

STATE OF MINNESOTA

BEFORE THE MINNESOTA

COUNTY OF HENNEPIN

DEPARTMENT OF HEALTH

In the Matter of the
Proposed Adoption of Rules
of the Department of Health
Governing the Delegation of
Prescription Writing to
Physician Assistants

STATEMENT OF NEED
AND REASONABLENESS

INTRODUCTION

This statement of need and reasonableness is prepared pursuant to the requirements set forth in Minnesota Statutes, sections 14.131 and 14.23. It contains a summary of the evidence and arguments in support of the need for and reasonableness of amendments to the physician assistant rules addressing physician delegation of authority to physician assistants to prescribe and administer legend drugs and medical devices. Also included is a statement addressing the impact of these rules on small businesses.

BACKGROUND

In 1987 a registration system for physician assistants was implemented in Minnesota. Since then, approximately 150 individuals have registered as physician assistants with the Board of Medical Practice (Board). The scope of physician assistant practice is limited to the provision of services within the training or experience of the physician assistant and to those services customary to the practice of the supervising physician and delegated by the supervising physician. Minnesota Rules, part 5600.2615, subpart 1. Currently, the scope of



practice includes developing comprehensive medical status reports; performing physical examinations; determining patient management and treatment; initiating diagnostic procedures; performing therapeutic procedures; instructing patients in medical care; and otherwise assisting the physician in the delivery of services to patients. See Minnesota Rules, part 5600.2615, subpart 2. Prescription writing for and administration of legend drugs and medical devices were not included in the original scope of physician assistant practice.

In 1989 the Minnesota Academy of Physician Assistants (MAPA) sought legislation which would allow physicians to delegate to physician assistants the authority to prescribe and administer legend drugs and medical devices. Prior to doing so, the organization conducted a survey of supervising physicians to determine their opinions regarding the delegation of prescriptive and administrative practices to physician assistants. Approximately 90% of the physicians responding to the survey were in favor of delegating prescriptive and administrative practices to physician assistants, providing the physician assistant is certified by the National Commission for Certification of Physician Assistants (NCCPA), registered with the Minnesota Board of Medical Examiners, and restricted from prescribing controlled substances. Nearly all of the physician assistants responding to the survey supported the delegation of prescriptive and administrative practices to physician assistants. MAPA, "A Survey of Minnesota Physicians Supervising Physician Assistants

Regarding Delegation of Prescriptive Practice to Physician Assistants", Jan., 1990.

One of the factors supporting the concept of physician assistant prescriptive and administrative practices is the shortage of physicians in the rural areas of Minnesota. Seventy per cent of the MAPA Fellow Members work in primary care. Of these, nearly 50% work in communities with populations of less than 60,000 people. Allowing delegation of the prescribing and administering of legend drugs and medical devices expands the utilization of physician assistants in these areas of need.

Twenty five states and the District of Columbia have provisions for the delegation of prescriptive privileges to physician assistants. Various regulatory schemes exist. NCCPA certification is generally required and some states require additional experience, education, or training. Restrictions on prescribing may exist and include limitation to areas of need; limitation to certain formularies; and restrictions on refilling the prescription, duration of the prescription, or amount of the drug which can be prescribed. Fourteen states allow the prescription of controlled substances under varying conditions.

The National Board of Medical Examiners' Physician Assistant Clinical Pharmacology Task Force determined in 1981 that the NCCPA examination adequately measures the physician assistant's knowledge in "clinical therapeutics". Examination content includes actions, indications, and contraindications of drugs across all body systems. Additional testing for pharmacology was

determined to be unnecessary by the task force. Minutes of the Physician Assistant Clinical Pharmacological Task Force meeting of October 21, 1981, Philadelphia, PA.

The Committee on Allied Health Education and Accreditation Essentials, used for determining accreditation of physician assistant training programs, indicate that pharmacology must be included within the physician assistant's training in order for the training program to receive accreditation. American Medical Association, "Essentials and Guidelines for an Accredited Educational Program for the Physician Assistant," revised 1990.

STATUTORY AUTHORITY

In 1990 the legislature mandated that the Commissioner of Health (Commissioner) promulgate rules to 1) identify physician assistants eligible to prescribe drugs and medical devices; 2) establish a method of determining the categories of drugs and medical devices that each physician assistant is allowed to prescribe; and 3) establish a system of transmitting information to pharmacies regarding those physician assistants eligible to prescribe drugs and medical devices and the types of drugs and medical devices they are allowed to prescribe. Minnesota Statutes, section 147.34, subdivision 1 (c). The legislature specifically authorized the Commissioner to promulgate rules to implement this law and to do so by amending the physician assistant registration rules previously adopted under the authority of Minnesota Statutes, section 214.13. Minnesota Statutes, section 147.34, subdivision 2.

COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS

General Procedures

The Department is proceeding according to the procedures in Minnesota Statutes, Chapter 14 in the preparation of these rule amendments. A notice of intention to solicit outside opinion concerning the proposed rule amendments was published in the State Register on July 9, 1991.

The Board of Medical Practice and the Physician Assistant Advisory Council were provided with a draft of the proposed rules January 4, 1991 according to Minnesota Statutes, section 214.13, subdivision 2. The Physician Assistant Advisory Council responded with comments for modifications of the proposed rules. These comments were taken into consideration in revision of the rules amendments.

In accordance with Minnesota Statutes, section 214.13, subdivision 1, the Board of Nursing and the Board of Pharmacy were provided copies of the draft rules and were asked to respond with any comments as evidenced by correspondence dated January 23, 1991. No written comments were received from the Board of Pharmacy or the Board of Nursing. The directors of each of these boards was contacted by telephone and no objections to the proposed rule amendments were voiced nor were any suggestions offered for rule modifications.

The Department has attempted to involve individuals and organizations which will most likely be affected by these rules. An advisory group was formed for consultation regarding technical

aspects of these rules. This group consisted of representatives from the Minnesota Academy of Physician Assistants, the Minnesota Medical Association, the Minnesota State Pharmaceutical Association, and the Board of Medical Practice. A group of pharmacists from various settings was also consulted in the process to determine which information would need to be reported to them and the best method for communicating the information to pharmacies in Minnesota. Their information was incorporated into the development of these rules.

The Department is proceeding under Minnesota Statutes, Chapter 14. A dual-track notice will be published in the State Register and notice mailed to those who have registered with the Department pursuant to Minnesota Statutes, section 14.14, subdivision 1a, to those physician assistants registered with the Minnesota Board of Medical Practice, and members of the Minnesota Academy of Physician Assistants. The notice will indicate the Department's intention to proceed to adopt the rules without a public hearing, and, in the alternative, notice that the Department will adopt the rules following a public hearing should 25 requests for a hearing be received within the 30 day comment period.

This Statement of Need and Reasonableness was filed with the Legislative Commission to Review Administrative Rules prior to publication of the proposed rule amendments and according to the requirements of Minnesota Statutes, section 14.131.

Approval of Commissioner of Finance

According to Minnesota Statutes, section 16A.128, subdivision 1a, if a fee is to be fixed by rule, the Commissioner of Finance must approve the fee, and the Commissioner's approval must be included in the statement of need and reasonableness. The Commissioner of Finance's approval of the fee for approval of an agreement containing a delegation of prescribing authority is contained in Appendix A which is incorporated into this statement of need and reasonableness.

Special Notice of Rulemaking

Promulgation of the proposed rules will not result in the expenditure of more than \$100,000 in public monies by local public bodies for the two years immediately following adoption of these rules nor have an impact on agricultural land. The proposed rules will require the payment of fees by physician assistants to the Board of Medical Practice and no other expenses. While a small number of physician assistants may be employed by facilities supported by local public bodies, these facilities are not being required to pay any monies; therefore, no further information need be provided under Minnesota Statutes, section 14.11.

Small Business Considerations

Minnesota Statutes, section 14.115 requires an administrative agency to examine whether proposed rules will affect small businesses, and, if so, consider methods to lessen the impact of the rules on small businesses. It is the

Commissioner's position with respect to these rules that the provisions of Minnesota Statutes, section 14.115 do not apply.

Minnesota Statutes, section 14.115, subdivision 7 specifies four types or classes of rules to which the small business requirements of section 14.115 are inapplicable. The proposed rules come within the exception in subdivision 7 (2) which states that agency rules that do not affect small businesses directly are not subject to small business considerations in rulemaking. These rules also come within the exemption for service businesses which are regulated by government bodies for standards and cost. Minnesota Statutes, section 14.115, subdivision 7 (3).

The proposed rules do not regulate small businesses directly but regulate individual physician assistants. Physician assistants are employees, supervised by physicians and cannot operate independently either as individuals or as small business entities. These rules therefore do not directly affect small businesses.

The rules also fall under the exemption for service businesses regulated by government bodies for standards and cost. Physicians and other employers of physician assistants are providers of medical care which are regulated by government bodies for standards and costs. Providers of medical care are specifically mentioned within the exception to the small business requirements for rulemaking. It is the Commissioner's position that any small businesses which may be affected by these proposed rules are exempted from small business protection because they

are providers of medical services regulated by government bodies for standards and costs.

Involvement of pharmacies in the physician assistant prescribing scheme does not cause these rules to be subject to small business considerations. The rules regulate physician assistants; pharmacies are not being regulated by these rules. No additional compliance or reporting requirements are being imposed on pharmacies. It is a requirement that the Board transmit information to pharmacies. Pharmacies are not required to report any information to the Board.

Although it is the Commissioner's position that these rules are exempt from the small business requirements, the Commissioner has nevertheless considered the five methods in section 14.115 for reducing the impact of the rules on small businesses. These five methods include: a) less stringent compliance or reporting requirements; b) less stringent schedules or deadlines for compliance or reporting requirements; c) simplification of compliance or reporting requirements; d) establishment of performance standards for small businesses to replace required design or operational standards; or e) exemption of small businesses from any or all requirements of the rule. Minnesota Statutes, section 14.115, subdivision 2.

The Commissioner has considered the feasibility of implementing each of the five methods for reducing the impact of the proposed rule amendments on small businesses, considered whether any of these methods are consistent with the statutory

objectives that are the basis for this rulemaking, and concluded that it would not be feasible to incorporate any of the five methods into these proposed rules. The Commissioner has also concluded that reducing the impact of these rules on small businesses would undermine the duty to protect the public through regulating the prescribing and administering of legend drugs and controlled substances as well as the statutory objectives that are the basis of these rules. Minnesota Statutes, section 14.115, subdivision 3.

Methods (a) through (c) of Minnesota Statutes, section 14.115, subdivision 2 relate to lessening compliance or reporting requirements for small businesses. The reporting requirements proposed by the Commissioner request provision of additional information by the supervising physician and physician assistant for inclusion in the agreement which is submitted to the Board. This agreement is submitted to the Board upon physician assistant registration and when the agreement is modified by the physician assistant and supervising physician. The additional information on physician assistant prescribing is essential to allow delegation of authority to prescribe and cannot be eliminated, further simplified, or requested on a less frequent basis if the public health, safety, and welfare is to be protected. For the same reason, standards cannot be reduced for small businesses nor small businesses exempted from the requirements of these rules.

It would be contrary to protection of the public health, safety, and welfare to reduce requirements or standards or to

exempt small businesses from these rules. A physician or medical group has the option of withholding authority to prescribe and administer legend drugs and medical devices from its physician assistants if it does not want to assume the responsibility of physician assistant prescribing. Because of the public health, safety, and welfare concerns, the Commissioner considers any of the five methods for reducing impact on small businesses as infeasible for implementation with these rules.

Should it be determined that the Commissioner is not exempt from the requirements of Minnesota Statutes, section 14.115, notice is hereby provided pursuant to Minnesota Statutes, section 14.115, subdivision 4 (a) that the rules may have an economic impact on small businesses. These rule amendments should result in time savings, therefore cost savings, for supervising physicians who choose to delegate prescribing and administering functions to the physician assistant. By allowing physician assistants to relieve physicians of more routine work, the physician is able to devote attention to more complicated medical problems.

GENERAL STATEMENT OF NEED AND REASONABLENESS

Supervising physician delegation of the authority to prescribe and administer drugs and medical devices to physician assistants was permitted, in part, to alleviate the shortage of physicians in rural Minnesota. This is consistent with recommendations made in the Final Report on Regulation of

Physician Assistants issued by the Minnesota Department of Health in April, 1990. Delegation of prescribing is critical to expanding the role of physician assistants and providing access to health care in rural areas. With prescription writing authority, the physician assistant will be able to perform a wider scope of duties and better support physician practice, relieving the physician from more routine duties and permitting him or her to attend to patients with more complex conditions and to provide specialized medical care. The proposed rules are needed to provide guidelines for supervising physicians and physician assistants in the delegation and exercise of this authority, assuring protection of the public from practices which do not meet medical standards or comply with legal regulations.

SPECIFIC STATEMENT OF NEED AND REASONABLENESS

5600.2600 DEFINITIONS

Subpart 2a. ADMINISTER. "ADMINISTER" MEANS TO DELIVER BY A PHYSICIAN ASSISTANT AUTHORIZED TO PRESCRIBE LEGEND DRUGS, A SINGLE DOSE OF A LEGEND DRUG, EXCLUDING CONTROLLED SUBSTANCES, TO A PATIENT BY INJECTION, INHALATION, INGESTION, OR BY ANY OTHER IMMEDIATE MEANS.

This term is necessary because it is used in these rules to identify an activity within the scope of physician assistant practice. This definition is reasonable because it consistent with the language used in Minnesota Statutes, section 152.01, subdivision 3 which defines the term for practitioners who are allowed to handle controlled substances. Since physician assistants will be performing the same activity, although not

with controlled substances, it is reasonable that the activity be described in terms that are familiar to health care providers.

Subpart 3. AGREEMENT. "AGREEMENT MEANS A DOCUMENT SIGNED BY THE PHYSICIAN AND THE PHYSICIAN ASSISTANT WHICH INCLUDES CONTENTS SPECIFIED IN PART 5600.2635, SUBPART 3. IF THERE IS A DELEGATION OF PRESCRIBING AND ADMINISTERING OF LEGEND DRUGS AND MEDICAL DEVICES, THE AGREEMENT INCLUDES THE DELEGATION FORM IN 5600.2670, SUBPART 6.

Identification of the delegation form as a part of the agreement is necessary because the form contains information required by Minnesota Statutes, section 147.34 and is required by this statute to be included in the agreement. It is reasonable to use a specified form in order to assure consistent means of identifying the information needed.

Subpart 7a. DELEGATION FORM. "DELEGATION FORM" REFERS TO THE FORM IN PART 5600.2670, SUBPART 6, USED TO INDICATE THE CATEGORIES OF DRUGS FOR WHICH THE AUTHORITY TO PRESCRIBE AND ADMINISTER HAS BEEN DELEGATED TO THE PHYSICIAN ASSISTANT AND SIGNED BY THE SUPERVISING PHYSICIAN, ANY ALTERNATE SUPERVISING PHYSICIANS, AND THE PHYSICIAN ASSISTANT. THIS FORM IS PART OF THE AGREEMENT AS DEFINED IN SUBPART 3.

It is necessary and reasonable to include this definition because the term is used in the rules to refer to a specific form to be used by physicians and physician assistants in the delegation of authority to prescribe and administer legend drugs and medical devices.

Subpart 8a. DRUG. "DRUG" HAS THE MEANING GIVEN IT IN MINNESOTA STATUTES, SECTION 151.02, SUBDIVISION 5, EXCLUDING CONTROLLED SUBSTANCES AS DEFINED IN MINNESOTA STATUTES, SECTION 152.01, SUBDIVISION 4.

The definition of drug is necessary because it is used within the rules to identify an item which physician assistants can be authorized to prescribe or administer. Because drugs,

except for controlled substances, are regulated by Minnesota Statutes, Chapter 151, it is reasonable that the definition provided in Minnesota Statutes, section 151.01, subdivision 5 be used for consistency and clarity.

Subpart 8b. DRUG CATEGORY. "DRUG CATEGORY" MEANS ONE OF THE CATEGORIES LISTED ON THE FORM IN PART 5600.2670, SUBPART 6.

This term needs to be defined because it is used in these rules to identify the parameters of physician assistant prescribing. It is reasonable that the form in 5600.2670, Subpart 6 is used as it contains a standardized organization for listing of drugs which is commonly used by various practitioners for prescribing.

Subpart 9a. INTERNAL PROTOCOL. "INTERNAL PROTOCOL" MEANS A DOCUMENT WRITTEN BY THE SUPERVISING PHYSICIAN AND PHYSICIAN ASSISTANT WHICH SPECIFIES THE POLICIES AND PROCEDURES WHICH WILL APPLY TO THE PHYSICIAN ASSISTANT'S PRESCRIBING AND ADMINISTERING OF LEGEND DRUGS AND MEDICAL DEVICES, AND LISTS THE SPECIFIC DRUGS AND MEDICAL DEVICES, WITH ANY EXCEPTIONS OR CONDITIONS, THAT THE PHYSICIAN ASSISTANT IS AUTHORIZED TO PRESCRIBE AND ADMINISTER.

Definition of this term is necessary and reasonable because it is used in the rules to identify a process required for those supervising physicians and physician assistants who wish to include the delegation of authority to prescribe or administer legend drugs or medical devices in their practice.

Subpart 9b. LEGEND DRUG. "LEGEND DRUG" HAS THE MEANING GIVEN IT IN MINNESOTA STATUTES, SECTION 151.01, SUBDIVISION 17, EXCLUDING CONTROLLED SUBSTANCES AS DEFINED IN MINNESOTA STATUTES, SECTION 152.01, SUBDIVISION 4.

It is necessary to define this term because it is used within the rules to identify an item which physician assistants can be authorized to prescribe. Because legend drugs, except for

controlled substances are regulated by Minnesota Statutes, Chapter 151, it is reasonable to use the definition in Minnesota Statutes, section 151.01, subdivision 17 for these rules so that the regulations governing prescription writing are clear and consistent with the statute.

Subpart 9c. MEDICAL DEVICE. "MEDICAL DEVICE" MEANS DURABLE MEDICAL EQUIPMENT, AND ASSISTIVE OR REHABILITATIVE APPLIANCES, OBJECTS, OR PRODUCTS THAT ARE REQUIRED TO IMPLEMENT THE OVERALL PLAN OF CARE FOR THE PATIENT.

Definition of this term is necessary because it is used in the rules to identify a category of items which physician assistants may prescribe. It is reasonable to include durable medical equipment because physician assistants often treat patients who need such equipment. Assistive or rehabilitative appliances, objects, or products are reasonably included because physician assistants may need to prescribe such items to initiate or complete a course of treatment for a patient. Inclusion of a detailed listing of each medical device would be lengthy and unduly burdensome for the delegation process. Prescribing or administering of medical devices by the physician assistant will be limited by the physician assistant's training and experience, the services customary to the practice of the supervising physician, and the delegation by the supervising physician.

Subpart 11a. PRESCRIBE. "PRESCRIBE" MEANS TO DIRECT, ORDER, OR DESIGNATE BY MEANS OF A PRESCRIPTION THE PREPARATION, USE OF, OR MANNER OF USING A DRUG OR MEDICAL DEVICE.

This term is necessary because it is used in these rules to identify an activity within the scope of physician assistant practice. It is reasonable to define prescribe as including

directing, ordering or designating because these are the means used by a physician assistant to provide a prescription.

Subpart 11b. PRESCRIPTION. "PRESCRIPTION" MEANS A SIGNED WRITTEN ORDER, OR AN ORAL ORDER REDUCED TO WRITING, GIVEN BY A PHYSICIAN ASSISTANT AUTHORIZED TO PRESCRIBE DRUGS FOR PATIENTS IN THE COURSE OF THE PHYSICIAN ASSISTANT'S PRACTICE, ISSUED FOR AN INDIVIDUAL PATIENT AND CONTAINING THE INFORMATION REQUIRED BY PART 5600.2670, SUBPART 4, ITEM C.

This definition is necessary because the term is used in the rules. The definition is reasonable for consistency and clarity because it contains language similar to that used in Minnesota Statutes, section 151. It is reasonable to substitute the language "physician assistant authorized to prescribe" instead of "practitioner licensed to prescribe" because physician assistants are not licensed to prescribe but may be authorized by their supervising physicians to prescribe. Inclusion of the name, address, and telephone number of the physician serving as supervisor is necessary and reasonable because this information may be needed by the pharmacist and it is not unduly burdensome for the physician assistant to provide.

5600.2605 PURPOSE

THE PURPOSE OF PARTS 5600.2600 TO ~~5600.2665~~ 5600.2670 IS TO ESTABLISH THE ADMINISTRATIVE STRUCTURE, THE PROCEDURES, AND THE REQUIREMENTS FOR THE REGISTRATION OF PEOPLE QUALIFIED TO BE PHYSICIAN ASSISTANTS AND THE REQUIREMENTS WHICH MUST BE MET BEFORE A PHYSICIAN ASSISTANT MAY PRESCRIBE AND ADMINISTER LEGEND DRUGS AND MEDICAL DEVICES.

It is reasonable and necessary to amend the statement of purpose for these rules because the scope of physician assistant practice has been modified by Minnesota Statutes, section 147.34. The amendment to this subpart incorporates the new and expanded

purpose of these rules.

5600.2610 RESTRICTIONS ON USE OF THE TITLE OF REGISTERED PHYSICIAN ASSISTANT

Subpart 1. PHYSICIAN ASSISTANT IDENTIFICATION. ONLY A REGISTERED PHYSICIAN ASSISTANT IN ACTIVE STATUS MAY USE THE TITLE "PHYSICIAN ASSISTANT" OR "REGISTERED PHYSICIAN ASSISTANT" WITHOUT RESTRICTION. ONLY A REGISTERED PHYSICIAN ASSISTANT IN ACTIVE STATUS SHALL ~~IDENTIFY HIMSELF OR HERSELF~~ BE IDENTIFIED AT THE PRACTICE SITE BY USING A NAME TAG OR NAME PLATE OR SOME OTHER IDENTIFYING DEVICE BEARING THE TITLE "REGISTERED PHYSICIAN ASSISTANT."

It is necessary and reasonable to add the word "only" to the rules to make clear what the statute already requires. Minnesota Statutes, section 214.001, subdivision 3 (c) restricts the use of titles protected by rules to those who meet predetermined qualifications. Part 5600.2610, as originally written, and standing apart from the statute, does not make it sufficiently clear that non-registered persons may not call themselves physician assistants. It is important to clarify this because the statutory authority for prescribing and administering only applies to persons who are registered.

5600.2615 SCOPE OF PHYSICIAN ASSISTANT PRACTICE

Subpart 2. PATIENT SERVICES MUST BE LIMITED TO:

...

H. PRESCRIBING AND ADMINISTERING LEGEND DRUGS OTHER THAN CONTROLLED SUBSTANCES AS DEFINED IN MINNESOTA STATUTES, SECTION 152.01, SUBDIVISION 4, AND MEDICAL DEVICES IF THIS FUNCTION HAS BEEN DELEGATED TO THE PHYSICIAN ASSISTANT BY THE SUPERVISING PHYSICIAN AND APPROVED BY THE BOARD, PURSUANT TO AND SUBJECT TO THE LIMITATIONS OF MINNESOTA STATUTES, SECTION 147.34 AND CHAPTER 151, AND PARTS 5600.2600 TO 5600.2670.

It is necessary to include the prescription and administration of drugs and medical devices in this section because the scope of physician assistant practice has been

expanded by the legislature to permit the delegation of these functions to physician assistants under certain conditions. This rule puts practitioners and the public on notice of this fact.

It is reasonable to place restrictions on physician assistant prescribing because physician assistants are a physician-dependent health care occupation, performing their job functions under the direction and supervision of a physician. The rules necessarily exclude delegating prescription of controlled substances because the legislature did not provide statutory language permitting such delegation. Minnesota physician assistants are unable to obtain Drug Enforcement Agency numbers allowing them to prescribe controlled substances because the state has not granted independent prescribing authority to physician assistants.

5600.2635 APPLICATION PROCESS FOR APPROVAL OF AGREEMENT BETWEEN PHYSICIAN AND PHYSICIAN ASSISTANT

Subpart 3. CONTENTS OF AGREEMENT. THE AGREEMENT MUST INCLUDE AT LEAST THE FOLLOWING:

...

D. A STATEMENT BY THE SUPERVISING PHYSICIAN REGARDING THE DELEGATION OR NONDELEGATION OF THE FUNCTIONS OF PRESCRIBING AND ADMINISTERING LEGEND DRUGS AND MEDICAL DEVICES TO THE PHYSICIAN ASSISTANT, AND, IF DELEGATION IS SPECIFIED, THE COMPLETED DELEGATION FORM AS REQUIRED BY PART 5600.2670.

It is necessary that a statement regarding delegation of prescribing functions be included in the physician/physician assistant agreement along with a separate form addressing delegation of prescribing so that the Board can, as required by law, inform pharmacies which physician assistants will be prescribing and which categories of drugs they may prescribe. It

is reasonable to require the supervising physician and physician assistant to carefully consider the functions of prescribing and administering in order to protect the public from potential harm. It is reasonable that the agreement contain such a statement and form because it is not unduly burdensome for the physician and physician assistant to provide this information regarding their practice. It is also reasonable that the primary responsibility for determining the parameters of physician assistant prescribing be placed on the supervising physician and physician assistant rather than the Board or Physician Assistant Advisory Council because the supervising physician and physician assistant can best determine the appropriate prescribing practice for their situation based upon the scope of the practice and the physician assistant's abilities and training. The Board and Advisory Council have a secondary responsibility to assure compliance with the rules and statute.

Minnesota Statutes, section 147.34, subdivision 1, c, (2) requires rules to establish method indicating which substances may not be prescribed and this is done by eliminating controlled substances.

This amendment to the rule is necessary and reasonable to clarify the requirement that the delegation of authority to prescribe and administer must be contained in the agreement terms and must be submitted to the Board for approval.

Subpart 5. PROCEDURE TO OBTAIN DELEGATION OF PRESCRIBING AND ADMINISTERING FUNCTIONS. TO OBTAIN DELEGATION OF PRESCRIBING AND ADMINISTERING FUNCTIONS, A PHYSICIAN ASSISTANT MUST:

A. SUBMIT AN AGREEMENT INDICATING DELEGATION OF

PRESCRIBING AND ADMINISTERING FUNCTIONS;

B. SUBMIT A COPY OF THE PHYSICIAN ASSISTANT'S CERTIFICATION CARD FROM THE NATIONAL COMMISSION ON CERTIFICATION OF PHYSICIAN ASSISTANTS SHOWING CURRENT CERTIFICATION;

C. SUBMIT THE COMPLETED AND SIGNED DELEGATION FORM IN PART 5600.2670, SUBPART 6; AND

D. SUBMIT THE FEES REQUIRED BY 5600.2655.

THE BOARD SHALL REVIEW EACH APPLICATION FOR APPROVAL OF AGREEMENTS CONTAINING DELEGATION OF PRESCRIBING IN A TIMELY MANNER AND NOTIFY THE APPLICANT IN WRITING OF ACTION TAKEN ON THE APPLICATION. IF THE AGREEMENT IS NOT APPROVED, THE BOARD MUST INDICATE THE GROUNDS FOR ITS ACTION IN THE NOTICE TO THE APPLICANT.

This section is necessary and reasonable to set forth the procedure to be used in applying for prescribing and administering functions.

5600.2645 APPLICATION PROCESS FOR REREGISTRATION

A PHYSICIAN ASSISTANT'S REGISTRATION EXPIRES EACH YEAR ON JULY 1. EACH PHYSICIAN ASSISTANT MUST REREGISTER ON OR BEFORE JULY 1 OF EACH YEAR BY SUBMITTING A COMPLETED APPLICATION FOR REREGISTRATION ON A FORM PROVIDED BY THE BOARD TOGETHER WITH THE ANNUAL REREGISTRATION FEE. PHYSICIAN ASSISTANTS WITH AUTHORITY TO PRESCRIBE AND ADMINISTER LEGEND DRUGS AND MEDICAL DEVICES MUST ALSO PROVIDE A COPY OF A CURRENT CERTIFICATION CARD ISSUED BY THE NATIONAL COMMISSION OF CERTIFICATION OF PHYSICIAN ASSISTANTS. THE INFORMATION SUPPLIED ON THE APPLICATION FOR REREGISTRATION MUST BE SUFFICIENT FOR THE BOARD TO DETERMINE WHETHER THE PHYSICIAN ASSISTANT CONTINUES TO MEET THE REQUIREMENTS FOR REGISTRATION IN PART 5600.2625 OR 5600.2640. IN ADDITION, THE APPLICANT MUST MEET THE REQUIREMENTS OF PART 5600.2650. THE BOARD MAY REQUEST A PHYSICIAN ASSISTANT TO SUBMIT ADDITIONAL INFORMATION TO CLARIFY INFORMATION PRESENTED IN THE APPLICATION FOR REREGISTRATION. AN APPLICATION SUBMITTED AFTER THE REREGISTRATION DEADLINE DATE MUST BE ACCOMPANIED BY A LATE FEE.

It is necessary to require physician assistants to submit proof of current certification by the National Commission on Certification of Physician Assistants upon reregistration because it is required by Minnesota Statutes, section 147.34, subdivision 1 (b). It is reasonable to require physician assistants who will be prescribing or administering legend drugs and medical devices

to provide proof of continued qualification to perform this function.

5600.2655 APPLICATION FEES

Subpart 4. FEE FOR APPROVAL OF AGREEMENTS. THE FEE FOR APPROVAL OF AN AGREEMENT BETWEEN A PHYSICIAN AND PHYSICIAN ASSISTANT BY THE BOARD SHALL BE ~~\$30-~~:

A. \$30 FOR AGREEMENTS NOT CONTAINING DELEGATION OF PRESCRIBING AND ADMINISTERING FUNCTIONS; OR

B. \$86 FOR AGREEMENTS CONTAINING DELEGATION OF PRESCRIBING AND ADMINISTERING FUNCTIONS. THE DELEGATION FORM MUST ACCOMPANY THE AGREEMENT.

It is necessary and reasonable that the fee for approval of agreements containing delegation of prescribing is greater than that for approval of agreements not containing delegation of prescribing to recover the extra costs associated with reviewing an agreement containing prescribing protocol. The Board has indicated that it will incur additional costs for administering those agreements containing the delegation of prescribing to the physician assistant including additional time spent in review of agreements, mailing costs for notifying pharmacies of prescribing physician assistants and anticipated disciplinary costs. It is reasonable that the fee be assessed to those actually requiring the extra administrative work; those physician assistants with prescribing protocol contained in their agreements.

5600.2660 PROCESS AND GROUNDS FOR DISCIPLINARY ACTION

Subpart 2. DISCIPLINARY OPTIONS OF BOARD. THE BOARD SHALL REFUSE TO GRANT OR RENEW A REGISTRATION, OR SHALL SUSPEND OR REVOKE A REGISTRATION, OR USE ANY LESSER REMEDY AGAINST A PHYSICIAN ASSISTANT IF THE ASSISTANT:

...

G. VIOLATES STATE OR FEDERAL LAWS REGARDING PRESCRIBING OR ADMINISTERING LEGEND DRUGS OR MEDICAL DEVICES;

H. PRESCRIBES OR ADMINISTERS LEGEND DRUGS OR MEDICAL

DEVICES IN A MANNER OTHER THAN UNDER THE PROCEDURES IN PARTS 5600.2600 TO 5600.2670.

I. PRESCRIBES OR ADMINISTERS LEGEND DRUGS OR MEDICAL DEVICES IN A MANNER WHICH IS INCONSISTENT WITH THE TRAINING AND EXPERIENCE OF THE PHYSICIAN ASSISTANT OR IN A MANNER WHICH FALLS BELOW THE COMMUNITY STANDARD OF CARE; OR

J. PRESCRIBES OR ADMINISTERS LEGEND DRUGS OR MEDICAL DEVICES IN VIOLATION OF THE AGREEMENT.

It is necessary and reasonable that the grounds for discipline available to the Board be expanded to specify and include illegal or inappropriate prescribing and administering of drugs and medical devices so that the Board can act appropriately to protect the public from a physician assistant who has demonstrated an inability to abide by professional and legal standards for prescribing.

Subpart 3. DISCIPLINARY ACTIONS. IF THE BOARD FINDS THAT A PHYSICIAN ASSISTANT SHOULD BE DISCIPLINED PURSUANT TO SUBPART 2, THE BOARD MAY TAKE ANY ONE OR MORE OF THE FOLLOWING ACTIONS:

...

G. REFUSE TO APPROVE DELEGATION OF PRESCRIBING AND ADMINISTERING AUTHORITY, REVOKE, SUSPEND, RESTRICT, OR CONDITION PRESCRIBING AND ADMINISTERING AUTHORITY.

It is necessary that the Board be able to remove or limit a physician assistant's prescribing and administering practice in order to protect the public should an individual demonstrate inadequate qualifications or inappropriate prescribing practices. This rule is reasonable because it allows the Board a variety of disciplinary options which can be tailored to the particular situation. It is also reasonable to designate the statutory standards for disciplining physician assistants to provide adequate notice of the expected standards of conduct in prescribing and administering practice.

5600.2665 PHYSICIAN ASSISTANT ADVISORY COUNCIL

Subpart 3. DUTIES. THE COUNCIL SHALL:

...

H. REVIEW DELEGATION OF PRESCRIBING AND ADMINISTERING AUTHORITY IN AGREEMENTS, REQUEST A COPY OF THE INTERNAL PROTOCOL OR OTHER ADDITIONAL INFORMATION FOR CLARIFICATION OF DELEGATION TERMS IF NECESSARY, AND RECOMMEND APPROVAL, DISAPPROVAL, OR MODIFICATION OF THE AGREEMENT BASED UPON THE STANDARDS IN MINNESOTA STATUTES, SECTION 147.34 AND PARTS 5600.2600 TO 5600.2670.

This rule is necessary because the Board has delegated the review of agreements to the advisory council and delegation of prescribing authority will be contained in the agreement. It is reasonable that the advisory council have this function delegated to it because its members have the technical expertise needed to review the delegation protocol and determine whether it meets the standards set forth in law and rules. It is reasonable to designate the standards for this review to assure consistency in council review of the delegation.

5600.2670 DELEGATION OF AUTHORITY TO PRESCRIBE AND ADMINISTER DRUGS AND MEDICAL DEVICES

Subpart 1. DELEGATION. A PHYSICIAN ASSISTANT MAY PRESCRIBE AND ADMINISTER LEGEND DRUGS AND MEDICAL DEVICES UNDER THE FOLLOWING CONDITIONS:

A. THE PHYSICIAN ASSISTANT IS CURRENTLY CERTIFIED BY THE NATIONAL COMMISSION ON CERTIFICATION OF PHYSICIAN ASSISTANTS AS EVIDENCED BY A COPY OF THE CERTIFICATION CARD WITH EXPIRATION DATE.

B. THE PHYSICIAN ASSISTANT IS REGISTERED WITH THE BOARD.

C. THE PHYSICIAN ASSISTANT'S SUPERVISING PHYSICIAN AND THE PHYSICIAN ASSISTANT HAVE COMPLETED AND SIGNED THE DELEGATION FORM IN SUBPART 6.

D. THE AGREEMENT HAS BEEN APPROVED BY THE BOARD BASED UPON THE STANDARDS IN MINNESOTA STATUTES, SECTION 147.34, AND PARTS 5600.2600 TO 5600.2670; AND

E. THE PHYSICIAN ASSISTANT'S PRESCRIPTION WRITING PRIVILEGES ARE NOT CURRENTLY RESTRICTED BY THE BOARD.

It is necessary to include language specifying the conditions under which a physician may delegate the prescription and administration of legend drugs and medical devices to physician assistants because the legislature has determined that supervising physicians may delegate these functions to physician assistants. It is reasonable to indicate in the rule that these functions are delegated only under certain conditions in order to protect the public. These conditions are aimed at making sure the physician assistant possesses adequate knowledge and training to enable him or her to safely and effectively perform these functions.

Minnesota Statutes, section 147.34, subdivision 1 (a) and (b) establishes conditions which a physician assistant must meet before being delegated prescribing and administering authority for drugs and medical devices. It is reasonable and necessary to restate the conditions in rule so that all persons affected by the rules have notice of all the requirements.

It is necessary and reasonable that the agreement be subject to the review of the Board because they have the expertise to determine whether the agreement conforms to the limitations in the physician assistant scope of practice as described in Minnesota Rules, part 5600.2615, subpart 1. It is also reasonable to designate the statutory standards for review of the agreement to provide guidelines for consistent review.

It is necessary and reasonable for the protection of the

public health and safety that the prescribing and administering of legend drugs and medical devices be limited to those physician assistants who have demonstrated adequate qualifications for assumption of prescribing. Physician assistants subject to restrictions on prescribing privileges have demonstrated an inability to prescribe within professional and/or legal guidelines and are therefore not qualified to prescribe.

Subpart 2. DOCUMENTATION. THE PHYSICIAN ASSISTANT SHALL ENTER EACH PRESCRIPTION ON THE PATIENT'S CHART.

THE SUPERVISING PHYSICIAN SHALL RETROSPECTIVELY REVIEW THE PHYSICIAN ASSISTANT'S PRESCRIBING AND ADMINISTERING PRACTICES ON A DAILY BASIS. REVIEW MAY EITHER BE IN PERSON OR BY TELECOMMUNICATION.

A. IF THE SUPERVISING PHYSICIAN PERFORMS THIS REVIEW IN PERSON, THE SUPERVISING PHYSICIAN SHALL DOCUMENT THE RETROSPECTIVE REVIEW BY SIGNATURE ON THE PATIENT'S CHART OR OTHER PERMANENT PRACTICE RECORD.

B. FOR FACILITIES STAFFED BY THE PHYSICIAN ASSISTANT THAT ARE SEPARATE FROM THE USUAL PRACTICE SITE OF THE SUPERVISING PHYSICIAN, THE PHYSICIAN ASSISTANT OR THE SUPERVISING PHYSICIAN SHALL DOCUMENT THE RETROSPECTIVE REVIEW BY SIGNATURE ON THE PATIENT'S CHART OR OTHER PERMANENT PRACTICE RECORD. AT EACH SITE VISIT, THE SUPERVISING PHYSICIAN SHALL DOCUMENT BY SIGNATURE AND DATE ON THE PATIENT'S CHART OR OTHER PERMANENT PRACTICE RECORD THAT THE PHYSICIAN ASSISTANT'S PRESCRIBING AND ADMINISTERING PRACTICES HAVE BEEN REVIEWED.

It is necessary to require documentation of review of physician assistant practices because it is required by Minnesota Statutes, section 147.34, subdivision 1 (b). Documentation helps to assure that drugs and medical devices are being properly prescribed and administered. It also assures that the supervising physician remains aware of the physician assistant's exercise of prescribing and administering authority.

Since it is required that the supervising physician regularly review and document the physician assistant prescribing

and administering practices, it is reasonable to provide alternate means of documentation. If only one method were provided, it would likely be unduly burdensome in some practice settings. The alternatives provided allow for development of a procedure for review by the supervising physician and physician assistant which will comply with the statutory requirements and fit the unique characteristics of individual practice settings. It is also reasonable that supervising physicians and physician assistants working in facilities separate from the physician's usual practice site be provided with flexibility of reporting to meet their special needs and circumstances.

Subpart 3. TERMINATION AND REINSTATEMENT OF PRESCRIBING AUTHORITY.

A. THE AUTHORITY OF A PHYSICIAN ASSISTANT TO PRESCRIBE AND ADMINISTER LEGEND DRUGS AND MEDICAL DEVICES SHALL END IMMEDIATELY WHEN:

- (1) THE AGREEMENT IS TERMINATED;
- (2) THE AUTHORITY TO PRESCRIBE AND ADMINISTER IS TERMINATED OR WITHDRAWN BY THE SUPERVISING PHYSICIAN; OR
- (3) THE PHYSICIAN ASSISTANT REVERTS TO INACTIVE STATUS, LOSES NATIONAL COMMISSION ON CERTIFICATION OF PHYSICIAN ASSISTANTS CERTIFICATION, OR LOSES OR TERMINATES REGISTRATION STATUS.

B. THE PHYSICIAN ASSISTANT MUST NOTIFY THE BOARD IN WRITING WITHIN 10 DAYS OF THE OCCURRENCE OF ANY OF THE CIRCUMSTANCES LISTED IN ITEM A.

C. PHYSICIAN ASSISTANTS WHOSE AUTHORITY TO PRESCRIBE AND ADMINISTER HAS BEEN TERMINATED SHALL REAPPLY FOR APPROVAL OF THE AGREEMENT UNDER PART 5600.2635 AND MEET THE REQUIREMENTS OF SUBPART 1, AND ANY OTHER REQUIREMENTS ESTABLISHED BY THE BOARD PRIOR TO REINSTATEMENT OF THE PRESCRIBING AND ADMINISTERING AUTHORITY.

It is necessary that the authority to prescribe is terminated if one of the above conditions occurs because the physician assistant is a physician-dependent health care professional and cannot operate independent of physician

supervision. It is also necessary to terminate prescribing authority if one of the above conditions occurs because they are statutory prerequisites for delegation of prescription writing privileges. It is reasonable to require a physician assistant to cease prescribing under these conditions in order to assure the health and safety of the public. It is necessary and reasonable to include these provisions in the rule so that supervising physicians and physician assistants have notice of when prescription authority expires and the requirements for regaining authority. It is necessary and reasonable to require the physician assistant notify the Board within a definite period of time to protect the public health and safety. The physician assistant has the information regarding termination of authority and it is not unduly burdensome for him or her to notify the Board.

Subpart 4. OTHER REQUIREMENTS AND RESTRICTIONS

A. THE SUPERVISING PHYSICIAN AND THE PHYSICIAN ASSISTANT MUST COMPLETE, SIGN, AND DATE AN INTERNAL PROTOCOL WHICH LISTS EACH DRUG OR MEDICAL DEVICE THE PHYSICIAN ASSISTANT MAY PRESCRIBE AND ADMINISTER. THE SUPERVISING PHYSICIAN AND PHYSICIAN ASSISTANT SHALL SUBMIT THE INTERNAL PROTOCOL TO THE BOARD UPON REQUEST. THE SUPERVISING PHYSICIAN MAY AMEND THE INTERNAL PROTOCOL AS NECESSARY, WITHIN THE LIMITS OF THE COMPLETED DELEGATION FORM IN SUBPART 6. THE SUPERVISING PHYSICIAN AND PHYSICIAN ASSISTANT MUST SIGN AND DATE ANY AMENDMENTS TO THE INTERNAL PROTOCOL. ANY AMENDMENTS RESULTING IN A CHANGE TO THE DELEGATION FORM IN SUBPART 6 MUST BE SUBMITTED TO THE BOARD ACCORDING TO PART 5600.2635, SUBPART 4 ALONG WITH THE FEE REQUIRED IN PART 5600.2655.

It is necessary that the supervising physician and physician assistant have a mutual understanding of and articulate how the physician assistant will be prescribing within a particular

practice. This rule provision requires them to detail and render the understanding in writing in the form of an internal protocol. Because this protocol specifies how prescribing will be done in the workplace rather than the parameters or scope of prescribing delegation, it need not be submitted to the Board unless the Board requests. The internal protocol is meant to relate to the internal operating procedures of the medical provider setting which may be unique and/or vary greatly among settings. This rule, in order to apply adequate safeguards to protect the public, is reasonable because it is not unduly burdensome for the supervising physician and physician assistant and because it provides an extra measure of precaution in the delegation of prescribing authority.

B. THE SUPERVISING PHYSICIAN AND PHYSICIAN ASSISTANT SHALL REVIEW DELEGATION OF PRESCRIBING AND ADMINISTERING AUTHORITY ON AN ANNUAL BASIS AT THE TIME OF REREGISTRATION. THE INTERNAL PROTOCOL MUST BE SIGNED AND DATED BY THE SUPERVISING PHYSICIAN AND PHYSICIAN ASSISTANT AFTER REVIEW. ANY AMENDMENTS TO THE INTERNAL PROTOCOL RESULTING IN CHANGES TO THE DELEGATION FORM IN SUBPART 6 MUST BE SUBMITTED TO THE BOARD ACCORDING TO PART 5600.2635, SUBPART 4, ALONG WITH THE FEE REQUIRED IN PART 5600.2655.

This rule is necessary to assure that prescribing practices of physician assistants are reviewed and updated at least on an annual basis with submission of any changes to the Board. It is necessary to inform the Board of any changes so that it may provide accurate information to pharmacies regarding those physician assistants who are prescribing and have information available regarding the categories of drugs from which they will be prescribing. It is reasonable to require an annual review by

the supervising physician and physician assistant because it is not unduly burdensome for them to conduct such a review and have it coincide with reregistration of the physician assistant.

C. EACH PRESCRIPTION INITIATED BY A PHYSICIAN ASSISTANT SHALL INDICATE THE FOLLOWING:

- (1) THE DATE OF ISSUE;
- (2) THE NAME AND ADDRESS OF THE PATIENT;
- (3) THE NAME AND QUANTITY OF THE DRUG PRESCRIBED;
- (4) DIRECTIONS FOR USE; AND
- (5) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF THE PRESCRIBING PHYSICIAN ASSISTANT AND OF THE PHYSICIAN SERVING AS SUPERVISOR.

This rule is necessary because it clearly identifies the information that is to be included on a prescription written by a physician assistant. It is necessary and reasonable to require this information because it is the type of information needed by a pharmacist to verify that the prescription has been issued by a legally authorized individual.

D. IN PRESCRIBING AND ADMINISTERING LEGEND DRUGS AND MEDICAL DEVICES, A PHYSICIAN ASSISTANT MUST CONFORM WITH THE AGREEMENT, MINNESOTA STATUTES, SECTION 147.34 AND CHAPTER 151, AND PARTS 5600.2600 TO 5600.2670.

It is necessary and reasonable that the physician and physician assistant confine their practice to current legal regulations because the laws were written to assure the safe prescription of legend drugs. This rule is also reasonable to provide guidelines for consistent review and approval of the delegation of prescription writing in the agreement.

Subpart 5. NOTIFICATION OF PHARMACIES

Minnesota Statutes, section 147.34, subdivision 1 (c) (3) requires the Commissioner to develop a method for transmitting information regarding prescribing physician assistants to

pharmacies. These rules provide a practical method of notification which is not unduly burdensome for the Board.

A. THE BOARD SHALL, WITHIN SIX MONTHS OF ADOPTION OF PARTS 5600.2600 TO 5600.2670 AND ANNUALLY THEREAFTER, PROVIDE TO THE BOARD OF PHARMACY AND TO REGISTERED PHARMACIES WITHIN THE STATE A LIST OF THOSE PHYSICIAN ASSISTANTS WHO ARE AUTHORIZED TO PRESCRIBE LEGEND DRUGS AND MEDICAL DEVICES.

This rule is necessary because the Commissioner is required by Minnesota Statutes, section 147.34, subdivision 1 (c) (3) to establish a system for transmitting to pharmacies a listing of those physician assistants eligible to prescribe. It is reasonable that the Board provide this listing because the Board will have this information available to them. It is reasonable that the Board provide this listing on an annual basis because physician assistants submit an application for reregistration to the Board on an annual basis therefore the Board will have current information needed by pharmacies.

B. THE BOARD SHALL PROVIDE TO THE BOARD OF PHARMACY A LIST OF PHYSICIAN ASSISTANTS AUTHORIZED TO PRESCRIBE LEGEND DRUGS AND MEDICAL DEVICES EVERY TWO MONTHS IF ADDITIONAL PHYSICIAN ASSISTANTS ARE AUTHORIZED TO PRESCRIBE OR IF PHYSICIAN ASSISTANTS HAVE AUTHORIZATION TO PRESCRIBE WITHDRAWN.

Updating the list of physician assistants authorized to prescribe on an interim basis is necessary because there may be physician assistants who receive authorization to prescribe prior to the annual release of the list to pharmacies. In addition, there may be physician assistants who have authorization to prescribe withdrawn prior to annual release of the list. It is reasonable to designate a schedule of six times per year because the Board will be meeting and reviewing delegations of

prescribing authority no more than every other month throughout the year. Pharmacies will be able to acquire current information from the Board or the Board of Pharmacy so that prescriptions can be lawfully filled.

C. THE LIST MUST INCLUDE THE NAME, ADDRESS, TELEPHONE NUMBER, AND MINNESOTA REGISTRATION NUMBER OF THE PHYSICIAN ASSISTANT, AND THE NAME, ADDRESS, TELEPHONE NUMBER, AND MINNESOTA LICENSE NUMBER OF THE SUPERVISING PHYSICIAN.

It is necessary and reasonable to require provision of this information so that pharmacies have a means of identifying the prescribing physician assistant and contacting the prescribing physician assistant should additional information be needed to correctly fill the prescription. Each pharmacy need not have a copy of each delegation form listing the drug categories the physician assistant may prescribe; it would be unduly burdensome for the Board to provide such information and information provided in this manner is not likely to be helpful to or utilized by pharmacists. The delegation form is available from the Board should the pharmacy wish to have this information.

D. THE BOARD SHALL PROVIDE THE FORM IN SUBPART 6 TO PHARMACIES UPON REQUEST.

This rule is necessary because the Commissioner is required to provide a system for transmission to pharmacies of a list of the drugs which physician assistants are allowed to prescribe. Minnesota Statutes, section 147.34, subdivision 1 (c) (3). It is reasonable to require the Board to disseminate the information since it will have the form in its possession. It is not unduly burdensome for the Board to provide this information to

pharmacies on a request basis.

Subpart 6. DELEGATION FORM FOR PHYSICIAN ASSISTANT
PRESCRIBING. THE DELEGATION FORM FOR PHYSICIAN ASSISTANT
PRESCRIBING MUST CONTAIN THE FOLLOWING:

(Please see next page)

DELEGATION FORM FOR PHYSICIAN ASSISTANT PRESCRIBING

The below-named physician assistant may prescribe and administer drugs and medical devices as indicated on this form. This form is hereby made a part of the agreement as required by Minn. Stat. section 147.34 and Minn. Rules part 5600.2635, subpart 3, item D.

Physician Assistant _____ Minn. Registration # _____
 Supervising Physician _____ Minn. License # _____

The physician assistant may prescribe from those categories checked in the following list:

Restrictions applicable to each category:

A. Drugs*

- | | |
|--|----------|
| 01 _____ Anesthetics | 01 _____ |
| 02 _____ Antiinfectives | 02 _____ |
| 03 _____ Antineoplastics/Immunosuppressants | 03 _____ |
| 04 _____ Cardiovascular Medications | 04 _____ |
| 05 _____ Autonomic & Central Nervous System
Drugs | 05 _____ |
| 06 _____ Dermatological Medications | 06 _____ |
| 07 _____ Diagnostic Agents | 07 _____ |
| 08 _____ Ear-Nose-Throat Medications | 08 _____ |
| 09 _____ Endocrine Medications | 09 _____ |
| 10 _____ Gastrointestinal Medications | 10 _____ |
| 11 _____ Immunologicals & Vaccines | 11 _____ |
| 12 _____ Musculoskeletal Medications | 12 _____ |
| 13 _____ Nutritional Products, Blood
Modifiers & Electrolytes | 13 _____ |
| 14 _____ Obstetrical & Gynecological
Medications | 14 _____ |
| 15 _____ Ophthalmic Medications | 15 _____ |
| 16 _____ Respiratory Medications | 16 _____ |
| 17 _____ Urological Medications | 17 _____ |
| B. _____ Medical Devices | B. _____ |

Physician assistants may not prescribe controlled substances regulated under Minn. Stat. Chapter 152. Other specific drugs or medical devices which the physician assistant may not prescribe include:

Supervising Physician (sign)

Physician Assistant (sign)

(type name/date)

(type name/date)

address

address

telephone # _____

telephone # _____

1. _____
Alternate Supervising Physician

(type name/date)

2. _____
Alternate Supervising Physician

(type name/date)

3. _____
Alternate Supervising Physician

(type name/date)

4. _____
Alternate Supervising Physician

(type name/date)

5. _____
Alternate Supervising Physician

(type name/date)

6. _____
Alternate Supervising Physician

(type name/date)

7. _____
Alternate Supervising Physician

(type name/date)

8. _____
Alternate Supervising Physician

(type name/date)

9. _____
Alternate Supervising Physician

(type name/date)

10. _____
Alternate Supervising Physician

(type name/date)

11. _____
Alternate Supervising Physician

(type name/date)

12. _____
Alternate Supervising Physician

(type name/date)

*The listed drug categories are based upon the chapter heading used in the Physicians Health Plan Drug Formulary:
Copyright 1988. United HealthCare Corporation.
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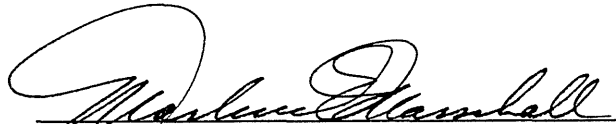
It is necessary to include this form in the agreement because it indicates what the physician assistant may prescribe as required by Minnesota Statutes, section 147.34, subdivision 1 (b). The form represents a balance between the need for sufficiently detailed information on the extent of delegation and the need for a form that will not burden physicians, physician assistants, pharmacies, and pharmacists to such an extent so as to make delegation not feasible and impractical.

Identification of the physician assistant is necessary so that the Board may determine whether the physician assistant meets the requirements for delegation of legend drug and medical device prescribing and administering as set forth in Minnesota Statutes, section 147.34, subdivision 1, (b). A listing of categories from which a physician assistant may prescribe is necessary to provide a clear and orderly indication of delegated prescribing and administering functions and to meet the requirements of Minnesota Statutes, section 147.34. The Physicians Health Plan format is being used with its permission as evidenced by correspondence from K. James Ehlen dated October 16, 1990 to identify categories of drugs which may be prescribed because it provides an orderly and consistent way of identifying those categories of drugs which will be prescribed by a particular physician assistant. This format is also used by the Minnesota Department of Human Services in the Medical Assistance and General Assistance Medical Care Provider Manual and is therefore familiar to medical providers. The column for

restrictions and the space for designating drugs or medical devices which the physician assistant may not prescribe are necessary to provide the supervising physician and physician assistant an opportunity to tailor the form to meet any limitations required by their individual practice situation. It is necessary to require the signatures of the physician assistant, supervising physician, and alternate supervising physicians because, by signing the form, the individuals indicate their agreement regarding the physician assistant's prescribing practices. It is necessary and reasonable that the physicians sign this form because they retain ultimate responsibility for the physician assistant's prescribing.

10/29/91

Date



Marlene E. Marschall
Commissioner of Health

ADDENDUM

STATEMENT OF NEED AND REASONABLENESS

Need

Minnesota Statutes, section 147.34, subdivision 2, authorizes the Commissioner to promulgate rules to implement the delegation of prescribing to physician assistants. Minnesota Statutes, section 214.13, subdivision 3, authorizes the Commissioner to assess fees. The Commissioner is empowered to assess an amount sufficient to recoup anticipated costs. See Minnesota Statutes, section 214.06, subdivision 1.

Reasonableness

The Department has proposed to adopt a fee for approval of the prescribing agreement. This fee was determined by totalling the costs for rulemaking (\$15,980.56) and dividing the total by 5 to spread the costs of rulemaking over a five year period. See Minnesota Statutes, section 214.06. The resulting amount (\$3,196.11) was added to the total yearly administrative costs (\$7,503.00). The sum (\$10,699.11) was divided by the number of physician assistants estimated to apply for prescribing authority (125) resulting in a fee for approval of a prescribing agreement of \$86.

Upon review of the above information justifying the reasonableness of the proposed fee and pursuant to the authority vested in the Department of Finance under Minnesota Statutes, section 16A.128, the fee set forth in this proposal of the Department of Health is hereby approved.

9-19-91

Date



Bruce Reddeman, Director
Budget Operations