit organization. They are usually located in an urban area and are similar in function, direction, and purpose to a rural health clinic established under 42 CFR, part 491 to serve a low income rural population. Such a rural clinic must provide its services under the direction of a physician. The definition is reasonable because it differentiates between the types of clinics providing similar health services but retains a consistent standard for supervision of the service by a physician. (See parts 9505.0250, subpart 2, item B and 9505.0255, subpart 3, 42 CFR 491.7(a), and Minnesota Statutes, section 256B.02, subdivision 8(4).)

Subp. 2. Eligible health services. This subpart is necessary to specify the services that are eligible for medical assistance payments as public health clinic services. All services listed in items A to E are primary care services that can be given in an alternative care setting such as a public health clinic and that are necessary to maintain good health (items A and D), prevent health problems (items B and D), or to meet the health needs of a special clientele (items C and E). This subpart is reasonable as it limits the eligible services to those medically necessary services that can be appropriately given as a first level of care in an alternative setting. (See part 9505.0255, subpart 2). Further establishing payment eligibility of a public health clinic payment for the same services provided by a community health clinic is consistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 2, that the program be uniformly administered throughout the state.

9505.0395 RURAL HEALTH CLINIC SERVICES

Subpart 1. Definition. "Rural health clinic service" is a term used in this part to describe a health service provided by a rural health clinic. A definition is necessary to set the standard for eligibility for payment under the medical assistance program. 42 CFR, Part 491 prescribes the conditions that a rural health clinic must meet in order to qualify for reimbursement under medical assistance. The provision is consistent with the federal regulation and is reasonable in order to inform affected persons of compliance requirements.

Subp. 2. Covered services. The provision is necessary to inform affected persons of the standards a clinic must meet in order to receive medical assistance payments for its health services. 42 CFR 491.8 specifies the staffing and 42 CFR 491.9 specifies the written policies on patient care that are necessary to be eligible for medical assistance payment. Furthermore, it is reasonable to apply to rural health clinic services the same limitations applicable under these rules to the same services in another setting because Minnesota Statutes, section 256B.04, subd. 2 requires the department to administer medical assistance in an impartial manner uniformly throughout the state. The subpart also is consistent with the comparability requirements of 42 CFR 440.240.

9505.0405 VISION CARE SERVICES.

Subpart 1. Definitions. This subpart is necessary to define terms used in this part and set a standard for eligibility for medical assistance payment.

A. "Complete vision examination" is a term used in this part that describes a set of visual services. Minnesota Statutes, section 256B.02, subdivision 7, includes within the definition of "vendor of medical care" a person furnishing visual services within the scope of his licensure. However neither the statutes nor federal regulations define visual services or the components of visual services. Therefore, a definition is necessary to clarify its meaning. The definition is reasonable because it describes a set of visual services that are within the scope of licensure of a physician, under Minnesota Statutes, Chapter 147, and that encompass the visual services regarded by physicians as the prevailing standard of practice.

B. Minnesota Statutes, section 256B.02, subdivision 7 includes "optical services" within the scope of its definition of "vendor of medical care." However, the statute does not define the term. One aspect of optical service is the preparation, fitting, and maintenance of devices designed to assist sight. Optical service may also be interpreted more broadly to include the prescribing of sight assisting devices. Minnesota Statutes, section 256B.02, subdivision 8(11) requires eyeglasses to be prescribed by a licensed practitioner in order to be eligible for medical assistance payment. Practitioners licensed in Minnesota to prescribe eyeglasses are physicians under Minnesota Statutes, Chapter 147, and optometrists under Minnesota Statutes, section 148.56. 42 CFR 440.120(d) requires eyeglasses to be "prescribed by a physician skilled in diseases of the eye or an optometrist." Thus the definition is reasonable because it is consistent with statute and federal regulations and because it uses a word (dispensing) commonly applied to the preparation and giving out of medicines. (See "dispensing", The American Heritage Dictionary of the English Langauge.)

C. Minnesota Statutes, section 256B.02, subdivision 8 (11), authorizes medical assistance payment for eyeglasses but does not define the term. Nor is the term defined in Minnesota Statutes, section 256B.04, subdivision 14 (1) which requires volume purchase of eyeglasses through competitive bidding. A definition is necessary to clarify the term. The definition is reasonable because it is consistent with 42 CFR 440.120 (d) which defines the term.

D. According to The American Heritage Dictionary of the English Language, an optician is one who makes or sells lenses and eyeglasses. Both Minnesota Statutes, section 256B.02, subdivision 8(11) and 42 CFR 440.120(d) require such lenses and eyeglasses to be prescribed by a licensed practitioner in order to be eligible for medical assistance payment. Thus the definition is reasonable as it is consistent with statutory and federal requirements for medical assistance.

E. Minnesota Statutes, sections 148.52 to 148.62, specify the licensing requirements for and the scope of practice of optometrists.

F. Under 42 CFR 440.120(d), eyeglasses prescribed by a "physician skilled in diseases of the eye" are eligible for medical assistance payment. However, the regulation does not define such a practitioner. Minnesota Statutes, chapter 147 sets the scope of practice of a physician but does

not define or set requirements for an area of specialized practice such as diseases of the eye. However, professionally accepted standards of current medical practice limit treatment of diseases related to the health of the eye to a physician who has had academic and supervised practical training in ophthalmology in addition to that required for licensure as a physician. The definition is reasonable because it is consistent with current standards of practice accepted by the medical profession.
G. This definition encompasses the two aspects of vision care: service by a practitioner licensed under Minnesota law and dispensing service based on the licensed practitioner's prescription. These services are all eligible for medical assistance payment. Thus the definition is reasonable because it provides an abbreviation which can be used to shorten this rule.

Subp. 2. Payment limitations. Minnesota Statutes, section 256B.04, subdivision 12, requires the department to place limits on the types of services and the frequency with which these services may be covered by medical assistance for an individual recipient. This subpart is necessary to comply with the statute.
A. The Minnesota Optometric Association recommended to the Governor's Task Force on Health Care in December 1981 that vision examinations "should be performed every two years rather than annually as currently prescribed by MA policy." Examinations at two year intervals are reasonable because the eye, except in the cases of children experiencing a growth spurt and persons suffering certain diseases, is a stable organ that does not change rapidly. Examinations more frequent than every 24 months may be medically necessary for an adolescent whose eyes may change significantly during a relatively brief period of rapid physical growth. More frequent examinations may also be medically necessary to monitor the vision and eye health of a person with a condition such as cataracts, glaucoma, and diabetes. Therefore exceptions are necessary to pay for more frequent examinations that are medically necessary. Prior authorization of the examination under parts 9505.5000 to 9505.5030 is a reasonable requirement because this program gives the department an opportunity to compare the recipient's need to the criteria established to determine medical necessity.
B. Determination of the medical necessity of eyeglasses is part of a complete vision examination. Thus the limit on the provision of eyeglasses is consistent with item A which also has a 24 month limitation on payment for a vision care service. Permitting a replacement of each lens to be eligible for medical assistance payment is reasonable to ensure the recipient obtains the medically necessary service. Requiring prior authorization of additional pairs or replacements of a lens within a 24 month period is reasonable because it is consistent with Minnesota Statutes, section 256B.04, subdivision 12 in regard to limiting the frequency of service while at the same time providing for medically necessary exceptions.

Subp. 3. Payment limitation; more than one recipient on same day in same long-term care facility. The provider of vision care services to recipients residing in a long-term care facility usually is not a full time staff member of the facility but is someone who comes to the facility at the recipient's request. The provider has a right to be paid for these services and for the expenses he may incur in travelling to the facility,

using the facility, and placing equipment at the facility. Thus, the payment amount set for a procedure code under part 9505.0445, item E includes an amount for administrative overhead, travel, and other non-repetitive costs a provider may incur in going to a long-term care facility. These costs are not incurred for the same provider's visits to other recipients in the same facility on the same day. Thus using the multiple visit code established by the department is reasonable because its use eliminates duplicate payments by medical assistance, reimburses the provider on a pro rata basis, and pays only for the provider's service to the additional recipients.

Subp. 4. Excluded services. Minnesota Statutes, section 256B.04, subdivision 12, requires the department to place limits on the types of services covered by medical assistance. Minnesota Statutes, section 256B.04, subdivision 15 requires medical assistance services to be medically necessary and appropriate. Furthermore, 42 CFR 440.240(d) authorizes service limits based on the criterion of medidcal necessity. None of the items A to I is medically necessary. Therefore excluding these items is reasonable because they do not meet the eligibility standard. The exclusion of items A to I is consistent with the past practice of the department.

J. A purpose of prior authorization is to determine the medical necessity of a health service before the service is given. If a required prior authorization is neither sought nor obtained, the service's medical necessity has not been established. Thus item J is reasonable because it excludes from payment a vision care service that has not been determined medically necessary.

K. A provider of vision care services is responsible for accurately and appropriately performing the services necessary for the recipient. An error in prescribing, selecting frames, or measuring a recipient for eyeglasses means the recipient does not receive the vision care service that is medically necessary. Because medical assistance payment is limited to medically necessary services, requiring the provider to bear the cost of correcting the error is reasonable.

L. Services that are experimental or nonclinically proven by prevailing community standards do not meet the criterion of medically necessary services. Thus item L is reasonable because MA payment is limited to medically necessary services.

9505.0415 LONG-TERM CARE FACILITIES; LEAVE DAYS

Subpart 1. Definitions. This subpart is necessary to clarify the meaning of terms that are used in this part. Clarification is reasonable to inform persons affected by the rule and thus to encourage compliance.
A. The term "certified bed" is used in this part. A definition is necessary to clarify its meaning. The definition is consistent with the requirement of Title XIX of the Social Security Act.
B. "Discharge" or "discharged" is a term used in this part. A definition is necessary to clarify its meaning. The definition is consistent with the cited rule part which is a provision of the rules establishing the categorical payment rates of hospitals participating in the medical assistance program.
C. The term "hospital leave" is used in this part in computing payments to hospitals and long-term care facilities. The definition is consistent with the principle embodied in 42 CFR 447.40 concerning payments for a bed during a recipient's temporary absence under a plan of care.
D. The term "leave day" is commonly used as a time standard in computing payments to long-term care facilities. The definition is consistent with 42 CFR 447.40. Limiting a leave day to any portion of a calendar day that exceeds 18 hours is reasonable because the 18-hour period permits residents to visit their families or other places of interest to them without counting this absence as a leave day. Thus, the restriction in the definition means that the absence of a recipient during all the hours a person is customarily awake will have no effect on the number of the recipient's leave days if the recipient returns within the 18-hour period.
E. The term "reserved bed" is used in this part as a standard in computing payments to long-term care facilties. The definition conforms to the long-standing practice of holding the place of the resident who must temporarily leave the long-term care facility for hospital care or for a therapeutic leave. It is consistent with Minnesota Statutes, section 256B.48, subd.1 (g).
F. The term "therapeutic leave" is used in this part to refer to a specific type of leave commonly taken by residents of long-term care facilities. The term affects payments to providers. It is necessary to distinguish between "therapeutic leave" and "hospital leave" as 42 CFR 447.40 permits payment for an absence other than hospitalization only when the absence is temporary and part of the plan of care. The leave gives the recipient an opportunity to have experiences consistent with his plan of care that are not available in the long-term care facility and that will benefit the recipient's health status. The definition is consistent with a long-standing practice of the department and with the requirement of Minnesota Statutes, section 256B.04, subd.4 about cooperating with the federal government to obtain financial aid.

Subp. 2. Payment for leave days. This subpart is necessary to set a standard about the medical assistance payment eligibility of leave days. The subpart is consistent with 42 CFR 447.40 which limits payment eligibility to hospital or therapeutic leave. It is reasonable to require a facility to hold a reserved bed for a recipient because the recipient needs a bed to return to at the end of the leave and returning to the same long-term care facility ensures the recipient continuity of care in familiar surroundings from staff who are acquainted with the recipient and his condition. Furthermore, if reserving a bed were not possible, there

would be the likelihood that the bed would be required for occupancy by some other individual when the nursing home meets or exceeds the certified occupancy rate for the same level of care required by the recipient or for the facility as a whole if all of the beds in the facility are certified for the same level of care.

Subp. 3. Hospital leave. and Subp. 4. Therapeutic leave. These two subparts specify the leave records that are required as a condition of payment eligibility for the leave. They are necessary to set a uniform standard of eligibility. The requirements are reasonable because they provide an audit trail which the department can use in monitoring the purposes of leaves to determine compliance with these rules and in computing payments for reserved beds on leave days. Requiring the same records for both types of leave is reasonable to ensure a uniform standard for an audit trail.

Subp. 5. Payment limitations on number of leave days for hospital leave. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types and frequency of services covered by medical assistance. This subpart is necessary to set the standard for the number of a recipient's hospital leave days that are eligible for medical assistance payment. The subpart is consistent with 42 CFR 447.40 (a) which permits payments to reserve a bed during a recipient's temporary absence and furthermore permits a state to specify the limitations on the reserved bed policy. It is also consistent with the requirements of Minnesota Statutes, section 256B.04, subd. 2 concerning carrying out medical assistance in an efficient and economical manner and with Minnesota Statutes, section 256B.04, subd. 15 concerning safeguarding against excess payments as this subpart will limit the period of duplicate payments for a recipient's beds in a hospital and a long-term care facility. Minnesota historically has allowed 18 consecutive leave days. The department believes that this limit has provided sufficient time to accomplish the purposes of the leave because the department knows of no hardships resulting from the limit. Therefore, the 18 day limit is reasonable as it balances the recipient's need for a reserved bed while on leave and the right of the facility to be paid for reserving the bed against the statutory requirement of safeguarding against excess payments. Futhermore, it is reasonable to limit the payments to separate and distinct episodes of hospitalization because this limit safeguards against underutilization or overutilization or inapproriate use of hospital services as required in Minnesota Statutes, section 256B.04, subd.15. Permitting an exception for an emergency is reasonable as an emergency cannot be anticipated and calls for immediate action. Limiting payment for rehospitalization for the same illness (other than an emergency) to an episode which recurs at least two days after discharge is reasonable because the interval of two days safeguards against premature discharge and underutilization of hospital services subject to a fixed rate rimbursement based on diagnostic category as required by Minnesota Statutes, section 256B.04, subd.15. It is necessary and reasonable to specify in item B that the health condition "was not evident at the time of discharge" because the recurrence of a previous health condition may not be evident in its initial stages.

Subp. 6. Payment limitations on number of leave days for therapeutic leave. 42 CFR 447.40 (a) allows payment only for a temporary absence and permits the state to place limits on the reserved bed policy. Minnesota Statutes, section 256B.04, subd. 12 requires the department to place limits on the types and frequency of service covered by medical assistance for an indiviudual recipient. Furthermore, Minnesota Statutes, section 256B.04, subd.15, requires the depar'ment to safeguard against excess payments. Therefore, this subpart is consistent with federal and statutory requirements and is necessary to establish a uniform standard.
A and B. 36 leave days per calendar year represent ten percent of a year's residence in the long-term care facility. Hospital leave days and day trips are not included in the 36-day limit. The limit is reasonable because a client who is capable of living away from a long-term care facility during a more extended leave may not require the level of care available in a skilled nursing or intermediate care facility and thus may be inappropriately placed in a long-term care facility.
C and D. Therapeutic leave for recipients residing in intermediate care facilities for persons with mental retardation or in long-term care facilities licensed to provide services for the physically handicapped can be a step toward normalization and living in the community in a less restrictive setting. (See part 9525.0210, subpart 14.) The more extensive leave affords time for the recipient to establish a pattern of daily living consistent with community-based living or for determining the continued need for ICF-MR or physically handicapped facility placement. An allowance of 72 days can also be used to permit the recipient to spend time with his family at home on weekends and during the Christmas season. Thus, the 72 day period is reasonable because it offers the recipient an appropriate opportunity to develop increased socialization skills and to spend time with his family.

Subp. 7. Payment limitation on billing for leave days. Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against excess medical assistance payments. This subpart establishes payment limits that apply to the circumstances of the long-term care facility itself rather than to the recipient as specified in subparts 5 and 6. The subpart is consistent with statute and also with 42 CFR 447.40 (a)(2) which permits the state to set limits on the reserved bed policy. One reason for paying for reserved beds is to ensure a bed will be available to the recipient returning from leave and to ensure that a facility does not incur a monetary loss from keeping the bed unoccupied until the recipient returns. However, a long-term care facility having vacant beds may have capacity in excess of the demand and would not be in danger of incurring a monetary loss by reserving the bed for the recipient. Therefore, it would be contrary to statute and to the concept of reserved beds to pay to reserve a bed at a time when the demand for beds is less than the facility's ability to meet the demand. Items A and B are reasonable because they provide evidence that the facility has at least one bed that is in excess of demand. Item C is consistent with Minnesota Statutes, section 256B.48, subd. 1 which establishes the principle of equalization as a condition of a nursing home's participation in the medical assistance program.

9505.0420 LONG-TERM CARE FACILITY SERVICES.

Subpart 1. Covered service. This subpart is necessary to inform affected persons of the eligibility of long-term care facility services for medical assistance payment and the standards that govern the eligibility. The subpart ensures consistency with the cited rules which set the standards.

Subp. 2. Payment limitation; skilled nursing care facility. This subpart is necessary to set limitations on the frequency and types of services eligible for medical assistance payment as required by Minnesota Statutes, section 256B.04, subdivcision 12.
A. This item is consistent with 42 CFR 440.40 (a). It is also consistent with 42 CFR 405.1123 and 42 CFR 405.1124. Consistency with these regulations is a condition for obtaining federal financial participation as required by Minnesota Statutes, section 256B.04, subdivision 4.
B. Parts 4655.0090 to 4655.9900 are rules of the Minnesota Department of Health that govern the licensing requirements for a skilled nursing care facility. Part 4655.5100, subpart 1 requires the facility to have adequate nursing staff at all times. Minnesota Statutes, section 144A.01, subdivision 6 defines the term "nursing care." The item is reasonable because it ensures consistency with statutes and licensing requirements. Furthermore, the item is consistent with 42 CFR 405.1124.
C. This item is reasonable to ensure consistency with other rules and to inform affected persons.

Subp. 3. Payment limitation; intermediate care facility, levels I and II. This subpart is necessary to set limitations on the frequency and types of services eligible for medical assistance payment as required by Minnesota Statutes, section 256B.04, subdivision 12.
A. This item is consistent with 42 CFR 440.150(a). Consistency with this regulation is a condition for obtaining federal financial participation as required by Minnesota Statutes, section 256B.04, subdivision 4.
B. This item is consistent with 42 CFR 442.307. Its inclusion is reasonable because it informs affected persons of a requirement about appropriate care.

Subp. 4. Payment limitation; intermediate care facility, mentally retarded. This subpart is necessary to set limitations on the frequesncy and types of service eligible for medical assistance payment as required by Minnesota Statutes, section 256B.04, subdivision 12. This subpart is consistent with the requirements of Minnesota Statutes, section 144.50 to 144.56 and Chapter 144 A concerning standards and licensing requirements for long-term care facilities and program standards set for intermediate care facilities for mentally retarded persons (ICF-MRs)in parts 9525.0210 to 9525.0430.
A. 42 CFR 442.418 sets the criteria for admission to an ICF-MR. Compliance with the criteria is necessary and reasonable to obtain federal financial participation as required in Minnesota Statutes, section 256B.04, subdivision 4.
B. 42 CFR 442.401 defines the term "qualified mental retardation professional." 42 CFR 442.411 requires an ICF-MR to have a qualified mental retardation professional and specifies the professional's responsibilities. This item is consistent with the federal regulation.

Consistency with the federal regulations is necessary and reasonable to obtain federal financial participation as required by Minnesota Statutes, section 256B.04, subdivision 4.

C. 42 CFR 435.1009 defines the term "active treatment in institutions for the mentally retarded " as a condition of eligibility for federal financial participation. This item is consistent with the federal regulation. Consistency with federal regulations is necessary and reasonable to obtain federal financial participation as required by Minnesota Statutes, section 256B.04, subdivision 4.

Subp. 5. Exemptions from federal utilization control. 42 CFR 456.251 defines skilled nursing care facility services. 42 CFR 456.351 defines intermediate care facility services. However, SNF and ICF services provided in Christian Science sanitoria are excluded from the definitions. Thus, federal regulations exempt Christian Science sanitoria from utilization control procedures required under 42 CFR, part 456, subpart E for SNF services and under 42 CFR, part 456, subpart F for ICF services. This subpart is necessary to clarify that SNFs and ICFs operated as Christian Science sanitoria are exempt from utilization control procedures. The subpart is consistent with the cited federal regulations.

9505.0425 RESIDENT FUND ACCOUNTS.

Subpart 1. Use of resident trust accounts. Minnesota Statutes, section 256B.35, subd. 4 authorizes the department to monitor the use of expenditures from a resident's personal funds held by a nursing home on behalf of the resident. Furthermore, Minnesota Statutes, section 256B.35, subdivisions 2 and 3 specify the purposes for which the funds may be used and prohibit the use of the funds by the nursing home. This statute enables the nursing home resident to choose whether the funds are kept in an account at the nursing home or elsewhere. This subpart is necessary and reasonable to inform affected parties including nursing homes and residents about the statutory requirements and permission.

Subp. 2. Administration of resident fund accounts. Minnesota Statutes, section 256B.35, subdivisions 2, 3, and 5 state the requirements placed on a nursing home that desires to maintain personal need accounts (which are also called resident accounts) for residents' funds. This subpart is necessary to state the requirements and thus inform affected persons. Federal regulations that set standards applicable to these accounts are 42 CFR 405.1121 (m), 42 CFR 442.320, and 42 CFR 442.406. Furthermore, the items in this subpart are consistent with parts 4655.4100 to 4655.4170. which regulate the handling and protection of the personal funds of residents by a nursing home that has chosen to accept such personal funds.
A. This item is consistent with the cited rules and federal regulations.
B. This item is consistent with Minnesota Statutes, section 256B.35, subd.3.
C. This item is consistent with the cited federal regulations, statute, and health department rules. It is reasonable to require a written record so that the department is able to carry out the field audits required by Minnesota Statutes, section 256B.35, subd.4. Allowing five working days to record the transaction is reasonable because it balances the resident's right to an up-to-date record against the possible workload of the staff assigned to maintain these financial records.
D. This item is consistent with Minnesota Statutes, section 256B.35, subd. 4 which requires the department to conduct field audits. The requirement that the resident sign a receipt for a withdrawal is reasonable because it protects the resident and the nursing home from misunderstandings about whether the withdrawal was authorized. In choosing the maximum that could be withdrawn without the resident's signature, it is necessary and reasonable to balance the need to protect the resident from possible misuse of funds and the burden that recordkeeping and authorization procedures place on the nursing home. The amount of $10 represents 20 percent of the monthly income of a resident whose only income is the personal needs allowance established pursuant to Minnesota Statutes, section 256B.35, subd.1. Therefore, the requirement of a signature to withdraw $10 or more is reasonable because the requirement protects many residents from possible unauthorized use of a significant portion of their monthly income.
E. This item is consistent with Minnesota Statutes, section 256B.35, subd. 2. The cost of staff time required to maintain resident fund accounts is reported as a general and administrative expense on the cost report required under part 9549.0040, subpart 7. Therefore, prohibiting a charge for this service is reasonable to prevent duplicate payments and to conserve resident funds.

F. This item is reasonable because it protects the resident from pressure and thus protects the right of the resident to use the funds as he or she deems appropriate for personal benefit.
G. This item is consistent with item F and with Minnesota Statutes, section 256B.35, subdivisions 2, 3, and 4.
H. The prohibition in this item is consistent with the prohibtion in Minnesota Statutes, section 256B.35, subdivision 3 that the nursing home may not "in any way use the funds for nursing home purposes."
I. This item is necessary and reasonable to inform persons who have an interest in or a fiducial responsibility for resident fund accounts. This item is consistent with part 4655.4170 which specifies how the funds of a resident shall be handled when the resident dies or is discharged from a nursing home.

Subp 3. Limitations on purpose for which resident fund account may be used. This subpart is necessary to specify the purposes for which a resident may not expend funds from his or her resident fund account. Minnesota Statutes, section 256B.35, subd. 3 states that a "nursing home may not.....in any way use the funds for nursing home purposes. Items A to F list supplies, furnishings, services, and drugs that relate to "nursing home purposes" in that all these items are routinely supplied by a long-term care facility and their costs are allowable in the determination of the long-term facility's payment rate under parts 9549.0010 to 9549.0080 or 9553.0010 to 9553.0080. However, it is reasonable to permit the recipient's expenditure of funds for items of his or her own choice and for his or her own personal convenience or pleasure as provided in the exceptions in item D and the provision about the purchase of a brand name supply or other furnishing that is not routinely supplied. Thus, the subpart is consistent with statute.

9505.0430 HEALTH CARE INSURANCE PREMIUMS.

Minnesota Statutes, section 256B.02, subdivision 8 (13) authorizes the use of medical assistance funds to pay health care insurance premiums of a recipient. This part is necessary to inform affected persons. It is consistent with Minnesota Statutes, section 256B.04, subdivision 2 in regard to carrying out the medical assistance program in an efficient and economical manner.

9505.0440 MEDICARE BILLING REQUIRED

This part applies the concept of "payer of last resort" to covered services which may be eligible for payment by Medicare. This is consistent with the submittal of billings to third party payers as required in part 9505.0070. It maximizes the use of federal funds in paying for health care; it minimizes the use of state funds and the burden placed on state taxpayers. The concept is consistent with 42 CFR 433.138 to 433.139 which broadly define "third party" and permit states to determine the option for payment of claims by third parties. However, Medicare attaches liability to providers' claims which are submitted for a covered service but are determined to be ineligible for Medicare payment. In this situation, Medicare regulations presume that the provider submitted the claims in good faith and will provide reimbursement, unless it is determined, based upon the provider's claim experience, that the presumption of good faith should be rebutted. If the provider bases his limitation on liability, he then bases reimbursement for all claims submitted in good faith but denied by Medicare. (See 42 CFR 405.195 to 405.196 and 42 CFR 405.330 to 405.332.) Since Medicare standards of coverage are not promulgated as administrative rules and can be changed at the discretion of the intermediary, it would be unreasonable for the Medicaid program to require prior submission to Medicare if the provider has reason to believe that a claim will be rejected. Such a submission would jeopardize the provider's limitation on liability and would result in a loss of reimbursability on all claims, not just those which would be subsequently sent to Medical Assistance. Although it is necessary to maximize state funds by requiring maximum Medicare payment, it would be unreasonable to institute a policy that might cause providers to lose payments to which they would otherwise be entitled under these rules. Thus, this part is necessary and reasonable to inform affected persons. It is necessary to specify the basis for determining that the provider's failure to submit the claim to Medicare is justified in order to set a standard and inform affected persons. Requiring documentation is reasonable because the documentation provides a written record that reduces the likelihood of dispute. Furthermore,requiring the documentation to be correspondence from Medicare or evidence of Medicare's denials of similar claims is reasonable because such items support the belief that submission of a similar claim likewise would be denied and would joepardize the provider's liability under the Medicare regulations.

9505.0445 PAYMENT RATES

Minnesota Statutes, section 256B.05, subd. 3, authorizes the Commissioner to "establish a schedule of maximum allowances to be paid by the state on behalf of recipients of medical assistance....." The rate setting mechanisms are prescribed in various state laws and rules or federal regulations. This part summarizes how rates are determined for all covered services under the medical assistance program.

Items A to D prescribe the rate setting mechanisms for long-term care facility services and hospital services. It is necessary and reasonable to include this information so that providers, recipients, and other affected persons are aware of how medical assistance payments of these services are coordinated.

E. Providers of services listed in item E are paid the lowest of three payment rates. It is necessary to specify how payments for these services are determined so that affected persons are informed. The first two rates are set by the commissioner under Minnesota Statutes, section 256B.05, subdivision 3 and the third rate is set by the legislature.
When the provider's submitted charge is the lowest of the three possible rates in this item, using the submitted charge as the rate is reasonable because sound economic practice dictates that a consumer should not pay more for a service or product than the value assigned by the producer of the product or service.
The provider's individual customary charge is an historical charge calculated as the average of a particular provider's submitted charges for a particular service over the calendar year specified in the legislation. This standard ensures that a provider's payment will not exceed the average value which he assigned to a particular service in the base year set by the legislature. To conserve funds and provide complete statistical reliability, the base year is a year prior to the one in which the services are delivered. The legislature considers payments based on charges in the base year to be fair and to reflect the amount the public is willing and able to spend for medical assistance services. When the provider's individual customary charge submitted during the calendar year specified in legislation governing maximum payment rates is the lowest of the three rates in this item, it is reasonable for medical assistance payment to be at this rate because it is fair to pay less for a product that costs less to produce and this practice conserves public funds.
The final standard listed in this item was established by the legislature in 1984 as a section of the appropriations bill.
It is reasonable to pay providers the lowest of the rates in this item because each rate is considered fair payment and payment of the lowest rate conserves public funds. This is consistent with Minnesota Statutes, section 256B.04, subdivision 15.
F. The lowest of four payment rates applies to clinic services other than those provided in a rural health clinic. The first three payment rates are the same rates as for the services in item E above and the same justifications apply. It is reasonable that these same three rates apply to clinic services other than rural health clinic services because the services provided in the clinics are those included under item E. The fourth rate that applies to clinic services, Medicare payment rates for comparable services under comparable circumstances, is required under 42 CFR 447.321. Specifying how the payment rate is determined is reasonable so that affected persons are informed.

G. Providers of outpatient hospital services are subject to the same payment rates as apply to providers of clinic services. The rates are justified as stated in the SNR for item F. Applying the same rates to outpatient services as to clinic services is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (4)and subjects hospital outpatient departments to the same reimbursements rates as all other providers of services except initial triage, emergency services, and services not provided or immediately available in clinics or physicians' offices or from other providers.

H. It is necessary to specify the payment methodology applicable to ambulatory surgical centers in order to set a standard and inform affected persons.

Medical assistance payment for facility services performed in ambulatory surgical centers or outpatient hospitals is the lower of the provider's submitted charge or the Medicare standard rate for facility services in ambulatory surgical centers. Facility services are items and services furnished by an ambulatory surgical center or an outpatient hospital in connection with a covered surgical procedure. Examples of facility services include:

1. Services in connection with covered surgeries furnished by nurses, technical personnel, orderlies, and other employees of the ambulatory surgical center or outpatient hospital who are involved in patient care.
2. Use by the patient of facilities such as operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the patient or offered for use by the patient's relative in connection with surgical services.
3. Drugs, biologicals, surgical dressings, splints, casts, appliances, and all other supplies and equipment commonly furnished by the ambulatory surgical center or outpatient hospital in connection with surgical procedures. (Drugs and biologicals are limited to those which cannot be self-administered.)
4. Diagnostic or therapeutic items and services furnished by the ambulatory surgical center or outpatient hospital staff and directly related to the provision of the surgical service, for example, diagnostic tests such as urinalysis and hemoglobin.
5. General administrative functions necessary to run the ambulatory surgical center or outpatient hospital, such as cleaning, utilities, rent, etc.
6. Blood and blood products.
7. Anesthesia and any material necessary for its administration.

Physicians' services, including the services of anesthesiologists administering or supervising the administration of anesthesia to patients and the patients' recovery from anesthesia, are not considered facility services and will be reimbursed separately according to the appropriate payment rate established in this part.

When the facility service charge submitted is the lower of the rates specified in this item, it is reasonable to base the medical assistance payment rate on this amount because sound economic practice dictates that a consumer should not pay more for a service than the value the provider assigns to the service.

The second payment rate specified in this item is the reimbursement methodology that Medicare applies to facility services in ambulatory

surgical centers. Under it, all surgical procedures which are commonly performed in an ambulatory surgical center are placed in one of four groups, with all procedures within a group reimbursed at a single rate. Reimbursement amounts under this methodology represent the average ambulatory surgical center charges for procedures within each group as found by a 1981 survey conducted by Medicare with the assistance of the Freestanding Ambulatory Surgical Association. These average amounts have been adjusted to reflect the 1981 local wage index and are the rates currently paid by Medicare to ambulatory surgical centers. (See the preamble and federal regulations published at 47 Federal Register 34088.) Since the statutes authorizing Medicare payment for ambulatory surgical center facility services reimbursement (sections 1832 (a)(z) and 1833 of the Social Security Act) represent an estimate of a fair fee for the costs of furnishing services, and because HCFA has not adjusted the rates since they were first published in 1982, the rates must be consistent with 1982 charges for ambulatory surgical center facility services. It is reasonable to base payment limitations for all providers on charges submitted in 1982 because setting the same limits for all promotes equitable treatment and efficient administration of the program. It is reasonable to use the Medicare standard rate because the rate is based on ambulatory surgical center facility charges and, as shown by Medicare's use of the standard, is a fair fee for the costs of furnishing services. Services provided at surgical centers are consistent with the definition of clinic services that is in 42 CFR 440.90. 42 CFR 447.321 limits medical assistance payment for clinic services to the amount allowed by Medicare for comparable services under comparable circumstances. The second payment rate is reasonable because it is consistent with this regulation. It is reasonable to apply the limit to outpatient hospital services because Minnesota Statutes, section 256B.02, subd. 8 (4) subjects outpatient departments to the same reimbursements as other enrolled vendors for all services, except initial triage, emergency services, and services not provided or immediately available in clinics or physicians' offices or from other enrolled providers

It is reasonable to base the medical assistance payment rate on the lower of the two payment rates because each rate is fair and public funds are conserved if the lower rate is paid.

I. It is necessary to specify the reimbursement methods applicable to outpatient hospital emergency charges in order to inform affected persons. Minnesota Statutes, section 256B.02, subdivision 8 (4) specifies that "hospital outpatient departments are subject to the same limitations and reimbursements as other enrolled vendors for all services, except initial triage, emergency services, and services not provided or immediately available in clinics, physicians' offices, or by other enrolled providers." Thus, facility fees for emergency outpatient hospital services are not subject to reimbursement levels which apply to other vendors. The commissioner is authorized under Minnesota Statutes, section 256B.05, subdivision 3 to "establish a schedule of maximum allowances to be paid by the state on behalf of recipients of medical assistance....." A customary facility fee for an emergency room was established in 1983 based on average charges reported by outpatient hospitals in 1983. This fee has not been adjusted. The fee was reasonable when it was established since it represented current charges reported by providers. Retaining the fee without adjustment since 1983 is also reasonable because this action conserved public funds. 42 CFR 447.204 requires that medical assistance "payments must be sufficient to enlist enough providers so that services under the state plan are

available to recipients at least to the extent that those services are available to the general population." Department records show that all licensed hospital outpatient departments in Minnesota are enrolled in the medical assistance program. This fact supports the belief that the facility fee for emergency outpatient hospital services is sufficient to meet the federal requirement regarding payment rates.

It is reasonable to base future adjustments to the outpatient hospital emergency facility fee on adjustments in legislation governing maximum medical assistance payment rates because these rates promote the equitable treatment of providers.

J. It is necessary to specify how payments are set for these services so that affected persons are informed. Payment for home health agency services is not set by legislation. Therefore, the maximum payment rates are set by the commissioner as provided in Minnesota Statutes, section 256B.05, subdivision 3. The maximum rate for home health agency services is the lower of the provider's submitted charge or the Medicare cost-per-visit limit based on Medicare cost reports submitted by free-standing home health agencies in the Minneapolis-St.Paul area in the calendar year specified in legislation governing maximum payment rates in item E. When the provider's submitted charge is the lower of the two rates in this item, it is reasonable that medical assistance payment be the lower amount because sound economic practice dictates that a consumer should not pay more for a product than the value assigned by the producer of the product. It is reasonable that the second choice of payment rate is based on Medicare cost reports submitted by home health agencies in the calendar year specified in legislation governing maximum payment rates in item E because this consistency promotes equitable treatment of providers. Medicare distinguishes between free-standing and hospital-based home health agencies and permits an add-on amount to each rate for hospital-based agencies. This add-on amount compensates hospital-based agencies for higher administrative and general costs incurred as a result of Medicare cost allocation reporting requirements. Since Medicare cost allocation methods are not used to determine medical assistance payment rates for outpatient hospital services, it is reasonable to base medical assistance payment to home health agencies on the Medicare amount that applies to free-standing agencies. Furthermore, this action is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (4).

Medicare home health agency basic payment rates are adjusted by the wage index which applies to the standard metropolitan statistical area (SMSA) in which the services are delivered. It is reasonable to base medical assistance payment rates on the wage index applied to the Minneapolis-St. Paul area because the highest volume of home health agency services are furnished in the Minneapolis-St. Paul SMSA. Counties that comprise the Minneapolis-St. Paul SMSA include Anoka, Carver, Chisago, Dakota, Hennepin, Isanti, Ramsey, Scott, Washington, Wright, and St. Croix in Wisconsin. This base is also reasonable because a consistent rate applicable to all providers promotes equitable treatment of providers and administrative ease. Finally, the use of the wage index assigned to the Minneapolis-St. Paul SMSA is reasonable because it is a higher index than those assigned to rural Minnesota or any other SMSA in Minnesota except the Rochester SMSA. Thus, basing the payment rate on the wage index for the Minneapolis-St. Paul SMSA ensures a fair rate for a significant number of providers.. Using the Medicare cost-per-visit rates enables the department to use the Medicare-audited cost report which is familiar to providers and is accepted by them as determining a reasonable rate for

home health agency services and, thus, this use avoids possible duplication of work for the provider or the department. The Medicare cost-per-visit rates ensure that payments for home health agency services do not exceed the average per diem costs of nursing home care. 42 CFR 440.70 limits home health agency nursing services to those which are intermittent and the cost-per-visit payment limitation ensures compliance with this requirement.

K. It is necessary to specify the payment rates that apply to private duty nursing services to set a standard and inform affected persons. The maximum rate for private duty nursing service was established by the Legislature in the Appropriations Act of the 1984 session. The commissioner acting pursuant to Minnesota Statutes, section 256B.05, subdivision 3 has determined that the maximum rates should be increased annually in order to maintain equity with personal care assistant rates and, thereby, to ensure the recipients' access to private duty nursing services as required under 42 CFR 447.204. Adjusting the rates according to the Consumer Price Index-Urban of the Minneapolis and St. Paul area is reasonable because this index prepared by the Bureau of Labor and Statistics of the United States Department of Labor measures the cumulative increase in the price of urban consumer goods and is used by business and labor to make wage and price adjustments. According to the Bureau of Labor Statistics, the Consumer Price Index-Urban of the Minneapolis and St. Paul area is the only index published for Minnesota. It is reasonable to base payment for private duty nursing services on the lower of the maximum rate set by the Legislature (adjusted for inflation) and the provider's submitted charge because sound ecomic practice dictates that a consumer should not pay more for a product than the value assigned by the producer.

L. This item is necessary to specify the payment limits that apply to personal care assistant services to set a standard and to inform affected persons. The maximum reimbursement rate for personal care assistant services was established by the commissioner under the authority of Minnesota Statutes, section 256B.05, subdivision 3. The present maximum is $6.08 per hour. The rate is reasonable because it is similar to the wages paid in the Minneapolis and St. Paul area to persons such as nursing aides who perform similar work. The wage scale for nursing assistants under the contract of the Hospital and Nursing Home Employees Union, Local 113 starts at $5.40 per hour. A telphone survey (completed on 10-28-86) of home health agencies in the metropolitan area found that the average hourly wage for home health aides is approximately $6.00 per hour. The payment rate for personal care assistant services was initially based on prevailing wages for nursing aides and similar providers in the Minneapolis-St. Paul area. Thereafter, the rate was adjusted as provided in applicable Appropriations Acts of the Legislature. At present, Minnesota Statutes, section 256B.02, subd. 8(17) requires the payment to be adjusted annually based upon the changes in the cost of living or the cost of providing services. It is reasonable to adjust the rates according to the Consumer Price Index-Urban for the Minneapolis- St. Paul area because this index is prepared by an agency responsible for such a statistic, the Bureau of Labor Statistics of the United States Department of Labor, and is accepted by business and labor as a measure of the cumulative increase in the price of urban consumer goods since the base year of the index. Use of the urban index for the Minneapolis-St. Paul area is reasonable because 66 percent of personal care services are furnished in this area of the state. See the SNR of item J for the

counties included in the Minneapolis-St. Paul standard metropolitan statistical area (SMSA). Furthermore, using one adjustment index is reasonable because one rate applicable to all personal care assistants promotes equitable treatment of personal care assistants and administrative efficiency. Finally, according to the Bureau of Labor Statistics, the Consumer Price Index-Urban for the Minneapolis and St. Paul area is the only index published for Minnesota. It is reasonable to base payment for personal care services on the lower of the maximum rate set by the Legislature (adjusted for inflation) and the provider's submitted charge since sound economic practice dictates that a consumer should not pay more for a service than the value assigned by the provider.
M. Part 9505.1590, subpart 5 establishes the payment rates and annual increases for EPSDT clinics. Including the citation here is necessary and reasonable to inform affected persons and ensure coordination of rules governing medical assistance services.
N. Part 9505.0340, subpart 7, items A to C establish the payment rates for pharmacy services. Citing this part in this item is necessary and reasonable to inform affected persons and ensure coordination of rules governing medical assistance services.
O. Specifying the payment rate for rehabilitation agency services is necessary so that affected persons are informed. Covered services provided by rehabilitation agencies include physician services, psychological services, and rehabilitative and therapeutic services. Because these services are included in the payment rates set in item E, it is reasonable to apply the rates of item E to services provided by rahabilitation sgencies. See the SNR for item E for justification of the three payment rates.
P. Specifying how payments are determined for rural health clinic services is necessary to inform affected persons. 42 CFR 447.371 specifies the methods of calculating medical assistance payment for rural health clinic services. The regulations offer the choice of paying for ambulatory services other rural health clinic services in clinics other than provider clinics either according to a comprehensive rate per visit determined by a Medicare carrier or according to the rate set for each service by the department. The comprehensive rate established by the Medicare carrier is based on current actual allowable costs as specified in 42 CFR 405.2426. Rates set by the department (that is by the commissioner) are based on charges in the year prior to the year in which the services are delivered. Thus, the latter method was chosen because it promotes equitable treatment of providers and conserves public funds. See also the SNR for item E.
Q. This item is necessary to specify the method used to determine payment rates for laboratory and x-ray services so that affected persons are informed. Justification for the first two payment rates in this item is the same as discussed under item E. Using the 50th percentile of usual and customary fees based upon billings submitted by all providers of the service in the calendar year specified in the legislation as a payment limitation for laboratory and x-ray services is reasonable because these services are specified in the legislation. (The most recently enacted legislation is the Appropriations Act of the 1984 session of the Legislature.) Use of the third method is consistent with Minnesota Statutes, section 256B.02, subdivision 8 (4) which subjects hospital

outpatient departments to the "same limitations and reimbursements as other enrolled vendors for all services except initial triage, emergency services, and services not provided or immediately available in clinics, physicians' offices or by other enrolled providers. The fourth method is consistent with section 9303 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (P.L.99-272) which states that medical assistance may not exceed the amount Medicare recognizes for the tests. It is reasonable to pay providers the lowest of the four rates because using the lowest rate conserves public funds and promotes cost effectiveness in the medical assistance program.

R. This item is necessary to set a pyament rate standard and to inform affected persons.

(1). Minnesota Statutes, section 256B.04, subdivision 12 requires the department to set maximum payment rates for "recognized provider(s) of transportation services." Furthermore, the statute requires the reimbursement to be made "at reasonable maximum rates that reflect the cost of providing the service regardless of the fare that might be charged by the provider for similar services to individuals other than" medical assistance recipients. Therefore, this subitem is necessary to set a standard. Minnesota Statutes, section 256B.04, subd. 15 requires the department to safeguard against excess payments. Therefore, limiting payment to the lowest of the possible charges is consistent with the statute. Medicare maximum charges are based on HCFA's review of payment claims submitted to HCFA. Similarly, the department establishes maximum allowable charges based on its experience of costs and claims for payment. When the provider's usual and customary charge or the charge submitted by the provider is the lowest, its use is reasonable because sound economic practice dictates that a consumer should not pay more for a service than the value assigned by the producer of the service. The choices are resonable because they are fair and conserve the public funds used to pay for services to medial assistance recipients.

Minnesota Statutes, section 256B.04, subd.12 (c) requires proration of payment when a provider transports two or more persons simultaneously in one vehicle. However, proration of the costs of ancillary services is not reasonable as an ancillary service is furnished on an individual basis according to a specific medical need. (See definition in part 9505.0315, subpart 1, item A.) It is reasonable to permit separate payment for these ancillary services according to the type of service because such payment will ensure the provider's costs are fairly reimbursed and at the same time conserve medical assistance funds by basing payment on the actual service used.

(2). Minnesota Statutes, section 256B.04 (12) requires the department to establish rates for payment of covered transportation services. This subpart is necessary to establish the rates and conditions for payment of special transportation services. Requiring the payment to be the lowest of the three possible charges is consistent with the requirement of Minnesota Statutes, section 256B.04, subd. 15 of safeguarding against unnecessary payment. When the provider's actual charge for the service or the provider's usual and customary rate is the lowest of the choices, its use is reasonable because sound economic practice dictates that a consumer should not pay more for a service than the value assigned by the producer of the service. The medical assistance maximum allowable charge is established by the department based on its experience of costs and claims

for payment. Therefore, the choices are reasonable because they are fair and conserve public funds used to pay for services to medical assistance recipients.

Minnesota Statutes, section 256B.04, subd. 12 requires the department to reimburse for "each additional passenger carried on a single trip at a substantially lower rate than the first passenger carried on that trip." Two components enter into the reimbursement schedule for special transportation: a flat rate for service to a recipient and a mileage rate. The mileage rate is prorated according to the number of persons in the vehicle so that the provider receives 100 percent of the rate. In setting the percent of the allowed base rate per person in the vehicle, the department considered both the statutory requirement to use a "substantially lower rate" and the need to set the rate high enough to encourage providers to carry several passengers at the same time. Achieving such a balance is necessary and reasonable because it is consistent with the statutory requirement to operate the progam in an economical and efficient manner. A provider who carries more than one passenger on the same run completes the run at less cost to himself and in a shorter time than several single-person runs would require. Thus the provider has an opportunity to enhance cost savings and to increase income through serving a greater number of persons in the same time. Under the prorated schedule, a provider's total payment for a run is: 160 percent of the one person base rate when two persons are carried; 210 percent of the base rate when three passengers are carried; 240 percent of the base rate when four passengers are carried; and so on. (The mileage reimbursement is added to these amounts.) Therefore, the prorated schedule is reasonable because it is consistent with the statutory requirement of "substantially lower" and provides a fair incentive to encourage a provider to carry several passengers at the same time.

(3) and (4). Minnesota Statutes, section 256B.04, subd. 12 requires the department to provide an opportunity for all recognized transportation providers of nonemergency transportation to be reimbursed at maximum rates established by the department. These subitems are necessary to specify the payment limitation required by statute. They are consistent with Minnesota Statutes, section 256B.02, subd.8(16).

(3). The carrier's usual and customary charge is the price paid by the general public for bus, taxicab, and other common carrier services. This choice is reasonable because it is equitable that persons who use the same service should be charged the same fee. Furthermore, it is reasonable to set the maximum at the department's maximum allowable payment because the maximum ensures compliance with the requirement of Minnesota Statutes, section 256B.094, subd. 15 of safeguarding against excess payments.

(4). This subitem is consistent with part 9505.0065, subpart 5, item D and with part 9505.0140, subpart 1, item B which specify the rate paid for private automobile transportation of a recipient. When a person uses a private vehicle, the use of the standard deduction per mile allowed by the United States Internal Revenue Service for actual miles driven for business purposes is reasonable for the following reasons: 1. It sets a clear, uniform mileage rate; 2. These rates are periodically adjusted upward to reflect inflation in the costs of operating a vehicled and thus remain reasonable accurate reflections of actual costs.

S. This item is necessary to specify the basis for making payment for medical supplies and equipment. The reimbursement shall be the lesser of the provider's submitted charge, the Medicare fee schedule amount, or, if no Medicare fee schedule amount exists, either the 50th percentile of the usual and customary charges submitted to the department for the item or medical supply in the previous calendar year, minus 20 percent or, in the event of a new item, the manufactureer's suggested retail price, minus 20 percent. The use of a three-tiered methodology for reimbursement is reasonable because it permits the department to meet the requirements of Minnesota Statutes, section 256B.04, subdivisions 2, concerning administration of medical assistance in an economical manner and 15, concerning safeguarding against excess payments.

42 CFR 447.304 requires that the Medicaid agency not pay more than specified in this regulation for services provided if the agency wants to claim federal financial participation for the services. 42 CFR 447.304 (b) states, "In the case of payments made under the plan for deductibles and co-insurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare." Thus, this regulation would limit the department's ability to provide reimbursement in excess of the Medicare allowable if a patient was covered under both Medicare and medical assistance. It is reasonable to adopt this methodolgy also with respect to all reimbursements for medical equipment and supplies as it insures equal access to these services by both MA and Medicare/MA recipients. It also is reasonable because the uniformity of payment methodolgy does not impose an extra burden on providers and facilitates the department's processing of requests for reimbursement. The Medicare reimbursement rates are widely known and available to providers of medical equipment and supplies. Using this method should enhance a provider's knowledge as to what the medical assistance reimbursement will be for a particular item.

It is necessary to establish a payment methodology for equipment for which Medicare has yet to establish a reimbursement amount. This may occur either because it is an item that Medicare does not cover or because the item is so new that Medicare as not yet determined a reasonable charge for it. In this case, the department proposes to tie the reimbursement to the 50th percentile of the usual and customary charges submitted to the department for the item or medical supply in the previous calendar year, minus 20 percent. This methodolgy is reasonable because of the availability of the usual and customary charges for all similar items paid for by medical assistance during a calendar year. Taking the 50th percentile of charges submitted by the providers ensures that the department determines the average of such submitted charges and thereby is not penalizing those providers who may submit charges higher or lower than the median. Taking the 50th percentile also insures that the department is not providing more reimbursement for an item of medical equipment or a supply than the average cost for the item amongst providers of the item. The mark-up or profit margin for providers of medical supplies and equipment is 40 percent. By reducing the 50th percentile of the usual and customary charges by 20 percent, the department is providing a profit of 20 percent to the provider. The reduction of the usual and customary 50th percentile by 20 percent is reasonable because most medical assistance services are tied to the 50th percentile of the usual and customary for 1982. (See Minnesota Statutes, section 256.967.) The increase in the consumer price index urban medical (CPIU-Medical) for the period from 1/1/83 to the present has been 31 percent. The corresponding increase in

the consumer price index-urban for the Minneapolis-St. Paul area is 11.85 percent. The blended rate of increase is about 21.4 percent. Thus, the 20 percent figure approximates the percentage reduction applied to many other services covered by medical assistance and general assistance medical care. Providers who seek reimbursement in an amount that is less than the 50th percentile will of course receive that amount instead. This lesser amount is reasonable because sound economic practice dictates that a consumer should not pay more for a service than the value assigned by the producer of the service.

It is reasonable to provide a reimbursement mechanism for an item of medical equipment or a medical supply for which there is no information about usual and customary charges in the previous calendar year. Such an item might be new and not previously covered under medical assistance. Thus, there would not have been an opportunity to develop a profile of usual and customary charges for the item. In these cases, the department will use the manufacturer's suggested retail price in lieu of the 50th percentile of the usual and customary price. In addition this price will be reduced by 20 percent, using the same rationale as discussed above. Employing this methodology is reasonable as it insures consistency and efficiency in administration. The manufacturer's suggested retail price also is a price that is easily verifiable and accessible to the department. Using this methodology ensures consistent and equal treatment of all providers of the service.

T. Payments for prosthetic and orthotic devices are not set by legislation. Therefore, this item is necessary to specify how payments are set for these services so that affected persons are informed. It is reasonable to allow one choice of payment to be the provider's submitted charge as this is the value assigned by the provider to his services or product. When the provider's submitted charge is the lower of the two rates in this item, it is reasonable that the medical assistance payment be the lower amount because sound economic practice dictates that a consumer should not pay more for a product than the value assigned by the producer of the product. It is reasonable that the other choice of payment rate is the fee from the Medicare schedule because the Medicare fee schedule is derived by Medicare from average charges submitted by providers of comparable services. Finally, when the fee from the Medicare schedule is the lower of the two rates in this item, using the Medicare fee as the medical assistance rate is reasonable because choosing the lower amount is consistent with the requirement of Minnesota Statutes, section 256B.04, subd. 2 of operating the medical assistance program in an efficient and economical manner. It also is consistent with the requirement of Minnesota Statutes, section 256B.04, subd.15 of safeguarding against excess payments.

U. This item is necessary to specify payment rates for services that are not included in one of the items A to T. It is reasonable to require the payment rate to be consistent with statutes, federal regulations, and state rules because the department must implement the statutes and regulations that govern the medical assistance program. However, the payment rate for a particular health service may not be set by statutes or regulations. Thus, it is necessary to specify how the rate for such a service is determined in order to set a standard and inform affected

persons. In this event, the use of competitive bidding is reasonable because competitive bidding that is based on fair and open competition allows the market place to determine the lowest price a qualified provider is willing to accept for his service or product and, thereby, results in the department obtaining the service at the lowest possible price. The use of competitive bidding, thus, is consistent with the requirement of Minnesota Statutes, section 256B.04, subd.15 of safeguarding against excess payments. It also is consistent with the requirement of Minnesota Statutes, section 256B.04, subd.2 of operating the medical assistance program in an efficient and economical manner. However, there may be circumstances in which competitve bids can not be obtained because, for example, there is only one provider of a particular service, only one provider can or is willing to meet the standards required by these rules, or only one provider bids on the requested service. In such circumstances, negotiating a rate with the provider is reasonable because the negotiation process provides an opportunity for each side to state its terms and reach a settlement that is acceptable to both.

9505.0450 BILLING PROCEDURES; GENERAL

Subpart 1. Billing for usual and customary fee. This subpart is necessary to establish the standard for billing medical assistance. It is consistent with the present practice of the department as specified in part 9500.1080, subpart 2. Billing for service after the service is given to or received by the customer is a standard business practice. Monitoring whether a recipient actually sought and received a service for which payment has been made in advance would be difficult, would possibly increase the reporting burden on the provider, and would be inconsistent with the requirement of Minnesota Statutes, section 256B.04, subdivision 2 to carry out the program in an effective and efficient manner. Finally, submitting a bill for services that have not been provided to a recipient is a fraudulent claim subject to the provisions cited in part 9505.0460. The definition of the term "usual and customary" is found in part 9505.0175, subpart 49.

Subp. 2. Time requirements for claim submission. This subpart is necessary to establish a standard concerning timeliness for submission of claims. It is consistent with 42 CFR 447.45 (d) (1) in regard to the 12-month requirement. A time limit for requesting an adjustment is reasonable because the department needs to be able to close its records on a claim. Customary business practice is to promptly notify the payer by rejecting the payment and requesting an adjustment. This item only requires the provider to request the adjustment and allows a period of six months after the payment date. The period of time is reasonable as it balances the need of the department to close its files in a timely manner against the right of the provider to request an adjustment. Furthermore, it is reasonable as subpart 3 does provide exceptions for circumstances beyond the provider's control.

Subp. 3. Retroactive billing. As provided in part 9505.0110, subpart 1, retroactive eligibility for medical assistance is available for three calendar months before the month of application if an individual satisfies the requirements of parts 9505.0010 to 9505.0150. Thus, if a person who is determined retroactively eligible received covered services during the three month period of retroactive eligibility, medical assistance will pay for the services to the extent of the person's eligibility under parts 9505.0010 to 9505.0150. This subpart is necessary to inform providers who have given covered services to retroactively eligible persons about the effect of the retroactivity on their billing procedures. It is reasonable to permit the provider to bill the department the provider's usual and customary charge so that the provider's claim is handled in the same manner as claims not involving services to a retroactively eligible person. This action is consistent with Minnesota Statutes, section 256B.04, subd. 2. which requires the department to administer medical assistance in an impartial manner. Furthermore, it is reasonable to require the provider to reimburse the recipient who paid the provider's usual and customary charge because such reimbursement will prevent the provider from receiving double payment for a covered service and also protect the right of the retroactively eligible person to receive medical assistance in meeting the cost of a covered service.

Subp. 4. Exceptions to time requirements. Although subpart 2 establishes timeliness standards for submitting claims, circumstances beyond the provider's control may make it impossible for the provider to comply with

subpart 2. This subpart is necessary to specify what these circumstances are so that providers will be eligible to submit claims for payment.
A. This item is consistent with 42 CFR 447.45 (d)(4)(ii).
B. This item is consistent with 42 CFR 447.45 (d) (4) (iv) which permits the department to make payments at any time in accordance with a court order. It is reasonable to require the claim for payment to be submitted within six months of the court order as this time limitation is consistent with the time period in which to request an adjustment under subpart 2.
C. and D. The department may erroneously reject a claim or a local agency may provide inaccurate or incomplete information. Therefore, it is necessary to provide a way to correct these errors which are not the fault of the provider. The department annually processes about eight million provider claims. It is not reasonable, and is certainly not cost effective, to expect the department to be able to pull information from the system once the time limit for submitting a claim is past. Furthermore it is a standard business practice to require the person requesting correction of an error to provide all the information necessary to make the correction. The information specified is reasonable as it is information that the provider has and the department does not. In item C, it is reasonable to require the local agency's verification of the recipient's eligibility in order to ensure compliance with Minnesota Statutes, section 256B.02, subd.8. The six month time limit is consistent with the time period to request an adjustment under subpart 2.

Subp. 5. Format of claim. The department needs certain essential pieces of information in order to accurately process a claim. This subpart is necessary to specify the required information. The items listed permit the department to use a computer billing system and thereby promote operation of the program in an efficient and economical manner. Some procedures and services such as surgeries and medical supplies vary sufficiently from routine so that a payment rate can not be provided unless there is full disclosure of records and reports. Therefore, the item is reasonable because it provides a way to make payments consistent with these rules and the requirement of Minnesota Statutes, section 256B.04, subdivision 2 to carry out the program in an efficient, economical, and impartial manner. Requiring the provider to include the information about a required prior authorization or second surgical opinion is reasonable to coordinate rules governing medical assistance services and inform affected persons of all requirements.

Sub. 6. Repeated submission of non-processible claims. Minnesota Statutes, section 256B.04, subd. 2 requires the department to carry out the medical assistance program in an efficient, economic and impartial manner and to the end that the program is uniformly administered throughout the state. As stated in the SNR for subpart 5, one method used by the department to carry out the statutory mandate is to specify the essential pieces of information needed to process a claim. The required information includes the data and documentation necessary to obtain a required prior authorization, approval of a surgical procedure requiring a second or third opinion, and hospital admission certification. It is the experience of the department that a few providers have a pattern of repeatedly submitting incomplete information so that the department can not process the claims without obtaining the required information. The department must repeatedly notify these providers that additional

information is required in order to process the claims. In doing so, the department is spending medical assistance funds and, thus, is being preventive from carrying out the medical assistance program in the efficient and effective manner required by statute. Therefore, this subpart is necessary to inform providers of the consequences of repeated submission of non-processible claims and to encourage compliance with these rules. Identifying such repeated behavior as abuse and making it subject to sanction is reasonable in order to conserve medical assistance funds as required by Minnesota Statutes, section 256B.04, subd. 2. It also is consistent with Minnesota Statutes, section 256B.04, subd. 10.

Subp. 7. Direct billing by provider. This subpart is necessary to inform affected persons about a billing procedure. Medical assistance is a payer of last resort. Therefore, it is necessary and reasonable to provide an exception from direct billing for circumstances where the recipient has third party coverage (part 9505.0070) or Medicare coverage (part 9505.0440). This subpart is consistent with 42 CFR 447.10.

9505.0455 BILLING PROCEDURE; BUSINESS AGENT

Some providers employ a business agent who handles the administrative and financial details connected with the provider's services. This part is necessary to inform affected persons of the conditions under which a provider's business agent may submit the provider's claims for payment. This part is consistent with 42 CFR 447.10 (f). This part also is consistent with 42 CFR 447.10 (h) which prohibits payment "to or through a factor, either directly or by power of attorney." Compliance with the cited regulations is a condition of obtaining federal financial participation as required by Minnesota Statutes, section 256B.04, subd. 4. The requirements are reasonable because they are related to the actual bill processing cost and thus comply with the requirement of Minnesota Statutes, section 256B.04, subdivision 15 in regard to safeguarding against excess payments.

9505.0460 CONSEQUENCES OF A FALSE CLAIM

A provider who wrongfully obtains medical assistance payment is subject to certain consequences which are set out in the federal law, state statutes and rules cited in this part. This part is necessary and reasonable to coordinate the rules and laws which specify the consequences and thereby to inform affected persons.

9505.0465 RECOVERY OF PAYMENT TO PROVIDER

Subpart 1. Department obligations to recover payment. Minnesota Statutes, section 256B.064 authorizes the commissioner to seek monetary recovery of medical assistance payments from any provider who has been determined ineligible because of certain specified conduct. This subpart is necessary to set the standard and inform affected persons. This subpart is consistent with parts 9505.1760 to 9505.2150.
A. This item is consistent with Minnesota Statutes, section 256B.064, subdivision 1a in regard to intentional error on the part of the provider for the purpose of obtaining greater compensation than that to which the provider is legally entitled. A payment that is obtained through the provider's unintentional error is a payment outside of the scope of the State plan. The provider is not entitled to such a payment and, if the federal audit disclosed it, the federal authorities would seek to recover the federal portion of such a payment from the state. Therefore, it is reasonable that the department recover the payment resulting from the provider's unintentional error as the department should have a right to recover the amount the federal government holds it responsible for. Such a recovery is not a punitive action but merely the correction of an error.
B. Authorization control requirements, prior authorization, and billing procedures are conditions for medical assistance payment eligibility. For example, under prior authorization, the department reviews the circumstances of each request to determine whether the procedure is medically necessary. Failure to comply negates the payment. The payment therefore is outside of the State plan. It is reasonable therefore to seek to recover such a payment as the payment was improperly authorized.
C. Medical assistance is the payer of last resort. A provider may bill medical assistance only for the difference between the amount of the medical assistance payment schedule and the amount paid by a third party payer. A provider who fails to properly report third-party payments obtains more money than he is entitled to. Therefore, it is reasonable to permit monetary recovery as the excess payment lies outside the State plan.
D. This item is consistent with Minnesota Statutes, section 256B.064, subdivision 1a and with parts 9505.1760 to 9505.2150. Its inclusion is reasonable to coordinate rules governing medical assistance payments and to inform affected persons.

Subp. 2. Methods of monetary recovery. This item is necessary to specify how to recover money obtained fraudulently or erroneously as specified in subpart 1. The subpart is consistent with Minnesota Statutes, section 256B.064, subdivision 1c in regard to recovery through the withholding of current payments if money is currently owed to the provider for other covered services and in regard to assessing and recovering payment, that is demanding payment, from the provider if money is not owed nor expected to be owed to the provider. Furthermore, the item is reasonable because it coordinates this proposed part with part 9505.1950, which also is a department rule related to monetary recovery.

Subp. 3. Interest charges on monetary recovery. The department incurs administrative expenses when it acts to recover money to which a provider is not entitled. Before the recovery occurs, the provider has had the use of the money while the state acting on behalf of the taxpayer has not. It is a common business practice to require a person who owes money to a creditor to pay interest if the amount owed results from an error or fraud of the debtor. Thus, the Minnesota Department of Revenue assesses interest on the money owed by a taxpayer who incorrectly reported his tax obligation. This item is reasonable because it is consistent with common business and government practice. Using the interest rate established by the Department of Revenue pursuant to statute is reasonable as the circumstances are similar, namely, money is owed to a state agency as a result of the debtor's error or fraud.

9505.0470 PROVIDER RESPONSIBILITY FOR BILLING PROCEDURE.

This part establishes the responsibility of the provider for all medical assistance claims for payment for health services furnished by the provider. Minnesota Statutes, section 256B.04, subd. 10 requires the department to establish procedures for presentment of claims and for investigation of facts presented by a vendor of medical care. This part is consistent with statute and is necessary to clarify the provider's responsibility. Placing the burden of responsibility on the provider is consistent with 42 CFR 455.18 which requires the use of claim forms carrying the provider's signed statement attesting to the truth, accuracy, and completeness of the information on the form and carrying a warning concerning prosecution of false claims. It is also consistent with 42 CFR 455.19 which permits a similar warning statement signed by the provider to be used on checks or warrants payable to the provider. The part is reasonable because the provider is the entity that signed the contract with the department concerning the provision of health care services and is the entity that will receive the benefits of payments pursuant to the contract. Likewise, holding the provider responsible for the claims for services furnished by his or her designee is reasonable because the provider is the entity who signed the contract with the department and is, thereby, responsible for fulfilling the terms and conditions of the contract. Parts 9505.1750 to 9505.2150 specify the procedures for identification and investigation of false statements or misrepresentation of material facts, presentment of false or duplicate claims, or fraud by a provider. Citation of these parts is reasonable because it informs the affected parties, the providers.

9505.0475 SUSPENSION OF PROVIDER CONVICTED OF CRIME RELATED TO MEDICARE OR MEDICAID.

Subpart 1. Crime related to Medicare. 42 CFR 455.208 denies federal financial participation in payments for services furnished by a Medicaid provider while the provider is excluded or terminated from Medicare or otherwise sanctioned because of fraud or abuse under the Medicare program under 42 CFR 420, subpart B and 42 CFR 455, subpart C. Requirements concerning notice of proposed exclusion or termination for fraud, abuse, or conviction of program-related crime and notice of and duration of exclusion or termination are also established in 42 CFR 420, subpart B and 42 CFR 455, subpart C. This part is consistent with Minnesota Statutes, section 256B.04, subd. 4, which requires the department to cooperate with the federal government as necessary to qualify for federal aid. The subpart is reasonable because it informs affected persons and encourages their compliance with the regulations and rules of the medical assistance program.

Subp. 2. Crime related to medical assistance. 42 CFR 455, subpart C denies federal financial participation in payments for services furnished by a Medicaid provider who has been determined guilty of fraud and abuse or convicted of a crime related to the medical assistance program. Requirements concerning the effective date and period of suspension are found in 42 CFR 455.211 and 42 CFR 455.230. The subpart is consistent with the cited regulations and also with Minnesota Statutes, section 256B.04, subd. 4 concerning cooperation with the federal government as necessary to obtain federal financial participation. The inclusion of the subpart is reasonable because it informs affected persons.

Subp. 3. Definition of "convicted." The term "convicted" is used in this part to set a standard that significantly affects the due process rights of providers. Therefore, a definition is necessary to clarify its meaning. 42 CFR 455.2 defines "Conviction" or "Convicted" as " a judgment of conviction (that) has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending." The subpart is consistent with the federal regulation.

Subp. 4. Suspension after conviction of person with ownership interest. 42 CFR 455.106 (c) permits the department to "refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider" is convicted of a criminal offense related to that person's involvement in a program established under Medicaid. A person who has an ownership or control interest in a provider is able to significantly influence decisions and actions of the provider. Implementation of the regulation permits the state to safeguard the interest of the public, including recipients and other providers, against providers who may be unduly influenced by persons convicted of crimes related to medical assistance. At the same time, it is necessary to protect the provider's rights and thus enable the provider's continued participation if the provider can reasonably be assumed as no longer subject to the influence of the convicted person. This subpart is consistent with 42 CFR 455, subparts B and C. It is necessary and reasonable because it safeguards the public interest, informs affected persons, and affords providers due process protection.

Subp. 5. Notice of suspension.
and
Subp. 6. Right to appeal. Minnesota Statutes, section 256B.064, subd.2, 42 CFR 455.205, and 42 CFR 455.206 specify requirements concerning the notice of suspension sent to the provider and the provider's right to appeal. These subparts are necessary to inform affected persons of the requirements and their rights. They are consistent with statute and federal regulations. They also are consistent with parts 9505.1750 to 9505.2150 which set the standards for the surveillance and utilization review program under medical assistance. Minnesota Statutes, section 256B.064,subd. 2 provides an opportunity for a suspended provider to have a hearing under Minnesota Statutes, chapter 14. Minnesota Statutes, sections 14.48 to 14.56 specify the procedures for contested case hearings conducted by administrative law judges. The hearing procedures are consistent with statute.

9500.1070 SERVICES COVERED BY MEDICAL ASSISTANCE

Part 9500.1070 is the existing rule that establishes the parameters for all health care services that are eligible for medical assistance payment. The major portion of part 9505.1070 will be repealed when parts 9505.0170 to 9505.0475 become effective. However, because proposed parts 9505.0170 to 9505.0475 do not address all of the services covered within part 9500.1070, it is necessary to retain the provisions of part 9500.1070 for those services that are not included within parts 9505.0170 to 9505.0475 in order to continue their eligibility for medical assistance payment. Therefore, it is necessary to amend part 9500.1070 in order to to continue the medical assistance eligibility of certain services. The subparts that must be retained are: the general provision on covered services in subpart 1; physician services as specified in subitem 5 of item A and B of subpart 4 (related to psychiatric services); services of other licensed practitioners as specified in item D (psychological services) of subpart 6; subpart 12, rehabilitative and therapeutic services; subpart 13, rehabilitative and therapeutic services in long-term care facilities; subpart 14, speech pathology, audiology, and physical therapy provided by independent practitioners; subpart 15, rehabilitation agencies; and subpart 23, mental health canters.
See also the REPEALER for a complete listing of the parts and subparts which will be repealed if parts 9505.0170 to 9505.0475 is adopted.

The department will not present expert witnesses to testify concerning the provisions of these proposed rules on behalf of the department.

February 26, 1987

Vicki Sleeper

VICKI SLEEPER, for
SANDRA GARDEBRING, Commissioner
Department of Human Services