

MINNESOTA BOARD OF PHARMACY



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November 13, 1992

Maryanne Hruby, Director
Legislative Commission to
Review Administrative Rules
55 State Office Building
St. Paul, MN 55155

Dear Maryanne:

Enclosed is a copy of the Statement of Need and Reasonableness for our proposed Rule Amendments and New Rules Relating to the Licensing of Pharmacies, Patient Counseling, Pharmaceutical Care, Standards of Practice, Inactive Status Licensure, Registration of Preceptors, and Dispensing by Non-Pharmacist Practitioners.

If you have any questions, please don't hesitate to contact me.

Very truly yours,

A handwritten signature in cursive script, appearing to read "David E. Holmstrom".

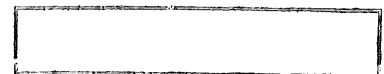
David E. Holmstrom
Executive Director

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Enc.

The Legislative Commission to
Review Administrative Rules

NOV 19 1992



STATE OF MINNESOTA

BEFORE THE MINNESOTA

COUNTY OF RAMSEY

BOARD OF PHARMACY

In the Matter of Proposed Rule Amendments and New Rules Relating to the Licensing of Pharmacies, Patient Counseling, Pharmaceutical Care, Standards of Practice, Inactive Status Licensure, Registration of Preceptors, and Dispensing by Non-Pharmacist Practitioners.

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. sections 14.22 to 14.28 and Minn. Rules part 1400.0500, hereby affirmatively presents the need for and facts establishing the reasonableness of the above captioned proposed amendments and additions to portions of the Board's rules. The statutory authority for these proposed rule changes is contained in Minn. Stat. section 151.06 subdivision 1 (1) and (c).

Up to the present time, the Board has had only a single category of licensure for pharmacies. Despite the fact that the majority of those practicing the profession of pharmacy differentiated between the various specialty areas within pharmacy, such as community retail pharmacy, hospital pharmacy, long-term care pharmacy, etc., the Board's system of licensure of pharmacies did not make such differentiation. Even the Board's own rules, as they relate to standards of practice for the various specialty areas within pharmacy, recognized such differentiation and the existence of specialty areas, but the licensure system did not.

Through these rules, specifically 6800.0100, subparts 2 through 6 and 13, 6800.0300, 6800.0350, and 6800.0500, the Board is proposing to differentiate between the specialty areas that have developed in pharmacy practice, and to identify the specialty area or areas that each licensed pharmacy proposes to operate in on the license certificate.

The general principle here is that the Board is attempting to identify the specialty areas within pharmacy practice which have evolved in the profession, is attempting to develop practice standards for each of the specialty areas, and will be requiring each licensed pharmacy to identify the specialty areas in which professional pharmaceutical services will be offered. The Board will then expect each pharmacy to meet the physical and practice standards identified for those practice areas.

Identifying the practice areas proposed by each pharmacy, will be of great assistance to Board surveyors during inspection visits. Board surveyors will be able to limit their inquiries and focus their attention on the specialty areas each pharmacy has identified themselves as engaging in.

License fees for pharmacies will not be changing as a result of this proposed differentiation. A pharmacy can propose to conduct business in any or all of the specialty areas identified for the same license fee. The pharmacy must be prepared, however, to meet the various physical plant and practice standards for each specialty area in which it proposes to engage.

In Minn. Rule 6800.0700, the Board is proposing to require that each community retail pharmacy develop an area where consultation between the patient and the pharmacist may be conducted with a reasonable expectation of privacy. As will be discussed elsewhere in this document, the Board is proposing to require pharmacists to consult with patients regarding their drug therapy. It has been the Board's experience, however, that most community retail pharmacies, even most of those where patient consultation is now occurring on a regular basis, are not physically arranged so as to provide privacy for the patient when conducting these discussions with the pharmacist.

Discussions between the pharmacist and the patient regarding the patient's drug therapy often involve matters of a confidential nature. Pharmacists should not expect patients to conduct discussions of a sensitive nature in a public area, such as that which exists at the check-out counter of most community retail pharmacies. The Board expects pharmacies to provide a designated patient counseling area that will provide a reasonable expectation of privacy. The Board is not proposing specific criteria for such a patient counseling area, however, in that the Board wishes to give pharmacists as much leeway as possible in tailoring the patient counseling area to the needs and physical layout of each pharmacy.

In Minn. Rule 6800.0800, subpart 3, the Board is attempting to address a problem associated with satellite pharmacies in hospitals. It is not uncommon for large hospitals to maintain, not

only the main pharmacy, but multiple "satellite pharmacies" throughout the hospital. It has long been the Board's position that these satellite pharmacies do not need separate licensure, but do need to have a specific pharmacist identified as being the pharmacist-in-charge of each satellite.

It has been the Board's experience that, not only do some pharmacies fail to identify a pharmacist-in-charge for each satellite pharmacy within the hospital, but in many cases the Board is not even made aware of the fact that a satellite pharmacy is in existence. In addition, issues have arisen as to what a "satellite pharmacy" is and when a pharmacy should no longer be considered a satellite, but should obtain separate licensure as a pharmacy.

In Minn. Rule 6800.0100, subpart 13, the Board is defining a satellite pharmacy and in 6800.0800, subpart 3, is requiring notification of the establishment of each satellite pharmacy. Separate licensure for satellite pharmacies is not being proposed, only notification of the existence of the satellite.

In Minn. Rule 6800.0910, the Board is proposing to require that Minnesota pharmacists consult with each patient regarding their drug therapy. The federal government, pharmacy regulators, pharmacy educators, other healthcare providers, and even pharmacists themselves all recognize that pharmacists have an important role to play in monitoring drug therapy and in optimizing the therapeutic outcome of a patient's drug therapy. For a myriad of reasons, however, pharmacists have been slow, to the point of

being immobile, in moving toward incorporating patient counseling, on a routine basis, into their professional practice.

The federal government, in the Catastrophic Health Insurance Bill of 1988, proposed to require patient counseling by pharmacists as part of that legislation. The federal government recognized that, through the educating of patients regarding their drug therapy, pharmacists could have a positive impact on reducing overall medical costs. That legislation was subsequently repealed for other reasons, but in keeping with its position that pharmacists have an important role to play in reducing overall medical costs by improving the effectiveness of drug therapy through overseeing drug utilization, the U.S. Congress, in passing the Omnibus Budget Reconciliation Act of 1990, again mandated patient consultation by pharmacists for all Medicaid recipients, effective January 1, 1993. In addition, Congress mandated prospective drug use review and the maintenance of patient profiles, by pharmacists, in that same piece of legislation.

Since pharmacists will be required to engage in patient consultation and drug use review for all Medicaid patients under the OBRA 1990 requirements; since the Board recognizes the important role pharmacists have to play in maximizing the effectiveness of drug therapy through patient counseling and drug use review; and since it does not make good sense to have pharmacists engage in drug use review and patient counseling for one segment of their patient population, but not for all; the Board

is proposing to require patient counseling and drug use review, by pharmacists, for all of their patients.

The National Association of Boards of Pharmacy, as one of its services to its member boards, has developed a model Pharmacy Practice Act and Model Regulations for use by the various states. Upon the passage of the OBRA-90 legislation, which mandated that each state develop programs which require that pharmacists perform prospective DUR and patient counseling for Medicaid patients, the NABP met with representatives from the Health Care Financing Administration and with representatives of the major national pharmacy organizations, in Washington, to attempt to develop language for its model rules, which, if adopted by the states and complied with by pharmacist, would allow those pharmacists to meet the requirement of the OBRA-90 legislation. The language being proposed by the Board in Minn. Rule 6800.0910, relative to patient counseling, comes from NABP developed model language.

In addition to all of this, the Minnesota Legislature, in passing Chapter 513, Article 7, Section 10, of the Laws of 1992, has directed the Board specifically to develop the rules required for the implementation of the requirements of OBRA-90. In order to avoid a two-tiered system of pharmaceutical services in Minnesota, with one set of standards for Medicaid patients and another for everyone else, the Board is proposing to make the requirements of OBRA-90 applicable to all patients.

The Board firmly believes that pharmacists who tailor their professional practice to remain in compliance with this proposed

rule will automatically be found to be in compliance with the patient counseling provisions of the OBRA-90 legislation. Thus, the Board's proposal here is both needed and reasonable.

6800.1010 is a new rule relating to the procedures a pharmacist must follow when closing a pharmacy. This section relates to pharmacies that are going out of business and are closing for good.

Currently, the US Drug Enforcement Administration has some requirements, that pharmacies that are going out of business must comply with, relating to controlled substance drugs. Minn. Rule 6800.1010 incorporates the DEA requirements and adds other requirements developed by the Board.

The basic concern of the Board is that the drugs of the closing pharmacy be properly secured, removed from the premises, and be distributed only to those licensed to possess such drugs; that records of the distribution be maintained, and that patient records be handled in such a way that patients will always have access to their prescription records and that the Board will be informed of where those records reside.

The essence of this regulation requires the pharmacist-in-charge of the pharmacy that is closing to take an inventory of controlled substances on hand at the time of closing, transfer the controlled substances to another licensee registered with the Drug Enforcement Administration, transfer the other prescription drugs to a licensee of the Board, transfer all patient records to another licensed pharmacy, and notify the Board and the US Drug Enforcement

Administration of all of the above. The protection of the public health demands nothing less.

In Minn. Rule 6800.1050, the Board is proposing to amend the list of acceptable references required to be maintained in each pharmacy in Minnesota.

Over time, some of the references, previously included in the list of acceptable alternatives, have become outdated and new references have become more commonly used. The Board is attempting to update its list of acceptable alternative references to recognize these changes.

In subpart 3 of Minn. Rule 6800.1050, the Board is attempting to address, with new language, the special needs of a pharmacy engaging in the preparation of sterile, parenteral solutions. Most often, these pharmacies will be licensed as hospital pharmacies or parenteral enteral/home health care pharmacies.

The preparation of sterile, intravenous solutions requires a sterile work environment, special equipment for the preparation of these sterile products, special references providing information on injectable drugs, and special precautions regarding the use and disposal of cytotoxic waste from the preparation of chemotherapy agents.

A clean environment for the preparation of sterile parenteral products can be developed through the utilization of "sterile hoods" or through the utilization of a "clean room." Either of these methods of maintaining a clean environment is acceptable as long as the mechanism used is capable of maintaining an environment

of less than 100 particles of 0.5 microns in diameter per cubic foot of air.

The second critical issue related to the preparation of sterile products is the handling of cytotoxic waste. Drugs used in the treatment of cancer are highly toxic substances. As a result, the preparation of these products requires special care and handling. The Occupational Safety and Health Administration (OSHA) has developed standards for the handling of these cytotoxic wastes. The Board rules simply require pharmacists involved in the preparation and handling of these products to follow OSHA's standards. Similarly, hospitals and pharmacies preparing parenteral products for home-care patients often receive back, from the patient or patient's caregivers, unused or partially used quantities of chemotherapy drugs, as well as tubing, needles, pumps, etc., used to deliver these drugs to the patient. All of these products must be presumed to be contaminated and, thus, handled with great care. Again, the Occupational Safety and Health Administration has developed standards for the handling of these products. The Board's proposed rules simply require pharmacists to comply with those standards.

Minn. Rule 6800.1150, addresses pharmacist license renewals. Previous language of this rule applied a late fee to any license renewal submitted to the Board after March 1 of each year. This resulted in the Board receiving license renewal applications, for a period of three or four days after the March 1 renewal date, that were dated prior to or on March 1. Thus, for several days a

determination had to be made whether the renewal was mailed after March 1 or before March 1, in order to determine whether a late fee is required. The Board is proposing to change this to eliminate the controversy and confusion involved here. The new language would require that the application for renewal be received in the Board office not later than March 1. Any license renewal application received by the Board after March 1 is subject to a late filing fee regardless of when it was placed in the mail.

The second paragraph of section 6800.1150 addresses the posting of a pharmacist's license and/or renewal certificate. Confusion occasionally existed among pharmacists as to whether they were required to post their large certificate, obtained upon original licensure by the Board, or whether they were required to post the annual renewal of license. Confusion also existed among pharmacists who worked at more than one location. The Board believes the language being proposed here will clarify this confusion by allowing pharmacists to post copies of their large certificate or the annual renewal, whichever is most recently issued to them by the Board.

In Minn. Rule 6800.1210, the Board is proposing to establish inactive status licensure in accordance with the authority granted the Board in Minnesota Statutes 151.095.

The Board is proposing to develop two categories of inactive licensure for Minnesota pharmacists; one called "inactive" licensure and one called "emeritus" licensure.

Inactive status licensure is intended for those pharmacists who are not now actively practicing pharmacy in Minnesota, but who may do so in the future. These individuals may be practicing pharmacy in another state or may be practicing another profession in Minnesota, but wish to maintain the option of practicing pharmacy in Minnesota in the future. 6800.1210 provides an opportunity for these people to discontinue participating in continuing education, required of all "active" licensees, until they seek to begin practice again in Minnesota. At that time, these individuals would have to show evidence of completion of the continuing education requirements. Completion of continuing education requirements can be demonstrated by a showing of participation in continuing education for pharmacists in another state or by participation in continuing education programming here in Minnesota. If an individual remains on inactive status for longer than five years, the individual must also take and pass the jurisprudence examination offered to candidates for licensure by reciprocity. This is needed to make sure the pharmacist has current knowledge of the laws under which he or she will practice.

Emeritus licensure is intended for those pharmacists who are completely retired from active pharmacy practice, but who wish to maintain contact with the profession and wish to continue to receive the Board's newsletter and other Board of Pharmacy mailings. Once an individual requests and is placed on emeritus status, the individual will not have to participate in continuing education for pharmacists nor will the individual be subject to the

annual renewal fees. Once a pharmacist is granted emeritus status, however, the pharmacist cannot be returned to active or inactive status.

The Board has received numerous requests from pharmacists for the establishment of some form of non-practicing licensure. The Board believes this proposal meets those needs while still protecting the public health.

Minn. Rule 6800.1460 provides notification that Minnesota licensed manufacturers of drugs, whose place of business is located within the state of Minnesota, must comply with the current Good Manufacturing Practices Regulations, published by the Food and Drug Administration.

Since FDA has jurisdiction only over those manufacturers engaged in distributing their products in interstate commerce, and since the Minnesota Board of Pharmacy, from time to time, licenses small drug manufacturers that are not engaged in interstate distribution of their products, it becomes necessary for the Board to establish standards which hold the in-state manufacturers to the same standards of care in the production and manufacturing of their drug products as is applicable to other manufacturers who distribute their products on an interstate basis.

The Good Manufacturing Practices Regulations are designed to protect the public through various sanitation, record keeping, and procedural requirements applied to those who would manufacture drug products in the United States. These Good Manufacturing Practices

Regulations are well known throughout the drug industry and copies are available from the Food and Drug Administration.

Adherence to the requirements of the GMP's will serve to prevent adulterated or misbranded drugs from entering the market.

Minn. Rule 6800.1500 contains a small change to subpart 2, clarifying the fact that each pharmacist is responsible for maintaining their own records of continuing education participation. Over the years, some pharmacists have found themselves unable to document their continuing education participation because they assumed that others, such as the program provider, were keeping track of their attendance. This section simply clarifies the fact that, even though program providers generally keep attendance records, each pharmacist is also responsible for maintaining their own record of attendance.

Subpart 6(a) of Minn. Rule 6800.1500 ties in with a requirement for registration of pharmacists who intend to act as preceptors for pharmacist-interns that will be discussed later. The Board is proposing to require all pharmacists, who intend to act as preceptors for pharmacy students, to participate in a training program on pharmacy law, established by the Board. Subdivision 6(a) allows the pharmacist to use that training program for a portion of their continuing education requirement.

Minn. Rule 6800.2150 attempts to clarify the existing rule requiring a licensed pharmacist to be physically present and on duty at all times that the pharmacy is open for the transaction of business.

Pharmacists in solo practice have often questioned the Board about whether they would be allowed to be briefly absent from the pharmacy, in order to make a deposit in the local bank or make an emergency visit to provide professional services to the local hospital or nursing home, without having to close their pharmacy. In the amendment to this rule, the Board is attempting to clarify that, while pharmacists in solo practice are not being given authority to leave the pharmacy open and unattended for lunch or other personal reasons, they may briefly depart from the pharmacy for matters arising out of the practice of pharmacy.

The second part of this rule establishes a long-standing Board position in rule form. That position being that, when a pharmacist is not on duty and the pharmacy is closed, other individuals are not to be allowed to have access to the pharmacy. This is necessary for security purposes and will serve to reduce the number of persons who might have access to narcotics and other drugs of abuse in the pharmacy. Further, since pharmacists are required to counsel all patients receiving prescriptions, it makes it clear that prescriptions are not to be dispensed in the absence of the pharmacist.

Minn. Rule 6800.2250 is the section that addresses unprofessional conduct on the part of pharmacists. Subpart 1, item E addresses itself to discrimination, on the part of pharmacists, between patients or groups of patients for various reasons. It is important, in this regard, that pharmacists not discriminate against and refuse to provide services to individuals with AIDS or

other serious diseases. Thus, the language "or disease" is being added to the other grounds on which discrimination is specifically prohibited.

Patient consultation by the pharmacist is rapidly becoming one of the keystones of pharmacy practice. Pharmacists can play an important role, in maximizing the effectiveness of drug therapy, through patient consultation. It is to the benefit of the public, then, that pharmacists be given encouragement to become more involved in providing this service. The existing language of Minn. Rule 6800.2250, subpart 1, item F, declares it to be unprofessional conduct for the pharmacist to refuse to consult with patients about their drug therapy. Similarly it is important that pharmacists, some of whom may be in a management position, not become involved in attempts to circumvent the consulting requirements, of the Board and of the Federal Government, or in discouraging patients from receiving consultation by whatever means. As a result, the Board is including, as unprofessional conduct, attempts to circumvent the consulting requirements or attempts to discourage the patient from receiving consultation.

With the rising cost of new medications, it is likewise important that pharmacists discuss with the patient the price of their prescriptions when requested to do so. The Board is thus adding, in 6800.2250, subpart 1, item E, language that declares it to be unprofessional conduct for a pharmacist to refuse to consult on prices of prescriptions as well as on the therapeutic value of the prescription.

Minn. Rule 6800.2250, subpart 4, is an entirely new section based on the Prescription Drug Marketing Act of 1987, which was passed by Congress in response to a nationwide problem of drug diversion from legitimate channels of distribution. Congress found that there was a significant black market trade going on involving prescription drugs. Drug samples were being diverted from legitimate channels of distribution and drugs intended for export were being re-imported back into the United States and re-sold. Often times these drugs were stripped from their identifying packaging and mixed with expired drugs or even counterfeit drugs and sold to drug distributors or pharmacists.

The Prescription Drug Marketing Act of 1987 provides for criminal penalties for anyone involved in these types of activities. It is important, therefore, to include the pertinent provisions, from the Prescription Drug Marketing Act, in the Board's rules so that pharmacists will be aware of what kind of activities are prohibited and, at the same time, provide the Board with the tools to take action on a pharmacist's license to practice if the pharmacist is found to be engaged in this type of drug diversion. That is what Minn. Rule 6800.2250, subpart 4, addresses.

Minn. Rule 6800.2300, contains requirements involved in the sanitation and physical appearance of licensed pharmacies. The Board has found that a disorderly pharmacy, a pharmacy with many piles of papers and other materials cluttering the prescription counter work space, creates an environment conducive to dispensing

errors and lost records. A pharmacy may be free from dirt and grime, but may still be disorderly to the point where it creates an environment conducive to errors which pose a danger to the public. As a result, the Board is revising 6800.2300 to require that pharmacies maintain orderly, clean, and sanitary conditions at all times.

From time to time, the Board has found that pharmacy school graduates or pharmacists from other states, who come to Minnesota as part of a hospital-based residency or fellowship program, for some reason assume that licensure as a pharmacist or registration as a pharmacist-intern is not required, since they are part of a formal residency or fellowship program. This most decidedly is not the case. As a result, the Board is placing a responsibility on the pharmacist-in-charge of all pharmacies, that might be participating in internship, residency, or fellowship programs, to make sure that all persons participating in those programs at their pharmacy are appropriately licensed or registered with the Board.

Minn. Rule 6800.2500 is being changed by deleting the term assistant pharmacist. Assistant pharmacists were a category of registrant developed in the 1920's, when graduation from a college of pharmacy program first became mandatory. Assistant pharmacists were those who had developed experience in the profession of pharmacy, but who did not hold a college degree. These people were given the opportunity to take a challenge examination, demonstrating their competence, and, if they successfully passed the examination, were licensed as "assistant pharmacists." All of

these people have now died and there is no need to continue a reference to them in this rule.

Minn. Rule 6800.2810 is a new section which requires all prescriptions, dispensed to patients other than hospital inpatients, to bear a unique prescription number and requires pharmacies to file the hard copy of each prescription dispensed in numerical order after dispensing. The Board has found that a few pharmacies have attempted to develop alternative systems of record keeping for prescriptions, in which the hard-copy prescriptions were filed by patient name or other methods. Failure to file prescription records numerically makes it extremely difficult, if not impossible, to accurately identify all prescriptions dispensed during specific time periods, in the event an audit becomes necessary, and impedes investigations of dispensing errors by making it virtually impossible to identify potential reasons for a dispensing error having occurred.

Minn. Rule 6800.3000 is being amended by adding a new subdivision 2, relating to the transmission of prescriptions by fax machines. Transmission of prescription orders by fax machine is rapidly growing in the pharmacy community. Fax machines allow physician offices to transmit prescription orders to pharmacies, through agents of the physician, without the vulnerability of miscommunication by staff in the physician's office or misunderstanding by the pharmacist. Fax transmissions allow the physician's handwritten order to be sent to the pharmacy directly, for interpretation by the pharmacist. Fax transmissions also allow

the pharmacist to request refill authorization from physician offices, without being required to wait on the phone while authorization from the physician is received, and give the pharmacist a written confirmation of refill authorization.

On the other hand, since fax machines electronically reproduce the original document, changes could be made to the original document which would be undetectable when transmitted by fax. As a result, it is important that the identity of the individual sending the transmission be maintained and that prescriptions for drugs with abuse potential not be transmitted by fax. In addition to the Board's position in this regard, the federal Drug Enforcement Administration also prohibits faxing of controlled substance prescriptions.

Another issue relating to fax transmission of prescriptions is the degradation of the quality of the paper used by many fax machines. Since pharmacists are required to maintain a more or less permanent hard copy of each prescription dispensed, it is important that the document representing a prescription received by fax transmission be of permanent quality. As a result, the Board is requiring pharmacists who use fax machines to receive prescription information to either photo copy the fax order or utilize plain paper fax machines that are capable of producing documents readily readable for a least five years.

Minn. Rule 6800.3100 is undergoing primarily grammatical changes. However, subpart 1, item G, and subpart 2 contain language recognizing the fact that, in many pharmacies,

prescription information is maintained electronically by the pharmacy's computer system and that refill records are most commonly, now, no longer maintained on the hard copy of the prescription, but are maintained instead within the computer.

Subpart 3 of Minn. Rule 6800.3100 deals with the certification (initialing) of documents providing a record of which individual takes responsibility for the accuracy and completeness of each prescription dispensed. The added language to subpart 3 recognizes that some licensed practitioners and most pharmacist-interns are also involved in the certification process and should be included the rule relating to certification.

The language added to item D of subpart 3 simply ties the review of the patient's medication profile together with the requirement that a pharmacist conduct a prospective drug use review. The requirement for prospective drug use reviews is found in Minn. Rule 6800.3110.

A critical element in the provision of pharmaceutical care is an evaluation of the patient's drug therapy in its totality. In addition to being a major tool in the provision of pharmaceutical care, drug use review is a requirement of the Omnibus Budget Reconciliation Act of 1990. In OBRA-90, the U.S. Congress has mandated that each state develop a program that will require pharmacists to perform prospective drug use reviews whenever a prescription is received for a Medicaid recipient and to provide patient consultation to that patient, in order to optimize the effectiveness of drug therapy.

The Minnesota Legislature, in addressing the requirements of OBRA-90, in the laws of Minnesota for 1992, Chapter 13, Article 7, section 10, mandates the Board of Pharmacy to adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. In order to avoid the establishment of a two-tiered system of pharmaceutical services in Minnesota, the Board is proposing, in 6800.3110, subpart 4, to require drug use review for all patients, not just Medicaid patients who are covered under the requirements of OBRA-90.

The various elements listed in Minn. Rule 6800.3110, subpart 4, as part of the drug use review required by the Board, are taken directly from the requirements found in the OBRA-90 legislation. It is important, here, to make certain that the requirements imposed by the Board for drug use review meet or exceed the requirements found in OBRA-90. Failure to at least meet the OBRA-90 requirements could cause significant problems for pharmacists in qualifying for reimbursement for services provided to Medicaid recipients.

Minn. Rule 6800.3120 addressed the transfer of prescriptions between pharmacies. The existing language of this rule allows a one time transfer from one pharmacy to another of prescriptions that are not classified as Schedule II controlled substances. The federal Drug Enforcement Administration, which regulates the dispensing of controlled substances drugs from a federal perspective, allows a one-time transfer of prescriptions categorized as Schedule III, IV, or V controlled substances, but,

since Schedule II controlled substance prescriptions cannot be refilled in any event, transfer of Schedule II prescriptions is prohibited. The Board's original language of 6800.3120 follows this one transfer philosophy.

The Board has received numerous comments from pharmacists over the past few years, since the development of the original language of 6800.3120, to the effect that the single transfer limitation causes hardship for patients and for pharmacists. In a number of instances, patients find it necessary to transfer a prescription on a temporary basis, such as when they are spending time at a cottage in northern Minnesota. The one transfer rule prohibits the patient from returning the prescription to their original pharmacy, at the conclusion of their vacation.

In response to the concern expressed by pharmacists and patients to the one transfer limitation, the Board is proposing to allow unlimited transfers of prescription information between pharmacists, so long as appropriate records are kept. The unlimited transfers, however, still will not apply to any controlled substance prescriptions in that DEA, at the federal level, still limits controlled substance transfers to one time only and, for Schedule II prescriptions, does not allow transfer at all.

Minn. Rule 6800.3200 deals with prepackaging and labeling of medications. For a number of years, the U.S. Food and Drug Administration has had a position regarding expiration dating on repackaged drugs. More recently, the USP has also taken a position regarding expiration dating of prepackaged drugs. At this point,

the Board of Pharmacy is incorporating that information into Minn. Rule 6800.3200 and is establishing an expiration date in conformity with the position taken by the USP and by FDA. The expiration date for prepackaged pharmaceuticals, those drugs prepackaged by the pharmacist into true unit dose packaging, must bear an expiration date of not more than one fourth of the period of time remaining to the manufacturer's expiration date or six months, whichever is less.

Minn. Rule 6800.3300 deals with bulk compounding by pharmacists. The changes here are primarily for purposes of clarification. The additions to Subpart 1 clarify the fact that bulk compounding by pharmacists is allowable only for preparing medications for future dispensing by that pharmacy and should not be confused with manufacturing for general distribution.

Minn. Rule 6800.3350 is a new section addressing expiration dates in general. The expiration dating found in Subparts 1 through 4 applies to different types of products in different types of packaging systems and is taken from the standards found in the official Compendia (the United States Pharmacopeia). Subpart 1 addresses pharmaceuticals prepackaged into prescription vials. If a pharmacist is prepackaging quantities of prescription drugs into ordinary prescription vials, the expiration date called for is one year from the prepackaging date or the manufacturer's expiration date, whichever is less.

Subpart 2 addresses expiration dating for bulk-compounded pharmaceuticals. Unless scientific stability studies have been

done, on each individual product bulk-compounded by a pharmacy, that would justify a different date, an expiration date of not more than one year from the compounding date must be placed on every container of bulk-compounded pharmaceuticals.

Subpart 3 addresses expiration dates for pharmaceuticals packaged in unit-of-use packaging or blister card packaging by pharmacists. As the rule indicates, an expiration date of not more than one fourth of the time, from the packaging date to the manufacturer's expiration date up to a maximum of six months, is required for these products. This limited expiration date is required whether the blister card or unit-of-use container is prepackaged by the pharmacist or packaged at the time of dispensing.

Subpart 4 addresses dispensing, by the pharmacist, in traditional prescription vials. In this circumstance, the United States Pharmacopeia and Subpart 4 of this rule require the product to be marked with an expiration date of not more than one year from the dispensing date or the time remaining to the manufacturer's expiration date, whichever is less.

All of these expiration date requirements are necessary to provide pharmacists and consumers with information relating to the stability and usefulness of medication. These expiration date requirements, developed by the United States Pharmacopeia, are based on scientific studies conducted by the USP and do not simply represent a philosophical position discouraging consumers from

storing unused medications in their medicine cabinets over a lengthy period of time.

Since the standards for pharmaceuticals, found in the United States Pharmacopeia, do have legal significance and since not every pharmacist purchases a copy of the United States Pharmacopeia, the Board has chosen to develop a section of rules bringing these expiration date requirements to pharmacists' attention.

Minn. Rule 6800.3400 contains two changes. One is an amendment to Subpart 1, item F, recognizing that it is often confusing to pharmacists and to consumers to require the name of the actual manufacturer, of the finished dosage form of a product, to be placed on the label of each prescription for that product. As often as not, the pharmacist and consumer are more familiar with the name of the distributor of the product, which might very well be different from the actual manufacturer of the dosage form. As a result, the Board is allowing pharmacists to use either the name of the true manufacturer of the dosage form, or the name of the distributor of the finished dosage form on the prescription label.

The second change represents a codification of a position held by the Board for a number of years. While the general rule is that every prescription drug dispensed must bear a label permanently attached to the immediate container of the drug, there are some cases where the extremely small size of the container (such as in the case of ophthalmic ointments or ophthalmic drops) makes it physically impossible to place a full prescription label on the immediate container. In those circumstances, the Board is allowing

pharmacists to place the drug container inside a larger container, such as a prescription vial or a small box, which contains the full labeling. The immediate container of the drug, then, is required only to have a small portion of a label attached to it, containing the patient's name and the prescription number. This minimal information, then, can be used to make sure that the small container, after some of the drug has been used, gets placed back into the correct larger container, which bears the complete labeling.

Minn. Rule 6800.3450 addresses the labeling of outpatient, intravenous admixture drugs. Over the past several years, more and more patients, who are still receiving intravenous medications, are doing so in the home setting. As a result, more and more pharmacies are becoming involved in the preparation of sterile, intravenous drugs for home use.

In order to address this emerging phenomenon, the National Association of Boards of Pharmacy convened a Task Force of Pharmacy practitioners, from across the country, to develop standards for the labeling of these products and standards for the physical facilities required of pharmacies that will be engaging in the preparation of these products. Minn. Rule 6800.3450 represents the labeling requirements for home intravenous drugs established by the special task force convened by NABP.

Since the use of intravenous drugs is much more technical in nature than the simple use of an oral medication, and since these products must maintain sterility at all times and have relatively

short expiration dates, additional pieces of information are required on the labeling as compared to ordinary oral medications.

Sterile, intravenous fluids are generally produced by drug manufacturers rather than by individual pharmacies. These base solutions may be used alone or may serve as the vehicle for the administration of other drugs, which are added to the base solutions by the pharmacist. These labeling requirements cover both situations. Subpart 1 deals with the labeling requirements for basic intravenous solutions while Subpart 2 addresses the requirements when additional drugs are added to the solutions.

Because of the critical nature of these pharmaceuticals, it is important that pharmacists preparing these products maintain an accurate audit trail, identifying not only the products used in the preparation of IV admixtures, but also the pharmacist and other personnel who might be involved in the preparation of each unit. The audit trail requirement is found in Subpart 3. The Board is not attempting to delineate a specified of audit procedure for pharmacists dispensing intravenous drugs to outpatients, but is allowing pharmacists flexibility to develop an audit trail suitable for their particular operation.

Minn. Rule 6800.3510 represents a new rule, placing limitations on the length of time a prescription may be refilled without either the patient or the pharmacist contacting the prescribing physician to check on whether the patient should still be utilizing this particular drug. Most states have such a

limitation in place. Of those states that do have limitations, the most commonly imposed limitation is that of one year.

Many patients, when told by the prescribing physician that they will need to take a certain medication "for the rest of their lives," often tend to take such advice literally and assume that their prescription for that particular product will be unending. Health practitioners know, however, that even chronic conditions change from time to time and need periodic review by a physician. It is the Board's position that no prescription should be continually refilled in excess of one year, without either the pharmacist or the patient contacting the physician to make sure that the drug being prescribed is still appropriate, in the same strength and with the same directions for use, after such a period of time. Minn. Rule 6800.3510 establishes, in a sense, an expiration date of one year for each prescription written. After 12 months from the date of issuance of a prescription, the pharmacist would be expected to obtain re-authorization from the physician and assign a new prescription to a new document continuing the patient's therapy.

Minn. Rule 6800.3850, Supportive Personnel. In order for pharmacists to fully participate in the patient counseling and prospective DUR, discussed elsewhere in this Statement of Need and Reasonableness, it will be necessary for pharmacists to delegate, to non-professional supportive personnel, those tasks which do not require the professional judgement of a pharmacist.

Since the mid-nineteen seventies, the Board has permitted the use of non-professional supportive personnel for performing manipulative tasks involved in preparing a prescription for dispensing, which do not require professional judgement. The permitted ratio of supportive personnel to pharmacists has been one-to-one with certain functions being permitted a three-to-one ratio. Pharmacists have indicated to the Board on numerous occasions that, if the Board expects pharmacists to play a greater role in patient counseling and DUR, the ratio of supportive personnel to pharmacists will have to increase.

After much deliberation by the Board, the Board proposes to change the allowable ratio to two technicians for one pharmacists. The Board believes that pharmacists can safely supervise two technicians performing manipulative tasks in the preparation of prescriptions for dispensing by the pharmacist and that the two-to-one ratio being proposed will not endanger the public health.

From time to time over the past years, the Board has received information from pharmacists of technicians being involved in drug diversion from pharmacies. Up to the present time, the Board has not required pharmacists to identify technicians when submitting proposals to the Board for review. As a result, technicians found to have been diverting drugs from a pharmacy often simply move on to another pharmacy, where they are, again, hired as pharmacy technicians and where they might again become involved in drug diversion. With a potential doubling of the number of technicians employed in pharmacies in Minnesota, the Board is of the opinion

there is now a need to keep track of those individuals employed as pharmacy technicians in Minnesota pharmacies and to require the reporting of drug diversion, on the part of technicians, to the Board. The Board would then be in a position to provide this information to other pharmacists who may be about to employ the same technician. With the Board keeping track of which individuals are employed as pharmacy technicians in Minnesota and which of those individuals might have been involved in drug diversion, the public can be safeguarded through the sharing of the this information with future prospective pharmacy employers of these individuals.

As a result of this need to identify individuals working as pharmacy technicians who would have access to dangerous drugs in Minnesota, and those who have been found to have diverted or misappropriated those drugs, the Board is proposing, in 6800.3850, Subpart 4, that pharmacists submit, to the Board, the identity of individuals proposed for employment as pharmacy technicians. The Board is further proposing, in Subpart 10 of 6800.3850, that pharmacists-in-charge be required to report to the Board whenever a technician is found to have diverted or misappropriated dangerous drugs from their pharmacies. In Subpart 11 of 6800.3850, the Board is required to maintain a record of those individuals working as pharmacy technicians and those individuals reported to the Board in accordance with the requirements of Subpart 10, and is required to provide potential pharmacist employers with any information in the

Board's possession regarding specific, identified supportive personnel.

Minn. Rule 6800.3950 describes the Board's rules for the use of electronic data processing and computer usage. Approximately 85 to 90 percent of the pharmacies in Minnesota now make use of computers in maintaining prescription information and as an aid in performing Drug Use Review. This being the case, it is appropriate that the Board establish rules relating to the use of computers for maintaining prescription records and in prescription processing.

In that there are numerous commercially available pharmacy software packages on the market and in use by Minnesota pharmacists, it is appropriate that each pharmacy maintain an up-to-date, written policy and procedure document, explaining the operational aspects of the system in use. This will allow Board inspectors to identify which documents or pieces of information are available from the system in use at each pharmacy.

At the federal level, the federal Drug Enforcement Administration has developed rules applicable to pharmacies that are using computers to maintain records of the receipt and distribution of controlled substance drugs. The Board's rules relating to the use of computers, in Subpart 2, follow closely the federal requirements.

The Board has found that, from time to time, errors are made in entering new prescription information into the computer for the first time. Unless the error is detected before the prescription is dispensed, the error is perpetuated each time the prescription

is refilled in that the original hard copy of the prescription is not referred to upon the refilling of the prescription and the refill is made based on the information in the computer. In order to avoid situations where errors are perpetuated when entered incorrectly at the beginning, the pharmacist must establish a system whereby the original hard copy of the prescription is retrieved and reviewed on the first refill or develop some other type of safeguards that will prevent the continuation of errors in this manner. In Subpart 4 of 6800.3950, the Board proposes to require pharmacists to review the original, hard copy of the prescription on the first refill or develop an alternative plan for safeguarding against errors being made and perpetuated through the computer.

From time to time, the Board has discovered that pharmacists have lost prescription information due to computer systems "crashing" or being stolen during a burglary. Subpart 5 of Minn. Rule 6800.3950 requires pharmacists to notify the Board within 72 hours whenever prescription information is lost due to any type of unscheduled system interruption, such as power failures, "system crashes," theft of computer hardware, or situations where the providers of on-line computer systems unexpectedly cease business.

Minn. Rule 6800.4150 addresses the labeling of controlled substances and certain other drugs. Since the mid-nineteen seventies, pharmacists have been required to place an auxiliary label on all controlled substance drugs, antihistamines, psychotherapeutic drugs, and other drugs deemed appropriate in the

professional judgment of the pharmacist, warning patients that "Taking this drug alone or with alcohol may impair your ability to drive." The operative philosophy here was that patients should be warned of the additive nervous system depressant effects of alcohol and drugs in the categories listed. In recent years, however, non-sedating antihistamines have been marketed and some psychotherapeutic agents have been developed where the required warning may be inappropriate. As a result, the Board is proposing to allow pharmacists to use their professional judgment in determining which antihistamines and psychotherapeutic agents should contain the warning about alcohol and driving.

At the federal level, DEA requires that all controlled substances in Schedules II through IV be labeled with an auxiliary label, when dispensed, that reads "Caution, federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." Since most pharmacists do not have a copy of the federal regulations and, even if they do have a copy of the federal regulations, have a difficult time in finding this labeling provision, the Board is incorporating it here as well. All pharmacists will have a copy of the Board rules and will, thus, become knowledgeable about the labeling required under the federal Act.

Minn. Rule 6800.4210 includes additions to the listing of Schedule I controlled substances. Schedule I controlled substances are those drugs which do not have a recognized legitimate medical use in the United States and which have a very high potential for

abuse. The additions to Minn. Rule 6800.4210 serve to bring the listing of controlled substance drugs, in Minnesota, into conformity with the listing of those substances, at the federal level, by DEA. Listing these substances at the state level, as well as the federal level, allows state authorities to prosecute individuals, found to be in possession of these substances, at the state court level.

Minn. Rule 6800.4220 is likewise being amended to add Carfentanil, which will serve to bring the drugs listed in Schedule II at the state level into conformity with the listing at the federal level.

Minn. Rule 6800.4230 is an attempt by the Board to list, for pharmacists, those commonly occurring brand names of anabolic steroids that were placed in both the state and federal lists of controlled substances recently. Anabolic steroids are widely abused by weight lifters, football players, and other athletes, often with tragic results. Minnesota Statutes 152 places anabolic steroids among those drugs listed as controlled substances, as does the Federal Controlled Substances Act. The statute, however, does not provide any guidance to pharmacists regarding which anabolic steroids currently being marketed are included as controlled substances. In 6800.4230, the Board provides pharmacists with such a list.

The change proposed for Minn. Rule 6800.4240 simply corrects a misspelling that currently exists in the name of one of the drugs listed.

In 6800.4250, the Board is proposing to add a section on stimulants to the Schedule V controlled substances section. Once again, this section is being added to bring state law into conformity with federal requirements.

A small change is being proposed in Minn. Rule 6800.4400 regarding the registration of controlled substance researchers. The old language of the rule did not appear to allow the Board to refuse to issue a registration. The new language allows the Board to refuse to issue a registration, as a controlled substance researcher, if the Board finds that the application is fraudulent and the individual making application is not engaged in bona fide research.

In Minn. Rule 6800.4500, regarding controlled substance samples, language, helping to clarify what is meant by fair market value, is added and language, which appeared to allow distribution of samples to a pharmacist, is being removed. The language appearing to allow distribution of drug samples to a pharmacist is being removed, since such distribution would be illegal under the Prescription Drug Marketing Act of 1987. The Prescription Drug Marketing Act of 1987 is a piece of federal legislation which restricts the distribution of drug samples in the United States. Pharmacists are not among those who are authorized to receive drug samples under that federal legislation. Since pharmacists may not legally receive drug samples under federal law, it is not appropriate for the Board to have a rule which appears to allow it.

Minn. Rule 6800.4600 is a new section requiring perpetual inventories of Schedule II controlled substances by all pharmacies. Schedule II controlled substance drugs are drugs which have a legitimate medical use, but which also have a high potential for abuse. Schedule II controlled substance drugs are often the target of burglaries, robberies, employee theft, and other types of drug diversion. Most major hospitals and most chain drug pharmacies, recognizing the potential for diversion of Schedule II controlled substances, have initiated a perpetual inventory system for those drugs, in their pharmacies. A perpetual inventory system will allow pharmacists to immediately detect diversion or loss of Schedule II controlled substances and, thus, more quickly take steps to stop the diversion. The Board is proposing that every pharmacy, located in Minnesota, develop a perpetual inventory system for Schedule II controlled substances. The system can be designed to fit the needs of the pharmacy in questions, so long as it provides total accountability and is reconciled on a monthly basis.

Minn. Rule 6800.4700 addresses drug control issues involving controlled substance distribution in hospitals. Controlled substance drugs are categorized as such under both state and federal law because of their potential for abuse. Having relatively high abuse potential, controlled substance drugs are often targets for diversion from hospitals. Controlled substance diversion by professional and other hospital staff is a major problem for the health professions and is one in which the hospital

pharmacy, through the development of drug distribution safeguards, can play an important role.

As often as not, controlled substance drugs are kept on floor stock supplies at hospital nursing stations. Usually these supplies of controlled substance drugs on nursing stations are accompanied by a sign-out sheet where each dose is required to be accounted for by nursing staff. The weak link in this accountability system, however, is often the record keeping associated with the delivery of the controlled substances to the nursing stations in the first place. Minn. Rule 6800.4700 requires each hospital pharmacy to develop and implement a plan that provides for pharmacist verification of the drug distribution records relating to the delivery of controlled substance drugs to the nursing stations. By developing such a system, the hospital pharmacy department can play a major role in reducing the likelihood of diversion of controlled substances from nursing stations in hospitals.

Minn. Rule 6800.5100 addresses the changes in the Board rules relating to internship. The change in Subpart 3 of 6800.5100 reflects the fact that pharmacy curricula are now moving to a six-year degree program instead of the old five-year program. Under the old five-year program, 75% of the average number of credit hours per term needed to graduate within five years resulted in the establishment of a definition for "concurrent time" as being that internship experience gained while the student is taking 12 or more quarter credits. Instead of going about this in the round-

about way of the previous rule, the Board is simply directly defining concurrent time as internship experience gained while taking 12 or more quarter credits.

Item D, of Subpart 5, is new language developed in response to a problem discovered by the Board from time to time wherein pharmacy school graduates, participating in various residency or fellowship programs at the University of Minnesota Hospitals and other major teaching hospitals, were, for some reason, under the impression that they could "practice pharmacy" without the necessity of licensure as a pharmacist or as a pharmacist-intern. These individuals were under the mistaken impression that, since they were part of a residency or fellowship program, that was all that was necessary to allow them to perform the functions restricted by law to pharmacists. It is necessary that these individuals understand that functions defined as falling within the "practice of pharmacy" are limited to those individuals licensed as pharmacists or pharmacist-interns. Participation in a college or hospital-based fellowship or residency program, without the requisite licensure, is not sufficient.

New language added to Subpart 6, the definition of "preceptor," serves to clarify the fact a pharmacist only becomes a "preceptor" when providing instruction and direction to pharmacist interns, relating to their practical experience. This addition is needed to differentiate pharmacists who are acting as teachers of pharmacy interns from other pharmacists.

Subpart 9, of 6800.5100, is new language addressing the supervision of pharmacist-interns in approved clinical programs. It is essential that pharmacy students be trained at clinical sites within acute care, long-term care, and ambulatory care settings. Students must develop the skills necessary to do proper patient assessment and perform other patient-oriented professional functions. It is not always possible, in these clinical settings, to provide direct, immediate supervision of the intern by their preceptors or other pharmacists. In recognizing the need for clinical experience on the part of pharmacy students and in recognizing the limitations inherent in supervision at those sites, the Board is proposing to require direct supervision of the intern only when the intern is making drug therapy recommendations to other health professionals that may directly affect patient therapy.

Subpart 10, of 6800.5100, relates to supervision in patient counseling situations. As was earlier discussed, pharmacist are now required, under both the Omnibus Budget Reconciliation Act of 1990 and these rules, to provide patient counseling upon the dispensing of each prescription. Pharmacy students are thus required, as part of their practical experience, to obtain patient counseling skills. Here again, the patient counseling situation, as in the case of drug information gathering for the purpose of patient assessment as discussed above, does not lend itself to direct supervision of the pharmacy student at all times. The Board, in Subpart 10, recognizes that direct supervision is not

always possible in patient counseling, patient education, or staff in-service situations and allows some independent action on the part of the pharmacy student provided that the preceptor for the intern is responsible for the accuracy and completeness of any statements made by the intern.

Minn. Rule 6800.5200 involves only technical amendments and will not be discussed further here.

Minn. Rule 6800.5300 addresses itself, once again, to the registration of individuals participating in residency or fellowship programs in Minnesota. The new language incorporated here allows the individual to complete a residency or fellowship program without necessarily having to obtain licensure as a pharmacist.

New language in Subpart 5, of 6800.5300, exempts candidates for licensure by score transfer from having to successfully pass the internship competency examination, otherwise required of all candidates for licensure by exam. The purpose of the internship competency examination is to provide assurance that the pharmacy student, before sitting for the licensure exam, has met the minimum competencies for an internship program established by the Board. Candidates for licensure in Minnesota, through the score transfer process, are those individuals who have already successfully passed the licensure examination in another state and are actively practicing pharmacy on the basis of that license. They are allowed to transfer their examination scores, from the NABPLEX and Federal Drug Law Examinations, from the state of their original licensure

to Minnesota, if they make application to do so at the time they take the examination in the other state. This score transfer process is possible because virtually all states administer the NABPLEX and Federal Drug Law Examinations and the examinations themselves are equated by the National Association of Boards of Pharmacy, who develop the examinations and distribute them nationally.

Minn. Rule 6800.5350 is new language requiring Minnesota pharmacists, who desire to act as preceptors for the training of pharmacy students, to be certified as such by the Board.

Prior to this time, the Board has allowed any licensed pharmacist to act as a preceptor for pharmacy students. The Board is now recognizing the fact that licensure as a pharmacist does not necessarily make one a good teacher of pharmacy students and is recognizing that, before a pharmacist can act as a preceptor for pharmacy students, they should have at least some minimal amount of actual practice as a pharmacist themselves.

In this section, the Board is requiring that pharmacists, who desire to act as preceptors for interns, have completed at least 4,000 hours of pharmacy practice after licensure as a pharmacist, be currently in full-time practice as a pharmacist, have a history of compliance with state and federal laws, have adequate reference libraries, be up-to-date on current laws and Board rules, and spend some minimal amount of time on educating the pharmacy student.

By requiring each pharmacist who desires to act as a preceptor to participate in an instructional program on pharmacy laws and

regulations, developed for such preceptors by the Board, the Board hopes to assure that pharmacists remain up-to-date in that area. As a result, they will be able to inculcate the student with the practical application of the various laws and Board rules.

In that the College of Pharmacy at the University of Minnesota has essentially similar standards for pharmacists who wish to act as preceptors in the college-based internship programs, commonly known as externships, the Board will recognize those University of Minnesota College of Pharmacy approved preceptors as meeting the Board's requirements for experience and training prior to acting as a preceptor for pharmacy students.

There are no fees associated with the certification of pharmacists as preceptors and the Board's instructional programs will be delivered without charge to pharmacists around the state.

Minn. Rule 6800.5400 contains technical amendments in Subpart 3 and contains some new language in Subpart 6. The new language in Subpart 6 again recognizes that pharmacy courses are expanding to a six-year program and recognizes that practical experience in pharmaceutical industry and pharmaceutical research as being valuable internship experience. Over the past several years, a number of students have petitioned the Board for internship credit for work in the pharmaceutical industry and/or in research and credit has generally been granted for these experiences. The Board now is simply including those internship experience sites in the Rule as acceptable internship experiences.

Similarly, language in Item C, of Subpart 6, puts in rule form a long-standing Board position regarding the granting of internship credit for the various patient-centered clinical rotations that are a part of the six-year, Pharm D program. In that most of these clinical rotations are of a nature that does not include compounding and dispensing, the Board is concerned that students might seek to obtain all of their internship hours in a non-dispensing mode. The Board is convinced that some practical experience in the compounding and dispensing aspects of pharmacy practice is still necessary and, thus, limits the number of hours of internship credit that may be acquired, through the Pharm D clinical rotations, to 800 of the 1,500-hour total and will grant those 800 hours only on condition that the remaining 700 hours be of a traditional compounding and dispensing nature.

Minn. Rule 6800.5600 contains only a technical change and does not require further comment.

Minn. Rule. 6800.6200 addresses prescription order communication in long-term care facilities. The only changes to this part involve the addition of language that recognizes the legitimacy of prescriptions faxed to a pharmacy from a long-term care facility.

The use of fax machines for prescription order communication and other communication between long-term care facilities and pharmacies has become widespread. There was, thus, a need to recognize the appropriate use of fax machines in transmitting prescription orders from long-term care facilities to pharmacies

serving patients in those facilities. The language here simply indicates that, as long as the pharmacist is following the requirements specified in 6800.3000, subpart 2, regarding prescription orders transmitted by fax, those prescription orders being faxed from long-term care facilities are legitimate.

Minn. Rule 6800.6300, relating to prescription labeling, contains only technical amendments and need not be discussed further.

Minn. Rule 6800.6500 addresses consultant services to long-term care facilities. Since the mid-seventies, every long-term care facility has been required by federal law to obtain the services of a consultant pharmacist who will perform various tasks relating to the proper storage, labeling, record keeping, and administration of drugs in long-term care facilities.

The first changes in Minn. Rule 6800.6500 are technical in nature. The first substantive change appears in Subpart 2, Item 8, where the consultant pharmacist will now be required to develop policies for the issuance of medications to residents who are going on leave from the facility. Residents of long-term care facilities are occasionally offered the opportunity to leave the facility for short periods of time, perhaps even for a few days, to spend holidays with relatives, etc. During these leaves from the facility, some arrangement must be made for the medications needed by the resident to be made available for their use. If it is known sufficiently far in advance that a resident is going on leave from a facility, it is expected that the pharmacy dispensing the

medication will prepare a properly labeled prescription vial containing enough medication to last the resident during the period of his or her absence from the facility. It is not always possible, however, to obtain notice sufficiently far in advance to allow for these procedures to be followed. The alternative then is to either deny the resident the opportunity to leave the facility or make some other arrangement for the medications needed by the resident. The new proposed language allows the nursing staff to supply a limited amount of medication for use by the patient when leaving the facility.

While the packaging and labeling of the medication under this rule is not ideal, it is workable and will allow the patient the opportunity to leave the long-term care facility, even on short notice.

In Subpart 3 of Minn. Rule 6800.6500, a small change is made in the language addressing the destruction of unused medications in long-term care facilities. The previous language indicated that such drugs must be destroyed by flushing them into the sewer system or by incineration. The new language is broader in scope and allows destruction in any environmentally acceptable manner. The changes in language here were needed as a result of tighter restrictions on incineration, imposed over the past few years, and the development of alternative mechanisms for the destruction of infectious wastes, hospital wastes, and other toxic substances, such as drugs.

Minn. Rule 6800.6700 addresses drugs used in emergency kits in long-term care facilities. The language in Subparts 1 and 2 simply recognize the fact that different committees are now responsible for determining drug supplies desired for inclusion in the emergency kit of the long-term care facilities. In addition, in Subpart 2, Item A, the Board is recognizing the needs expressed by numerous pharmacists involved as consultants or providers to long-term care facilities, indicating that it is often desirable for starter doses of some antibiotics to be included in the emergency kit.

In that Minnesota Statutes prohibit stock supplies of prescription drugs in nursing homes, the drug supply contained in the emergency kit must be kept to a minimum and should be limited to those drug items needed for true, life-threatening emergencies. The case has been made, on numerous occasions, however, that it is occasionally necessary to start antibiotic therapy as soon as possible for the benefit of residents in long-term care facilities. While the need for immediate administration of an antibiotic is extremely rare. The inclusion of minimal doses of certain antibiotics in the emergency kit will increase the likelihood of a positive therapeutic outcome for the patient and will serve to eliminate suffering by the patient. As a result, the Board is proposing to expand the scope of medication allowed in the emergency kit of long-term care facilities.

New language added to Item B of Subpart 2 recognizes the fact that it is not always the pharmacist who seals the emergency drug

supply in long-term care facilities, but, at the same time, recognizes that the sealing of the kit is the responsibility of the pharmacist.

Item D of Subpart 2 recognizes that the drugs contained in the emergency drug supply, of the long-term care facility, continue to be considered to be in the stock of the pharmacy which has provided the emergency drug supply. As a result, whenever drug items are used from the emergency kit, a prescription for the item used must be made available to the pharmacist. The pharmacist can then verify that the correct drug was removed from the emergency kit and can replace the used item while maintaining a record of the item that was used.

Subpart 3 of Minn. Rule 6800.6700 addresses the record keeping required for the inclusion of controlled substances in the emergency drug supply. Since federal law requires that all records of the receipt and distribution of controlled substance drugs be maintained for a period of two years, the Board believes it is appropriate to make it clear to readers of the Rule that the records of controlled substances in the emergency drug supplies must also be maintained for two years.

Subpart 4 of Minn. Rule 6800.6700 is essentially a technical change that recognizes the fact that stock supplies of legend drugs, such as those contained in the emergency drug supply, are not technically allowed to be maintained by long-term care facilities. As a result, the stock supplies of legend drugs found in the emergency drug supply are considered to remain the property

of the pharmacy supplying the kit until such time as the drug is used. As a result, it is the pharmacy's privilege to maintain an emergency kit in a long-term care facility, it is not the facility's right to have such a kit supplied by a pharmacy.

Minn. Rule 6800.7100, et. seq., address issues relating to pharmacy services in hospitals. The first substantive change to Board rules relating to operations in hospitals occurs in Minn. Rule 6800.7510. Item F under this part requires that pharmaceutical service policies address the use of drugs brought into the hospital by or with a patient. The Item requires that pharmaceutical service policies address the issues related to the use of these medications by a patient while in the hospital, but does not require that the policies address the issue of what should be done with the drugs if they are not to be returned to the patient upon discharge from the hospital. In addition, the Rule did not require pharmaceutical service policies to address issues of investigational drugs and the serious surrounding the preparation, use, and disposal of chemotherapy drugs. All of these matters will now be required to be addressed by the pharmacist and included in the pharmaceutical service policies of the hospital pharmacy under this new language.

Minn. Rule 6800.7520 contains new language in Subpart 1, Item G, requiring that the pharmaceutical service policies address issues of drug control arising from the outpatient dispensing of medications, through the emergency room, after regular pharmacy hours. Many small hospitals do not maintain 24-hour a day pharmacy

services and, on occasion, run into situations requiring the dispensing of medications to patients being seen in the Emergency Room after regular pharmacy hours. Some pharmacists have been doing a good job in addressing the issues surrounding these unique dispensing situations, while others have not addressed these issues at all. The Board, thus, sees a need for pharmacists to address these issues so that the packaging, labeling, and record keeping associated with this drug dispensing is appropriate.

Item M, under Subpart 1 of 6800.7520, is again new language which recognizes the unique nature of hospital pharmacy practice and allows hospital pharmacists some flexibility in establishing a system of accountability of drugs dispensed to hospital inpatients. Minn. Rule 6800.3100 requires that pharmacists "certify" each prescription being dispensed. In Item M, the Board is attempting to allow hospital pharmacists some flexibility in establishing a system of accountability meeting the intent of the certification requirement. The Board believes that this flexibility will not compromise patient care, in that pharmacists will still be responsible for the accuracy of each dose of medication dispensed or administered.

Item P of Subpart 1 requires that policies developed by the hospital pharmacist must address the proper preparation of parenteral products in the hospital's pharmacy. Several tragic situations have arisen across the country involving the improper preparation of parenteral products by hospital pharmacists and the Board is concerned that each hospital pharmacy address the issue,

of the proper preparation of parenteral products, in their policies. Item P of Subpart 1 requires pharmacists to address these issues.

Item S of Subpart 1 is new language, again needed because of the significant problem of diversion of controlled substance drugs from hospital supplies. By requiring the hospital pharmacist to develop policies which will maintain strict control and record keeping of controlled substance drugs throughout the hospital, the Board is attempting to meet the need of the public in assuring that controlled substance drugs are not being diverted, for illegal purposes, from hospital drug supplies and that patients, who receive controlled substance drugs in a hospital situation, are in fact being given the drug prescribed in a form that is not adulterated and has not been tampered with.

Most hospital pharmacies in Minnesota already have procedures in place that address most of these issues. This rule will serve to guide pharmacists in the development of their in-house policies and procedures in areas where better control is needed.

Item T of Subpart 1 requires hospital pharmacists to develop policies, similar to those discussed previously for patients in long-term care facilities, relating to the issuance of medications to patients who are going on leave from the facility. Hospital patients undergoing lengthy treatment programs occasionally go on short leaves from the facility. While away from the facility, the patient must continue on their drug therapy so arrangements must be made for the issuance of medications to the patients, covering the

time period they are away from the facility. In the hospital setting, as in the long-term care setting, nursing staff is being allowed, under limited circumstances, to prepare medications for use by the patient when away from the facility. The Board believes that policies addressing these issues, prepared by the hospital pharmacist, will provide adequate safeguards for the patients in need of medication during their absences from the facility while, at the same time, allowing the patient an opportunity to leave the facility for brief periods of time.

Minn. Rule 6800.7530, in Subpart 3, contains a small change clarifying what was always the intent of this provision, that being the emergency access to a hospital pharmacy, after hours, for the purpose of withdrawing limited doses of medication, for administration to inpatients. Over the years, there has been some confusion, from time to time, as to whether access to the pharmacy can be utilized for removing drugs for dispensing to outpatients. The emergency access provision has always been intended to apply to inpatients only, as is indicated by the use of the term "administration" in describing the purposes for which entry to the pharmacy was authorized. In order to clarify the misinterpretation that was occasionally evidenced, the Board is including language specifically identifying inpatients as the recipients of the drugs being removed from the pharmacy.

Minn. Rule 6800.7900 addresses the issue of labeling of prescriptions dispensed to hospital inpatients. Since hospital inpatients do not, as a general rule, self-administer their

medications, the Board recognizes that it is not necessary to include the name and address of the hospital's own pharmacy on prescription labels that are not leaving the hospital premises. As a result, identification of the pharmacy is being eliminated as one of the label requirements. Being added to the label requirements, however, is the location of the patient for whom the medication is intended. With the possibility of multiple patients with the same names becoming more of a concern as hospitals grow in size, it becomes more important to further identify the patient for whom medication is intended. Thus, the Board is including the room number, or other location identification for the patient, on the prescription label, in addition to the patient name.

Subpart 4 and Subpart 5, or Minn. Rule 6800.7900, have frequently caused confusion among pharmacists as to exactly what the requirement is for the labeling of parenteral solutions. In an attempt to clarify this issue for pharmacists, the Board is proposing to delete most of the language of Subpart 4 and to add some the deleted language to Subpart 5. These deletions and additions will serve to clarify the labeling requirements for parenteral solutions and IV admixtures for hospital pharmacists.

Minn. Rule 6800.7950 addresses the issue of satellite pharmacies within a hospital setting. This section clarifies the fact that hospitals may establish satellite pharmacies within the hospital facility, without the necessity of securing additional licenses, providing the Board is informed of the location of each satellite and providing also that the pharmacist-in-charge of the

hospital pharmacy assumes professional responsibility for the practice of pharmacy within each satellite.

Language requiring the appointment of a separate pharmacist-in-charge for satellite pharmacies is being deleted. Comments received from hospital pharmacy directors indicated that satellites generally were staffed by a rotating group of pharmacists and identifying an individual pharmacist who spent the majority of his time in the satellite, as was required for the naming of a pharmacist-in-charge, was problematical. To help hospital pharmacies address the needs of satellite pharmacies, the Board is proposing to delete the pharmacist-in-charge requirement from Minn. Rule 6800.7950.

Minn. Rules 6800.8000 to 6800.8008 address pharmacy operations in parenteral/enteral home health care pharmacies. These pharmacies, which may be physically located in a hospital or in a community setting, focus on the provision of sterile parenteral products to home care patients. In that the focus of operation of these specialty pharmacies is sterile products, special care must be taken and the highest standards of cleanliness and record keeping must be maintained.

In the mid-1980's, as parenteral/enteral home health care pharmacies were beginning to emerge as a defined specialty area, the National Association of Boards of Pharmacy convened a special Task Force to develop model rules relating to this practice. Experts in the area, from around the country, were brought together for meetings to discuss the issues and the appropriate standards

which should be applied to the these specialty pharmacies. The Board's proposals in Minn. Rule 6800.8000 to Minn. Rule 8008 are taken in large part from the model rules developed by these experts, under the auspices of the National Association of Boards of Pharmacy.

Minn. Rule 6800.8001 addresses the requirement for a policy and procedures manual. Because of the critical nature of the drug products being prepared in parenteral/enteral home health care pharmacies, it is essential that the pharmacy have a written operations manual, more commonly known as a policy and procedures manual, identifying the manner in which products will be prepared, labeled, and disposed of.

Rather than the Board attempting to identify every piece of equipment needed in each pharmacy and rather than identifying each procedure to be carried out in each pharmacy, the Board is leaving some discretion in the hands of the pharmacists involved. Because of the unique nature of these specialty products, the equipment and other procedures used or required will vary with the products being prepared and the location in which the pharmacy is situated. The Board is of the opinion that these variations can be best addressed by the pharmacist-in-charge through the policy and procedures manual. In Minn. Rule 6800.8001, the Board is simply identifying, for the pharmacist-in-charge, the topics that must be covered in the policy and procedures manual.

Minn. Rule 6800.8002 addresses the physical requirements of the pharmacy itself. Again, because of the critical nature of

these products, it is essential that the sterile work environment required be structurally separated from other areas and that access to the sterile environment be limited.

Subpart 3 of Minn. Rule 6800.8002 gives pharmacies, that desire to provide services in this specialty area, 90 days, from the effective date of these rules, in which to comply with Subparts 1 and 2 regarding space and equipment.

Minn. Rule 6800.8003 addresses personnel in parenteral/enteral home health care pharmacies. It is of critical importance that the pharmacist-in-charge of such a pharmacy be well-versed in the specialized functions of preparing and dispensing compounded, sterile parenteral products. The preparation and handling of these products is substantially different from that of most pharmaceuticals. Specialty training programs or prior experience, in hospitals or other parenteral/enteral home health care pharmacies, is essential.

Supportive personnel are essential to the efficiently run sterile products operation. Once again, due to the unique nature of these drugs products, the personnel must have specialized training in the field and must work under the immediate supervision of a licensed pharmacist. While the training of supportive personnel can be composed of on-the-job training or more formalized training, the training provided must be described in writing in a training manual. Again, because of the critical nature of these products, there is a great need for the monitoring of the duties assigned to or assumed by supportive personnel, to assure that

these duties are consistent with their training and experience. The pharmacist-in-charge of each parenteral pharmacy must assume responsibility for the proper use of supportive personnel. Subpart 3 of Minn. Rule 6800.8003 requires that a pharmacist be accessible at all times to respond to patient or practitioner questions and needs. Because of the critical nature of these products, arrangements must be made for a pharmacist to be on call and available in emergencies 24 hours a day.

Minn. Rule 6800.8004 addresses the handling of the prescription, the labeling of the product, and the delivery of the product to the patient. Prescriptions for sterile products are handled in the same way as prescriptions for other legend drug items. The sterile product must not be dispensed without such a prescription and prescriptions must be received, handled, and filed in the same manner as for other drugs. Similarly, each container of a sterile product must be appropriately labeled, as described in 6800.3450. Again, because of the unique nature of these products and the fact that, in most cases, patients are self-administering these products, there is a great need for proper labeling.

Delivery of sterile products to the patient is addressed in Subpart 4 of 6800.8004. Most of the prepared sterile products must be refrigerated or kept in a cool place until used. It is essential, particularly in the summer months, that temperature-controlled delivery containers be used to transport these products to the patient's home and that the products be stored appropriately

in refrigerators in the patient's home. Improper storage of these products can cause the degradation of very expensive drug products.

In that some of the products being utilized by patients, particularly terminal cancer patients, are narcotic analgesics and are highly desirable on the illicit drug market, it is critical that an audit trail be maintained for the delivery of these products to the patient.

Minn. Rule 6800.8005 addresses the issue of cytotoxic drugs, which are often prepared by parenteral/enteral home health care pharmacies. Because of the significant toxic nature of these products, special care must be taken in the preparation and in the disposal of these products. Both OSHA and the Environmental Protection Agency are involved in establishing standards for the handling and disposal of these agents.

Ordinary laminar-flow, sterile hoods, used in the preparation of most other sterile parenteral products, are not sufficient for the preparation of cytotoxic drugs. Special, vertical-flow, biological safety cabinets must be utilized in the preparation of these products. Special filters are needed to clean the exhaust air of any particles of drug that may have escaped during the compounding process and protective apparel must be worn by the pharmacist or technician performing these compounding tasks. All-in-all, special handling is required in every aspect of the preparation and use of these cytotoxic agents. The Board is meeting this need through the language proposed in 6800.8005.

Minn. Rule 6800.8006 serves to make it clear that a systematic process of drug use review is necessary for home care patients receiving sterile parenteral products. The critical nature of these patients makes it all the more essential that pharmacists carefully monitor all of their drug use.

Minn. Rule 6800.8007 addresses patient care guidelines. Because of the severe nature of the patients' illnesses, which require intravenous therapy, and because of the complicated and sometimes technical nature of the administration of these products, it becomes essential that the various health care providers have a clear understanding of who among them will take responsibility for each area of the patient's needs. The pharmacist should document all of these issues in the patient's profile record.

Among those items specifically documented is patient training. The pharmacy providing sterile parenteral products to patients must, either perform the patient training necessary to allow the patient or the patient's family to manage this type of therapy in the home environment, or must document training performed by other health care practitioners.

Patient monitoring is essential for patients receiving home parenteral therapy. In addition to a complete drug history, which is generally obtainable from the pharmacy's own records and the drug use review previously discussed, it is essential that the pharmacist obtain as much information as possible about other aspects of the patient's care. Ongoing monitoring is a responsibility of the pharmacist and, if not done personally by the

pharmacist, the identity of the health care provider doing the monitoring should be maintained in the patient's pharmacy records. All of these requirements imposed on the pharmacist are needed to safeguard the patients in this critical situation.

Minn. Rule 6800.8008 addresses quality assurance, which is essential for pharmacies preparing sterile, intravenous solutions. Since it is a truism in pharmacy that the product received by the patient can never be tested, a valid quality assurance program must be implemented by each pharmacy. While the Board is not specifying what each pharmacy's quality assurance program must look like, there are certain elements which must be addressed in every quality control program. Every quality control program must monitor personnel performance, equipment, and facilities. Primary among the equipment monitoring is the sterile hood, which provides the environment in which sterile products are prepared. Other areas of particular concern are in regard to the filters and pre-filters, expiration dates of the products prepared, and sterility and pyrogenicity testing when non-sterile chemicals are used in preparing a sterile end product.

Lack of a good quality assurance program could result in the distribution of products that could be harmful or even deadly to the patient who receives them. Thus, there is a critical need for regulations requiring quality assurance programs. Minn. Rule 6800.8008 is designed to meet that need.

Minn. Rule 6800.8100 et. seq. address nuclear pharmacy practice, that is, pharmacy practice resulting in the dispensing of

radioactive drugs. The changes proposed in Subparts 1 and 3, of Minn. Rule 6800.8100, are merely grammatical. Subpart 4, of Minn. Rule 6800.8100, provides a definition, previously absent from the rules, for nuclear pharmacy practice. As was the case in previous sections of these proposed rules, the language in this section was taken from the model pharmacy regulations developed by the National Association of Boards of Pharmacy.

Changes proposed by the Board, in Minn. Rules 6800.8200, 6800.8300, and 6800.8400, are merely grammatical changes.

Minn. Rule 6800.8500 expands the previous definition of a pharmacist-in-charge of a nuclear pharmacy. Again, the model rules of the National Association of Boards of Pharmacy were used to obtain the language for this amendment. It is certainly reasonable to expect that a pharmacist, who will be on record with the Board as being in charge of a nuclear pharmacy, have some specific education and training in the area of nuclear pharmacy practice. The Board is proposing that a pharmacist-in-charge be a Minnesota licensed pharmacist, who has been certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties, (a national organization which tests and certifies licensed pharmacists in various identifiable specialty areas within the scope of pharmacy practice, among these being nuclear pharmacy), or must have obtained specific education or experience in the area of nuclear pharmacy. By requiring a pharmacist-in-charge of a nuclear pharmacy to meet the need for demonstrated knowledge, education, or experience, the Board is meeting the need for public protection

while, at the same time, providing reasonable mechanisms by which the pharmacist involved can meet the various requirements.

Once again, as was the case earlier, the proposed changes to Minn. Rules 6800.8600 and 6800.8700 are merely grammatical in nature.

Minn. Rule 6800.9200 and Minn. Rule 6800.9700, relating to disciplinary proceedings, also have merely grammatical or technical amendments being proposed.

In Minn. Rule 6800.9900, relating to waivers and variances, the Board is proposing a new subpart which will expand the circumstances under which pharmacists may apply for a variance to existing Board rules. During the past few years, three or four different pharmacy organizations have approached the Board, requesting variances for research projects. The Board believes, however, that most pharmacists do not realize that a variance for research projects may be available to them. Thus, the Board is providing additional information to the pharmacy community in Minnesota, regarding the mechanism by which research in pharmacy can be conducted.

Minn. Rule 6800.9923 is being proposed for change as a result of a change in federally required labeling of legend medical gases. Tanks of medical oxygen, for instance, no longer need to bear a label of "Caution, federal law prohibits dispensing without prescription." Other federal labeling requirements are still applicable, however. As a result, the Board is proposing Minn. Rule 6800.9923 to reflect these federal changes.

Minn. Rule 6800.9924 addresses record keeping relating to the distribution of legend medical gases. It has been brought to the Board's attention that most distributors of legend medical gases, such as medical oxygen, don't obtain and retain a "prescription" for tanks of medical oxygen. Thus, it was impossible for them to record refill information on the patient's prescription record, as was previously required by this rule. This being the case, there was a need to change the language of this rule to conform with the standard of practice of the industry.

Records of medical oxygen distribution are maintained by distributors of legend medical gases, but they are not maintained in the same manner in which prescription records are maintained in other pharmacies. As a result, the Board is proposing to change the record keeping requirement to eliminate reference to prescription records.

Minn. Rules 6800.9950 through 6800.9954 address dispensing by non-pharmacist practitioners. Experience has shown that, when drugs are dispensed to patients by practitioners other than pharmacists, in many if not most cases, the medication is dispensed in containers that are not in compliance with light resistance and moisture permeability standards, and are not appropriately labeled. Furthermore, experience has shown that such dispensing is often not appropriately recorded.

The Board believes that this is due, in part, to lack of knowledge on the part of practitioners as to what the standards and legal requirements are. As a result, the Board has developed this

series of rules, which place, in one spot, the requirements from various state and federal laws. The requirements of all of these standards for the dispensing by non-pharmacist practitioners are found in various sections of Minnesota Statutes, Chapter 151 and in the federal Food, Drug, and Cosmetic Act.

The requirement for separate prescription records is found in Minnesota Statutes, Chapter 151.34 (11). Packaging of prescription drugs is found in Minnesota Statutes, Chapter 151.06, subdivision 1 (a) (3), and 151.34 (1), (2), and (3). Packaging requirements are also found in Section 502 (p) of the federal Food, Drug, and Cosmetic Act. Labeling requirements are found in Minnesota Statutes, Chapter 151.06, subd. 1 (a) (3); 151.212, subd. 1; 151.34 (1), (2), and (3); and 151.36 (4). Additional labeling requirements are found in Section 503 (b) (2) of the federal Food Drug and Cosmetic Act and Minnesota Statutes 151.212 subd. 2. Further, Sections 301 (a) and (b), of the federal Food Drug and Cosmetic Act, declare improperly labeled prescription drugs to be misbranded.

Record keeping requirements are found in Minnesota Statutes 151.211 and section 503 (b) (1), of the federal Food Drug and Cosmetic Act.

Finally, the personal involvement required of practitioners, who are dispensing prescription drugs, is found in Minnesota Statutes 151.37, subd. 2, and 151.15, subd. 4.

The Board has condensed the essence of all of these sections and developed Minn. Rules 6800.9951 through 6800.9954.

The end result of all this is that Minnesota residents, regardless of whether they get their prescription drugs from a pharmacist or directly from a non-pharmacist practitioner, can be assured of uniform packaging, labeling, and record keeping standards. The Board is not attempting to prohibit dispensing by non-pharmacist practitioners, but is simply bringing to everyone's attention the fact that identical standards of packaging, labeling, and record keeping apply regardless of who is dispensing the medication.

Finally, the Board is proposing to repeal the language currently found in Minn. Rule 6800.4400, subpart 2, relating to the exemption of registration for physicians conducting research involving controlled substances, and Minn. Rule 6800.7400, subpart 6, relating to the responsibility for the directing of pharmacy services in the absence of the director of record.

Regarding 6800.4400, subpart 2, the Board has found that most physicians, doing research with controlled substances, expect to be required to obtain licensure by the state. Further, the Drug Enforcement Administration, which requires registration at the federal level of all controlled substance researchers, relies upon state registration and inspection as a basis for federal registration. The Board's current exemption, of physicians doing research with controlled substances, causes confusion, not only among the physicians involved, but also among the staff of the Drug Enforcement Administration responsible for federal registration of

those individuals. The Board is proposing to eliminate this confusion by repealing this section of the existing rules.

Regarding Minn. Rule 6800.7400, subpart 6, the Board is of the opinion that this really is superfluous language. Regardless of the size of the institution involved, if the director is contemplating a temporary absence, another pharmacist is always designated as being responsible for the operation of the pharmacy. It appears totally unnecessary for the Board to require this in its rules.

In summary, these rules are need to meet the needs of a rapidly changing pharmacy profession. Entirely new specialty areas, such as home IV therapy and federally mandated pharmacist involvement in prospective drug use review and patient counseling, have created dramatic shifts in the pharmacy paradigm over the past few years. It is essential that Board rules be developed to guide pharmacy practice in these new areas, in order to adequately protect the public. In addition, it is essential that Board rules be kept current in other evolving areas of pharmacy practice. If Board rules become outdated, archaic, and in many cases no longer applicable to current practice situations, disrespect for the rules quickly follows. It is essential that the Board keep its rules up-to-date and maintain high standards of practice for pharmacists and drug dispensing in Minnesota. The Board believes that its proposals, in this regard, are quite reasonable in that the language in many cases is taken directly from federal requirements,

state or federal statutes, or model rules developed by the National Association of Boards of Pharmacy.

Whenever an agency proposes a new rule or seeks to amend an existing rule, Minn. Stat. section 14.115 requires the agency to consider whether the rule change will have an impact on small business. If the agency determines that the rule changes will, the agency must consider whether certain methods, set forth in subdivision 2 of that statute, could be adopted to reduce the impact of the rule changes on small businesses. The statute requires that agency to document, in its Statement of Need and Reasonableness, how it considered these methods and the feasibility of adopting any of the specific methods.

The Board of Pharmacy currently licenses, and has licensed for over 100 years, pharmacists and pharmacies, the business entities affected by the present rule changes. The Board has reviewed the impact, if any, its proposed rule changes would have on such businesses.

Minn. Stat. 14.115, subdivision 2, enumerates the following five methods an agency must consider to reduce the impact of the rules on small businesses:

- A. The establishment of less stringent compliance and reporting requirements for small businesses;
- B. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

- C. The consolidation or simplification of compliance or reporting requirements for small businesses;
- D. The establishment of performance standards for small businesses, to replace design or operational standards required in the Rule, and;
- E. Exemption of small businesses from any or all requirements.

While approximately 75% to 80% of the pharmacies licensed by the Board meet the definition of "small business," the Board is unable to establish a less stringent requirement for a small business and is unable to exempt small business from any or all of the requirements of these rules, in that in many cases the federal government has mandated minimum requirements that all pharmacies must comply with, and further, patients obtaining pharmaceutical services from a "small business" pharmacy are just as deserving of the protections afforded them by these rules as are those patients who do business with large pharmacies. In that the proposed rules generally do not exceed the federally mandated minimums, the statutorily mandated minimums, or the requirements found in model rules, the Board is unable to further accommodate small business.

The adoption of these rules will not result in the expenditure of public monies, by local public bodies spending in excess of \$100,00, in either of the first two years following the rules' adoption, nor will these rules affect agricultural land.

While these rules do not establish new fees nor change the amounts of any existing fees, copies of these rules are being

submitted to Chairs of the House Appropriations Committee and the Senate Finance Committee prior to publication of the Notice, as required by section 16A.128, subdivision 2a. Copies are being sent to these individuals because the pharmacy licenses issued under the Board's proposals will no longer simply list the licensed entity as a "pharmacy," but will list the licensed entity as a pharmacy authorized to provide services in certain designated practice specialties. In that the changes being proposed here, by the Board, will neither increase nor decrease total revenues for the Board, nor will they increase or decrease the fees paid by any of the Board's licensees, these rules have not been submitted to the Department of Finance for approval.

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