8

STATE OF MINNESOTA

DEPARTMENT OF PUBLIC WELFARE

IN THE MATTER OF THE PROPOSED RULE OF THE DEPARTMENT OF PUBLIC WELFARE GOVERNING THE SURVEILLANCE AND UTILIZATION REVIEW PROGRAM, 12 MCAR § 2.064 (RULE 64)

STATEMENT OF NEED AND REASONABLENESS

The above captioned rule is a newly proposed rule of the Department of Public Welfare ("DPW" or "the state agency"). The statutory authority of DPW to promulgate this rule is contained in Minn. Laws 1980 § 2, 3, 9 which specify that the Commissioner establish by rule general criteria and procedures for the identification and investigation of suspected fraud, theft, and abuse by vendors of medical care (providers) and by eligible individuals receiving medical care (recipients) in the Minnesota Medical Assistance program (MA), the General Assistance Medical Care program (GAMC), and the Catastrophic Health Expense Protection Program (CHEPP).

The need to initiate the administrative rule-making process for the State's Surveillance and Utilization Review activity is not limited solely to the above noted legislative directives. It is through proposing these rules, and the holding of the public hearing thereon, that the public, all interested parties, and all affected parties are afforded the opportunity to comment upon the procedures and requirements used by the state agency in carrying out the legislative mandates.

The proposed rules, designated as 12 MCAR 2.064, are hereby affirmatively presented by DPW in accordance with the provisions of the Minnesota Administrative Procedures Act. Minn. Stat. § 15.0412 and state Rule Hearing Procedures 9 MCAR § 2.101.

Agency Exh. No. 8
File No. DPW-81-010-JL
Date 1-14-81

A. INTRODUCTION

Sections 2.064 A.1 and 2. set forth the scope and purpose of the proposed rule and give cross references to related laws regarding the State's fraud and abuse control activities in publically funded health care programs, i.e., Medical AssistanceA (medicaid), General Assistance Medical Care - GAMC, and Catastrophic Health Expense Protection Program - CHEPP. The reasonableness and necessity of the proposed rule should be viewed in light of both federal and state mandate for the detection of suspected fraud and abuse, and the determination of medical necessity of health care reimbursed by the programs. See [1977] U.S. Code Cong. & Ad. News 3039, Minn. Laws 1980, ch. 349.

The Medical Assistance program in Minnesota is a joint federal-state program to implement the provisions of Title XIX of the Social Security Act by providing for the medical needs of low income or disabled persons (42 U.S.C. § 1396a). The statutory authority for rule is thus derived from both federal and state law. Specifically, federal regulation at 42 C.F.R. § 456.3 requires that the state medicaid agency (DPW) must implement a statewide surveillance program to "safeguard against unnecessary or inappropriate use of Medicaid services and against excess payments". See also 42 C.F.R. § 455.10. Correspondingly, state law requires the Commissioner to establish rules for the identification and investigation of suspected medical assistance fraud, theft, or abuse (Minn. Laws 1980, ch. 349, § 3.) and to investigate whether or not the medical care was medically necessary (Minn. Laws 1980, ch. 349, § 7.).

Justification for the proposed rule is further supported by the provisions of Minn. Stat. § 256B.04 subd. 4, which states, in part, that the state agency 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". Given that

continued federal financial participation is contingent upon an effective surveillance and utilization review activity (42 U.S.C. 1396a) it is reasonable for the state agency to promulgate a rule which will achieve compliance with federal and state law.

The statutory authority to promulgate rules governing the identification and investigation of suspected fraud, theft or abuse in the CHEPP and GAMC programs are contained in Minn. Laws 1980, ch. 349, § 2, 9 respectively. Moreover, 12 M.C.A.R. § 2.0581, which governs administration of the GAMC program specifies that local agencies choosing to have the centralized disbursement system process their GAMC claims agree to "accept all reimbursement standards and audits of the system which are applied to Title XIX payments" (12 MCAR § 2.058 E.5.b.(1)), and to "not allow payments of medical provider claims which exceed the fee schedules established by the Commissioner for the Medical Assistance Program" (12 MCAR § 2.058.E.8.). Similarly, the CHEPP rule requires use of MA enrollment forms and provider agreements for CHEPP providers and specifies that a provider's acceptance of CHEPP payments "shall be deemed to extend the provider's agreement with the Medical Assistance Program to cover services to CHEPP beneficiaries" (12 MCAR § 2.060 D.5.). The CHEPP rule further provides that "procedures used by the Minnesota Medical Assistance Program for review of the appropriateness or medical necessity of health services shall be used for the review of claims for CHEPP payments" (12 MCAR § 2.060 D.9.).

Section 2.064 A.3. sets forth that DPW will issue instructional material to assist in the interpretation of this rule, as well as other program requirements related publically funded health care. It is acknowledged that policy material does not have the force of law.

Section 2.064. A.4 states that the provisions of the rule are binding on all providers, recipients, and state and local welfare agencies participating in, or administering the programs.

B. DEFINITIONS

The agency will affirmatively present the need for and reasonableness of proposed definitions, except that definitions which are solely for the purpose of identification, e.g., "Commissioner", shall be presumed both needed and reasonable without further justification.

1. The term "abuse" is defined as to distinguish it from fraud and theft. The latter terms are defined by case law and statutes, and are characterized by intentional wrongdoings. The definition of abuse as proposed is both needed and reasonable in that it specifies practices which are unacceptable or inappropriate under the programs even if they are committed unintentionally. The House report on the Medicare-Medicaid Antifraud and Abuse Amendments recognizes the need to regulate such abuse. "Program abuse is less clearly defined [than fraud] and includes activity wherein providers, practitioners, and suppliers of services operate in a manner inconsistent with accepted, sound medical or business practices resulting in excessive and unreasonable financial cost to either medicare or medicaid." [1977] U.S. Code Cong. & Ad. News 3039, 3050. Errors can and do routinely occur in the billing practices of health care providers. However, isolated or occasional errors or irregularities will not be sanctionable; abuse is defined as repeated conduct.

The rule sets forth ten conditions or practices which represent a departure from acceptable billing practices for medicaid services. Items (a.)-(c). represent billing procedures which are counter to billing procedures set forth in the handbook and materials supplied to each provider. The handbooks clearly detail the necessary data for a billing invoice, the reference source which contains the appropriate procedure codes to be used and any service limitations applicable to a particular provider category. An identifiable series of claims with such repeated inconsistencies is reasonably considered inappropriate use of the medicaid services.

Item (d.) establishes that failure to develop and maintain records as provided by 12 MCAR § 2.047D.4.c., 42 C.F.R. § 431.107, and the provider agreement is in direct conflict with the conditions of participation for health care providers. Failure to document health care in the record has the effect of negating the agency's responsibility to determine the extent of services actually provided program recipients.

Item (e.) indicates that generally accepted accounting principles must be used unless otherwise provided. This provision is in keeping with the requirements established for nursing home providers under the Medical Assistance program, as set forth at 12 MCAR § 2.049C.1.b., and is reasonably extended to other health care providers.

Item (f.) establishes that health care billed to the programs that is not within the generally accepted scope of the providers' practice or specialty is abusive. Federal regulations at 42 C.F.R. §§ 440.50 and 440.60 clearly indicate that services paid by the programs must be within the scope of practice of the provider. It is reasonable that the state agency considers as inappropriate and abusive, the billing of service which the provider is not qualified to provide.

Item (g.) defines as abusive the practice of inflating the quantity of services necessary to adequately treat the presenting condition. The agency acknowledges that health care requested by a recipient may not fully treat the underlying health problem, and it is not the intent of this rule to address that situation. The rule is more reasonably concerned with all services which are in excess of generally accepted practice for a particular health care condition. The medicare system treats such unnecessary services as abusive. 2 CCH Medicare-Medicaid Guide ¶ 13,895.23.

Items (h.) - (j) identify as abusive recipient practices which result in the programs paying for health care to which the recipient is not entitled or which is greater than that to which he/she is entitled. This interpretation is consistent with the provisions of statute at Minn. Stat. § 256.98 governing assistance wrongfully obtained by a recipient.

2. The term "Commissioner" refers to the Commissioner of Public Welfare or his designated agent.

3. For the purpose of the rule, the term "health care" has been broadly defined so as to encompass all services,equipment, and supplies provided for a program recipient and paid for by the programs. The term "health" has been used rather than "medical" to acknowledge the participation of the wide range of vendors as defined by Minn. Stat. § 256B.02, subd. 7.

4. The phrase "health care record" is used to describe those documents reasonably related to the care or services provided for a program recipient, by a provider other than a medical doctor (M.D.). The distinction between "health care record" and "medical record" is again made to acknowledge those providers whose services are not medical in the restrictive, non-generic sense of the word. The concept of a record to document the nature, extent, and evidence of the medical necessity of care is consistent with the provision of

12 MCAR § 2.047 D.4.c. which states that providers participating in the MA program shall "maintain for at least five (5) years, in the manner prescribed by DPW in accordance with applicable federal regulations, medical and financial records fully disclosing the extent of services provided, the medical necessity for such service and payment claimed under the MA program". Specifying that the health care record must document the nature, extent, and evidence of the medical necessity of health care is consistent with Minn. Laws 1980, ch. 349, §§ 2, 3, 9. These statutes place upon the state agency the burden of identifying and investigating the "presentment of false or duplicate claims, presentment of claims for services not medically necessary, or false statement or representation of material facts". It is only through documentation in the health care record that the agency can determine if the claim for reimbursement submitted by a provider is indeed legitimate.

5. The phrase "Medicaid Management Information System" or MMIS represents a computer system implemented in Minnesota to administer the centralized disbursement system within DPW. Minn. Stat. § 256B.041. This system is an internal management tool which enables the state agency to receive, process, pay and monitor all invoices submitted for reimbursement by eligible providers. Utilization of a centralized, automated, processing system enables Minnesota to qualify for enhanced federal financial participation for costs related to the administration of the Medicaid program.

6. The phraise "medical record" is used to describe those documents reasonably related to the care or services provided by a program recipient by a medical doctor (M.D.) or by ancillary personnel under the authority of the M.D. The distinction between "medical record" vs. "health care record" is made in this rule to avoid semantic conflict and to ensure that the records of all providers are encompassed within the scope of this rule. The need and reasonableness of the definition follows the justification presented above for "health care records".

7. DPW is authorized to review medical necessity by Minn. Laws 1980, ch. 349, §§ 2, 3, 9 which all state in part that the Commissioner shall investigate the "presentment of false claims for services not medically necessary". The requirement that "medically necessary" care be within the generally accepted standards of practice of the provider is consistent with the concept of care as set forth in federal and state regulations. Specifically, at 42 C.F.R. §§ 440.50, 440.60 and 12 MCAR § 2.047 F.1., care and services eligible for reimbursement under the MA program are those provided "within the scope of practice" of the particular vendor of care. The categories of medically necessary care, set forth in items a. - f. of the definition, can be separated into two functional classifications. Items b., c. and d. are representative of those conditions for which care is necessary and essential to maintain the health and well-being of the recipient. These items represent care which is provided in response to a condition or ailment about which the provider must make a professional judgment regarding the course of that condition. The second classification of items a, e, and f are representative of services which are considered to be medically necessary for surveillance and utilization review purposes, but not in the literal, medical sense. Items a., e. and f. do however, represent services, along with items b., c. and d., which are reimbursable under the programs as set forth at 42 C.F.R. § 440, subpart A and 12 MCAR § 2.047 E., and as such are within the scope of the agency's investigatory responsibility. Inclusion of item a., e., and f are therefore reasonable in this definition to enable the agency to investigate claims which are not medically necessary, i.e. not covered.

8. The term "pattern" is reasonably defined as an "identifiable series of events or activities" relating to the presentment of claims and to the making of false statements of material facts by providers. In the rule, the term is used in the definition of abuse and in the section dealing with grounds for

administrative sanctions. In both instances, the term places upon the agency the burden of proving that a particular event or activity is one of a series of occurrences. Series means a "group or number of related or smaller. . .things or events (Webster's New World Dictionary, 2nd edition). This distinction of related group occurrences is important in that a single or occasional false claim should not be considered in terms of abuse or grounds for administrative sanction, but rather as a separate, isolated incidence. The burden of proving a relationship between false claims or false statements of material facts is consistent with the provisions of Minn. Laws 1980, ch. 349, §§ 3, 6. The former authorizes the Commissioner to establish procedures for identification and investigation of the presentment of false claims or material facts, while the latter requires that a pattern of such conduct be shown prior to imposition of an administrative sanction. The proposed definition of the term "pattern" reasonably describes the concept of relatedness and thereby affords the appropriate degree of protection under the law.

9. "Programs" identifies the publically funded health care systems, i.e. MA, GAMC, and CHEPP, which are within the purview of the state agency's fraud and abuse control activity.

10. The term "provider" relates specifically to all vendors of services, equipment, or supplies who have entered into agreement with, and accept payment from, any of the programs. Minn. Stat. § 256B.02, subd. 7.

11. "Recipient" identifies individuals who have applied to and established their eligibility to receive health care paid for by the programs. This definition includes individuals who have submitted an application, those currently eligible and those previously eligible but no longer participating in the programs. The condition of eligibility for MA, GAMC and CHEPP are those set forth in 12 MCAR §§2.047, 2.058 and 2.060 respectively.

12. The term "records" as used in the rule references all medical, health care, and financial records which reflect costs billed to the programs. DPW is authorized to review such records in order to verify the propriety of the claim and the medical necessity of care provided. Minn. Laws 1980, ch. 349, §§ 1, 7, 10. Each provider has signed a "provider agreement" with DPW agreeing to furnish DPW information concerning submitted claims. 42 C.F.R. § 431.107.

13. "State agency" identifies the Minnesota Department of Public Welfare as the designated agency responsible for the administration of the programs.

14. The phrase "Surveillance and Utilization Review" or SUR identifies that activity of the state agency responsible for the control of fraud and abuse in Minnesota's publically funded health care program. Specifically, 42 C.F.R. § 455.13 provides that "the Medicaid agency must have (a) methods and criteria for identifying suspected fraud cases; (b) methods for investigating these cases. . .". In addition, 42 C.F.R. § 456.23, require that the state Medicaid agency "have a post payment review process that -

(a) allows state personnel to develop and review -

(1) recipient utilization profiles;

(2) provider service profiles; and

(3) exception criteria; and

(b) identifies exceptions so that the agency can correct practices of recipients and providers."

DPW is permitted to review medical records for the purpose of identifying or investigating suspected fraud and abuse. Minn. Laws 1980, ch. 349, §§ 2, 7, 10. Similarly, 12 MCAR § 2.047D.10.a(2) establishes a post-payment review process responsible for activities cited above from 42. C.F.R. § 456.23.

The definition of "Surveillance and Utilization Review", as well as later provisions of the rule, specifically exclude the activities of the utilization control unit (defined in #19.) of the state agency. The utilization control (UC) unit, while organizationally related to SUR is functionally distinct and should not fall within the scope of the rule. The utilization control program monitors the effectiveness of the state health agency (Minnesota Department of Health) in its efforts to review the appropriateness and effectiveness of Medicaid services provided in long term care facilities. It is required by federal and state regulations. 42 C.F.R. § 456, 12 MCAR § 2.047 D.10. The UC program has separate line staff from the SUR unit and does not investigate fraud and abuse. Information gathered by UC staff is not used to seek monetary recoveries or administrative sanctions and therefore Minn. Laws 1980, ch. 349, § 7 does not apply to UC functions.

15. "Suspending participation" as a form of sanction is authorized by Minn. Laws 1980, ch. 349, § 6. The concept of suspension for a stated period of time is consistent with common usage of the term, i.e., stop temporarily.

16. The phrase "suspension of payments" can reasonably be defined as stoppage of any or all payments based upon the statutory authorization noted in Minn. Laws 1980, ch. 349, § 5. This statute allows the Commissioner to "suspend or reduce payment to a vendor of medical care, . . .prior to a hearing if in the Commissioner's opinion that action is necessary to protect the public welfare and the interests of the program". Further, the Commissioner is authorized by Minn. Laws 1980, ch. 349, § 6 to suspend or withhold payments based upon the outcome of an investigation. Given common usage of the term suspension, defined in Webster's New World Dictionary 2nd edition as "temporary stoppage of payments", and the Commissioner's statutory authority to suspend payments, this definition is reasonable.

17. Terminating participation" as a form of sanction is authorized by Minn. Laws 1980, ch. 349, § 6. The concept of permanent exclusion is consistent with common usage of the term, "terminate", i.e., to bring to an end.

18. Utilization control" refers to the UC program described in the definition of Surveillance and Utilization Review above. It is organizationally related to SUR, but functionally distinct.

19. The withholding of payments as another form of monetary recovery is authorized in the provision of Minn. Laws 1980, ch. 349, § 6. The act of reducing or adjusting payments for the purpose of offsetting overpayments is implicit in the language which allows the Commissioner to assess and recover monies erroneously paid.

C. RECORDS

1. The provisions of this section are intended to set forth the record keeping requirements of providers participating in the programs, as well as the state agency's responsibilities regarding the use and access of such records.

a. The state agency is permitted access to records related to the health care provided program recipients. Minn. Laws 1980, ch. 349, § 1, 8, 10. Providers are required to develope and maintain records to fully disclose the extent of service provided. 42 C.F.R. § 431.107 and 12 MCAR § 2.047D.4.C.(1). Further, at Minn. Stat. § 256B.27 Subd. 1 the Commissioner may require any reports, information and audits of medical vendors which he deems necessary. There is a contractual, as well as statutory, basis for providers to to maintain records. The contract which all providers sign obligates them "to keep such records as are necessary fully to disclose the extent of the services provided. . .".

b. The requirement that a medical or health care record be legible to at least those individuals providing care is inherent in the concept of the medical or health care record as a dynamic, as well as historical, account of health care. The significance of a

legible record is at least two- fold. The record is first and foremost the document which contains information specific to the health of the recipient and should be legible to ensure continuity of care. Second, a legible record must be available if the agency is to interpret record content pursuant to Minn. Laws 1980, Ch. 349, § 7 to determine if the vendor has submitted a claim which the vendor knows is false in whole or in part or if the health care was medically necessary. The concept of legibility in the medical record is not unprecedented in regulations regarding health care paid by the programs. Federal regulations at 42 C.F.R § 442.499(b) require that any individual who makes an entry into the record of an ICF/MR resident "must make it legibly, date it, and sign it". In addition, at least one other state, Pennsylvania, has the condition of legibility established in rule at § 1101.43e. of the Pennsylvania Medical Assistance Regulations.

c. This provision of the rule designates those items which must be entered into the medical or health care record if program funds are paid for health care.

(1) It is not unreasonable to assume that each page of a record should identify the patient to ensure that all information pertains to recipient in question. This requirement is appropriate both for the continuity of care of the patient and for the agency's investigatory needs. Federal regulations at 42 C.F.R. § 442.202 require that skilled nursing facilities meet the medical standards at 405.1132 which require that the record contain sufficient information as to identify the patient clearly.

(2) All entries into the record represent segments of information, which, when combined, form a descriptive account of the patient's health condition. To require the date a particular service is provided and the signature of the person providing care, validates the legitimacy of the record as a health care document. This concept of documentation is supported by the requirement at 42 C.F.R. § 405.1132 which requires entries into the record of a

skilled nursing facility by a physician to be signed and dated, and by the requirement at 42 C.F.R. § 442.499 which requires that all entries into the record of an ICF/MR resident be legible, dated, and signed. This requirement does not mandate countersignature by a licensed provider for all entries made by personnel under the supervision and authority of that provider, such as, entries made by the nursing staff of a hospital in response to a physician's order. However, the rule does reasonably require that the licensed provider countersign record entries for health care provided by ancillary personnel under the supervision of the licensed provider and billed directly to the program using the providers number. This provision stems from the fact that the programs will pay, at a reduced rate, for services provided by a non-entrolled vendor under the direct, on-site supervision of the licensed provider. An example of this billing situation would be the psychiatrist or psychologist who employs a non-enrolled counselor or therapist to provide psycho-therapy services for the licensed provider's clients. The enrolled provider may bill the programs directly for the counselor services at one-half (1/2) the allowed rate and must have provided direct on-site supervision of the services provided by the counselor. Since this service is billed using the provider's number, even though the provider did not physically provide the service, it is reasonable that the provider be aware of the care provided and accept professional responsibility for that care.

(3) - (11) Rule requirements contained in items (3) - (11) essentially spell out the components of a medical and health care record necessary to reveal the care provided, the reasonableness of costs incurred by the programs, and the medical necessity of the health care. The initial and final diagnoses, patient care history, plan of treatment, quantities of dosages of drugs ordered and/or administered, results of diagnostic tests, indication of patient's progress, consultation reports, dates of hospitalization and surgical summaries are all data which reflect the medical necessity

of care provided and as such are reasonable. In support of these rule requirements, federal regulations for hospitals, at 42 C.F.R 405.1026 require a standard record content of identification data, chief complaint, present illness, past history, family history, physical examination, provisional diagnosis, clinical laboratory reports, X-ray reports, consultations, medical and surgical treatment, final diagnosis, progress rate, discharge summaries, and autopsy findings. In addition, federal requlations for skilled nursing facilities at 42 C.F.R § 442.202 require a standard record content which essentially duplicates the record keeping perameters outlined in the rule and in the federal regulations for hospitals. The existence of a nearly uniform record data set for the two provider groups cited can be extrapolated to other providers. See also Stoffan v. Pennsylvania Department of Public Welfare, (1977). CCH Medicare-Medicaid Guide ¶ 28,548. (Disqualification of Physician from Program due in part to inadequate medical records.)

d. The medical or health care record is not an appropriate record to be required of several vendors of services and supplies, notably pharmacies, laboratories, ambulance services and medical transportation providers and suppliers of medical equipment and non-durable supplies. For this particular group of providers, the rule requests specific records or documentation needed to determine if claims submitted were false in whole or in part or if care was medically necessary. Unless otherwise noted, records required by this rule are already required by the provision of 12 MCAR § 2.047.

(1) Prescriptions are maintained in accordance with 12 MCAR § 2.047.E.2.n. which requires pharmacists to maintain prescriptions for 5 years, subject to audit at any reasonable time. While recipient drug profiles are not required to be maintained it is reasonable for the agency to access such records to support tHe validity of provider claims.

(2) Laboratories' services are paid for by the program in accordance with the provision of 12 MCAR, § 2.047E.2.m. which requires that the service was provided by or under the direction of a physician or licensed provider. The requirements for documentation of provider orders and of test results are reasonable to substantiate billing claims.

(3) In accordance with the provision of 12 MCAR § 2.047E.2.r., the programs will not pay for medical transportation which is routine and determined not to be medically necessary, and which was provided when other transportation would suffice. The rule requirement for the physician's authorization for medical transportation and the trip ticket are reasonable documents to access in determining compliance with state regulations. The agency is further justified in requesting documentation of supplies and equipment expended on a recipient and billed to the programs.

(4) The provisions of 12 MCAR § 2.047E.2.i require that supplies prescribed by a physician or licensed provider must be within the scope of his profession and that they must be medically necessary. It is therefore reasonable for the agency to require access to documentation which validates that order or prescription.

2. The authority to require the development and maintenance of financial records pertaining to the provider's costs and charges for health care provided follows from the Commissioner's authority to examine records for the purpose of "investigating whether or not a health service vendor has submitted a claim for reimbursement, a cost report or a rate application which the vendor knows to be false in whole or in part". Minn. Laws 1980, ch. 349, §§ 1, 7, 10.

Further, at Minn. Stat. § 256B.27 Subd. 1 the Commissioner may "require any reports or information and audits of medical vendors which he deems necessary". In addition, providers are under a contractual obligation to provide such information. 42 U.S.C. § 1396a(a)(27), 42 C.F.R. § 431.107, 12 MCAR § 2.047D.7. The

specific items listed in this section, i.e., purchase invoices, accounting records, contracts for supplies and service, evidence of usual and customary charges, records of third party claims, charges and payments, and (for long term care facilities) records of deposits and expenditures from patient personal needs allowance accounts are integral elements of the claims for reimbursement, cost reports or rate applications the state agency is empowered to investigate. The evidence of third party claims is necessitated by 42 USC § 1396a(a)(25), 12 MCAR § 2.047 D.5.

The provision of rule which requires "written evidence of charges to non-recipient patients" has been written so as to prevent violation of non-recipient patient rights to confidentiality. This can be accomplished in several ways which will protect that right, e.g. having the provider display a ledger or a copy of a ledger with all identifying characteristics covered. This random review of a non-recipient patient charge is necessary to ensure that the usual and customary charges provided by the provider are indeed factual and not manufactured. Access to evidence of the usual and customary charges is necessitated by 12 MCAR § 2047 F.2.

3. The authority of the state agency to access records related to health care billed to the programs is set forth in Minn. Laws 1980, ch. 349, § 1, 7, 10. The requirements that the agency provide 24 hours notice prior to access and to provide written consent forms as requested is contained in the same statutes which also make recipient consent to the Department's access to their medical records a precondition of eligibility. Courts have upheld access to records without search warrants or subpoenas. CCH Medicare-Medicaid Guide ¶ 28,634,29050.

Any privilege to keep the records private belongs to the recipient and once waived by the recipient cannot be raised on his behalf by the provider. (Even if a recipient refused to consent it can be argued that the state agency is entitled to access. "The statutory

provision which prohibits a physician from releasing treatment information without the consent of his patient, does not apply to agency compliance audits of medical records of Medicaid recipients." Department of Social and Health Services v. Letta, 92 Wash.2d 812, 601 P.2d 520 (1979) as cited in CCH Medicare-Medicaid Guide ¶ 30.386. Accord Matter of Hayes, CCH Guide ¶ 30,607 (1980)).

The Minnesota Government Data Practices Act does not prohibit DPW's access to recipient medical records. This law primarily concerns the dissemination of data wich state agencies have collected. Minn. Stat. § 15.162 et. seq. However, certain disclosures must be made to the subjects of the data prior to its collection. Minn.Stat. § 15.165. The application forms used by the state agency in conjunction with all three programs (MA, GAMC, CHEPP) contain the required disclosures.

In addition, state law concerning the Patient's Bill of Rights, Minn. Stat. § 144.651(15), cannot be construed as conflicting with this rule since it allows the patient to approve or refuse release of their records "except as otherwise provided by law".

A provider's refusal to grant the state agency access, during regular business hours, to examine all necessary records is grounds for sanctions as provided in Minn. Laws 1980, ch. 349, § 6.

4. In seeking the authority to duplicate recipient records, the state agency hopes to facilitate the investigation process and to minimize the inconvenience associated with an audit. During the course of an investigation, a large number of records may be examined over an extended period of time. Since this may prove to be disruptive and make records unavailable to a provider, photocopying is proposed as a reasonable course of action.

5. The requirement that records be retained for five years is consistent with provisions at 12 MCAR § 2.047 D.4.c.

6.-7. In the event of a change of ownership or of termination or withdrawl of a provider, the records must be maintained and available for review. That the record is to be maintained by the party assuming responsibility for care is reasonable for continuity of health care. The rule does not specify the contractual relationship which might develop between parties, but rather, is concerned only with the relative availability of all documents necessary to support the determinations required by law. The rule makes clear that the buyer is not liable for any of the conduct reflected by the seller's record.

8. As noted above, Minnesota law specifically states that no persons shall be eligible for assistance under the programs, unless he or she has authorized the Commissioner of Public Welfare in writing to examine all personal medical records developed while the recipient received publically funded health care. The fact that eligibility is established and that the recipient or responsible guardian has applied for and accepts health care under the programs implies that participation and all that it entails was knowingly sought. This means that expressed written consent for release of records was made; that the recipient waives any right to approve or refuse release of records as afforded by the patient Bill of Rights; and that the provider is released from all liability attendant upon release of records to the state agency.

D. PROVIDER SURVEILLANCE AND UTILIZATION REVIEW

The provisions of Section D set forth the scope and purpose of SUR activities relating specifically to providers of health care participating in the programs.

1. The statutory authority to promulgate rules regarding identification of suspected fraud and abuse is clearly cited at Minn. Laws 1980, ch. 349, § 2, 3, 9.

a. Rule language describing the responsibilities of the state agency in the identification of suspected fraud and abuse is essentially taken from the above statutory citations. Language of the statutes has been quoted so that the state agency's authority in this area is clear and unambiguous.

b. The provisions of this section identify the sources of information the Commissioner may use to identify inappropriate activity by health care providers. The use of MMIS computer reports to identify exceptional provider activity is embodied in the requirements of the federal regulations at 41 C.F.R. § 456.23 which states that the state Medicaid agency "must have a postpayment review process that - (a) allows state personnel to develop and review - (1) recipient utilization profiles; (2) provider service profiles; and () exceptions criteria. . .". The use of computer generated profiles which compare groupings of providers having similar characteristics (peer groups) forms the basis for determining what may be exceptional system utilization.

c. In determining the necessity of care provided it is required that the state agency utilize health care professionals in the review process. Minn. Laws 1980, ch. 349, §§ 6, 7.

2. The statutory authority to promulgate rules regarding the investigation of suspected fraud and abuse is contained in the same citations given for the identification process in D.1. above.

a. The purposes of an investigation follow directly from federal regulation. Specifically, at 42 C.F.R. § 455.15 the state "agency must conduct a full investigation to determine if (a) the allegation is true; and (b) there is sufficient evidence that can be developed to support a civil or criminal fraud or abuse action under state law".

b. In conducting an investigation, the state agency must necessarily be authorized to utilize all sources of information which confirm or refute the suspected fraud or abuse. The state agency acknowledges that this authority must be tempered by the

requirements of due process and data privacy, but that the items listed at b. (1) - (7) are ordinary and reasonable investigative activities.

c. Federal regulations regarding the agency's fraud investigation program specifically require at 42 C.F.R. § 455.16 that an investigation, once started

> "must continue until -
>
> (a) Appropriate legal action is initiated;
>
> (b) The case is closed or dropped because of insufficient evidence to support the allegations of fraud or abuse; or
>
> (c) The matter is resolved between the agency and the provider. This resolution may include but is not limited to -
>
> (1) Sending a warning letter to the provider giving notice that continuation of the activity in question will result in further action;
>
> (2) Suspending the provider from participation in the Medicaid program.
>
> (3) Terminating the provider from participation in the Medicaid program; or
>
> (4) Seeking recovery of payments made to the provider."

The above cited provisions encompass and fully justify the items contained at section D.2.c., namely:

> (1) a determination that no further action is warranted corresponds with the closing or dropping of a case because of insufficient evidence;
>
> (2)-(3) imposing administrative sanctions and recovery of money is drawn directly from 42 C.F.R. § 455.16 (c); and
>
> (4) referral of the case to the Attorney General is required by state law which provides that "if it appears to the state agency that a vendor of medical care may have acted in a manner warranting civil or criminal proceedings, it shall so inform the Attorney General in writing." Minn. Laws 1980, ch. 349, § 3. See also Minn. Stat. §§ 609.466, 609.52, subd. 2(d).

3.a. The authority to impose administrative sanctions and to seek monetary recovery and the grounds upon which to do so are clearly and unambiguously provided at Minn. Laws 1980, ch. 349,

§ 6. The statutory language was essentially duplicated in the rule to avoid any confusion. For the purpose of monetary recovery, DPW is specifically exempted from the requirement to establish a pattern of improper billing which is a precondition to sanctioning for false claims, duplicate claims, claims for services not medically necessary, or false statements. The state agency is also authorized to sanction a provider for refusal to grant the state agency access to examine rules, when authorized. Minn. Laws 1980, ch. 349, § 6. The authority to sanction providers who have been suspended or terminated from the Medicare (Title XVIII) program is taken from 42 C.F.R. § 455.212 which prohibits the state from expending Medicaid program dollars for any service by, or under the direct supervision of a provider suspended from the Medicare program. See also 42 U.S.C. § 1396a(a)(39).

b. The methods by which the state agency may seek monetary recovery of monies erroneously paid are drawn from Minn. Laws 1980, ch. 349, § 6. This statute which permits the Commissioner to assess and recover monies, and debit from future accounts, clearly encompasses the proposed methods of recovery. In actual practice, the state agency has historically given providers the option of voluntary payback by means of a provider initiated payment or by automatically debiting the providers' future payments to recover the monies. In the event that voluntary payback or account debiting is not possible, the agency is justified in recovering monies by any legal process.

c. The provisions of this section permit the Commissioner to recover monies erroneously paid a provider by use of statistical sample rather than by an individual claim by claim review. Recovery on the basis of statistical sample permits the state agency to sample a specific, defined group of claims (specified by procedure code), to determine the percentage of program monies inappropriately paid in the sample and then to extrapolate or apply that percentage to the entire population of all similar claims. The rule requires

the use of generally accepted statistical procedures to ensure that the sample is truly random, hence representative of the general population. Given the costly and time consuming nature of a claim by claim review, it is reasonable for DPW to use a more efficient, economical method of audit.

The validity of statistical sampling as a method of recovering overpayments is supported by the decision resulting from the State of Georgia's challenge to the Department of H.E.W. for use of sampling as a valid audit technique. State of Georgia v. Joseph A. Califano, Jr., 446 F. Supp. 404 (N.D. Ga., (1977). In this case, the State of Georgia sued H.E.W. for reimbursement of some $3.5 million which was paid by Georgia for services provided Medicaid recipients by health care providers. Georgia brought suit to cause the release of federal financial participation funds withheld by H.E.W. on the grounds that state payments to physicians exceeded amounts determined by application of federal regulations. The audit which was performed by H.E.W. to determine if federal dollars had been used to pay excessively high claims was conducted on the basis of random statistical samples of claims paid. Georgia asserted that to determine overpayment based upon extrapolation from a random sample was arbitrary and capricious. The court concluded that the use of statistical sample was not improper and that projection of the nature of a large population through review of a relatively small number of its components has been recognized as a valid audit technique.

Sampling and extrapolation technique is currently used by several states in the administration of their Medicaid programs. Pennsylvania established in statute, Article XIV, Section 1407 (c)(1) of the Public Welfare Code, that "the department shall have the authority to use statistical sampling methods to determine the appropriate amount of restitution due from the provider". Similarly, California establishes in rule at Title 22, § 51488.2 of

California Code that a "probability sample may be used in auditing to determine the recoverable amount due from a pharmacy provider".

d. The sanctions which the Commissioner is empowered to impose are stated in Minn. Laws 1980, ch. 349, § 6 which authorizes: "referral to the appropriate state licensing board, suspension or withholding of payments to a vendor, and suspending or terminating participation in the program". The proposed rule further provides lesser sanctions which limit the provider agreement without accomplishing full exclusion from the programs. Establishment in rule of lesser sanctions which permit the provider to conditionally participate in the programs is a reasonable interpretation of the Commissioner's authority in administration of the Medicaid program.

e.(1) - (2) The agency's responsibility to provide notice of intent to recover monies or impose sanction established by the provisions of Minn. Laws 1980, ch. 349, § 5. The content of the notice, as established by this section of the rule, complies with notice requirements applicable to contested case hearings as set forth in Minn. Stat. § 15.0418.

(3) Providers have 20 days to notify the agency that they wish to contest proposed action. This is the same time period that defendants have to serve their answers in civil proceedings. Minn. R. Civ. P. 12.01. Further, to circumvent problems assiciated with delay of mail delivery, the agency accepts the burden of notification by certified mail. The agency feels that a full 20-day notice period affords ample time for providers to consider a future course of action, i.e. compliance or appeal. It should be noted that the 20-day appeal period for providers is well in excess of the 10-day notice period afforded recipients according to the federal regulations at 42 C.F.R. § 431.211. The Commissioner's authority to impose a pre-hearing suspension or reduction of payments is clearly set forth at Minn. Laws 1980, ch. 349, § 5 as is the exemption from this provision for nursing homes or board and care homes. The determination of when such a pre-hearing action might be imposed is addressed in section D.6 of the rule.

Following a hearing on appeal in which the state agency's position is upheld, it is reasonable to grant the Commissioner the discretion to delay imposition of the sanction based upon the interests of program recipients. Notably, in the case of nursing homes, in-patient hospitals and individual providers in isolated rural areas, a period of time may be needed to facilitate patient transfers, discharges, etc. Federal regulations at 42 C.F.R. §§ 455.202, 455.212 provide for delayed implementation dates which is directly compatible with the provisions proposed in this section of the rule.

f. The determination of sanctions to be imposed must necessarily be a discretionary power of the Commissioner. This discretion must take into consideration the gravity of the misconduct, the providers past conduct, and the likelihood of future compliance. It has been the experience of the state agency in five years of operation that circumstances may differ greatly between two participants determined to have committed the same offense. What may be an appropriate sanction to impose against a multi-specialty metro area clinic, for example, may be entirely inappropriate to impose against an individual practioner in a rural practice. To determine sanctions in advance without investing discretionary power in the Commissioner will likely produce inequitable results and unintended hardships.

g.-h. Federal regulations at 42 C.F.R. § 455.212(d) specifically provide that "the agency may not make Medicaid payments for any service furnished directly by, or under the supervision of, the suspended practitioner during the period of suspension". This provision is applicable to the individual providers, as well as clinics or hospitals who may attempt to bill the programs for services performed by the suspended or terminated provider while in their employ. Given the specific prohibition against billing for an ineligible provider, it is reasonable for the agency to recover monies and to consider imposition of sanction for such false claims.

3. Federal regulations at 42 C.F.R. § 455.17 set forth specific reporting requirements for the state agency regarding sanctions imposed against a provider. In addition, the state agency considers it within the public interest to inform appropriate agencies or associations concerned with the professional conduct of health care providers of any sanctions imposed.

4. The simultaneous imposition of a sanction along with monetary recovery is implicitly authorized by Minn. Laws 1980, ch. 349, § 6 which states that "the Commissioner may seek monetary recovery and impose sanctions against vendors of medical care.

5. The authority of the state agency to conduct random, routine audits, a generally accepted method of ascertaining program compliance, is drawn from the agency's overall responsibility to "safeguard against unnecessary utiliztion of [MA] and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy and quality of care." 42 U.S.C. 1396a(a)(30), 42 C.F.R. § 456.3, 42 C.F.R. 456.22 (requiring state agency to do ongoing evaluation on a sample basis of the need for and quality of Medicaid services). See also CCH Medicare-Medicaid Guide ¶ 30,113 (federal requirement of random recipient audits to ascerain whether providers are supplying services for which the agency is billed).

6. As stated previously in this statement, the Commissioner is authorized by statute to suspend or withhold payments to a provider prior to a hearing if it is necessary to protect the public welfare and the interests of the program. Given the complexity and individuality of each case it is reasonable for the Commissioner to exercise discretionary judgment regarding the implementation of this provision. The rule does however provide guidelines which limit the degree of discretion which may be exercised.

7. In keeping with the provision of Minn. Stat. § 256B.04 Subd. 4, the rule resolves conflicts regarding sanctions in favor of Federal law.

E. RECIPIENT SURVEILLANCE AND UTILIZATION REVIEW

1. a.-c. The state agency has general authority to develop rules regarding recipient utilization of the programs. Minn. Laws 1980, ch. 349, § 1, 8, 10. In addition federal regulation at 42 C.F.R. §§ 456.3 and 456.23 provide for a surveillance system and post payment review process which will address inappropiate use by recipients of Medicaid services, and will profile recipient activity in the Medicaid System. The Commissioner's authority to utilize specific sources of information in the identification of suspected fraud and abuse, and to utilize health care professionals for the determination of medical necessity is similar to that established for provider surveillance and has already been addressed in the statement.

2.a. The investigation of suspected fraud and abuse by a recipient in the programs is authorized by the same citations presented in the preceding section. An investigation is conducted to confirm the existence of a fraudulent condition and to support the application of the appropriate corrective action.

3.a. The imposition of sanctions against recipients of the programs is taken from federal regulation at 42 C.F.R. § 456.3 which requires the state agency to implement a program which, among other things, will provide for the control of the utilization of all services provided by the Medicaid program. Grounds 3a(1)-(4) implement DPW's authority to restrict the use of MA identification cards "to prevent duplication or documented abuse of service, to prevent violations of prior authorization requirements or to assure continuity of care." 12 MCAR § 2047 D.6. The grounds for imposing sanctions upon a recipient for fraud are detailed in sections 3a(5)-(11). These find a legal basis in the provisions governing theft and wrongful attainment of assistance. Specifically, Minn. Stat. § 256.98 provides that:

"whoever obtains or attempts to obtain, or aids or abets any person to obtain by means of a willfully false statement or representation, or by impersonation or other fraudulent device, assistance to which he is not entitled, or assistance greater than that to which he is entitled. . . shall be guilty of theft. . ." Grounds for sanction proposed in the rule at E.3.a. (1) - (11) are reasonable in that each item represents an event or activity which results in the recipient obtaining, or aiding others to obtain, assistance to which they are not entitled.

3.b. The sanctions proposed in rule at E.3.b. are reasonable actions to correct misutilization by recipients. 42 C.F.R. § 456.3 (c), 42 C.F.R. § 456.23 (b) and 12 MCAR § 2.047 D.6. Health counseling E.3.b.(1) as a form of sanction enables the agency to correct inappropriate health care utilization by the recipient, e.g. visiting multiple providers and obtaining multiple prescriptions for potentially incompatible drugs. However, it is possible that counseling alone may be ineffective or perhaps the recipients's pattern of abuse is so dangerous as to require more direct control. The proposed rule would enable the state agency to restrict the recipient to obtaining his or her health care from a core of designated providers. The recipient may choose a physician, dentist, pharmacy or other enrolled provider to provide all non-emergency health care. The purpose of the restriction program is to change the recipient's pattern of health care utilization by limiting program payment to care provided by those few providers. The restriction is imposed for a limited period of time and is removed if the recipient's pattern of utilization improves during this time period. Program payment remains available for emergency health care and services provided upon referral by the primary providers. The fact that a recipient is under restriction is indicated on the medical identification card so that providers will know that the programs will not pay for any care provided this individual unless it is emergency or by referral. The Department

believes that the restriction program is a reasonable way to control abuse of the program by recipients while assuring that medically necessary care remains available to them.

Recovery of monies E.3.b.(2), from a recipient for assistance wrongfully obtained is authorized by Minn. Stat. § 256.98 which indicates that assistance incorrectly paid and established by judicial determination "shall be recoverable from the recipient". In addition, referral of the recipient's case to the Attorney General is permitted by the same citation, i.e. the Attorney General. . . may institute a criminal or civil action.

A recipient may be terminated from participation for that period for which he refuses to sign a consent for release of records. Minn. Laws 1980, ch. 349 § 1, 8, 10. (No person shall be eligible for assistance for health care unless he has authorized the Commissioner in writing to examine all records developed while receiving publically funded health care).

c. Federal regulations at 42 C.F.R. §§ 431.206 and 431.211 require that the state agency provide notice of its proposed action at least 10 days before the date of action. In addition, at 42 C.F.R. § 431.210 the regulations address the content of the notice. The rule provisions at E.3.c. regarding notice to recipients complies with federal regulation in both the content, which explains reason for the intended action and the right of the recipient to dispute and appeal the action.

d. The intent of the programs restriction activity is to control abuse of the programs by recipients and to afford the recipient consistent, coordinated health care. Obviously, emergency situations can and do exist which would require that health care be provided by other than the designated provider(s). The agency is aware of the need for an emergency exemption in its restriction program, but is justified in requiring documentation to confirm an emergency condition.

e. In addition to emergency care, the agency is aware that health care may be needed which is not within the scope of practice or specialty of the designated provider of a restricted recipient. However, it is reasonable that the care be contingent upon referral from the designated provider to ensure that consistent and coordinated care is provided.

F. APPEAL

1. The provider's right to appeal an agency determination is fully protected by incorporation of the contested case provisions cited at Minn. Stat. § 15.0418.

2. The recipient's right to appeal an agency determination is protected by the incorporation of Minn. Stat. § 256.045, subds. 2-3. Further authority is found at 42 C.F.R. § 431.206.

3. The purpose of this section is to provide for an informal dispute resolution process by which a provider or recipient may discuss the agency's proposed action. If the matter is not resolved, the provider or recipient may institute the formal appeal process.

4. Generally, in contesed cases the party proposing that certain action be taken must prove the facts at issue by a preponderance of the evidence. 9 MCAR § 2.217 C.S. (as amended in 4 S.R. 1814). However, when the matter in dispute is a monetary one in which the provider or recipient has possession or control of the records and information that best determines questions of fact, the burden shifts to them after the agency has established a prima facie case. In the Matter of the Contested Case of Anoka Nursing Home, et al., DPW-80-036-JL, "Order on Motion for Determination of Burden of Proof." Oct. 28, 1980, Hospital Ass'n. of New York State v. Tora, 473 F. Supp. 917, 935-36 (S.D. N.Y. 1979).

The standard of proof for the suspension or revocation of a providers license may be the "clear and convincing" standard. However, a proceeding under this rule would be more analogous to a contract dispute.

In assessing a constitutional attack on 42 U.S.C. 1320c of the medicaid act a federal court noted that the provision concerned "conditions of compensation" not "criminal sanctions" or "severance from the medical profession" and should be scrutinized by the courts accordingly. Ass'n. of American Physicians and Surgeons v. Weinberger, 395 F. Supp. 125, 138 (N.D. Ill. 1975), aff'd., 423 U.S. 975 (1975).

The state agency will not call any outside expert witnesses.

Dated:

ARTHUR E. NOOT
Commissioner of Public Welfare