BEFORE THE MINNESOTA
BOARD OF PHARMACY

In the Matter of the Proposed Rule Amendments Relating to Pharmacy Practice and Drug Wholesaling, including Definitions, Applications for Pharmacy Licenses, Pharmacy License Categories, Transfers of Pharmacy Ownership, Pharmacy Counseling Areas, Supervision of Pharmacy Areas, Automated Counting Devices, Closing a Pharmacy, Applications for Pharmacist Licensure, Drug Manufacturer and Wholesaler Licensure, Registration of Pharmacy Technicians, Training and Educational Requirements for Pharmacy Technicians, Unprofessional Conduct, Answering Machines and Electronic Voice Recording Devices, Compounding, Prospective Drug Reviews, Patient Profiles, Transfer of Prescriptions between Pharmacies, Prepackaging and Labeling, Radiopharmaceutical Labeling, Veterinary Prescription Drug Labels, Interns and Preceptors, Consulting Services to Licensed Nursing Homes, Emergency Kits, Pharmaceutical Services Policies, Variances, and Medical Gas Distributor Registrations, *Minnesota Rules*, 6800.0100 et. seq.

STATEMENT OF NEED AND REASONABLENESS

## I. INTRODUCTION

The Minnesota Board of Pharmacy (Board), pursuant to Minnesota. Statutes §§ 14.22 through14.28 and Minnesota Rules Parts 1400.2000 through 1400.2570, hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendments to portions of the Board's rules relating to pharmacy practice.

## II. ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request for an alternative format, contact Cody Wiberg at the Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, Minnesota 55414-3251, phone at (651) 201-2825, fax at (651) 201-2837, or e-mail at cody.wiberg@state.mn.us. TTY users may call (800) 627-3529.

## III. STATUTORY AUTHORITY

The statutory authority for these proposed rule changes is contained in Minnesota Statutes Sections 151.06, which provides the Board with general rule-making authority relating to the practice of pharmacy and drug wholesaling.

## IV. NEED FOR AND REASONABLENESS OF THE RULES

Since this is a large package of proposed rule changes, the Board is presenting both the need for and the reasonableness of the rules together in this section – rather than two separate sections. The Board believes that the reader will be better able to follow the issues if the needs and reasonableness sections are combined.

These proposed changes are needed because the professional practice of pharmacy continuously evolves, requiring the Board to periodically revise its existing rules to address changes in practice. In addition, actions of the United States Congress, the Food and Drug Administration, the Drug Enforcement Administration and other federal agencies often require changes in the Minnesota Rules for pharmacy and for drug wholesaling.

In developing this package of proposed rule changes, the Board of Pharmacy sought input from a number of different sources. The final package of proposed changes was developed with the assistance of three advisory committees. The Board's long-standing Internship Advisory Committee (IAC) reviewed proposed changes to the rules involving internship. The IAC includes representatives of the Board and of the University Of Minnesota College Of Pharmacy. Two ad-hoc committees were formed to help the Board develop proposed rule changes in other areas. The Technician Rules Advisory Committee (TRAC) included representatives of the Minnesota Pharmacists Association (MPhA), the Minnesota Society of Health-System Pharmacists (MSHP), the National Association of Chain Drug Stores, the Minnesota Retailer's Association, and the University Of Minnesota College Of Pharmacy. The TRAC reviewed proposed changes involving the registration of pharmacy technicians. The TRAC grew out of an earlier task force that was established by the MPhA in 2005. The General Rules Advisory Committee (GRAC) reviewed all other proposed rule changes. The GRAC consisted of representatives of MPhA and MSHP, plus volunteers who were selected to represent major practice areas such as community, hospital and long-term care pharmacy.

All meetings of the three advisory committees were open to the public and many people offered comments during the meetings. In addition, the Board has received many written comments about the proposed rule changes since work first began on this package in 2008. The Board has made a number of changes to the original rules draft in response to the comments received. By convening three advisory committees and making changes based on comments received, the Board has acted to ensure that the proposed rules are reasonable.

The proposed changes to the Board's rules address various issues. The need for and reasonableness of the proposed changes will be addressed by Rule Part:

### 6800.0100 DEFINITIONS

Subpart 1c. **Central service pharmacy.** The proposed change in this subpart is one instance of a number of changes throughout this rules package that inserts the word "filled" before the word "prescription". Currently in Chapter 6800, the word "prescription" is used to indicate both a prescription order (e.g. a piece of paper on which a physician has written an order for the dispensing of a drug) and the drug product that is dispensed in a properly labeled

container pursuant to such an order. This can cause confusion and so this change is necessary. The Board is proposing to use the word "prescription" to mean only a prescription order (and not also the product that results from the filling of a prescription order). The Board intends for the phrase "filled prescription" to mean the drug product that is dispensed, in an appropriately labeled container, pursuant to a prescription drug order. This change is reasonable in that it simply eliminates any confusion about what the Board means when it uses the word "prescription" in Chapter 6800.

Subpart 2. **Community/outpatient pharmacy.** The use of the phrase "retail pharmacy" is frowned upon by many members of the profession because it emphasizes the retail *sale* of drugs rather than the provision of professional services. The phrases "community pharmacy" and "outpatient pharmacy" are now more frequently used for pharmacies of this classification. Therefore, the Board is proposing to replace the word "retail" with the word "outpatient". This change is reasonable given that most members of the profession no longer use the word "retail" when describing this type of pharmacy.

Subpart 2a. **Community satellite.** The Board added a definition of "community satellite" when it adopted rule changes in May, 2007. At the time, the Board had approved variances that allowed the remote locations of telepharmacy operations to operate as satellites of the hub pharmacy. The Board has since decided that the remote locations should be licensed as separate pharmacies. The Board made this decision for several reasons. For example, there is some question about the propriety under federal law of allowing a remote, unlicensed "satellite" to store and dispense controlled substances. (The U.S. Drug Enforcement Administration recently announced that it would be conducting a review of telepharmacy operations to determine how they fit in with existing federal statutes and rules). Also, licensing the remote locations separately allows the Board to recover some of the additional costs involved in conducting inspections and complaint investigations at the remote sites. Since community satellites are no longer being allowed, it is reasonable to eliminate this definition. The change is also necessary so that individuals who are considering options for community pharmacy operations don't erroneously assume that the inclusion of a definition of a "community satellite" in Chapter 6800 means that the Board is still allowing such facilities to operate.

Subpart 4. **Long-term care pharmacy**. This subpart contains the phrase "community/retail" pharmacy, which the Board is proposing to replace with "community/outpatient" pharmacy for the reasons given above (see the explanation provided for Subpart 2c – Community/outpatient pharmacy).

Subpart. 6. **Home health care pharmacy.** The Board is proposing to drop the phrase "parenteral-enteral" from this definition because it is rarely used to describe this class of pharmacies. In addition, these pharmacies currently dispense more than just parenteral or enteral products. Thus, this change is needed so that individuals reviewing the rules don't erroneously conclude that home health care pharmacies are only allowed to dispense enteral and parenteral products. This subpart also contains the phrase "community/retail" pharmacy, which the Board is proposing to replace with "community/outpatient" pharmacy for the

reasons given above (see the explanation provided for Subpart 2c – Community/outpatient pharmacy).

Subpart 11. **Prescription drug order;** Subpart 11a. **Prescription; and** Subpart 11b. **Chart order.** The primary purpose of these proposed changes is to distinguish between two types of prescription drug orders. The Board is proposing that the word "prescription" be used for prescription drug orders that are written for the outpatient setting (i.e. that are written for patients who will be using the drug at home or in some other outpatient setting). The Board is proposing to use the phrase "chart order" to refer to prescription drug orders issued for an inpatient setting (i.e. – prescription drug orders issued for patients admitted to hospitals, nursing homes or other health care facilities).

The reason and need for making this distinction is that different types of information need to be included on prescription drug orders that are issued in different settings. For example, the addresses of the patient and the practitioner (and the telephone number of the practitioner) do not need to be included on chart orders issued for the inpatient setting. The home address of the patient is recorded in the demographic section of his or her chart. Likewise, the facility typically maintains contact information for the practitioners authorized to issue chart orders.

The Board is proposing that a telephone number at which a practitioner can be reached be required for prescriptions issued for the outpatient setting. This has actually been the standard of practice for many years, thus making this proposed change reasonable. However, the Board has received a number of reports from pharmacies about prescriptions issued at some clinics – particularly the newer urgent care clinics that are located in retail settings. These prescriptions either had no telephone number at all or had a toll-free number answered at a location other than the one at which the prescription was written. The lack of an appropriate telephone number has made it difficult for pharmacists to contact practitioners when there are questions about a prescription. That, in turn, has lead to a delay in care for patients. This also has an impact on patient safety, since some pharmacists who cannot readily contact the prescriber may make incorrect "guesses" if they have a question concerning a prescription. This change is therefore needed to protect patient safety and to minimize the delay that a patient experiences when it is necessary for the pharmacist to contact the prescriber about a prescription.

The Board is including in the definition of "prescription" under subpart 11a, its interpretation of Minnesota Statutes §151.01, subd. 16. That subdivision reads, in part (emphasis added):

> "The term 'prescription' means **a signed written order**, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice".

The following is an excerpt from the January 2007 edition of the Board's newsletter which provides the rationale for the Board's interpretation of this subdivision:

> **"ELECTRONIC PRESCRIPTIONS.** Board staff frequently receives questions about 'electronic prescriptions'. For example, a common question is as follows: is a prescription

that is electronically generated still valid if the prescriber prints it out on a sheet of paper and gives it to the patient? Once a prescription is printed out and given to the patient, it is no longer an electronic prescription. Consequently, it is valid only if it is manually signed by the prescriber. A rubber-stamped signature does not constitute a manual signature. A notation on a paper prescription such as "electronically signed by the prescriber" does not make it a legally valid prescription.

Minnesota Statutes §151.01, subd. 16 defines a prescription as follows, "The term "prescription" means a signed written order, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice, issued for an individual patient and containing the following: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber". Given that this law was written long before the advent of electronic prescribing, the word "signed" must be interpreted to mean a manual, handwritten signature. A pharmacist who receives a paper prescription that has not been manually signed may contact the prescriber to verify the prescription and may treat it as an oral order".

There are important policy considerations that helped guide the Board's interpretation of this subdivision. If an electronically generated prescription is printed out on a piece of paper and it is not signed, it is difficult for a pharmacist to determine the legitimacy of the prescription. It is extraordinarily easy for anyone with a computer, word-processing software and a printer to create documents that look exactly like some of the prescriptions that are being electronically generated in some clinics and practitioner offices. Therefore, requiring a manual signature on electronically generated prescriptions that are printed on paper reduces the risk that unlicensed individuals will create fraudulent prescriptions. Before publishing the above mentioned newsletter article, the Board regularly received calls from pharmacists expressing concern about the legitimacy of unsigned, electronically-generated (but printed) "prescriptions".

Requiring a practitioner to either manually sign a paper prescription or to personally affix his/her electronic signature to a prescription that is transmitted electronically can reduce prescribing errors. Even though the standard for electronic prescribing is to have the practitioner personally enter the prescription information into the system, the Board is aware that order entry is often delegated to some other person. Whenever another person transcribes a practitioner's order, there is a risk that the transcription will done incorrectly. Requiring the practitioner to manually or electronically sign a prescription before it is given to the patient or transmitted to the pharmacy affords the practitioner the opportunity to check for and correct such errors.

Even though this process involves slightly more effort on the part of practitioners and their staff, this proposed change is reasonable given that: 1). it helps protect patient safety by reducing the risk of transcription errors; 2). it actually reduces the workload for pharmacy and clinic staff that occurs when the pharmacist feels compelled to verify the accuracy of an unsigned paper prescription and 3). this has been the de facto standard of practice since the Board issued the above-mentioned interpretation.

Subpart. 14. **Nonsterile product compounding and** Subp. 15. **Sterile product compounding.** The Board is proposing to add pharmacy license categories for sterile and nonsterile compounding (see discussion below for Part 6800.0350). Thus, there is a need to add definitions of nonsterile product compounding and sterile product compounding. The definitions are reasonable given that they describe the processes involved in compounding and they reference the USP Chapter 795 and 797 standards that the Board adopted, by rule, in 2007.

Subpart. 16**. Limited service pharmacy.** The Board is proposing to add a pharmacy license category for limited service pharmacies. Thus, there is a need to add a definition of "limited service pharmacy". (See discussion below for Part 6800.0350 for an explanation of why the Board feels that creating a limited service pharmacy license category is reasonable).

Subpart. 17. **Unique identifier.** Many of the rule changes that the Board is proposing make use of the phrase "unique identifier" or "unique identifiers". Most often, these phrases are in some way replacing the words "initials" or "initialing". In the past, individuals would manually initial some portion of a record to indicate that they had taken some action or had reviewed the record. (Manual initials are still often used). However, many processes are now done entirely electronically – with no paper record produced. In some cases, initials are still stored electronically; but other forms of identifiers are also frequently used. This proposed new subpart defines what the Board means when it uses the phrase "unique identifier". Given that manual initials are no longer the only method used to indicate that an individual has been involved in a process, it is necessary and reasonable to make these changes. In some cases, these changes will eliminate the need for pharmacies to submit variance requests in order to use newer technologies that make use of biometric identifiers, electronic signatures, etc. (Reducing regulatory burden while maintaining patient safety is certainly a reasonable thing to do).

**6800.0300 PHARMACY LICENSE AND FEE REQUIRED.**

One proposed change involves substituting the words "medications" and "prescription medications", which are not defined in either statutes or rules, with the phrase "legend drugs", which is defined in Minnesota Statutes §151.01, subd. 17. These substitutions are made throughout this package of proposed rule changes. These substitutions are being made for the sake of consistency, since some rules use "medications" and other rules use "legend drugs" to mean the same thing. Consistency in the language used in a Chapter of rules is a reasonable thing to strive for.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for

the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing that an application for a pharmacy license, which has not been completed within 12 months of the date on which the board received the application, will no longer be valid. The Board regularly receives applications for pharmacy licenses that are not complete. The applicant sometimes does not submit the information needed to complete the application, even when requested to do so by Board staff. In addition, applicants for pharmacy licenses sometimes do not make arrangements to have required pre-licensing inspections completed. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. In addition, long delays often results in Board staff having to repeat work (such as reviewing floor plans or sometimes even repeating inspections). Therefore, it would be reasonable to require that an applicant, who has not completed all of the steps necessary for pharmacy licensure within 12 months, reapply so that the Board can review any changes in circumstances and recover extra costs associated with the delay.

**6800.0350 LICENSE CATEGORIES**

Two of the proposed changes in this part involve only changes in the phrase used to describe already existing license categories. Please see the discussion above under Part 6800.0100, subparts 2 and 6 for the Board's rationale in proposing to use "community/outpatient" rather than "community/retail" and "home health" rather than "parenteral-enteral/home health care".

In recent years, more pharmacies have started to specialize in nonsterile and/or sterile compounding. In addition, many other pharmacies also engage in compounding, although they do not specialize in it. The United States Pharmacopoeia (USP) has updated its standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). In order to protect the public, it is important and necessary for the Board to know which pharmacies engage in sterile or nonsterile compounding so that resources can be devoted to ensure that those pharmacies are following the relevant standards. Therefore, the Board is proposing the creation of nonsterile and sterile compounding license categories. This is a reasonable change, given that the Board is only trying to better identify pharmacies that provide compounding services and not trying to impose any new standards or other requirements.

In the past several years, pharmacists have begun practicing pharmacy in a variety of settings other than a traditional pharmacy. These settings are also not places, such as hospitals or clinics, where pharmacists have traditionally performed clinical activities. For example, pharmacy benefit managers that operate mail order pharmacies have set up offices that receive new prescriptions, which are entered into computers by technicians or pharmacists. If completed by a technician, the data entry is checked by a pharmacist, who also does a drug utilization review (DUR). Once reviewed and approved by the pharmacist, the prescription data is transmitted to a mail order pharmacy located in another state, where an automated process places the drug in an appropriately labeled container to be shipped to the patient. No drugs are stored at these offices, nor do they have the equipment that a normal pharmacy usually has.

The Board considers data entry, verification of data entry and DUR to be integral parts of the dispensing process that must, as such, take place in a licensed pharmacy. Consequently, the Board has issued pharmacy licenses to offices such as those described in the previous paragraph, even though only a limited portion of the dispensing process occurs in those offices. The Board has also issued pharmacy licenses to other facilities in which a narrow range of the activities that constitute the practice of pharmacy are performed.

The Board proposes the creation of a new "limited service" license category into which these sorts of facilities would be placed. One reason for doing so is that such facilities often do not need to have possession of any drugs. By issuing a limited license, the Board can alert drug wholesalers that the facility should not be allowed to purchase legend drugs.

Creating this new license category would also allow the Board to better track the new types of facilities and practices that seem to be rapidly evolving and proliferating. These facilities are often engaged in activities that, if not done correctly, could have a detrimental impact on patient safety. It is therefore critical for the Board to require that these facilities apply for pharmacy licensure in the proposed new limited license category. This is a reasonable change, given that the Board is simply trying to better track pharmacies that provide only limited services and to better alert the public and other businesses, such as wholesalers, that a pharmacy is only authorized to provide limited services.

It is also important for a pharmacy to get approval from the Board before providing services in a new license category. For example, a pharmacy that had not been providing sterile compounding services would most likely have to undergo significant remodeling before it could safely provide such services. It is reasonable for the Board to require pharmacies to get approval before making such significant changes so that the Board can ensure that the changes are not made in a manner which could endanger the public.

**6800.0400 ANNUAL LICENSE RENEWAL DATE AND FEES.**

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in the Statutes instead

**6800.0500 SEPARATE LICENSE REQUIRED.**

The Board is proposing to eliminate the "addition, deletion, or change of categories of licensure" as actions that would constitute a change of ownership. As mentioned above in the discussion of proposed changes to Part 6800.0350, it is important for the Board to be notified of (and to approve) any changes in license categories that a pharmacy makes. Pharmacies will be more likely to comply with this requirement if a change in license category is not considered to be an "ownership change" for which a licensing fee must be paid. This change is reasonable in that it reduces regulatory burden.

The Board is proposing a new subpart that provides a timeline for pharmacy ownership transfers. The Board frequently gets questions about this issue, specifically:

- When does an application for transfer of ownership have to be received by the Board; and
- Can a pharmacy continue to operate under the old license for a period of time after the transfer of ownership and, if so, for how long?

The new language that the Board is proposing clarifies that such applications must be received in the Board offices prior to the transfer of ownership. The Board would like the application to be received close to the date of transfer, rather than weeks in advance. This is because the Board has, in the past, processed ownership changes and issued a new license – only to have one of the parties cancel the sale at the last minute. Currently, even when the Board does receive an application for a transfer of ownership, staff does not issue the new license until a day or two before the specified transfer date.

Unfortunately, unforeseen complications occur (e.g. – a need to advance the closing date of a sale by several days). Sometimes, the parties involved in the sale simply don't get the paperwork submitted to the Board until immediately before the scheduled date of sale. That sometimes results in a transfer of ownership before Board staff can issue a new license. Consequently, the Board is proposing adopting language that is used by several other states that allows the new owner to operate a pharmacy, under the previously issued license, for up to 14 days after the effective date of an ownership change. This change will help protect the public from an unexpected, temporary closing of a pharmacy that would have to occur if an unforeseen circumstance as mentioned above occurred and the pharmacy was not allowed to operate until a new license was issued. This proposed change is reasonable in that it protects the public from an interruption in service while actually providing some "cushion" for the new licensee by allowing a little more time for the processing of paperwork.

**6800.0700 PHARMACY, SPACE AND SECURITY**.

Approximately 15 years ago the United States Congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA-90). Incorporated within the various sections of OBRA-90 was a provision requiring each state to develop laws or rules requiring pharmacists to provide prospective drug-utilization review and to provide patient counseling services to all Medicaid patients, in order to maximize the effectiveness of drug therapy for these patients and, as a result, to decrease the overall healthcare costs to the federal government.

In this state, the Legislature amended Minnesota Statutes § 151.06, directing the Board of Pharmacy to mandate the OBRA-90 DUR and patient counseling requirements through its rulemaking process. In 1992 and 1993, the Board worked to promulgate rules necessary to implement the requirements of OBRA-90. As was done in most other states, the Board of Pharmacy proposed to expand the DUR and patient counseling requirements of OBRA-90 to all patients in Minnesota, rather than limiting the requirement for these services only to Medicaid patients. The Board's proposal met with significant opposition at the hearing held on the proposed rules and the DUR and patient counseling requirements of OBRA-90 were, subsequently, limited to Medicaid patients only. Minnesota, thus, became one of only ten states that did not expand the DUR and patient counseling requirements of OBRA-90 to all patients within the state.

By 2001, when the Board addressed this issue again, additional studies had taken place that validated the hypothesis that drug use review and patient counseling play a valuable role in maximizing the effectiveness of drug therapy and lowering overall healthcare costs. In addition, support for the concept of pharmacist involvement in drug therapy management had grown among members of the profession. There also appeared to be general support within the profession in Minnesota for the expansion of the DUR and patient counseling requirements of OBRA-90 to all patients within the state. Therefore, the Board proposed changes to Minnesota Rules Parts 6800.0910 and 6800.3110 to eliminate the double standard of pharmaceutical care that had been in existence in this state for the previous ten years. The rule change was adopted, and it was hoped that all patients in Minnesota would receive DUR and patient counseling services from their pharmacist.

Since patient counseling often involves the discussion of sensitive health care information, it is important and necessary for a pharmacy to have an area in which counseling can occur with a reasonable assurance of privacy. Subpart 1, paragraph E of this rule part requires community pharmacies to have such a counseling area but does not specify any design features that must be present. As a result, some pharmacies have counseling areas that, in the judgment of the Board, do not provide a reasonable assurance of privacy. This is particularly true for older pharmacies that were constructed prior to 1999 and have never been remodeled. This problem has been somewhat mitigated since the Board's development of guidelines for counseling areas several years ago.

The Board is proposing to amend the rules to require pharmacies that use partitions to use the dimensions and materials that have heretofore only been specified in Board guidelines. Pharmacies would be allowed, with Board approval, to have other types of counseling areas. Existing pharmacies, without an adequate counseling area, would have two years from the date of the adoption of this rules package to develop one. Given that pharmacy owners have had no major objections to following the Board's guidelines for the past several years, it is reasonable to now move the standards specified in the guidelines into the Rules. It is reasonable to require existing pharmacies to bring their counseling areas up to these standards since most of them that are out-of-compliance were supposed to have upgraded their counseling areas by February 1, 2001 per a rule amendment adopted in the late 1990's.

**6800.0910 PATIENT ACCESS TO PHARMACISTS .**

The first and last changes in subpart 2 insert the word "filled" before the word "prescription". Please see the discussion for part 6800.0100, subpart 1c for the rationale for making this change.

The second proposed change in subpart 2 replaces the word "medication" with the word "drug". Please see the discussion for part 6800.0300 for the rationale for making that change. Note that "legend drug" is not used because pharmacists must provide counseling for all new filled prescriptions – whether the drug being dispensed is a legend or a non-legend drug.

The third proposed change in subpart 2 deletes the phrase "or a new prescription drug order". As noted above, in the discussion for part 6800.0100, subpart 11, the Board is proposing to distinguish between two different types of prescription drug orders – "prescriptions" and "chart orders". If that proposed change is adopted, the word "prescription" will be used for prescription drug orders that are written for the outpatient setting. So the deletion of this phrase will clarify that the mandatory counseling rule applies to prescription drug orders written for the outpatient setting. That is reasonable given that the Board has not required counseling for patients who have been admitted to and are inpatients within institutional settings.

**6800.0950 REQUIREMENT FOR A SUPERVISED PHARMACY AREA**

As explained in the discussion for part 6800.0350, the Board is proposing to create a new "limited service" pharmacy license category. As noted in the discussion for Part 6800.0350, some of the facilities to which the board has issued pharmacy licenses do not stock drugs. These facilities therefore do not compound or dispense drugs, nor do they display or sell, "other items used in the cure, mitigation, treatment or prevention of disease". Consequently, the changes proposed for part 6800.0950 are necessary for the adoption of the changes proposed for part 6800.0350. See the section discussion for Part 6800.0350 for an explanation of why the Board considers the creation of a "limited service" pharmacy license to be reasonable.

**6800.1010 CLOSING A PHARMACY**

The proposed change in subpart 2 substitutes the word "legend" for the word "prescription". See the discussion for Part 6800.0300 for the rationale for making this change.

The Board is proposing the creation of a new subpart 3 that would require a licensed pharmacy to provide a public notification when closing a pharmacy. The notification would have to include the date on which the pharmacy will close and the name, address and phone number of the pharmacy to which the prescription files will be transferred.

The Board has determined that this change is necessary due to the regular calls it receives from the public concerning the closing of pharmacies. Citizens have complained that they have experienced difficulty in determining where to have their prescription refilled after their pharmacy closed. In addition, some individuals would have liked to have had their prescriptions transferred to a pharmacy other than the one that had purchased the prescription files – often because they did not want an individual who worked at that pharmacy to have access to their protected health information.

Some individuals who represent pharmacies have expressed the concern that the adoption of the proposed subpart 3 might decrease the value of the sale of prescription files when a pharmacy closes. The Board has addressed this concern by allowing pharmacies to select from a variety of notification options and by shortening the notification time frame. The Board considers this to be a reasonable compromise between the desire of the seller of a closing pharmacy's prescription files to maximize the value of the sale and the need to protect the right of patients to chose where to get their prescriptions filled and to be assured that they will be able to get their prescriptions refilled in a timely manner after the pharmacy that they have been frequenting closes.

**6800.1050 REQUIRED REFERENCES BOOKS AND EQUIPMENT**

As might be expected, reference books concerning the practice of pharmacy, prescription drugs and toxicology change in terms of their content, format and availability. Since this rule was last amended, some reference books have gone out of print and new ones have been written. In addition, the titles of some references have changed. Consequently, it is necessary to update the list of suggested references. This proposed change is reasonable given that the Board is merely deleting references that are no longer on the market or updating the titles of references. Some pharmacies that still have copies of references that are no longer published may have to buy new references. However, given the rapid change in knowledge about drugs, it is reasonable to expect pharmacies to periodically update their references.

The final proposed change in this part replaces the word "prescription" with the word "legend". Please see the discussion for Part 6800.0300 for the rationale for making this change.

**6800.1250 APPLICATIONS FOR LICENSURE**

Some of the changes being proposed for this part are being made to provide clarification, in Rule, about the requirements for pharmacist licensure. For example, one change in Subpart 1 would clarify that a board applicant must provide the Board with an official and certified final transcript from an ACPE accredited college or school of pharmacy showing the date on which the applicant graduated. The existing rule contains the more nebulous requirement that the applicant provide the Board with "evidence of graduation". In fact, the "evidence of graduation" that the Board has long deemed necessary is an official and certified final transcript from an ACPE accredited college or school of pharmacy. Similarly, the Board has also long required that birth certificates be "official and certified".

The proposed changes also separate into several subparts the licensure requirements for graduates of ACPE accredited colleges of pharmacy, graduates of Canadian colleges of pharmacy and graduates of other foreign pharmacy schools. The proposed rule language is taken from the checklists for pharmacist licensure that the Board has used for quite some time. Consequently, these proposed changes in Rule are reasonable, given that the Board is not proposing any new requirements that applicants for pharmacist licensure will have to meet. Instead, long-standing requirements are simply being put into Rule.

The change being proposed in the new Subpart 3, clause B, makes it clear in rule that graduates of four-year foreign pharmacy schools, colleges, or programs are not eligible for licensure as pharmacists. The Foreign Pharmacy Graduate Examination Committee determined that, as of January 1, 2003, a change from a four-year to a five-year educational curriculum requirement was necessary to ensure consistency with the revised standards of US pharmacy school curricula. (By that date, all U.S. pharmacy schools had eliminated their Bachelor of Science programs in favor of Doctor of Pharmacy programs, which require an additional year of training). The Board has determined that it is desirable and necessary to require foreign pharmacy graduates to adhere to all of the requirements of the FPGEC certification process. Failure to adhere to the FPGEC certification requirements might cause other states to reject applicants for pharmacist licensure by reciprocity when the reciprocity is based on a license issued by our Board. In addition, the Board would most likely be inundated with applications if it were to adopt a lower standard for licensure of foreign pharmacy school graduates than is used by other states. The Board does not have the resources necessary to handle a large increase in licensure applications. Again, this is a reasonable change because a long-standing requirement is simply being put into Rule.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The proposed new Subpart 4 clarifies, in Rule, that applicants for a pharmacist license must provide the Board with their Social Security number. Provision of a Social Security number is required by Minnesota Statutes, § 270C.72, subdivision 4. The Board hopes that adding this Subpart will decrease the number of questions that the Board receives concerning the legal basis for requiring a Social Security number to be provided during the application process. It is reasonable in that it does not create a new requirement but merely alerts potential licensees about this requirement in the chapter of Rules administered by the Board – which they are more likely to be aware of and check than the relevant section of the Statutes.

The Board is proposing changes in Subpart 2 (which will become the new Subpart 6) that reflect the fact that the Board no longer requires applicants for licensure by examination to pass a practical examination. As a result, there is a need to update this rule to reflect the fact that applications for licensure by examination are now considered at any time during the year, not just in January and June. That makes obsolete the requirement for applicants to notify the Board 45 days in advance of their intended examination date. This is a reasonable change given that it

simply reflects the procedures that the Board has had in place since it stopped administering a practical examination.

The Board is proposing that the time during which an applicant can retake an examination be increased from 14 to 18 months. It is not uncommon for applicants who have failed an examination more than once to want to take additional time to study for the examination. This change will give such applicants additional time to study - without them having to request a variance to this rule. (The Board has routinely granted such requests in the past). This proposed change is reasonable in that it provides benefit to applicants while not creating any additional work for Board staff or any increased risk to the public.

**6800.1300 LICENSURE TRANSFER (RECIPROCITY)**

The term "Licensure Transfer" is being added to the title of this Part because that term is used by the National Association of Boards of Pharmacy to describe the reciprocal licensure process that it administers on behalf of all of the states. It is reasonable to use the term that is used by the national organization that administers the licensure transfer process used by all states.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing to eliminate the requirement that an applicant for licensure transfer must have practiced in the profession for at least one year after licensure in another state which is an active member of the National Association of Boards of Pharmacy before the applicant will be considered eligible to reciprocate to Minnesota. This requirement was established when the Board still administered a practical examination which required the exam taker to actually compound drug products. In order to avoid taking that examination, applicants would get licensed in another state that did not require a practical examination and then immediately reciprocate back to Minnesota. The one year waiting period was meant to discourage that practice. Since the Board no longer administers a practical examination, this requirement is obsolete. This proposed change is reasonable because it decreases the regulatory burden faced by applicants for licensure transfer while not creating any additional work for Board staff or any increased risk to the public.

The remaining changes in this part are meant to update the rules to better reflect the internship hour requirements that the Board has long required applicants to meet. They are reasonable because they do not create any new requirements but merely clarify the requirements that the Board already has in place.

**6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE**

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing that an application for a drug manufacturer or wholesaler license which has not been completed within 12 months of the date on which the board received the application will no longer be valid. The Board regularly receives applications for such licenses that are not complete. The applicant sometimes does not submit the information needed to complete the application, even when requested to do so by Board staff. In addition, in-state applicants for such licenses sometimes do not make arrangements to have required pre-licensing inspections completed. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. In addition, long delays often results in Board staff having to repeat work (sometimes even repeating inspections). Therefore, it would be reasonable to require that an applicant who has not completed all of the steps necessary for manufacturer or wholesaler licensure within 12 months, reapply so that the Board can review any changes in circumstances and recover extra costs associated with the delay.

The Board is proposing to require that any location outside of Minnesota from which drugs are shipped into Minnesota, pursuant to a wholesale transaction, be licensed. Currently, only the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies must be licensed. (Although many companies have voluntarily undertaken to license each facility from which they ship drugs into Minnesota). That means that the Board does not always know the locations from which drug products are shipped into Minnesota. Nor does the Board always know if a particular facility operated by a nonresidential manufacturer or wholesaler has been the subject of regulatory scrutiny in another state.

The Board needs to know which facilities ship drugs into the state and which have been subject to regulatory scrutiny in order to better protect the public from potentially adulterated or misbranded products. While some companies may end up licensing additional facilities and

paying additional fees, the Board considers this reasonable given that the alternatives, such as requiring wholesalers to be accredited through the Verified-Accredited Wholesale Distributors program of the National Association of Boards of Pharmacies could be even costlier for some companies.

Many companies today act as "virtual" or "sponsor" manufacturers. They hold the right to manufacture a drug and are considered by the Food and Drug Administration to be manufacturers. However, they contract the actual manufacturing of the drug out to another manufacturer and never take actual possession of the drugs. Since they are "doing business with accounts in this state" the Board has taken the position that they must be licensed as manufacturers pursuant to Minnesota Statutes §151.25. The Board is proposing to clarify, in Rule, that a manufacturer which does not ship drugs into this state from any location that it directly operates must nevertheless obtain a license pursuant to Minnesota Statutes §151.25 if it does business with accounts in this state and that doing business with accounts in this state includes any sale of a manufacturer's drugs to any individual or business within Minnesota.

The proposed change is reasonable given that it simply reflects the Board's long-standing interpretation of the provisions of Minnesota Statutes §151.25. In addition, not licensing "virtual" or "sponsor" manufacturers would allow them to evade the gift limitations of Minnesota Statutes §151.461 and the reporting requirements of Minnesota Statutes §151.47, subd. 1(f).

**6800.1430 PERSONNEL**

The word "prescription" is being stricken because the Legislature passed language during the 2010 Session that clarifies that wholesalers that sell only non-legend (i.e. OTC or nonprescription drugs) must be licensed. Therefore the rules that apply to wholesalers will apply to all drugs, not just "prescription" drugs. This change is reasonable in that it merely reflects a statutory change enacted by the Legislature.

**6800.1440 REQUIREMENTS FOR WHOLESALE DRUG DISTRIBUTORS.**

The word "prescription" is being stricken in several places because the Legislature passed language during the 2010 Session that clarifies that wholesalers that sell only non-legend (i.e. OTC or nonprescription drugs) must be licensed. Therefore the rules that apply to wholesalers will apply to all drugs, not just "prescription" drugs. This change is reasonable in that it merely reflects a statutory change enacted by the Legislature.

**6800.1500 CONTINUING EDUCATION**

Most of the proposed changes in this part concern the establishment of a continuing education requirement for pharmacy technicians. Please see the special section below that addresses all of the changes that the Board is proposing that relate to the registration requirements for pharmacy technicians.

The Board is proposing a change in Subpart 4a that is not directly related to the establishment of a continuing education requirement for pharmacy technicians. The Board is proposing to allow pharmacists and technicians to submit a continuing education program approval form up to 90 days after attending a CE program – rather than the current 45 days. A number of pharmacists have asked for exceptions to the 45 day requirement because they had not received confirmation of attendance from the CE provider within 45 days. Given that fact, it is reasonable to allow pharmacists and technicians to have up to 90 days following completion of a CE program to submit a CE program approval form. Allowing an additional 45 days for submission will not increase the workload of Board staff nor have any adverse impact on the public.

The proposed change in Subpart 6a reflects the fact that some CE providers have started to develop programs that specifically target the needs of preceptors. As a result, the Board has approved many such programs as being acceptable for meeting the preceptor CE requirement of Part 6800.5350, subpart 3(D). This is necessary, given that the Board's limited resources has made it difficult to internally develop new preceptor CE programs in a timely fashion. It is reasonable in that it provides many more CE options for preceptors – including programs that have been developed by organizations with more expertise than the Board has in developing educational programs.

**6800.2250 UNPROFESSIONAL CONDUCT**

Many of the changes proposed in this part substitute the word "legend" for the word "prescription" – and "nonlegend" for "nonprescription". Please see the discussion for Part 6800.0300 for the rationale for making those changes.

In Subpart 1(C), the Board is proposing to insert "prescription drug order" in place of the word "prescription". As noted in the discussion for Part 6800.0100, subpart 11, the Board is proposing that the word "prescription" be used for prescription drug orders that are written for the outpatient setting (i.e. that are written for patients who will be using the drug at home or in some other outpatient setting). The Board is proposing to use the phrase "chart order" to refer to prescription drug orders issued for an inpatient setting (i.e. – prescription drug orders issued for patients admitted to hospitals, nursing homes or other health care facilities). This proposed change would clarify that the Board considers it to be unprofessional conduct for a pharmacist to refuse to fill a prescription drug order that a pharmacist would be reasonably expected to fill – regardless of the treatment setting. It is certainly reasonable to expect a pharmacist to fill a prescription drug order whether the patient is being served in a community pharmacy or is an inpatient in a hospital or long-term care facility. (As long as any pharmacist would be reasonably expected to fill the prescription drug order in question).

Subpart 1(E) makes it unprofessional conduct to discriminate against individuals who have certain characteristics. The proposed change for Subpart 1 (E) adds sexual orientation and marital status to the list of those characteristics. In addition, it substitutes the word "disability" for the word "disease". Disability is the word used throughout Minnesota's Human Rights Act (Minnesota Statutes Chapter 363A). Adding sexual orientation is reasonable in that Minnesota Statutes §363A.17 makes it unfair discriminatory practice for a person engaged in a business,

such as a pharmacy, to discriminate against an individual on the basis of sexual orientation. In addition, a pharmacy is also a "place of public accommodation" as defined in Minnesota Statutes §363A.03. Pursuant to Minnesota Statutes §363A.11, it is an unfair discriminatory practice to deny any person the full and equal enjoyment of the goods, services, facilities, privileges, advantages, and accommodations of a place of public accommodation because of, among other things, marital status and sexual orientation. The Board finds that engaging in unfair discriminatory practice by denying needed pharmaceuticals and pharmacy services to individuals because of the characteristics listed in this part would reasonably be considered unprofessional conduct.

The proposed addition of Subpart 1(K) would make it unprofessional conduct to engage in any pharmacy practice which constitutes a danger to the health, welfare, or safety of a patient or the public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist and which harmed or could have harmed a patient. From time-to-time, the Board receives a complaint about a pharmacist who has done something that, while perhaps not specifically or clearly prohibited by statute or rule, is nevertheless far outside the bounds of what a prudent pharmacist would do. As an example, a couple of years ago the Board investigated two complaints alleging that pharmacists were dispensing drugs based on purported prescriptions that originated from illegitimate Web sites. Most of the drugs are commonly abused and some were controlled substances. At the time, the action of these pharmacists was not as clearly prohibited by law as it is now. Fortunately, the Board was able to get the pharmacists involved to voluntarily agree to sign stipulation and consent orders. If they had not agreed to sign the orders, the Board would've had an easier time pursuing disciplinary action if the language we are proposing now would've been in place then.

This proposed change is reasonable given that other Minnesota health licensing boards have similar provisions in either statute or rule. For example, the state's nursing practice act, Minnesota Statutes §148.261 makes it grounds for disciplinary action to engage in "unprofessional conduct, including, but not limited to, a departure from or failure to conform to board rules of professional or practical nursing practice that interpret the statutory definition of professional or practical nursing as well as provide criteria for violations of the statutes, or, **if no rule exists, to the minimal standards of acceptable and prevailing professional or practical nursing practice,** or any nursing practice that may create unnecessary danger to a patient's life, health, or safety". (Emphasis added). Likewise, the state's medical practice act, Minnesota Statutes §147.091, subd. 1 makes it grounds for disciplinary action to engage in unprofessional conduct, which includes "any departure from or the failure to conform to the minimal standards of acceptable and prevailing medical practice".

**6800.2400 PHARMACIST-IN-CHARGE**

The Board is proposing to require a successor pharmacist-in-charge (PIC) to submit an acknowledgment of an awareness and understanding of any variances that the pharmacy has been granted according to part 6800.9900. The successor PIC would then be responsible for ensuring that any conditions imposed by the board on granted variances continue to be met. This

change is reasonable in that it actually decreases both regulatory burden and the Board's workload. Currently, a successor PIC must submit a complete variance request, including supporting documentation, in order for the pharmacy to continue using an approved variance. The Board's staff then has to process the request for review and approval by the Variance Committee and then the entire Board. This process was put into place after Board Surveyors reported that many successor PICs had no knowledge of the variance requests that had been approved for their pharmacies.

The proposed change will allow the PIC to submit only a brief document acknowledging awareness and understanding of any variances that the pharmacy has been granted. This document will be filed with the pharmacy's records and will not have to be reviewed by the Variance Committee or the full Board. This new procedure will accomplish the same goal as does the current procedure – ensuring that a successor PIC is aware of variances issued to the pharmacy and that he or she acknowledges that the conditions of the variance will be met.

**6800.2600 AUTOMATED COUNTING AND DISTRIBUTION**

The Board believes that this part needs to be amended for two reasons. First, the use of automated counting and distribution devices has increased significantly since this part was first promulgated. There has also been a proliferation in the type of devices that are in use. These changes make it necessary for the Board to update this part to better reflect current usage of these devices. Second, the Board wants to decrease the regulatory burden faced by the pharmacies that use the devices.

Currently, any pharmacy that wants to use an automated counting device must submit a variance request to the Board. Any pharmacy that wants to use an automated distribution system must submit a policies and procedures document to the Board. The Board and its staff then review either the policy and procedure document or the variance request. The Board processes hundreds of policy and procedure documents and variance requests for these devices every year. Virtually all of the requests are approved – although sometimes only after the pharmacy has made recommended changes.

In handling the variance and policy review requests, the Board has made approval conditional upon adherence to guidelines for the use of automated counting and distribution devices. The guidelines were developed by the Board's professional staff (i.e. the Surveyors) and were approved by the Board. They reflect current best practices for the use of such devices and are drawn from extensive consultation with pharmacists who use these devices. The guidelines also reflect relevant U.S. Food and Drug Administration good manufacturing procedures. It should be noted that the Institute for Safe Medication Practices actually based their guidelines for these devices on our Board's guidelines.

These proposed changes are reasonable given that the Board is simply putting into rule these guidelines - which it has long required pharmacies to adhere to as a condition of variance and policy review approval. Thus, pharmacies that use these devices will not face any new requirements. In fact, they will face less regulatory burden because they will not have to submit variance and policy review requests prior to using the devices. The Board, of course, will retain

the authority to require a pharmacy to stop using a device if it finds that the pharmacy is not using the device in accordance with this amended part.

**6800.3000 PRESCRIPTIONS AND DISTRIBUTION OF DRUGS**

Several of the changes proposed for this part involve distinguishing between "prescription drug orders" and "filled prescriptions". Please see the discussion for Part 6800.0100, subpart 11 for the rationale for making those changes.

The Board is proposing a change that would allow a pharmacy to deliver filled prescriptions to the place of employment of the patient or of a designated caregiver of the patient. This change would be of most benefit to patients who receive temperature-sensitive drugs by mail or other means of delivery. The Board has received complaints from patients when such drugs are left by delivery personnel in excessively hot or cold environments, such as the front porch of the patient's house. If such drugs were delivered to the patient's workplace, at his or her request, he or she could make sure that the drugs were appropriately stored. (Presumably, if a patient requests delivery at the workplace, he or she will have made sure that drugs that are temperature-sensitive can be stored adequately). The proposed changes will require the delivering pharmacy to take certain steps to ensure that the patient's privacy is protected.

Despite the proposed change that would allow delivery of filled prescriptions at a patient's place of employment, some drugs will still be delivered to the homes of patients. In addition, there can be unexpected delays in the deliveries of filled prescriptions. Consequently, the Board is proposing new language that would require pharmacies to use adequate storage and shipping containers and processes to ensure drug stability and potency during deliveries. In developing these proposed changes, Board staff reviewed the statutes and rules that other states have adopted in this area. Thus, the proposed language is largely based on rules and statutes that pharmacies successfully follow in other states. Given that patients can be harmed if they take temperature-sensitive drugs that have not been properly handled and given that the Board has received complaints about improper handling of delivered drugs, the proposed language is necessary. Given that pharmacies in other states have been able to comply with very similar laws and rules, the proposed language is reasonable.

The proposed changes to Subpart 3 basically require electronic prescribing to be in compliance with Minnesota Statutes §62J.497 and any rules promulgated thereunder by the state Department of Health. In enacting Minnesota Statutes §62J.497, the Legislature established certain standards and requirements that must be adhered to by anyone involved in the electronic prescribing process. The Board is proposing to reference Minnesota Statutes §62J.497 in the chapter of rules that it administers because pharmacists are much more likely to periodically review Chapter 6800 than sections of statute administered by other agencies.

The changes proposed for Subpart 4 are meant to place into rule the Board's policy concerning the use of answering machines and interactive voice recording (IVR) devices. Such devices are now commonly used in pharmacies. Patients can leave messages asking that prescriptions be refilled – or even just punch in the prescription number that they want refilled. In addition, prescribers can leave a voice message in which they issue a new prescription for a

patient. Since Part 6800.3100, Subp.1 (B) allows only pharmacists and pharmacist-interns to receive verbal orders for new prescriptions, the Board has taken the position that only pharmacists and pharmacist-interns can take new prescription messages off of answering machines and IVRs. However, Board Surveyors continue to discover pharmacies where technicians are allowed to take such messages off of these devices.

Some pharmacists have argued that technicians ought to be able to write down new prescriptions that have been left on these devices, as long as a pharmacist listens to the message and double-checks what the technician has written down. The Board disagrees because of the problem of confirmation bias, which is a form of cognitive error based on the tendency to seek out information which supports one's beliefs, while ignoring contradictory information. In this context, a pharmacist who strongly believes in the competency of a technician is more likely to miss an error made by that technician. Given that messages saved on these devices can sometimes be hard to understand, a pharmacist who is just double-checking what a technician has written down may end up misinterpreting an indistinct message in the same manner as the technician.

**6800.3100 COMPOUNDING AND DISPENSING**

Several of the changes proposed for this part involve distinguishing between "prescription drug orders" and "filled prescriptions". Please see the discussion for Part 6800.0100, subpart 11 for the rationale for making those changes.

The change proposed for Subpart 1 (E) will officially allow pharmacies to have technicians assist in extemporaneous compounding, which is the compounding of a drug product for an individual patient pursuant to a prescription drug order. Under a literal reading of the current rule, such compounding may only be done by pharmacists and pharmacy-interns. However, in some settings, the Board has not enforced a literal reading of the rule for years. Most notably, technicians in hospital and home health care pharmacies often participate in the extemporaneous compounding of drugs, including drugs that must be compounded under sterile conditions. In short, the use of technicians in this manner has become widely accepted within the profession. (Note that technicians are tacitly allowed to assist in *bulk c*ompounding pursuant to Part 6800.3850, Subpart 6 – since the Board established a 3:1 technician:pharmacist ratio in that Subpart).

Since this proposed change removes the requirement that all aspects of extemporaneous compounding be done only by pharmacists and pharmacist-interns, technicians will be allowed to assist in such compounding. However, there is a limit to what the Board can allow technicians to do. Minnesota Statutes §151.102, Subdivision 1 states, in part (emphasis added):

> "A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing **nonjudgmental** tasks and works under the personal and direct supervision of the pharmacist".

The Board cannot amend the rules in a way that conflicts with state statutes. Consequently, the Board cannot allow technicians to perform tasks that require the professional judgment of a

pharmacist. The Board finds that the establishment and verification of the initial formulation record for a compounded preparation requires the professional judgment of a pharmacist. In order to properly compound a drug and prepare a formulation record, the pharmacist must answer questions such as the following, which are taken from the USP, Chapter 795:

- Have the physical and chemical properties and medicinal, dietary, and pharmaceutical uses of the drug substances been reviewed?
- Are the quantity and quality of each active ingredient identifiable?
- Will the active ingredients be effectively absorbed, locally or systemically according to the prescribed purpose, from the preparation and route of administration?
- Are there added substances, confirmed or potentially present from manufactured products that may be expected to cause an allergic reaction, irritation, toxicity, or undesirable organoleptic response from the patient?
- Are there added substances, confirmed or potentially present, that may be unfavorable (e.g., unsuitable pH or inadequate solubility)?
- Were all calculations and measurements confirmed to ensure that the preparation will be compounded accurately?

Answering these questions requires the professional training and judgment of a pharmacist. Consequently, under these proposed changes, technicians will not be allowed to establish and validate the initial formulation records for compounded preparations. (See also a proposed change to Part 6800.3300, subpart 6 that formally requires "stage-checking" for compounded products).

One of the changes proposed for Subpart 1 (G) replaces the words "prescribers or their agents" with the phrase "practitioners or other individuals allowed to prescribe legend drugs according to Minnesota Statutes, section 151.37, subdivision 2". The Board believes that this change will clarify that only licensed practitioners and certain "appropriately certified, registered or licensed health professionals" designated by practitioners are allowed to authorize refills. (e.g a registered nurse working under a protocol pursuant to Minnesota Statutes §148.235). A mere "agent" of a practitioner may transmit the practitioner's instructions concerning refills to a pharmacy but cannot authorize a refill. The current language of this rule might be misinterpreted to mean that an agent of a prescriber can independently authorize a refill.

For a discussion of a second proposed change to Subpart 1(G), which substitutes the phrase "unique identifier" for the word initials, please see the discussion for Part 6800.0100, Subpart 17.

For Subpart 1(H), the Board is proposing to change the description of the nonprofessional duties that clerical personnel can perform. At the time that this part was originally promulgated, "looking up" and "filing" refills most likely meant retrieving paper prescriptions from file folders and filing them after the pharmacist was done using them. Currently, nearly all pharmacies utilize computers - and "looking up prescription refills" generally means accessing electronically stored prescription data. The process of accessing the prescription data usually includes a drug utilization review (DUR) process that checks for such things as drug interactions, high dose, low dose, etc. The process of entering data for a new prescription triggers a DUR.

Unregistered clerical personnel, who will probably lack the training that the Board is proposing to require of technicians, should not be involved in prescription data entry or retrieval of refill information. In fact, the Board has long required pharmacies to have policies in place that require even technicians who are doing data entry to have a pharmacist review and handle all DUR alerts. This proposed change is reasonable in that it simply clarifies the language of this Subpart to reflect the Board's long-standing interpretation.

In the first sentence of Subpart 3, the Board is proposing to replace the word "the" with the phrase "an individual". The Board is doing so to clarify its long-standing interpretation that a single, individual pharmacist must certify the accuracy of a filled prescription. The Board continues to find that it is important to have a single pharmacist take responsibility for the accuracy of the entire filling process. The Board may grant a variance to this rule that does allow individual pharmacists to take responsibility for just one portion of the process but will do so only if the pharmacy requesting the variance initially demonstrates, and continues to demonstrate, that its alternative certification process does not result in a significant increase in dispensing errors or missed, significant drug utilization review alerts.

This clarification is reasonable given that the Board has granted variances to this rule and has received complaints about dispensing errors that may have been prevented if only one pharmacist had verified the accuracy of the entire filling process. The Board has required pharmacies to alter their policies and procedures as a condition for continued variance approval in order to minimize the risk of additional errors. Given the receipt of these complaints, it is reasonable for the Board to require pharmacies that want to divide the responsibility for ensuring the accuracy of the filling process between two or more pharmacists to have their procedures periodically reviewed through the variance process.

For a discussion of a second proposed change to Subpart 1(H), which substitutes the phrase "unique identifier" for the word "initialing", please see the discussion for Part 6800.0100, Subpart 17.

For Subpart 3a, the Board is proposing the use of the phrase "unique identifier" in place of the phrase "documentation to identify the names, initials, or identification codes". Please see the discussion for Part 6800.0100, Subpart 17 for the rationale. The Board is also proposing that the documentation required by this Subpart be maintained for a minimum of two years, which is reasonable since it is consistent with the time period required by the Board for the maintenance of other records. It is important for the Board to have access to this data when it investigates complaints that allege that a dispensing error has taken place. Knowing which personnel were involved in the alleged error can help Board staff make recommendations to the pharmacy for minimizing the risk that future errors of the same type will occur. The Board is also proposing the addition of language that clarifies that while more than one individual may be involved in the prescription-filling process, it is important to have a single pharmacist take responsibility for the accuracy of the entire process (as discussed in the previous paragraph).

**6800.3110 PATIENT MEDICATION PROFILES**

Several of the changes proposed for this part involve distinguishing between "prescription drug orders" and "filled prescriptions". Please see the discussion for Part 6800.0100, subpart 11 for the rationale for making those changes.

The changes proposed for the last paragraph of this part clarify the manner in which the Board has long interpreted the requirements for handling drug utilization review alerts. (Namely, that only a pharmacist or pharmacist-intern may override such alerts). Although pharmacy technicians are allowed to do data entry and process refills, they cannot override DUR alerts because doing so is a judgmental task that they are not allowed to perform. It is reasonable to make this clarification since Minnesota Statutes §151.102 allows technicians to perform only nonjudgmental tasks.

The Board is proposing to repeal Subpart 6 which allowed pharmacies to not create patient profiles in circumstances:

- When the patient does not want a profile established; and
- When a hospital pharmacy serving only inpatients prepares discharge prescriptions for a patient.

The information that pharmacies are required to collect and maintain in patient profiles is critical to the proper dispensing of drugs. Date of birth or age, gender, disease states, known drug allergies and adverse reactions, and a list of current medications must all be known by the pharmacist if he or she is to adequately assess the appropriateness of a new prescription drug order. It would be unreasonable for a patient to withhold this information and still expect a pharmacist to provide quality pharmaceutical care. Likewise, if a pharmacist provides care to a patient it is important to maintain a record of the care that is given. In the case of a hospital pharmacy preparing discharge prescriptions, the hospital pharmacy should have collected the information required to be in a patient profile in order to provide care for the patient while he or she was hospitalized.

**6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES**

Patients commonly either want or need to have a prescription transferred between pharmacies. This rule spells out in detail the procedures to be followed when a prescription is transferred. The Board is proposing to clarify that a registered intern may transfer prescription information to a licensed pharmacist or another registered intern. The Board has long taken the position that interns can transfer prescriptions so this change is reasonable in that it is simply meant to clarify this in Rule.

As currently written, this part only allows a transfer for the "purpose of *refilling* a prescription". Technically, that means that a pharmacy cannot transfer prescription drug information for the purpose of the *initial* filling of the order. It is not uncommon for a pharmacy to receive a prescription drug order that the patient does not want immediately filled. Such orders are usually "put on hold" or "profiled", meaning the information is entered into the

pharmacy's computer but the prescription is not actually filled and dispensed to the patient. Since the pharmacy has never actually filled the prescription, it can't transfer prescription information to another pharmacy because such a transfer would not be for the purpose of refilling the prescription. Similarly, a prescription drug order may be telephoned by the prescriber to the wrong pharmacy. The current wording of this Part would prevent the correct pharmacy from receiving a transfer from the incorrect pharmacy – again, because it would not be for the purpose of refilling the prescription.

The board is proposing to allow pharmacies to transfer prescription drug order information in such situations provided that the procedures described in the new Subpart 8a are followed. Those procedures should ensure that either the transfer occurs from the original prescription drug order or from computerized records of the prescription that have been double-checked through the quality assurance process required by Part 6800.3950, subpart 4. Note that the quality assurance process would usually have been completed in those cases where a transfer was for the purpose of refilling a prescription. (Because the QA process must be completed within 72 hours of the initial filling of the prescription and most transfers for the purpose of refilling a prescription happen after those 72 hours have elapsed).

In Subparts 3 and 4, the Board is proposing that the transferring and receiving pharmacists or interns exchange names and telephone numbers (rather than just addresses). Requiring the exchange of names is consistent with rules that require a pharmacist to record the name of a practitioner or practitioner's agent that telephones a prescription to the pharmacy. If a complaint alleges that a prescription has been improperly transferred, it is important for the Board to know which individuals were involved in the transfer. Exchanging telephone numbers can expedite communication between the pharmacies should any questions arise after the transfer has occurred. This proposed change is reasonable given that it would take very little extra time to exchange names and phone numbers.

In Subpart 9, the Board proposes language that indicates pharmacists and interns - not pharmacies – can provide informational copies of prescriptions to other interns and pharmacists. The Board further proposes clarifying that drug therapy information may be provided not only to physicians, but to any licensed, registered or certified health professional who is currently providing services to or acting on behalf of the patient. This is necessary and reasonable given that advanced practice nurses, physician assistants, dentists, podiatrists, optometrists and other professionals may need such information in order to appropriately provide services to patients.

The change proposed for Subpart 10 is reasonable and necessary because the U.S. Drug Enforcement Administration recently adopted interim final rules that allow for the electronic transmission of Schedule II controlled substances as long as certain requirements are met. This means that Schedule II prescriptions no longer always have to be "written".

**6800.3200 PREPACKAGING AND LABELING**

The Board is proposing the changes in Subpart 1(B) because sometimes it is a distributor, rather than a manufacturer, that assigns lot numbers and expiration dates to the drugs used by a pharmacy. For the rationale for replacing "initials" with "unique identifier" in Subpart 1(E) and

(F), please see the discussion above for Part 6800.0100, Subpart 17. The Board is proposing to add a new part 6800.8550 concerning the labeling of radiopharmaceuticals and thus needs to add Subpart 2(G) in this part to reference that new part. Please see the discussion for the proposed Part 6800.8550 for further information.

**6800.3300 PHARMACY COMPOUNDING PRACTICES**

As mentioned above in the discussion for Part 6800.3100, the Board is proposing to formally allow pharmacies to have technicians assist in extemporaneous compounding, which is the compounding of a drug product for an individual patient pursuant to a prescription drug order. As also noted above, the use of technicians in this manner has become widely accepted within the profession and the Board has not enforced a literal reading of Part 6800.3100 in quite some time.

Having technicians assist in extemporaneous compounding is not without its potential problems, however. The Board has investigated complaints involving errors made by technicians who were assisting in extemporaneous compounding. In the judgement of the Board, at least some of these errors could have been avoided if the process of stage-checking had been used by the pharmacists who supervised the technicians. As the proposed new language describes, stage-checking involves having a pharmacist certify that each component used in the compounding of a drug product has been accurately weighed, measured or subdivided, as appropriate, at each stage of the compounding procedure. This affords the pharmacist the opportunity of checking to make sure that the correct ingredients, in the correct amounts have been added to the compounded preparation in the correct sequence.

The language that the Board is proposing to include in a new Subpart 6 is taken nearly verbatim from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, (Appendix B - Good Compounding Practices Applicable to State Licensed Pharmacies, Subpart F). Nearly identical language is used by at least seven other states, including Iowa. It is reasonable for the Board to adopt language that was developed by NABP and used in many other states.

**6800.3350 BEYOND-USE DATES**

The Board is proposing the change the language in Subpart 4 to clarify its intent. The current language is read by some pharmacists to mean that beyond-use dates *must* be printed on the label of prescription vials. In fact, the Board has only required that *if* the pharmacy chooses to place a beyond-use date on a prescription vial, then the standards described in the subpart must be followed. The proposed language is reasonable in that it should make the Board's long-standing intent much clearer.

**6800.3400 PRESCRIPTION LABELING**

As mentioned above, the Board is proposing the creation of a new Part 6800.8550 that will specifically address the labeling of radiopharmaceuticals. Consequently, the Board is noting at the beginning of Part 6800.3400 that the part no longer applies to radiopharmaceuticals. It is also

proposing a new Subpart 5 that states that the labeling of radiopharmaceuticals must be done in accordance with the new Part 6800.8550.

The change proposed for Subpart 1(A) does not actually change the intent of that clause. It merely replaces somewhat confusing verbiage with language that is more precise. The same is true for the change proposed for Subpart 1(J).

The Board is proposing a change to Subpart 1(K) that would extend certain labeling requirements to nonlegend drugs that are not dispensed in the manufacturer's original container. Currently, this part requires that any dispensed prescription medication be labeled with its physical description, including any identification code that may appear on tablets and capsules. This requirement was adopted in 2007 by the Board as a means of reducing the risk of a patient actually consuming an incorrectly dispensed drug. (If the label says, for example, that the drug is a white, oblong tablet but the patient receives a pink and round tablet, he or she will probably contact the pharmacy to verify whether or not the correct drug has been dispensed).

It is reasonable to extend this requirement to nonlegend (over-the-counter) drugs when they are not dispensed in the original manufacturer's container. When they are not dispensed in the original manufacturer's container, the patient has no more information about the appearance of the drug than he or she would have about the appearance of a legend drug. Consequently, the same rationale for requiring a description of the drug on the label prepared by the pharmacy applies.

The Board is also proposing to exempt drugs dispensed as part of an investigational drug study from the requirement found in Subpart 1(K). Blinding is often an essential component of such studies. (i.e. – neither the patient nor the investigator knows which patients receive an active drug and which patients receive a placebo). Labeling a drug with a description of the drug can sometimes interfere with the blinding process.

The Board adopted Subpart 4, concerning the labeling of veterinary prescription drugs, in 2007. Until earlier in this decade, most such drugs were dispensed directly by the veterinarian to the owner of the animal or animals for which the drug was prescribed. However, there are now many pharmacies specializing in dispensing veterinary drugs to animal owners. Since labeling requirements are different for veterinary prescriptions, the Board added this Subpart to describe the minimum necessary information that must be included, by a pharmacy, on a veterinary prescription label. This Subpart was adapted from the labeling requirements enforced by the Minnesota Board of Veterinary Medicine as found in Minnesota Statutes § 156.18, subd. 2. The Board is now proposing to amend this Subpart to also reflect the labeling requirements established by the U.S. Food and Drug Administration (FDA) pursuant to the Animal Medicinal Drug Use Clarification Act (AMDUCA). It is reasonable for the Board to require veterinary prescription labels to conform to the requirements already enforced by the Minnesota Board of Veterinary Medicine and AMDUCA.

**6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS**

Please see the discussion for Part 6800.0100, subpart 17 for the Board's rationale for proposing to use the phrase "unique identifier" in place of the word "initials".

**6800.3510 REFILL LIMITATIONS**

Please see the discussion for Part 6800.0100, subparts 11 and 11a for the Board's rationale for at times using the term "prescription drug order", rather than the word "prescription".

**6800.3750 UNIT DOSE DISPENSING**

Please see the discussion for Part 6800.0100, subparts 11 and 11a for the Board's rationale for using the term "prescription drug order", rather than the word "prescription".

The Board is proposing a change to Subpart 9 that distinguishes between controlled substances and noncontrolled substances in regards to how they are stored when a unit dose system is being utilized. Currently, all drugs must be stored in a locked area or locked cart at all times. The proposed language will still require all controlled substances to be stored in that manner, since such drugs are most likely to be diverted (i.e. stolen). If the proposed language is adopted, noncontrolled substances will have to be stored in a locked area or a locked cart only when the patient care area is not staffed. This change is reasonable in that it will make it easier in certain circumstances for noncontrolled drugs to be administered to patients while still making sure that adequate measures are in place to prevent the diversion of controlled substances.

**6800.3850 PHARMACY TECHNICIANS**

The Board is proposing major changes in the registration requirements for pharmacy technicians. All of the changes will be discussed here, including a proposal to require technicians to complete 20 hours of CE every two years as a condition of being eligible for renewed registration. (See the proposed language change in the Revisor's Draft for Part 6800.1500).

Supportive personnel have assisted pharmacists in the preparation and dispensing of pharmaceutical products for many years (several decades, at least). However, the Board did not begin registering technicians until it was empowered to do so when the Legislature added Subdivision 1(a)(9) to Minnesota Statutes §151.06 in 1997. At the same time, the Legislature also added a definition of "technician" to Minnesota Statutes §151.01 and created Minnesota Statutes §151.102, which describes the manner in which pharmacies may utilize technicians.

Up until now, the registration of technicians has been solely for the purposes of identifying, tracking and, when necessary, disciplining individuals thus registered. The only registration requirements that the Board has established are a minimum age of 16 and an annual fee of $20. The Board is proposing to significantly expand technician registration requirements by:

- increasing the minimum age to 18;

- requiring high school graduation or GED;
- requiring the completion of a formal training program prior to the first time that a technician renews a registration; and
- requiring the completion of 20 hours of continuing education as a pre-requisite for registration renewal.

The Board finds that these changes are necessary at this time for a variety of reasons. Per Minnesota Statutes §151.102, technicians may only assist pharmacists by performing "nonjudgmental tasks" while working "under the personal and direct supervision of the pharmacist". However, even "nonjudgmental" tasks sometimes require a technician to have a great deal of knowledge and training. For example, technicians are routinely used in hospital and home health care pharmacies to prepare complex intravenous admixtures, such as total parenteral nutrition solutions. Technicians are also used by some pharmacies in the bulk compounding of drug products. The consequences of having a technician make a mistake while performing such tasks can be devastating if the supervising pharmacist fails to detect the error while certifying the accuracy of the work. Adopting the increased requirements described above should result in technicians, on average, being better trained and therefore less likely to make errors.

The Board is not alone in its belief that the time has come to increase the registration standards for technicians. As mentioned above, the Technician Rules Advisory Committee (TRAC) that reviewed the proposed changes involving technician registration included representatives of the Minnesota Pharmacists Association (MPhA), the Minnesota Society of Health-System Pharmacists (MSHP), the National Association of Chain Drug Stores (NACDS), the Minnesota Retailer's Association, and the University of Minnesota College of Pharmacy. The TRAC grew out of an earlier task force that was established by MPhA 2005. That earlier task force included even more organizations, including the Minnesota Grocer's Association (representing grocery stores with pharmacies), the then extant Pharmacy Technician Training Program of Century College, and the Board of Pharmacy. While these organizations do not agree on all aspects of this issue, they do all agree that the standards for technician registration must be strengthened.

For example, the Minnesota Society of Health-System Pharmacists, the professional association that has proposed the most rigorous standards for technician registration, published a white paper in 2007 in which stated that the: "following recommendations are the vision of where MSHP believes pharmacy technician education, training and competency need to be set:

I. Require a minimum age of 18 to practice as a pharmacy technician
II. Require Pharmacy Technician Certification within one year of becoming registered as a pharmacy technician and maintaining the certification to maintain registration beginning in 2008

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    a. The certification exam would be a psychometrically sound exam that assesses a pharmacy technician's ability to critical think through problems.

III. Require the employer to have a site based, board approved technician training program and have site based annual competencies by 2010.

    a. This training will be for newly hired pharmacy technicians and the training would occur within 3 months of the hire.
    b. Completing the training would be contingent to register as a pharmacy technician.
    c. Competencies would be completed in a calendar year.

IV. Require ASHP Accredited Training Program by 2015 (either employer or college based 15 week training program)
V. Require formal education by 2020".

Other organizations and individuals that participated in the MPhA Technician Task Force and/or served on the TRAC favor less rigorous standards. The rule changes that the Board is proposing for technician registration represent the consensus that was reached by the MPhA task force and the TRAC. No consensus was reached on one issue, namely the certification of technicians. There are two organizations that administer national technician certification programs: The Pharmacy Technician Certification Board (PTCB) and the Institute for the Certification of Pharmacy Technicians (ICPT). Both organizations are accredited and both administer psychometrically validated certification examinations. The Board recognizes both programs for the purposes of Minnesota Statutes §151.102, Subd. 1 which allows a pharmacy to exceed the ratio of pharmacy technicians to pharmacists permitted in that subdivision or in rule by a total of one technician at any given time in the pharmacy, provided at least one technician is certified.

Some members of the MPhA task force and of the TRAC (including MSHP representatives) recommended that the Board set a date by which all technicians would have to be certified. Those individuals, and the groups that they represent, believe that certification is an indication of competency. Other members of the MPhA task force and of the TRAC recommended against requiring all technicians to be certified as a condition of registration. Those individuals, and the groups that they represent, do not believe that certification is necessarily an indication of competency. While the National Association of Boards of Pharmacy has called for all states to require certification of technicians by 2015, no more than a third of the states currently require certification as a condition of registration. Given that there is no consensus within the profession in this state for requiring certification, it is reasonable for the Board to not establish a certification requirement at this time. The Board will continue to study the issue and may adopt a certification requirement in the future.

In contrast to certification, more states (23) do require that an individual be at least 18 years old and/or have a high school diploma or GED before registering as a technician. Since many other states have adopted these requirements and since the consensus among TRAC members favored them, it is reasonable for the Board to adopt these requirements.

Most other states (at least 35) also have some sort of training requirement. Almost all states that have a training requirement allow it to be met through the completion of an on-the-job training program developed by the pharmacist-in-charge or by the pharmacy. A handful of states,

at most, require completion of a more formal, accredited training program. Some members of the MPhA Technician Task Force and/or the TRAC recommended that the Board require completion of a formal, accredited training program. However, other members recommended against such a requirement, arguing that rural, independent community pharmacies would find it difficult to attract technicians that had completed a formal, accredited training program.

Given that the majority of states have a technician training requirement and that the consensus of the TRAC was to support such a requirement, it is reasonable for the Board to establish a training requirement at this time. Given that almost no other states require the completion of a formal, accredited training program, it is reasonable for the Board to not require completion of such a program. Note that the Board is proposing language that would recognize completion of a formal, accredited training program as one option for completing the training requirement. The Board will continue to study the issue and may adopt different training requirements in the future.

Please also note that the Board is not proposing to require the completion of a training program prior to initial registration as a technician. Such a requirement would effectively eliminate the option of an employer-developed, Board-approved, on-the-job training program. (Since an individual cannot work as a pharmacy technician without being registered as such). The Board considered establishing a new "technician-in-training" registration category to allow initial registrants to work in a pharmacy while completing training. Unfortunately, the Board does not have the resources at this time to pay for the upgrade to its licensing system that would be required. Consequently, the Board is tying the completion of the training requirement to the first registration renewal. An individual will need to complete the required training before their first technician registration renewal. Note that the Board will probably establish a policy for granting variances to individuals who initially register as technicians in the couple of months prior to the January 1st renewal deadline for technicians. The variances would allow such individuals to have until their second registration renewal to complete the required training. Such variances would be granted due to the fact that it would be difficult to complete the training in just a couple of months.

Only about a third of the states require pharmacy technicians to complete continuing education programs as a condition of renewing registrations. However, given that the consensus among TRAC members was to support a CE requirement, it is reasonable for the Board to adopt such a requirement. The practice of pharmacy is continuously evolving, with new drugs, new technologies and new practices being introduced on a very regular basis. It is important for pharmacy technicians to complete CE programs so that they can try to keep up-to-date with these changes.

The proposed change in Subpart 1 of this Part is meant to reinforce the fact that an individual who works in a pharmacy as a technician must be registered as such. Some pharmacists mistakenly believe that there is a "grace period" during which new employees can work as technicians before they can be registered. At least several times each year, the Board is notified about an individual who has been fired for misconduct (such as the theft of narcotics) and who had not been properly registered as a technician. The Board's ability to identify, track and discipline such individuals is hampered when they have not been properly registered. In

other cases, the Board has discovered multiple individuals working in a single pharmacy as technicians who have never been registered. Also, given the above-described proposed changes in registration requirements, it will be even more important to have technicians registered in the future. This proposed change is reasonable in that it simply makes crystal clear the long-standing rule that individuals must be registered as technicians before they are allowed to work as such.

The proposed change in Subpart 1a of this Part, clarifies that the Board may place limitations on the registration of a technician who has been found to be in violation of pharmacy-related laws and rules. At times, establishing a limitation is the most appropriate course of action for the Board to take. For example, if a technician is being disciplined for the theft of a controlled substance, it may be appropriate to limit the places at which the technician may work to facilities that do not handle controlled substances. This change is reasonable in that Minnesota health licensing boards routinely place limitations on the registrations and licenses of the individuals that they discipline. There is no reason that registered pharmacy technicians should not also be subject to limitations, when appropriate.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

In Subpart 1e (A), the Board is proposing an exception to the requirement that a pharmacy technician must wear a name badge while on duty that clearly identifies the person as a technician. The proposed change would exempt technicians assisting in the preparation of sterile compounded products (i.e. complying with the requirements of USP Chapter 797) from wearing a name badge. A name badge worn during the preparation of sterile compounded products would be a possible source of bacterial or viral contamination. In addition, the reason for requiring technicians to wear a name badge is so that they will not be mistaken as a pharmacist by patients or non-pharmacy staff. However, such individuals are typically not present in the work areas in which sterile compounding takes place. Consequently, it is reasonable for the Board to allow this exception.

Notwithstanding the fact that a new, general training requirement is being proposed, the Board still finds that it is necessary for the pharmacist-in-charge of a pharmacy to ensure that technicians have specific training that relates to the tasks that they will be performing. This requirement is made explicit by the addition of a new Subpart 1h (c) to this Part. The duties performed by technicians working in different types of pharmacies (and sometimes even within a single pharmacy) vary widely. For example, technicians working in hospital pharmacies often

assist in the preparation of sterile compounded products- something that technicians working in community pharmacies rarely do. The Board finds that it is clearly reasonable to expect that technicians have training that is specific to the tasks that they will be performing. Not requiring such specific training would put patients at risk for receiving improperly prepared drug products.

The change proposed for Subpart 5 would require a pharmacist-in-charge to update technician policies every time a significant change in the way in which technicians are used occurs. The current language requires an update in technician policies only once every five years. Board Surveyors have investigated complaints about errors that involved technicians who were engaged in activities that were not described in the pharmacy's technician policies manual. The errors might have been prevented had the technicians been following clearly defined policies and procedures. Therefore, the Board finds it reasonable to require a pharmacist-in-charge to update technician policies whenever a significant change in the way in which technicians are utilized occurs.

The changes proposed for Subpart 7 clarify, in Rule, the Board's long-standing interpretation of this Subpart. Since filing, billing, completing sales transactions and delivery are not currently mentioned in this Subpart, it is common for Board staff to receive questions about whether individuals engaged in such activities have to be included for the purpose of determining compliance with technician-to-pharmacist ratios. The Board has long held the position that individuals engaged in such activities do not have to be included when determining compliance with the ratios. This change is reasonable in that it is simply a clarification of the rule.

The change proposed for Subpart 9 would make it unprofessional conduct for anyone to falsify any documents pertaining to the training of pharmacy technicians. Given that the Board is proposing a new technician training requirement and will be requiring technicians to show proof of having completed such training, it is reasonable for the Board to adopt this language. By explicitly making falsification of such records unprofessional conduct, the Board hopes to deter those individuals who might be tempted to engage in such conduct. This language is also consistent with similar language making it unprofessional conduct to falsify records pertaining to an application for pharmacist licensure.

**6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE**

Some of the proposed changes for this Part merely replace antiquated terminology with more up-to-date language. For example, the phrase "electronic data processing" is a more accurate description of the devices that are the subject of this Part than is the word "automated". Likewise, the phrase "system's storage devices and databases" is being used to replace the now seldom-used phrase "data bank".

Please see the discussion above for Part 6800.0100, Subpart 11 for the rationale for making the changes involving the phrase "prescription drug order". Please see the discussion above for Part 6900.0100, Subpart 17 for the rationale for making the changes involving the phrase "unique identifier".

One of the changes proposed for Subpart 4 clarifies that pharmacist-interns are allowed to complete the quality assurance process that is required by that Subpart. The Board has actually been allowing pharmacist-interns to complete the quality assurance process for quite some time. This change makes merely clarifies the Board's long-standing interpretation of this rule. The Board has interpreted the rule in this manner since Part 6800.3100 allows interns to complete the closely related process of certification.

**6800.4075 CENTRALIZED PRESCRIPTION PROCESSING AND FILLING**

Please see the discussion above for Part 6800.0100, Subparts11 for the rationale for making the changes involving the phrase "prescription drug order".

The change proposed for Subpart C acknowledges that the Legislature substituted its judgment for the Board's by enacting Minnesota Statutes §151.215.

**6800.4200 INCLUSIONS AND EXCEPTIONS**

Please see the discussion above for Part 6800.0100, Subparts11 for the rationale for making the change involving the phrase "prescription drug order". Please see the discussion above for Part 6900.0100, Subpart 17 for the rationale for making the changes involving the phrase "unique identifier".

**6800.4300 DISPENSING SCHEDULE II CONTROLLED SUBSTANCES FOR PATIENTS IN LONG-TERM CARE FACILITIES AND TERMINALLY ILL PATIENTS**

Please see the discussion above for Part 6800.0100, Subparts11 for the rationale for making the changes involving the phrase "prescription drug order".

**6800.5100 DEFINTIONS**

Many of the changes being proposed for this Part (and for the other Parts that relate to internship) are necessary because of changes made by the University of Minnesota College of Pharmacy (COP) to its curriculum. (Other colleges of pharmacy across the country have made similar changes). Some of those changes, in turn, were necessary because the Accreditation Council for Pharmacy Education (ACPE) modified the accreditation standards that it uses for colleges of pharmacy.

The changes being proposed for Subpart 2 reflect changes in the terminology used by the COP and ACPE. The pharmacy practice experience component of college of pharmacy curricula is now commonly referred to as the "experiential education program". The word "externship" is less commonly used. This proposed change is reasonable in that it simply reflects the fact that this sort of training is now referred to as "experiential education".

The Board is proposing the change in Subpart 3 in part to clarify that pharmacy students can't register as interns until they have completed their first year of pharmacy school. The phrase "fourth, fifth and sixth academic year" was adopted at a time when most pharmacy students

completed just two years of pre-pharmacy education. In those days, the "third academic year", was the first professional academic year (i.e. the first year of pharmacy school). Likewise, the "fourth, fifth and sixth academic years" corresponded to the "second, third and fourth professional academic years". Now, however, it is extremely common for students admitted to pharmacy school to have completed three or four years of pre-pharmacy coursework. For those students, their first year in pharmacy school is not their "third academic year". Consequently, the Board finds it necessary and reasonable to use the phrase "second, third and fourth professional academic years". Using that phrase makes the number of years of pre-pharmacy coursework completed irrelevant for the purpose of this Subpart.

The change proposed for Subpart 5 (D) simply clarifies that an individual participating in a pharmacy residency or fellowship program, who is licensed as a pharmacist in Minnesota, does not also have to be registered as an intern. That has been the Board's long-standing interpretation of this Subpart, since there is no valid policy reason for requiring a licensed pharmacist to register as an intern simply because he/she is participating in a residency or fellowship program.

The change proposed for Subpart 6 will allow a licensed pharmacist serving in a federal health care facility (such as a Veteran's Administration or Indian Health Service hospital) to act as a preceptor. Pharmacists working at federal facilities are not required to be licensed by the Board but are required to be licensed by some state Board of Pharmacy. The Board finds that it is reasonable to allow these pharmacists to serve as preceptors given that they do have to be licensed in at least one state. Also, it would be beneficial for interested students to be allowed to complete internship experiences at the federal facilities, given the unique populations that they serve.

The Board is proposing to repeal Subpart 7, which defines the word "Quarter" because the College of Pharmacy no longer operates on the basis of quarters. Instead, the College now operates on the basis of semesters. It is reasonable to repeal language that refers to something that is obsolete.

The Board is proposing to repeal Subparts 8, 9 and 10 because it makes more sense to deal with the important topic of intern supervision in Subpart 6800.5400, which deals with training, than to include it in a definitions subpart. Please see the discussion for Subpart 6800.5400 for additional information.

**6800.5300 REGISTRATION AND REPORTING**

One of the changes proposed for Subpart 1 clarifies that it is not always necessary for a person who is participating in a residency or fellowship program to register as an intern. Please see the discussion above for Part 6800.5100, Subpart 5 (D) for additional information.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The

Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The remaining changes being proposed for Subpart 1 better state the procedures that the Board has long followed concerning the submission of certain internship documentation. The Board has required interns to submit notices of employment and progress report affidavits for many years. The Board has not required interns to complete pre- and post-internship examinations for years. Therefore, reference to "examinations" is being removed. These changes are reasonable in that they will not actually result in any change in the procedures that the Board has followed for quite some time.

The change proposed for Subpart 2 would eliminate the requirement for interns to surrender their pocket registration cards on termination of their registration as an intern. The Board has not rigorously enforced this requirement. In addition, the Board now has an online license and registration verification system which is the preferred method for verifying the current license or registration status of an individual or business licensed or registered by the Board.

The Board is proposing the repeal of Subpart 4 because it is obsolete. The Board has not required the submission of any "additional records" of an "intern's professional activities" for years, nor has it required interns to take any internship-related examinations. Since the Board no longer requires the submission of additional records or the completion of examinations, it is reasonable to repeal this Subpart.

The Board requires registered interns who complete at least 240 internship hours within Minnesota to complete an Intern Competency Manual that describes the competencies that interns are expected to master during the course of their practical experience. Each time an intern masters a particular competency, their preceptor initials the competency statement. The Board is proposing a change to Subpart 5, that would allow interns to complete up to 400 internship hours within Minnesota before they would be required to complete the Internship Competency Manual.

Most University of Minnesota College of Pharmacy students complete more than 400 hours of internship within the state, so this change will not have an impact on them. This change will primarily affect students of the North Dakota State University College of Pharmacy, many of whom do complete a substantial number of internship hours in Minnesota. Currently, the experiential education program of the NDSU COP includes eight, five-week Advance Pharmacy Practice Experience (APPE) rotations. (i.e. each APPE rotation consists of 200 hours of experience). Consequently, 240 hours bears no logical relationship to the NDSU rotation structure, whereas 400 hours equal the amount of experience that NDSU students receive in two

of their APPE rotations. For this reason, the Board finds the change proposed for Subpart 5 to be reasonable.

The Board is proposing to change Subpart 6 so that individuals who are completing residencies and fellowships will not be allowed to continue their registration as interns if they terminate efforts towards completing their residency or fellowship. Since "pharmacist-intern" and "intern" are defined to mean, among other things, a participant in a residency or fellowship program, it stands to reason that an individual who is no longer a resident or fellow cannot remain registered as an intern unless he/she meets another part of the definition of "intern". A person in this situation could retain their internship by submitting the proper applications and fees to become a licensed pharmacist, thereby satisfying Part 6800.5100, subpart 5 (C).

**6800.5350 PRECEPTORS**

In Subpart 1, the Board is proposing to strike the phrase "in licensed pharmacies" to reflect the fact that many pharmacists act as preceptors in settings other than licensed pharmacies. For example, there are preceptors who offer rotations in settings such as poison centers and clinics. If those rotations are not associated with the College of Pharmacy's experiential education program, the pharmacists should be registered by the Board as preceptors. That helps ensure that only pharmacists who are aware of the Board's rules concerning internships and who have not been the subject of disciplinary action serve as experiential educators for interns. In addition, interns completing internship experiences outside of the College's experiential education program are required to submit notices of employment and progress report affidavits signed by a registered preceptor. For these reasons, and because it is desirable for pharmacy students to complete some internship experiences in non-traditional settings, it is reasonable for the Board to make this change. The rest of the changes proposed for Subpart 1 are meant to simply clarify the process through which the Board has issued preceptor certificates. The Board has always required pharmacists to submit an application and supporting documentation before sending them preceptor certificates.

The change proposed for Subpart 2 (B) clarifies the Board's interpretation of that provision. Individuals sometimes ask if the 2,000 and 4,000 hour requirements for "pharmacy practice" can be met by interns who are participating in residency and fellowship programs without being licensed as pharmacists. The proposed change clarifies that those hourly requirements must be met while working as a licensed pharmacist.

The Board is proposing the change in Subpart 3 (c) because of complaints that it has received from interns concerning the amount of time that their preceptors spend educating them. In some cases, preceptors reportedly meet with students for the purpose of providing educational instruction only once or twice during the internship experience. The Board believes that it is reasonable to expect preceptors to meet at least weekly with interns to provide them with instruction that will help them to meet the competencies of the internship requirement.

**6800.5400 TRAINING**

Due to the changes mentioned in the discussion for Subpart 6800.5100, pharmacy students are now expected to complete what are known as Introductory Pharmacy Practice Experiences (IPPE) earlier in their academic career. This has resulted in the need to have more experiential education "slots" available for students. Unfortunately, there are not always enough preceptors available to accommodate the number of students being placed into the slots. The College of Pharmacy therefore asked the Board to consider changing the intern-to-preceptor ratio found in Subpart 4 from 1:1 to 2:1.

The Board concurs that this would be an acceptable change in regards to the educational component of internships. In other words, the Board believes that a single preceptor can provide adequate educational instruction to two interns at one time. However, the Board firmly maintains that there is a difference between providing educational instruction to interns and supervising the work that they do – especially in regards to intern participation in the dispensing and compounding process. In regards to internships, the Board has two basic goals. The most important goal, as always, is to protect the health, safety and welfare of the public. The secondary goal, which is also important, is to make sure that interns receive adequate experiential training so that they master the competencies that they will need to have when they practice pharmacy on their own.

Given that protection of the public is the most important goal, the Board proposes that a licensed pharmacist continue to be limited to supervising one intern who is performing tasks associated with dispensing and compounding. Given the allowed technician-to-pharmacist ratios, if the Board permitted a 2:1 intern-to-pharmacist ratio for supervision purposes, one pharmacist could be asked to supervise as many as five unlicensed technicians and interns. In regards to unit-dose dispensing, intravenous admixture compounding, bulk compounding and pre-packaging, one pharmacist might be supervising as many as six unlicensed interns and technicians.

Since an intern is permitted to certify the prescriptions that he/she processes or that a technician has processed, pharmacies might end up using interns as if they were actually licensed pharmacists. In fact, the Board has already encountered situations in which pharmacies have replaced licensed pharmacists with registered interns, presumably due to the significant cost-savings involved. In another case, a Board Surveyor walked into one pharmacy where a single pharmacist and five interns were simultaneously on duty. Apparently, the pharmacists at the store believed that the 1:1 ratio applied only to educational activities of the internship and not to the supervision of interns.

In the judgment of the Board, allowing one pharmacist to supervise up to six unlicensed individuals or to replace licensed pharmacists with registered interns pose unacceptable risks to the public. Note that any licensed pharmacist on duty at the internship site can supervise the intern – the intern's preceptor does not have to be on duty at all times that an intern is working. Consequently, one preceptor can have two interns assigned for the purpose of providing educational instruction. However, another licensed pharmacist would be allowed to supervise interns who were involved in compounding or dispensing processes. Thus, the Board's proposed

changes will more than likely still increase the number of internship slots that are available. Also note that direct supervision of interns is not required when they are completing medication histories, formulating pharmaceutical care plans, making drug therapy medications, counseling patients, participating in medical rounds or providing education to other staff – provided that all drug therapy and related recommendations must be reviewed by a licensed pharmacist.

The Board is not proposing substantive changes to Subpart 6. Instead, the proposed changes merely "clean up the language" of the Subpart so that it is easier to understand, replaces wording with more current terminology or strikes obsolete material.

**6800.5500 LICENSURE TRANSFER STANDARDS**

Please see the discussion above for Part 6800.1300 for an explanation of the Board's rationale for no longer requiring an applicant for licensure transfer to work as a licensed pharmacist in another state for at least 12 months prior to reciprocating.

**6800.6200 PRESCRIPTION ORDER COMMUNICATION**

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrase "prescription drug order". One of the changes proposed for Subpart 3 clarify that orders for Schedule II controlled substances for residents of long-term care facilities must be manually signed by the prescriber if they are written on paper. This is consistent with the requirements of the federal Controlled Substances Act, as interpreted by the U.S. Drug Enforcement Administration. The other change proposed for Subpart 3 clarifies that Schedule II controlled substance orders can be electronically prescribed. (However, the Board notes "interim final" rules recently adopted by the DEA must be followed).

**6800.6500 CONSULTING SERVICES TO LICENSED NURSING HOMES**

The Board is proposing to clarify in Subpart 2 (H) that only licensed nursing personnel are allowed to prepare up to a 72-hour supply of medications for residents who are temporarily leaving a nursing home. It is the Board's understanding that while unlicensed individuals are involved in administering medications in nursing homes, licensed nursing personnel are still "responsible for overseeing medication administration". Since the current rule language states that personnel responsible for overseeing medication administration are allowed to prepare the 72-hour supply of medications, the Board considers this proposed change to only be a clarification of the rule.

The Board is proposing to add Subpart 2 (I) to require consultant pharmacist to prepare policies and procedures for the disposition of medications that conform to Parts 4658.1350 and 6800.2350. The proper disposition of medications has taken on added importance in recent years because the Minnesota Pollution Control Agency (MPCA) has been more vigorously enforcing laws and rules concerning the handling of pharmaceutical waste. In the Board's judgement, it is reasonable to have the nursing home's consultant pharmacist involved in developing the policies and procedures for drug disposition. The consultant pharmacist is in a better position than facility staff to understand the requirements and limitations for returning drugs to pharmacies that are

discussed in Part 4658.1350. The consulting pharmacist is also more likely to understand the process of determining which drugs are considered hazardous pharmaceutical waste (as is required by the MPCA).

The Board is proposing to repeal Subpart 3 because the first paragraph is unnecessary and the second paragraph is obsolete. Part 4658.1350 already requires nursing homes to contact the Board of Pharmacy to obtain the necessary forms (and related instructions) for the disposal of controlled substances. Consequently, paragraph 1 of Subpart 3 of Part 6800.6500 is redundant. Paragraph 2 of Subpart 3 is obsolete in that destroying drugs at the nursing (which has most commonly been done by flushing down a sink or toilet) is not always allowed under the statutes and rules administered by the MPCA. The Board can't reasonably continue to require witnessed destruction of drugs at a facility when such destruction may be in violation of other statutes and rules.

**6800.6700 DRUGS FOR USE IN EMERGENCY KITS**

In Subpart 2 (A), the Board is proposing to replace the word "expiration" with the phrase "beyond-use". In 2007, the Board adopted rules that replaced "expiration date" with "beyond-use" date, when appropriate, but unfortunately missed this instance. The United States Pharmacopoeia (USP) defines "beyond-use date" as the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. The manufacturer certifies that the product will maintain at least 90% of its original potency until the expiration date. The certification requires the product to be stored according to label directions with the original packaging intact and unopened. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date. It is reasonable for the Board to make this change, since it is merely correcting an oversight that occurred when similar changes were made throughout Chapter 6800 in 2007.

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrase "prescription drug order".

The Board is proposing a change to Subpart 4 that would allow controlled substance sedative drugs to be stored in emergency kits. There are, in fact, emergency situations (such as acute agitation and some types of seizures) for which the administration of drugs classified as "sedatives" is appropriate. The Board has granted quite a few variances to this Subpart to allow sedatives to be stored in emergency kits. Given these facts, the Board finds that this change is reasonable.

**6800.7520 PHARMACEUTICAL SERVICE POLICY**

The Board is proposing changes to Subpart 1 (P) to bring it into accordance with Part 6800.3300, subpart 2. The Board amended Part 6800.3300 in 2007 to require that nonsterile compounding be done in accordance with the United State Pharmacopeia (USP), Chapter 795

and that sterile compounding be done in accordance with USP Chapter 797. This proposed change for Subpart 1 (P) should have been made at that time.

The USP is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in many other countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years. The USP has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding.

The Board is proposing the change to Subpart 1(S)(1)(a) because there are certain situations in which licensed health care professionals other than nurses procure controlled substances. (For example, a physician may sometimes procure a drug). The Board finds no good reason for limiting the procurement of a controlled substance to nurses - so long as it is done by a licensed health care professional. Limiting procurement to only licensed nurses might actually be detrimental to patient care in some circumstances.

The Board is proposing to further modify Subpart 1(S)(1) to allow for the use of a computer system which utilizes electronic distribution records of controlled substance transactions as long as certain conditions are met. Many hospitals have moved from paper-based drug distribution record systems to computerized systems. Provided that the conditions specified in the Board's proposed language are met, these computerized systems can be used to accurately track the distribution of controlled substances and to minimize the risk of diversion. The Board believes that it is reasonable to allow for the use of emerging technologies – provided that they do not pose any increased risks to the public.

The Board is proposing to amend Subpart 1(S)(2) to allow licensed individuals other than nurses or pharmacists to witness the wasting of doses of controlled substances – provided that they are authorized to have access to controlled substances. The Board finds no good reason for limiting the wasting of a controlled substance to nurses and pharmacists - so long as it is done by a licensed health care professional authorized to have access to controlled substances.

The Board is proposing the amendment to Subpart 1(S)(4) because there are instances in which it would be beneficial to allow controlled substances to be stored in patient care areas other than nursing stations. For example, an area where surgeries are performed may not necessarily be on a nursing station and yet there would obviously be a need to have controlled substances stored in such areas. The Board finds that it is reasonable to allow storage of controlled substances in such areas as long as they are stored under lock.

For Subpart 1(T), the Board is proposing to clarify that only registered nurses are allowed to prepare up to a 72-hour supply of medications for residents who are temporarily leaving a facility. This is basically consistent with the requirement, described above, that allows only licensed nursing personnel to prepare similar supplies of medications for patients temporarily

leaving nursing homes. The Board believes that allowing unlicensed personnel to prepare such supplies of medication would increase the risk of errors that might adversely affect patients.

**6800.7900 PRESCRIPTION LABELING**

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrases "prescription drug order" and "chart order".

For Subpart 5, the Board is proposing to change the required elements that must be placed on the labels of intravenous admixture products. Since the lot number, the identity of the pharmacist who prepares or certifies the admixture, and the date and time of compounding are contained in the compounding records, there is no need to place them on the label. Including the date and time of administration is not always necessary (e.g. if an admixture is meant to be given immediately after it is compounded).

In Subpart 5 (H), the Board is proposing to replace the word "expiration" with the phrase "beyond-use". In 2007, the Board adopted rules that replaced "expiration date" with "beyond-use" date, when appropriate, but unfortunately missed this instance. The United States Pharmacopoeia (USP) defines "beyond-use date" as the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. The manufacturer certifies that the product will maintain at least 90% of its original potency until the expiration date. The certification requires the product to be stored according to label directions with the original packaging intact and unopened. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date. It is reasonable for the Board to make this change, since it is merely correcting an oversight that occurred when similar changes were made throughout Chapter 6800 in 2007.

The change being proposed for Subpart 6 acknowledges that there are some situations for which the labeling of medications is not done by pharmacy staff. In the judgement of the Board, however, the hospital pharmacy service should be responsible for ensuring that labeling not done by pharmacy staff is done in accordance with applicable statutes and rules. (e.g – by developing appropriate policies and procedures). Pharmacy staff is more likely to be aware of those laws and rules than other hospital staff.

**6800.8000 SCOPE AND PURPOSE**

Please see the discussion above for Part 6800.0100, subpart 6 for an explanation of the Board's proposed changes related to the use of "home health care pharmacies" in place of "parenteral-enteral/home health care pharmacies".

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrase "prescription drug order".

**6800.8004 DRUG DISTRIBUTION AND CONTROL**

In Subpart 1, the Board is proposing to replace the word "physician's" with the word "practitioner's". This is reasonable given that "practitioner" is defined in Minnesota Statues §151.01, subd. 23 to include all licensed health care professional who are authorized to issue prescription drug orders – and not just physicians.

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrases "prescription drug order" and "chart order".

The Board is proposing to require home health care pharmacies to delivery medications as required in Part 6800.3000. Please see that part for an explanation of the Board's proposed new delivery requirements. Since a home health care pharmacy might deliver drugs to the home of a patient, just as a community pharmacy might, it is reasonable for the Board to require the same delivery standards be followed.

**6800.8007 PATIENT CARE GUIDELINES**

In several places, the Board is proposing to replace the word "physician" with the word "practitioner". This is reasonable given that "practitioner" is defined in Minnesota Statues §151.01, subd. 23 to include all licensed health care professional who are authorized to issue prescription drug orders – and not just physicians.

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrases "prescription drug order" and "chart order".

**6800.8550 LABELING OF RADIOPHARMACEUTICALS**

A radiopharmaceutical is basically a radioactive pharmaceutical used for diagnostic or therapeutic purposes. Due to potential toxicity, the preparation, distribution and use of such products require special procedures. Having received questions concerning the labeling of radiopharmaceuticals, the Board is proposing to add a new Part 6800.8550 that specifies requirements for such labeling. In developing this new language, the Board researched applicable standards and consulted with pharmacists who specialize in the use of radiopharmaceuticals. The Board believes that the proposed changes are reasonable in that they adhere to the applicable standards and were deemed to be accurate by the specialists that were consulted.

**6800.9900 VARIANCES**

The Board is proposing to require a successor pharmacist-in-charge (PIC) to submit an acknowledgment of an awareness and understanding of any variances that the pharmacy has been granted according to part 6800.9900. The successor PIC would then be responsible for ensuring that any conditions imposed by the board on granted variances continue to be met. This

change is reasonable in that it actually decreases both regulatory burden and the Board's workload. Currently, a successor PIC must submit a complete variance request, including supporting documentation, in order for the pharmacy to continue using an approved variance. The Board's staff then has to process the request for review and approval by the Variance Committee and then the entire Board. This process was put into place after Board Surveyors reported that many successor PICs had no knowledge of the variance requests that had been approved for their pharmacies.

The proposed change will allow the PIC to submit only a brief document acknowledging awareness and understanding of any variances that the pharmacy has been granted. This document will be filed with the pharmacy's records and will not have to be reviewed by the Variance Committee or the full Board. This new procedure will accomplish the same goal as does the current procedure – ensuring that a successor PIC is aware of variances issued to the pharmacy and that he or she acknowledges that the conditions of the variance will be met.

**6800.9921 REGISTRATION**

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing that an application for a medical gas distributor registration which has not been completed within 12 months of the date on which the board received the application will no longer be valid. The Board regularly receives applications for medical gas distributor registrations that are not complete. The applicant sometimes does not submit the information needed to complete the application, even when requested to do so by Board staff. In addition, applicants for medical gas distributor registration sometimes do not make arrangements to have required pre-licensing inspections completed. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. In addition, long delays often results in Board staff having to repeat work (such as repeating inspections). Therefore, it would be reasonable to require that an applicant who has not completed all of the steps necessary for medical gas distributor registration within 12 months, reapply so that the Board can review any changes in circumstances and recover extra costs associated with the delay.

## V. REGULATORY ANALYSIS

Minnesota Statutes § 14.131 sets out several factors that must be considered in the Statement of Need and Reasonableness. Each factor is listed separately and is followed by the Board's analysis.

**1. "a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;"**

The parties most directly affected by the proposed rule changes are the following individuals or businesses that are licensed or registered by the Board: pharmacists, pharmacy technicians, pharmacist interns, pharmacy owners, drug wholesalers and manufacturers, controlled substance researchers and medical gas manufacturers and distributors. Staff in hospitals, long-term care facilities and home health agencies would be more indirectly affected by some of the proposed changes that concern drug distribution and pharmacy services in those settings.

Many of the proposed rule changes will have no discernable impact on anyone. In some cases, the Board is proposing changes simply to clarify its existing interpretation of the rule part in question. In other cases, the Board has already had to make changes to a procedure, usually due to circumstances beyond its control, and the new proposed rule change just reflects those changes. In either instance, the individuals and businesses affected by the rule are already being required to act according the new proposed rule language.

Individuals that want to open "limited service" pharmacies will benefit by having a more formal process for gaining Board approval. Currently, such individuals may not even be aware that the Board has been allowing, through the variance process, the operation of what amount to limited service pharmacies. Some members of the public will benefit from the availability of additional limited service pharmacies.

Individuals who are purchasing a pharmacy will benefit by having an additional, short period time during which they can operate under the existing license. The public will benefit by not having their pharmacy unexpectedly close if there is some last-minute problem during the ownership transfer process.

Members of the public who obtain prescriptions from certain pharmacies will benefit when those pharmacies improve their counseling areas. The pharmacies that need to upgrade counseling areas will bear a cost. However, the reader should keep in mind that many of those pharmacies were supposed to have upgraded their counseling areas by February 1, 2001 under a rule change adopted in the late 1990's.

A pharmacy that closes and the pharmacy that purchases its prescription files *may* bear a cost if the closing pharmacy has to notify the public in advance about the closing. The pharmacy purchasing the files may find them to be less valuable because patients may transfer their

prescriptions to a third pharmacy before the closing date. Consequently, the purchasing pharmacy may offer to pay the closing pharmacy less money for the files. The impact is hard to determine, however, because I certain percentage of patients transfer their prescriptions from the purchasing pharmacy to a third pharmacy even when they have not been notified in advance of the closing. In fact, the Board is aware of patients who have transferred their prescriptions specifically because they were upset that they were never told that their pharmacy was closing. Also, members of the public will benefit from this proposed rule change. They will not be caught unawares when their pharmacy closes and should thus be less likely to have trouble refilling prescriptions. In addition, they will have more freedom to choose the pharmacy that they want to use once their original pharmacy closes.

Pharmacists who apply for licensure transfer (reciprocity) and the pharmacies that want to hire them will benefit by having the Board drop the requirement that pharmacist practice in another state for at least 12 months before they can reciprocate into Minnesota.

Pharmacists who are also registered preceptors will benefit by having a wider variety of preceptor CE programs to choose from.

Up until now, the registration of technicians has been solely for the purposes of identifying, tracking and, when necessary, disciplining individuals thus registered. The only registration requirements that the Board has established are a minimum age of 16 and an annual fee of $20. The Board is proposing to significantly expand technician registration requirements by:

- increasing the minimum age to 18;
- requiring high school graduation or GED;
- requiring the completion of a formal training program prior to the first time that a technician renews a registration; and
- requiring the completion of 20 hours of continuing education as a pre-requisite for registration renewal.

The public will benefit as well, since the Board expects that errors attributable to fatigue will decrease. Pharmacy owners will benefit from this change by enjoying better morale and less staff turnover.

Pharmacists and pharmacies will benefit because they will be able to submit fewer variance requests. The Board is replacing guidelines with rules in some areas and new pharmacists-in-charge will not have to resubmit variance requests.

Members of the public will benefit in that pharmacies will be able to deliver filled prescriptions to their places of employment. Pharmacies may possible incur new costs by having to make sure that temperature-sensitive drugs are delivered in appropriate containers, using appropriate procedures. However, members of the public will benefit if such containers and procedures are used since they will be less likely to experience adverse reactions to drugs that were improperly delivered.

Members of the public, pharmacists and pharmacy owners will benefit from having increased standards for technician registration. These new standards should help raise the overall quality of the technician workforce. That should result in fewer dispensing and compounding errors, thereby increasing public safety. Pharmacists may find that they are more comfortable delegating non-professional tasks to better qualified and trained technicians. Pharmacy owners will benefit by having better qualified and trained employees. Some pharmacy owners believe that the new registration standards for pharmacy technicians will drive up their salaries, resulting in increased labor costs. On the other hand, some pharmacists believe that pharmacy owners will replace pharmacists with technicians to the extent possible and actually have decreased labor costs. Technicians may experience some slight costs associated with completing continuing education. However, there are many CE programs available that are low cost or even free. Technicians will have a cost if they choose to obtain formal training. Pharmacies that do not already have a formal technician training program may incur some costs to develop one if they choose to do in-house training.

Applicants for pharmacy, wholesaler and manufacturer, controlled substance researcher, and medical gas distributor licenses or registrations will face an increase cost if they fail to complete the application process within 12 months. Wholesalers and manufacturers that currently license only the primary location of the parent entity will experience increased costs to the extent that they have to license additional facilities from which drugs are shipped into the State of Minnesota.

Pharmacist-interns and the College of Pharmacy may benefit because there may be an increase in the number of available internship "slots".

Finally, the public will benefit from many of the proposed changes since the changes, in various ways, will result in the safer distribution of drugs and in better standards of pharmacy practice.

**2. "the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule, and any anticipated effect on state revenues;"**

The Board will incur some costs because of changes that will need to be made to its licensing system. (For changes related to the registration of technicians and the licensing of pharmacies). The Board may also have a slight increase in costs related the requirement that technicians complete continuing education. However, those costs can readily be absorbed within the Board's existing appropriation because the Board included these costs when developing the budget for this biennium – in anticipation of adopting these rule changes. None of the other Board proposals result in any costs to the Board. To the extent that any pharmacy has increased costs due to these proposed changes, pharmacies operated by state agencies (DHS, MnSCU, Veteran's Homes) may have similar increased costs. No other state agencies should have any increased costs. There may be a slight increase in the amount of fees collected from drug wholesalers and manufacturers, since some of them will need to license each facility from which they ship drugs into the state – instead of just the primary headquarters.

**3. "a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;"**

Most of the Board's proposed changes don't involve any costs at all – either to licensees/registrants or to the Board. Most of the changes are not intrusive, either.

In regards to counseling areas, the Board did makes some changes to its first proposed draft – and those changes will provide more flexibility to pharmacies that must finally come into compliance with this rule (that was first adopted in the late 1990's). Pharmacies will be allowed to propose designs for counseling areas other than ones that utilize the partitions that most pharmacies use. For some pharmacies, this may decrease costs by not requiring remodeling as extensive as might be required by using partitions. In the Board's judgment, other less intrusive measures, such as allowing a pharmacy to put up a sign saying something like "Please stand back at least 10 feet to ensure the privacy of other customers", will not be sufficient to adequately achieve the purpose of the proposed rule change.

As noted above in the discussion of Part 6800.1010, some "individuals who represent pharmacies have expressed the concern that the adoption of the proposed subpart 3 might decrease the value of the sale of prescription files when a pharmacy closes. The Board has addressed this concern by allowing pharmacies to select from a variety of notification options and by shortening the notification time frame. The Board considers this to be a reasonable compromise between the desire of the seller of a closing pharmacy's prescription files to maximize the value of the sale and the need to protect the right of patients to chose where to get their prescriptions filled and to be assured that they will be able to get their prescriptions refilled in a timely manner after the pharmacy that they have been frequenting closes". The Board believes that it has compromised as much as it can if the purpose of the rule change is to be achieved.

In regards to the proposed changes in technician registration requirements, the Board has chosen a middle ground between those individuals see no need for making any changes at all and those individuals and organizations that prefer even more stringent requirements than the Board is proposing. The Board believes that the proposed changes are the least intrusive ones that can be made if the purpose of the proposed rule changes is to be achieved.

**4. "a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;"**

This is actually addressed in the previous section. Most of the proposed changes do not involve any costs, aren't particularly intrusive, are not controversial and, in some cases, will not require licensees and registrants to make any significant changes. The Board did not seriously consider any alternatives for those proposed changes.

The Board seriously considered alternatives in regards to counseling areas, the closing of pharmacies, and technician registration requirements. The Board changed its original proposed language in the regards to the closing of pharmacies and counseling areas. The Board rejected a

proposal to allow pharmacies to remain open while the only pharmacist on duty went on break. The proposed technician registration changes were developed through a lengthy process of consultation with the major organizations that represent various aspects of the pharmacy profession. They reflect the consensus that came out of meetings of the Minnesota Pharmacists Association Technician Task Force and the Board's Technician Rules Advisory Committee. The Board has chosen to stick with that admittedly fragile consensus, even though some individuals and organizations would like the Board to move towards their positions.

**5. "the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;"**

Pharmacies that need to remodel in order to have adequate counseling areas will have costs that vary depending on the extent of the remodeling that needs to be done. The costs may range from hundreds to thousands of dollars.

Individuals that do not complete applications for pharmacy, wholesaler, manufacturer, medical gas distributor and controlled substance researcher licenses or registrations within 12 months will have to submit a new application, along with a fee ranging from $50 - $180, depending on the type of business involved. There were presumably be some costs associated with reapplying, such as labor, postage, etc.

Manufacturers and wholesalers that have only licensed the primary location of their business will need to pay a fee ranging from $130 to $180 for each additional location that they need to license. (Which would be any location from which they ship products into the state of Minnesota). There would presumably be some costs associated with processing the additional applications, such as labor, postage, etc.

The probable cost, if any, of requiring a closing pharmacy to notify the public about the closure is unknown.

The probable costs, if any, associated with the proposed technician registration requirements is unknown. As mentioned above, some individuals have expressed the belief that labor costs will increase because technicians will demand higher salaries while others hold that labor costs will go down because pharmacies will have technicians perform some tasks that they currently have much higher paid pharmacists perform.

**6. "the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;**

In the judgment of the Board, many of these proposed rule changes will promote the safer use of medications. They will reduce medication errors and drug-related morbidity and mortality. If these rules are not adopted, patients will be more likely to experience these problems. That will result in increased costs to patients, insurers, employers, federal, state and local governments

and society in general. Pharmacies may also have increased costs due to more costly malpractice insurance premiums and to legal judgments rendered against them

.

7. **"an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference."**

There are no known differences between the proposed rule changes and existing federal regulations.

8. **"… a description of how the Board, in developing the rules, considered and implemented the legislative policies supporting performance--based regulatory systems set forth in Section 14.002."**

Many of the proposed rule changes simply clarify existing interpretations of the relevant Part. Others are putting into rule some of the guidelines that the Board is already requiring pharmacies to follow as a condition of approving variance requests. Still others will actually decrease the regulatory burden faced by licensees and registrants by, for example, decreasing the need to request rule variances. Thus, the regulatory burden of licensees and registrants is not being increased by most of the proposed changes in rule language.

In developing these rules, the Board has allowed flexibility in meeting the requirements in several areas. As noted above, pharmacies will be allowed to propose designs for counseling areas other than ones that utilize the partitions that most pharmacies use. For some pharmacies, this may decrease costs by not requiring remodeling as extensive as might be required by using partitions. Technicians will be able to choose from several training options and most will be given up to one year to complete the required training (longer in some cases). The owners of pharmacies that will be closed will be allowed to choose from several different options for notifying customers of the closure. Preceptors will have a wider selection of preceptor continuing education program to choose from.

9. **"The agency must consult with the commissioner of management and budget to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."**

The Board did consult with Minnesota Management and budget, as required. The Board received a written evaluation from MMB on January 4, 2011. MMB concluded that:

- The changes proposed cover a wide range of topics in pharmacy practice.
- There would be no impact on most local governments since they do not provide pharmacy services.
- In a small number of cases, cities and counties own public hospitals containing pharmacies.
- The rule changes specify guidelines for patient counseling areas in pharmacies. These provide further clarification and specificity to prior rule requirements made in 2001. The requirements for these areas are general, so pharmacies that have not

already made these changes will be allowed to purpose alternatives to the partitions that are normally used. If a pharmacy does not now have these areas, costs for making these modifications are estimated from hundreds to thousands of dollars. A more precise estimate of potential costs is not available.

- Other proposed rule changes are not anticipated to have a fiscal impact on pharmacies in public hospitals operated by local governments.

**Minnesota Statutes § 14.127** requires an agency to determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees. It is the determination of the Board that the cost for complying with the proposed rule changes will not exceed $25,000 for any business or any statutory or home rule charter city. The costs considerations are addressed in items number 5 and 9 in this section. A business or a city that owns a pharmacy might have to remodel in order to have a counseling area that provides a reasonable assurance of privacy. However, the cost of such a remodel should not exceed $25,000. The probable costs, if any, associated with the proposed technician registration requirements is unknown. As mentioned above, some individuals have expressed the belief that labor costs will increase because technicians will demand higher salaries while others hold that labor costs will go down because pharmacies will have technicians perform some tasks that they currently have much higher paid pharmacists perform. However, even if technician salaries do increase, that increase is not likely to happen within the first year after the rules are adopted, since the changes to technician registration requirements will be phased in over several years.

**Minnesota Statutes § 14.128** requires an agency determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. It is the determination of the Board that no local government will need to adopt or amend an ordinance or other regulation to comply with the proposed rules. To the Board's knowledge, local governments do not adopt ordinances and regulations concerning the operation of pharmacies. Local governments might have ordinances and regulations that apply to all businesses (zoning restrictions, etc). The Board's proposed rule should not require local governments to adopt or amend those more general ordinances and regulations.

## VI. Additional Notice

Minnesota Statutes, Sections 14.131 and 14.23, require the Board to describe the efforts made to provide additional notification to persons or classes affected by the proposed rule or explain why such efforts were not made. The Board proposes the following steps to provide notice to any affected parties:

1. The Board has published a Request for Comments in the State Register and has mailed or e-mailed a copy of it to all persons on the Board's rulemaking list.

2. The Board will publish the Dual Notice in the State Register and will mail copies of it to all persons on the Board's rulemaking list. The Board will also mail or e-mail a copy of the proposed rules to all such persons.

3. The Board has posted the Request for Comments and the Revisor's Draft of the proposed rule changes on its Web site. The Statement of Need and Reasonableness, the Dual Notice and other relevant documents will also be posted on the Board's Web site. A notice of the Web site posting of the aforementioned documents will be sent, via e-mail, to every pharmacist, pharmacist intern, preceptor, pharmacy technician, pharmacy, drug wholesaler and drug manufacturer for whom the Board has an e-mail address. A notice of the Web site posting of the aforementioned documents will also be posted on the Board's Facebook page.

4. The Board will make copies of the aforementioned documents available in alternative formats, as requested.

## VII. List of Witnesses

If the rules go to a public hearing, the Board anticipates having the following witnesses testify in support of the need and reasonableness of the rule:

Cody Wiberg, Executive Director
Minnesota Board of Pharmacy

This individual would testify regarding all aspects of the Board's proposal.

## VIII. Contact with Legislative Sponsors about the Proposed Rule

According to Minnesota Statutes § 14.116, if the mailing of a Notice of Intent to Adopt Rules is within two years of the effective date of the law granting the agency authority to adopt the proposed rules, an agency must make reasonable efforts to send a copy of the Notice and the Statement of Need and Reasonableness to all sitting legislators who were chief house and senate authors of the bill granting the rulemaking authority. Since the law granting the Board of Pharmacy the authority to develop rules to regulate pharmacy practice appears to have been passed in 1937, the requirement to notify the chief authors expired long ago.

Minnesota Statutes § 14.116 also requires an agency to send a copy of the Notice and the Statement of Need and Reasonableness to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules. Therefore, a copy of the Notice of Intent to Adopt Rules and a copy of the Statement of Need and Reasonableness will be sent to: Senators John Marty and Paul E. Koering, Chair and Ranking Minority Member, respectively, of the Health, Housing and Family Security Committee; Senators Linda Berglin and Michelle L. Fischbach, Chair and Ranking Minority Member, respectively, of the Health and Human Services Budget Division; Representatives Paul Thissen and Jim Abeler, Chair and Lead-GOP, respectively, of the Health Care and Human Services Policy and Oversight Committee; Representatives Karen Clark and Dan Severson, Chair and Lead-GOP, respectively, of the Housing Finance and Policy and Public Health Finance Division and Representatives Thomas Huntley and Matt Dean, Chair and Lead-

GOP, respectively, of the Health Care and Human Services Finance Division. A certificate of mailing will be done to acknowledge the mailings and will be included with the documents submitted to the Office of Administrative Hearings as part of the rulemaking record.

## IX. Summation

This rules package is being proposed in order to make changes that are necessary, in the Board's judgment, to better protect the health, safety and welfare of the public. The Board has worked hard to develop proposed rule changes that should also be acceptable to a majority of the members of the profession and to most of the owners of pharmacies, drug wholesalers and drug manufacturers. Board staff conducted background research to assess the current state-of-the-art for pharmacy practice and to identify rules in need of updating. The Board also used three advisory committees to assist it in the development of this rules package. These committees included individuals representing many areas of the pharmacy profession in Minnesota. Included on the committees were representatives of the two major professional associations of pharmacists in Minnesota (MPhA and MSHP) and of the Minnesota Retailer's Association, the National Association of Chain Drug Stores and the College of Pharmacy. The Board also received many comments about the proposed rule language and made many changes as a result of those comments.

From the information contained in this Statement of Need and Reasonableness, the Board has demonstrated that it is fulfilling its responsibility to protect the public's health, safety and welfare Minnesota while also providing flexibility to licensees and registrants in the manner in which they choose to practice or conduct their business.

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director
Minnesota Board of Pharmacy

1/11/2011
Date

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BEFORE THE MINNESOTA
BOARD OF PHARMACY

In the Matter of the Proposed Rule Amendments Relating to Pharmacy Practice and Drug Wholesaling, including Definitions, Applications for Pharmacy Licenses, Pharmacy License Categories, Transfers of Pharmacy Ownership, Pharmacy Counseling Areas, Supervision of Pharmacy Areas, Automated Counting Devices, Closing a Pharmacy, Applications for Pharmacist Licensure, Drug Manufacturer and Wholesaler Licensure, Registration of Pharmacy Technicians, Training and Educational Requirements for Pharmacy Technicians, Pharmacy Work Conditions, Unprofessional Conduct, Continuous Quality Improvement Programs, Answering Machines and Electronic Voice Recording Devices, Compounding, Prospective Drug Reviews, Patient Profiles, Transfer of Prescriptions between Pharmacies, Prepackaging and Labeling, Radiopharmaceutical Labeling, Veterinary Prescription Drug Labels, Interns and Preceptors, Consulting Services to Licensed Nursing Homes, Emergency Kits, Pharmaceutical Services Policies, Variances, and Medical Gas Distributor Registrations, *Minnesota Rules*, 6800.0100 et. seq.

STATEMENT OF NEED AND REASONABLENESS

## I. INTRODUCTION

The Minnesota Board of Pharmacy (Board), pursuant to Minnesota. Statutes §§ 14.22 through14.28 and Minnesota Rules Parts 1400.2000 through 1400.2570, hereby affirmatively presents the need for and facts establishing the reasonableness of the above-captioned proposed amendments to portions of the Board's rules relating to pharmacy practice.

## II. ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make a request for an alternative format, contact Cody Wiberg at the Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, Minnesota 55414-3251, phone at (651) 201-2825, fax at (651) 201-2837, or e-mail at cody.wiberg@state.mn.us. TTY users may call (800) 627-3529.

## III. STATUTORY AUTHORITY

The statutory authority for these proposed rule changes is contained in Minnesota Statutes Sections 151.06, which provides the Board with general rule-making authority relating to the practice of pharmacy and drug wholesaling.

## IV. NEED FOR AND REASONABLENESS OF THE RULES

Since this is a large package of proposed rule changes, the Board is presenting both the need for and the reasonableness of the rules together in this section – rather than two separate sections. The Board believes that the reader will be better able to follow the issues if the needs and reasonableness sections are combined.

These proposed changes are needed because the professional practice of pharmacy continuously evolves, requiring the Board to periodically revise its existing rules to address changes in practice. In addition, actions of the United States Congress, the Food and Drug Administration, the Drug Enforcement Administration and other federal agencies often require changes in the Minnesota Rules for pharmacy and for drug wholesaling.

In developing this package of proposed rule changes, the Board of Pharmacy sought input from a number of different sources. The final package of proposed changes was developed with the assistance of three advisory committees. The Board's long-standing Internship Advisory Committee (IAC) reviewed proposed changes to the rules involving internship. The IAC includes representatives of the Board and of the University Of Minnesota College Of Pharmacy. Two ad-hoc committees were formed to help the Board develop proposed rule changes in other areas. The Technician Rules Advisory Committee (TRAC) included representatives of the Minnesota Pharmacists Association (MPhA), the Minnesota Society of Health-System Pharmacists (MSHP), the National Association of Chain Drug Stores, the Minnesota Retailer's Association, and the University Of Minnesota College Of Pharmacy. The TRAC reviewed proposed changes involving the registration of pharmacy technicians. The TRAC grew out of an earlier task force that was established by the MPhA in 2005. The General Rules Advisory Committee (GRAC) reviewed all other proposed rule changes. The GRAC consisted of representatives of MPhA and MSHP, plus volunteers who were selected to represent major practice areas such as community, hospital and long-term care pharmacy.

All meetings of the three advisory committees were open to the public and many people offered comments during the meetings. In addition, the Board has received many written comments about the proposed rule changes since work first began on this package in 2008. The Board has made a number of changes to the original rules draft in response to the comments received. By convening three advisory committees and making changes based on comments received, the Board has acted to ensure that the proposed rules are reasonable.

The proposed changes to the Board's rules address various issues. The need for and reasonableness of the proposed changes will be addressed by Rule Part:

**6800.0100 DEFINITIONS**

Subpart 1c. **Central service pharmacy.** The proposed change in this subpart is one instance of a number of changes throughout this rules package that inserts the word "filled" before the word "prescription". Currently in Chapter 6800, the word "prescription" is used to indicate both a prescription order (e.g. a piece of paper on which a physician has written an order for the dispensing of a drug) and the drug product that is dispensed in a properly labeled container pursuant to such an order. This can cause confusion and so this change is necessary. The Board is proposing to use the word "prescription" to mean only a prescription order (and not also the product that results from the filling of a prescription order). The Board intends for the phrase "filled prescription" to mean the drug product that is dispensed, in an appropriately labeled container, pursuant to a prescription drug order. This change is reasonable in that it simply eliminates any confusion about what the Board means when it uses the word "prescription" in Chapter 6800.

Subpart 2. **Community/outpatient pharmacy.** The use of the phrase "retail pharmacy" is frowned upon by many members of the profession because it emphasizes the retail *sale* of drugs rather than the provision of professional services. The phrases "community pharmacy" and "outpatient pharmacy" are now more frequently used for pharmacies of this classification. Therefore, the Board is proposing to replace the word "retail" with the word "outpatient". This change is reasonable given that most members of the profession no longer use the word "retail" when describing this type of pharmacy.

Subpart 2a. **Community satellite.** The Board added a definition of "community satellite" when it adopted rule changes in May, 2007. At the time, the Board had approved variances that allowed the remote locations of telepharmacy operations to operate as satellites of the hub pharmacy. The Board has since decided that the remote locations should be licensed as separate pharmacies. The Board made this decision for several reasons. For example, there is some question about the propriety under federal law of allowing a remote, unlicensed "satellite" to store and dispense controlled substances. (The U.S. Drug Enforcement Administration recently announced that it would be conducting a review of telepharmacy operations to determine how they fit in with existing federal statutes and rules). Also, licensing the remote locations separately allows the Board to recover some of the additional costs involved in conducting inspections and complaint investigations at the remote sites. Since community satellites are no longer being allowed, it is reasonable to eliminate this definition. The change is also necessary so that individuals who are considering options for community pharmacy operations don't erroneously assume that the inclusion of a definition of a "community satellite" in Chapter 6800 means that the Board is still allowing such facilities to operate.

Subpart 4. **Long-term care pharmacy**. This subpart contains the phrase "community/retail" pharmacy, which the Board is proposing to replace with

"community/outpatient" pharmacy for the reasons given above (see the explanation provided for Subpart 2c – Community/outpatient pharmacy).

Subpart. 6. **Home health care pharmacy.** The Board is proposing to drop the phrase "parenteral-enteral" from this definition because it is rarely used to describe this class of pharmacies. In addition, these pharmacies currently dispense more than just parenteral or enteral products. Thus, this change is needed so that individuals reviewing the rules don't erroneously conclude that home health care pharmacies are only allowed to dispense enteral and parenteral products. This subpart also contains the phrase "community/retail" pharmacy, which the Board is proposing to replace with "community/outpatient" pharmacy for the reasons given above (see the explanation provided for Subpart 2c – Community/outpatient pharmacy).

Subpart 11. **Prescription drug order;** Subpart 11a. **Prescription; and** Subpart 11b. **Chart order.** The primary purpose of these proposed changes is to distinguish between two types of prescription drug orders. The Board is proposing that the word "prescription" be used for prescription drug orders that are written for the outpatient setting (i.e. that are written for patients who will be using the drug at home or in some other outpatient setting). The Board is proposing to use the phrase "chart order" to refer to prescription drug orders issued for an inpatient setting (i.e. – prescription drug orders issued for patients admitted to hospitals, nursing homes or other health care facilities).

The reason and need for making this distinction is that different types of information need to be included on prescription drug orders that are issued in different settings. For example, the addresses of the patient and the practitioner (and the telephone number of the practitioner) do not need to be included on chart orders issued for the inpatient setting. The home address of the patient is recorded in the demographic section of his or her chart. Likewise, the facility typically maintains contact information for the practitioners authorized to issue chart orders.

The Board is proposing that a telephone number at which a practitioner can be reached be required for prescriptions issued for the outpatient setting. This has actually been the standard of practice for many years, thus making this proposed change reasonable. However, the Board has received a number of reports from pharmacies about prescriptions issued at some clinics – particularly the newer urgent care clinics that are located in retail settings. These prescriptions either had no telephone number at all or had a toll-free number answered at a location other than the one at which the prescription was written. The lack of an appropriate telephone number has made it difficult for pharmacists to contact practitioners when there are questions about a prescription. That, in turn, has lead to a delay in care for patients. This also has an impact on patient safety, since some pharmacists who cannot readily contact the prescriber may make incorrect "guesses" if they have a question concerning a prescription. This change is therefore needed to protect patient safety and to minimize the delay that a patient experiences when it is necessary for the pharmacist to contact the prescriber about a prescription.

The Board is including in the definition of "prescription" under subpart 11a, its interpretation of Minnesota Statutes §151.01, subd. 16. That subdivision reads, in part (emphasis added):

> "The term 'prescription' means **a signed written order**, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice".

The following is an excerpt from the January 2007 edition of the Board's newsletter which provides the rationale for the Board's interpretation of this subdivision:

> **"ELECTRONIC PRESCRIPTIONS.** Board staff frequently receives questions about 'electronic prescriptions'. For example, a common question is as follows: is a prescription that is electronically generated still valid if the prescriber prints it out on a sheet of paper and gives it to the patient? Once a prescription is printed out and given to the patient, it is no longer an electronic prescription. Consequently, it is valid only if it is manually signed by the prescriber. A rubber-stamped signature does not constitute a manual signature. A notation on a paper prescription such as "electronically signed by the prescriber" does not make it a legally valid prescription.
>
> Minnesota Statutes §151.01, subd. 16 defines a prescription as follows, "The term "prescription" means a signed written order, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice, issued for an individual patient and containing the following: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber". Given that this law was written long before the advent of electronic prescribing, the word "signed" must be interpreted to mean a manual, handwritten signature. A pharmacist who receives a paper prescription that has not been manually signed may contact the prescriber to verify the prescription and may treat it as an oral order".

There are important policy considerations that helped guide the Board's interpretation of this subdivision. If an electronically generated prescription is printed out on a piece of paper and it is not signed, it is difficult for a pharmacist to determine the legitimacy of the prescription. It is extraordinarily easy for anyone with a computer, word-processing software and a printer to create documents that look exactly like some of the prescriptions that are being electronically generated in some clinics and practitioner offices. Therefore, requiring a manual signature on electronically generated prescriptions that are printed on paper reduces the risk that unlicensed individuals will create fraudulent prescriptions. Before publishing the above mentioned newsletter article, the Board regularly received calls from pharmacists expressing concern about the legitimacy of unsigned, electronically-generated (but printed) "prescriptions".

Requiring a practitioner to either manually sign a paper prescription or to personally affix his/her electronic signature to a prescription that is transmitted electronically can reduce prescribing errors. Even though the standard for electronic prescribing is to have the practitioner personally enter the prescription information into the system, the Board is aware that order entry is often delegated to some other person. Whenever another person transcribes a practitioner's

order, there is a risk that the transcription will done incorrectly. Requiring the practitioner to manually or electronically sign a prescription before it is given to the patient or transmitted to the pharmacy affords the practitioner the opportunity to check for and correct such errors.

Even though this process involves slightly more effort on the part of practitioners and their staff, this proposed change is reasonable given that: 1). it helps protect patient safety by reducing the risk of transcription errors; 2). it actually reduces the workload for pharmacy and clinic staff that occurs when the pharmacist feels compelled to verify the accuracy of an unsigned paper prescription and 3). this has been the de facto standard of practice since the Board issued the above-mentioned interpretation.

Subpart. 14. **Nonsterile product compounding and** Subp. 15. **Sterile product compounding.** The Board is proposing to add pharmacy license categories for sterile and nonsterile compounding (see discussion below for Part 6800.0350). Thus, there is a need to add definitions of nonsterile product compounding and sterile product compounding. The definitions are reasonable given that they describe the processes involved in compounding and they reference the USP Chapter 795 and 797 standards that the Board adopted, by rule, in 2007.

Subpart. 16**. Limited service pharmacy.** The Board is proposing to add a pharmacy license category for limited service pharmacies. Thus, there is a need to add a definition of "limited service pharmacy". (See discussion below for Part 6800.0350 for an explanation of why the Board feels that creating a limited service pharmacy license category is reasonable).

Subpart. 17. **Unique identifier.** Many of the rule changes that the Board is proposing make use of the phrase "unique identifier" or "unique identifiers". Most often, these phrases are in some way replacing the words "initials" or "initialing". In the past, individuals would manually initial some portion of a record to indicate that they had taken some action or had reviewed the record. (Manual initials are still often used). However, many processes are now done entirely electronically – with no paper record produced. In some cases, initials are still stored electronically; but other forms of identifiers are also frequently used. This proposed new subpart defines what the Board means when it uses the phrase "unique identifier". Given that manual initials are no longer the only method used to indicate that an individual has been involved in a process, it is necessary and reasonable to make these changes. In some cases, these changes will eliminate the need for pharmacies to submit variance requests in order to use newer technologies that make use of biometric identifiers, electronic signatures, etc. (Reducing regulatory burden while maintaining patient safety is certainly a reasonable thing to do).

**6800.0300 PHARMACY LICENSE AND FEE REQUIRED.**

One proposed change involves substituting the words "medications" and "prescription medications", which are not defined in either statutes or rules, with the phrase "legend drugs", which is defined in Minnesota Statutes §151.01, subd. 17. These substitutions are made throughout this package of proposed rule changes. These substitutions are being made for the sake of consistency, since some rules use "medications" and other rules use "legend drugs" to mean the same thing. Consistency in the language used in a Chapter of rules is a reasonable thing to strive for.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing that an application for a pharmacy license, which has not been completed within 12 months of the date on which the board received the application, will no longer be valid. The Board regularly receives applications for pharmacy licenses that are not complete. The applicant sometimes does not submit the information needed to complete the application, even when requested to do so by Board staff. In addition, applicants for pharmacy licenses sometimes do not make arrangements to have required pre-licensing inspections completed. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. In addition, long delays often results in Board staff having to repeat work (such as reviewing floor plans or sometimes even repeating inspections). Therefore, it would be reasonable to require that an applicant, who has not completed all of the steps necessary for pharmacy licensure within 12 months, reapply so that the Board can review any changes in circumstances and recover extra costs associated with the delay.

**6800.0350 LICENSE CATEGORIES**

Two of the proposed changes in this part involve only changes in the phrase used to describe already existing license categories. Please see the discussion above under Part 6800.0100, subparts 2 and 6 for the Board's rationale in proposing to use "community/outpatient" rather than "community/retail" and "home health" rather than "parenteral-enteral/home health care".

In recent years, more pharmacies have started to specialize in nonsterile and/or sterile compounding. In addition, many other pharmacies also engage in compounding, although they do not specialize in it. The United States Pharmacopoeia (USP) has updated its standards for non-sterile and sterile compounding. (USP Chapters 795 and 797). In order to protect the public, it is important and necessary for the Board to know which pharmacies engage in sterile or nonsterile compounding so that resources can be devoted to ensure that those pharmacies are following the relevant standards. Therefore, the Board is proposing the creation of nonsterile and sterile compounding license categories. This is a reasonable change, given that the Board is only trying to better identify pharmacies that provide compounding services and not trying to impose any new standards or other requirements.

In the past several years, pharmacists have begun practicing pharmacy in a variety of settings other than a traditional pharmacy. These settings are also not places, such as hospitals or clinics, where pharmacists have traditionally performed clinical activities. For example, pharmacy benefit managers that operate mail order pharmacies have set up offices that receive new prescriptions, which are entered into computers by technicians or pharmacists. If completed by a technician, the data entry is checked by a pharmacist, who also does a drug utilization review (DUR). Once reviewed and approved by the pharmacist, the prescription data is transmitted to a mail order pharmacy located in another state, where an automated process places the drug in an appropriately labeled container to be shipped to the patient. No drugs are stored at these offices, nor do they have the equipment that a normal pharmacy usually has.

The Board considers data entry, verification of data entry and DUR to be integral parts of the dispensing process that must, as such, take place in a licensed pharmacy. Consequently, the Board has issued pharmacy licenses to offices such as those described in the previous paragraph, even though only a limited portion of the dispensing process occurs in those offices. The Board has also issued pharmacy licenses to other facilities in which a narrow range of the activities that constitute the practice of pharmacy are performed.

The Board proposes the creation of a new "limited service" license category into which these sorts of facilities would be placed. One reason for doing so is that such facilities often do not need to have possession of any drugs. By issuing a limited license, the Board can alert drug wholesalers that the facility should not be allowed to purchase legend drugs.

Creating this new license category would also allow the Board to better track the new types of facilities and practices that seem to be rapidly evolving and proliferating. These facilities are often engaged in activities that, if not done correctly, could have a detrimental impact on patient safety. It is therefore critical for the Board to require that these facilities apply for pharmacy licensure in the proposed new limited license category. This is a reasonable change, given that the Board is simply trying to better track pharmacies that provide only limited services and to better alert the public and other businesses, such as wholesalers, that a pharmacy is only authorized to provide limited services.

It is also important for a pharmacy to get approval from the Board before providing services in a new license category. For example, a pharmacy that had not been providing sterile compounding services would most likely have to undergo significant remodeling before it could safely provide such services. It is reasonable for the Board to require pharmacies to get approval before making such significant changes so that the Board can ensure that the changes are not made in a manner which could endanger the public.

**6800.0400 ANNUAL LICENSE RENEWAL DATE AND FEES.**

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set

by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in the Statutes instead

**6800.0500 SEPARATE LICENSE REQUIRED.**

The Board is proposing to eliminate the "addition, deletion, or change of categories of licensure" as actions that would constitute a change of ownership. As mentioned above in the discussion of proposed changes to Part 6800.0350, it is important for the Board to be notified of (and to approve) any changes in license categories that a pharmacy makes. Pharmacies will be more likely to comply with this requirement if a change in license category is not considered to be an "ownership change" for which a licensing fee must be paid. This change is reasonable in that it reduces regulatory burden.

The Board is proposing a new subpart that provides a timeline for pharmacy ownership transfers. The Board frequently gets questions about this issue, specifically:

- When does an application for transfer of ownership have to be received by the Board; and
- Can a pharmacy continue to operate under the old license for a period of time after the transfer of ownership and, if so, for how long?

The new language that the Board is proposing clarifies that such applications must be received in the Board offices prior to the transfer of ownership. The Board would like the application to be received close to the date of transfer, rather than weeks in advance. This is because the Board has, in the past, processed ownership changes and issued a new license – only to have one of the parties cancel the sale at the last minute. Currently, even when the Board does receive an application for a transfer of ownership, staff does not issue the new license until a day or two before the specified transfer date.

Unfortunately, unforeseen complications occur (e.g. – a need to advance the closing date of a sale by several days). Sometimes, the parties involved in the sale simply don't get the paperwork submitted to the Board until immediately before the scheduled date of sale. That sometimes results in a transfer of ownership before Board staff can issue a new license. Consequently, the Board is proposing adopting language that is used by several other states that allows the new owner to operate a pharmacy, under the previously issued license, for up to 14 days after the effective date of an ownership change. This change will help protect the public from an unexpected, temporary closing of a pharmacy that would have to occur if an unforeseen circumstance as mentioned above occurred and the pharmacy was not allowed to operate until a new license was issued. This proposed change is reasonable in that it protects the public from an interruption in service while actually providing some "cushion" for the new licensee by allowing a little more time for the processing of paperwork.

**6800.0700 PHARMACY, SPACE AND SECURITY**.

Approximately 15 years ago the United States Congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA-90). Incorporated within the various sections of OBRA-90 was a provision requiring each state to develop laws or rules requiring pharmacists to provide prospective drug-utilization review and to provide patient counseling services to all Medicaid patients, in order to maximize the effectiveness of drug therapy for these patients and, as a result, to decrease the overall healthcare costs to the federal government.

In this state, the Legislature amended Minnesota Statutes § 151.06, directing the Board of Pharmacy to mandate the OBRA-90 DUR and patient counseling requirements through its rulemaking process. In 1992 and 1993, the Board worked to promulgate rules necessary to implement the requirements of OBRA-90. As was done in most other states, the Board of Pharmacy proposed to expand the DUR and patient counseling requirements of OBRA-90 to all patients in Minnesota, rather than limiting the requirement for these services only to Medicaid patients. The Board's proposal met with significant opposition at the hearing held on the proposed rules and the DUR and patient counseling requirements of OBRA-90 were, subsequently, limited to Medicaid patients only. Minnesota, thus, became one of only ten states that did not expand the DUR and patient counseling requirements of OBRA-90 to all patients within the state.

By 2001, when the Board addressed this issue again, additional studies had taken place that validated the hypothesis that drug use review and patient counseling play a valuable role in maximizing the effectiveness of drug therapy and lowering overall healthcare costs. In addition, support for the concept of pharmacist involvement in drug therapy management had grown among members of the profession. There also appeared to be general support within the profession in Minnesota for the expansion of the DUR and patient counseling requirements of OBRA-90 to all patients within the state. Therefore, the Board proposed changes to Minnesota Rules Parts 6800.0910 and 6800.3110 to eliminate the double standard of pharmaceutical care that had been in existence in this state for the previous ten years. The rule change was adopted, and it was hoped that all patients in Minnesota would receive DUR and patient counseling services from their pharmacist.

Since patient counseling often involves the discussion of sensitive health care information, it is important and necessary for a pharmacy to have an area in which counseling can occur with a reasonable assurance of privacy. Subpart 1, paragraph E of this rule part requires community pharmacies to have such a counseling area but does not specify any design features that must be present. As a result, some pharmacies have counseling areas that, in the judgment of the Board, do not provide a reasonable assurance of privacy. This is particularly true for older pharmacies that were constructed prior to 1999 and have never been remodeled. This problem has been somewhat mitigated since the Board's development of guidelines for counseling areas several years ago.

The Board is proposing to amend the rules to require pharmacies that use partitions to use the dimensions and materials that have heretofore only been specified in Board guidelines.

Pharmacies would be allowed, with Board approval, to have other types of counseling areas. Existing pharmacies, without an adequate counseling area, would have two years from the date of the adoption of this rules package to develop one. Given that pharmacy owners have had no major objections to following the Board's guidelines for the past several years, it is reasonable to now move the standards specified in the guidelines into the Rules. It is reasonable to require existing pharmacies to bring their counseling areas up to these standards since most of them that are out-of-compliance were supposed to have upgraded their counseling areas by February 1, 2001 per a rule amendment adopted in the late 1990's.

**6800.0910 PATIENT ACCESS TO PHARMACISTS .**

The first and last changes in subpart 2 insert the word "filled" before the word "prescription". Please see the discussion for part 6800.0100, subpart 1c for the rationale for making this change.

The second proposed change in subpart 2 replaces the word "medication" with the word "drug". Please see the discussion for part 6800.0300 for the rationale for making that change. Note that "legend drug" is not used because pharmacists must provide counseling for all new filled prescriptions – whether the drug being dispensed is a legend or a non-legend drug.

The third proposed change in subpart 2 deletes the phrase "or a new prescription drug order". As noted above, in the discussion for part 6800.0100, subpart 11, the Board is proposing to distinguish between two different types of prescription drug orders – "prescriptions" and "chart orders". If that proposed change is adopted, the word "prescription" will be used for prescription drug orders that are written for the outpatient setting. So the deletion of this phrase will clarify that the mandatory counseling rule applies to prescription drug orders written for the outpatient setting. That is reasonable given that the Board has not required counseling for patients who have been admitted to and are inpatients within institutional settings.

**6800.0950 REQUIREMENT FOR A SUPERVISED PHARMACY AREA**

As explained in the discussion for part 6800.0350, the Board is proposing to create a new "limited service" pharmacy license category. As noted in the discussion for Part 6800.0350, some of the facilities to which the board has issued pharmacy licenses do not stock drugs. These facilities therefore do not compound or dispense drugs, nor do they display or sell, "other items used in the cure, mitigation, treatment or prevention of disease". Consequently, the changes proposed for part 6800.0950 are necessary for the adoption of the changes proposed for part 6800.0350. See the section discussion for Part 6800.0350 for an explanation of why the Board considers the creation of a "limited service" pharmacy license to be reasonable.

**6800.1010 CLOSING A PHARMACY**

The proposed change in subpart 2 substitutes the word "legend" for the word "prescription". See the discussion for Part 6800.0300 for the rationale for making this change.

The Board is proposing the creation of a new subpart 3 that would require a licensed pharmacy to provide a public notification when closing a pharmacy. The notification would have

to include the date on which the pharmacy will close and the name, address and phone number of the pharmacy to which the prescription files will be transferred.

The Board has determined that this change is necessary due to the regular calls it receives from the public concerning the closing of pharmacies. Citizens have complained that they have experienced difficulty in determining where to have their prescription refilled after their pharmacy closed. In addition, some individuals would have liked to have had their prescriptions transferred to a pharmacy other than the one that had purchased the prescription files – often because they did not want an individual who worked at that pharmacy to have access to their protected health information.

Some individuals who represent pharmacies have expressed the concern that the adoption of the proposed subpart 3 might decrease the value of the sale of prescription files when a pharmacy closes. The Board has addressed this concern by allowing pharmacies to select from a variety of notification options and by shortening the notification time frame. The Board considers this to be a reasonable compromise between the desire of the seller of a closing pharmacy's prescription files to maximize the value of the sale and the need to protect the right of patients to chose where to get their prescriptions filled and to be assured that they will be able to get their prescriptions refilled in a timely manner after the pharmacy that they have been frequenting closes.

**6800.1050 REQUIRED REFERENCES BOOKS AND EQUIPMENT**

As might be expected, reference books concerning the practice of pharmacy, prescription drugs and toxicology change in terms of their content, format and availability. Since this rule was last amended, some reference books have gone out of print and new ones have been written. In addition, the titles of some references have changed. Consequently, it is necessary to update the list of suggested references. This proposed change is reasonable given that the Board is merely deleting references that are no longer on the market or updating the titles of references. Some pharmacies that still have copies of references that are no longer published may have to buy new references. However, given the rapid change in knowledge about drugs, it is reasonable to expect pharmacies to periodically update their references.

The final proposed change in this part replaces the word "prescription" with the word "legend". Please see the discussion for Part 6800.0300 for the rationale for making this change.

**6800.1250 APPLICATIONS FOR LICENSURE**

Some of the changes being proposed for this part are being made to provide clarification, in Rule, about the requirements for pharmacist licensure. For example, one change in Subpart 1 would clarify that a board applicant must provide the Board with an official and certified final transcript from an ACPE accredited college or school of pharmacy showing the date on which the applicant graduated. The existing rule contains the more nebulous requirement that the applicant provide the Board with "evidence of graduation". In fact, the "evidence of graduation" that the Board has long deemed necessary is an official and certified final transcript from an ACPE accredited college or school of pharmacy. Similarly, the Board has also long required that birth certificates be "official and certified".

The proposed changes also separate into several subparts the licensure requirements for graduates of ACPE accredited colleges of pharmacy, graduates of Canadian colleges of pharmacy and graduates of other foreign pharmacy schools. The proposed rule language is taken from the checklists for pharmacist licensure that the Board has used for quite some time. Consequently, these proposed changes in Rule are reasonable, given that the Board is not proposing any new requirements that applicants for pharmacist licensure will have to meet. Instead, long-standing requirements are simply being put into Rule.

The change being proposed in the new Subpart 3, clause B, makes it clear in rule that graduates of four-year foreign pharmacy schools, colleges, or programs are not eligible for licensure as pharmacists. The Foreign Pharmacy Graduate Examination Committee determined that, as of January 1, 2003, a change from a four-year to a five-year educational curriculum requirement was necessary to ensure consistency with the revised standards of US pharmacy school curricula. (By that date, all U.S. pharmacy schools had eliminated their Bachelor of Science programs in favor of Doctor of Pharmacy programs, which require an additional year of training). The Board has determined that it is desirable and necessary to require foreign pharmacy graduates to adhere to all of the requirements of the FPGEC certification process. Failure to adhere to the FPGEC certification requirements might cause other states to reject applicants for pharmacist licensure by reciprocity when the reciprocity is based on a license issued by our Board. In addition, the Board would most likely be inundated with applications if it were to adopt a lower standard for licensure of foreign pharmacy school graduates than is used by other states. The Board does not have the resources necessary to handle a large increase in licensure applications. Again, this is a reasonable change because a long-standing requirement is simply being put into Rule.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: “an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law”. A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The proposed new Subpart 4 clarifies, in Rule, that applicants for a pharmacist license must provide the Board with their Social Security number. Provision of a Social Security number is required by Minnesota Statutes, § 270C.72, subdivision 4. The Board hopes that adding this Subpart will decrease the number of questions that the Board receives concerning the legal basis for requiring a Social Security number to be provided during the application process. It is reasonable in that it does not create a new requirement but merely alerts potential licensees about

this requirement in the chapter of Rules administered by the Board – which they are more likely to be aware of and check than the relevant section of the Statutes.

The Board is proposing changes in Subpart 2 (which will become the new Subpart 6) that reflect the fact that the Board no longer requires applicants for licensure by examination to pass a practical examination. As a result, there is a need to update this rule to reflect the fact that applications for licensure by examination are now considered at any time during the year, not just in January and June. That makes obsolete the requirement for applicants to notify the Board 45 days in advance of their intended examination date. This is a reasonable change given that it simply reflects the procedures that the Board has had in place since it stopped administering a practical examination.

The Board is proposing that the time during which an applicant can retake an examination be increased from 14 to 18 months. It is not uncommon for applicants who have failed an examination more than once to want to take additional time to study for the examination. This change will give such applicants additional time to study - without them having to request a variance to this rule. (The Board has routinely granted such requests in the past). This proposed change is reasonable in that it provides benefit to applicants while not creating any additional work for Board staff or any increased risk to the public.

**6800.1300 LICENSURE TRANSFER (RECIPROCITY)**

The term "Licensure Transfer" is being added to the title of this Part because that term is used by the National Association of Boards of Pharmacy to describe the reciprocal licensure process that it administers on behalf of all of the states. It is reasonable to use the term that is used by the national organization that administers the licensure transfer process used by all states.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing to eliminate the requirement that an applicant for licensure transfer must have practiced in the profession for at least one year after licensure in another state which is an active member of the National Association of Boards of Pharmacy before the applicant will be considered eligible to reciprocate to Minnesota. This requirement was established when the Board still administered a practical examination which required the exam taker to actually

compound drug products. In order to avoid taking that examination, applicants would get licensed in another state that did not require a practical examination and then immediately reciprocate back to Minnesota. The one year waiting period was meant to discourage that practice. Since the Board no longer administers a practical examination, this requirement is obsolete. This proposed change is reasonable because it decreases the regulatory burden faced by applicants for licensure transfer while not creating any additional work for Board staff or any increased risk to the public.

The remaining changes in this part are meant to update the rules to better reflect the internship hour requirements that the Board has long required applicants to meet. They are reasonable because they do not create any new requirements but merely clarify the requirements that the Board already has in place.

**6800.1400 DRUG MANUFACTURER OR WHOLESALER LICENSE**

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing that an application for a drug manufacturer or wholesaler license which has not been completed within 12 months of the date on which the board received the application will no longer be valid. The Board regularly receives applications for such licenses that are not complete. The applicant sometimes does not submit the information needed to complete the application, even when requested to do so by Board staff. In addition, in-state applicants for such licenses sometimes do not make arrangements to have required pre-licensing inspections completed. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. In addition, long delays often results in Board staff having to repeat work (sometimes even repeating inspections). Therefore, it would be reasonable to require that an applicant who has not completed all of the steps necessary for manufacturer or wholesaler licensure within 12 months, reapply so that the Board can review any changes in circumstances and recover extra costs associated with the delay.

The Board is proposing to require that any location outside of Minnesota from which drugs are shipped into Minnesota, pursuant to a wholesale transaction, be licensed. Currently, only the primary location of the parent entity and any divisions, subsidiaries, or affiliated companies must be licensed. (Although many companies have voluntarily undertaken to license each facility from

which they ship drugs into Minnesota). That means that the Board does not always know the locations from which drug products are shipped into Minnesota. Nor does the Board always know if a particular facility operated by a nonresidential manufacturer or wholesaler has been the subject of regulatory scrutiny in another state.

The Board needs to know which facilities ship drugs into the state and which have been subject to regulatory scrutiny in order to better protect the public from potentially adulterated or misbranded products. While some companies may end up licensing additional facilities and paying additional fees, the Board considers this reasonable given that the alternatives, such as requiring wholesalers to be accredited through the Verified-Accredited Wholesale Distributors program of the National Association of Boards of Pharmacies could be even costlier for some companies.

Many companies today act as "virtual" or "sponsor" manufacturers. They hold the right to manufacture a drug and are considered by the Food and Drug Administration to be manufacturers. However, they contract the actual manufacturing of the drug out to another manufacturer and never take actual possession of the drugs. Since they are "doing business with accounts in this state" the Board has taken the position that they must be licensed as manufacturers pursuant to Minnesota Statutes §151.25. The Board is proposing to clarify, in Rule, that a manufacturer which does not ship drugs into this state from any location that it directly operates must nevertheless obtain a license pursuant to Minnesota Statutes §151.25 if it does business with accounts in this state and that doing business with accounts in this state includes any sale of a manufacturer's drugs to any individual or business within Minnesota.

The proposed change is reasonable given that it simply reflects the Board's long-standing interpretation of the provisions of Minnesota Statutes §151.25. In addition, not licensing "virtual" or "sponsor" manufacturers would allow them to evade the gift limitations of Minnesota Statutes §151.461 and the reporting requirements of Minnesota Statutes §151.47, subd. 1(f).

**6800.1430 PERSONNEL**

The word "prescription" is being stricken because the Legislature passed language during the 2010 Session that clarifies that wholesalers that sell only non-legend (i.e. OTC or nonprescription drugs) must be licensed. Therefore the rules that apply to wholesalers will apply to all drugs, not just "prescription" drugs. This change is reasonable in that it merely reflects a statutory change enacted by the Legislature.

**6800.1440 REQUIREMENTS FOR WHOLESALE DRUG DISTRIBUTORS.**

The word "prescription" is being stricken in several places because the Legislature passed language during the 2010 Session that clarifies that wholesalers that sell only non-legend (i.e. OTC or nonprescription drugs) must be licensed. Therefore the rules that apply to wholesalers will apply to all drugs, not just "prescription" drugs. This change is reasonable in that it merely reflects a statutory change enacted by the Legislature.

**6800.1500 CONTINUING EDUCATION**

Most of the proposed changes in this part concern the establishment of a continuing education requirement for pharmacy technicians. Please see the special section below that addresses all of the changes that the Board is proposing that relate to the registration requirements for pharmacy technicians.

The Board is proposing a change in Subpart 4a that is not directly related to the establishment of a continuing education requirement for pharmacy technicians. The Board is proposing to allow pharmacists and technicians to submit a continuing education program approval form up to 90 days after attending a CE program – rather than the current 45 days. A number of pharmacists have asked for exceptions to the 45 day requirement because they had not received confirmation of attendance from the CE provider within 45 days. Given that fact, it is reasonable to allow pharmacists and technicians to have up to 90 days following completion of a CE program to submit a CE program approval form. Allowing an additional 45 days for submission will not increase the workload of Board staff nor have any adverse impact on the public.

The proposed change in Subpart 6a reflects the fact that some CE providers have started to develop programs that specifically target the needs of preceptors. As a result, the Board has approved many such programs as being acceptable for meeting the preceptor CE requirement of Part 6800.5350, subpart 3(D). This is necessary, given that the Board's limited resources has made it difficult to internally develop new preceptor CE programs in a timely fashion. It is reasonable in that it provides many more CE options for preceptors – including programs that have been developed by organizations with more expertise than the Board has in developing educational programs.

**6800.2160 PHARMACY WORK CONDITIONS.**

The Board is proposing to promulgate work condition rules that should have a positive impact on patient safety. It is not unusual for pharmacists, technicians and interns to be required to work shifts in excess of eight hours – usually in the range of 10 to 12 hours, but sometimes more than 12 hours. It is also not unusual for pharmacists to have no formal breaks – despite working such long shifts. The Board firmly believes that evidence exists which shows that working long hours with no breaks can lead to pharmacists, technicians and interns being fatigued and therefore more likely to make errors. Consequently, the Board views this proposed rule change as being allowed within its authority under Minnesota Statutes §151.06 to regulate the practice of pharmacy.

This proposed change is reasonable for several reasons. First, there are at least ten other states that have promulgated rules or passed a resolution concerning breaks for pharmacy staff. The language that the Board is proposing was adapted from rules that were promulgated by the North Carolina Board of Pharmacy. (See 21 NCAC 46 .2512 PHARMACIST WORK CONDITIONS at www.ncbop.org/LawsRules/rules.2500.pdf).

The following excerpt from the book *Pharmacy Practice and the Law*, by Richard Abood, summarizes how a dispute involving the North Carolina rules was resolved in that state:

> "As another example, the North Carolina Board of Pharmacy proposed a regulation limiting the number of continuous hours a pharmacist may work to 12 hours, and requiring that pharmacists be given one 30 minute and one 15 minute break if working longer than 6 continuous hours. Chain drug stores argued against the proposed regulation and the Rule Review Commission (RRC) (which must approve state agency regulations) vetoed the rule on the basis that the Board lacked statutory authority to regulate pharmacists' working conditions. The Board sued to force publication, but the trial court and state court of appeals, in a split decision, found for the RRC, concluding that the pharmacy board did not have the authority to regulate work conditions and that this is a function of the North Carolina Department of Labor. The appellate court majority also concluded that setting limits on work hours and requiring breaks does not concern filling prescriptions. On appeal, the North Carolina Supreme Court reversed the court of appeals and sided with the dissenting appellate court judge that the Board did have the authority to issue the regulation and that there is a relationship between continuous work hours and the accuracy of filling prescriptions. (*North Carolina Board of Pharmacy v. Rules Review Com'n*, 620 S.E. 2d 893 {App. Ct. N.C. 2005}; reversed 637 S.E. 2d 515 (N.C. 2006))".

The following are excerpts from the opinion of the appellate court judge:

> "The majority asserts that there is no relationship between the continuous hours worked by a pharmacist and their ability to accurately perform their work. Clearly this is not correct. The consequences of an improperly filled prescription can be deadly to a customer"; and

> "In the instant case, the purpose of the proposed rule was the protection of the welfare of the general public from the hazards inherent in over-worked and over-tired pharmacists filling prescriptions".

Thus, for the most pertinent case in this area that has been litigated, the courts ultimately determined that there is a relationship between the continuous hours worked by pharmacists and their ability to accurately perform their work.

Courts in other states have acknowledged that dispensing conditions affect the safe dispensing of drugs. In *CVS Pharmacy, Inc. v N.C. Bd. Of Pharmacy* 162 N.C. App 495, 497-98, 591 S.E. 2d 567, 568-69 (2004), the North Carolina Court of Appeals addressed three instances in which pharmacists made serious dispensing errors while working long shifts. Two of those pharmacists had already worked 12 hours when they made the dispensing errors and all three pharmacists were filling prescriptions at a fast rate. The Court affirmed the disciplinary orders issued by the North Carolina Board against the chain that employed the pharmacists and set their schedules.

In *Hundley v. Rite Aid of S.C., Inc,*. 529 S.E. 2d 45, 49 (S.C. Ct. App 2000), the South Carolina Court of Appeals chastised a pharmacy for routinely scheduling a pharmacist to work twelve-hour shifts, five days a week, without having the opportunity to be relieved by another

pharmacist for a break. In *Hundley,* the pharmacist made an error near the end of a twelve-hour shift that caused damage to the patient, a child.

Published studies concerning the practice of pharmacy also provide evidence that overwork and fatigue can contribute to pharmacy dispensing errors. The 1999 edition of the book *Medication Errors,* edited by Michael Cohen (who is President of the Institute for Safe Medication Practices), reveals that pharmacists "in community and institutional practice settings rank work overload as the most significant cause of dispensing errors". In a later edition of the same book, Michael Cohen notes that a pharmacist's working conditions, including "nonstop activity" can "create potential for a broad range of errors". He further notes that he has found that pharmacists' fatigue causes "impaired judgment and flawed performance of job functions", including errors in filling prescriptions. To reduce the likelihood of errors, Cohen recommends that pharmacies "schedule adequate staffing to allow for staff meals and breaks" and "prohibit shifts longer than 12 hours".

A study conducted by University of Arizona College of Pharmacy researchers – and supported by a grant from the federal Agency for Healthcare Research and Quality, Centers for Research and Education on Therapeutics – found that high workloads for pharmacists increase the potential for medication errors. (*Med Care*. 2007 May; 45(5):456-62). That study showed that the risk of dispensing potentially harmful combinations of medications that could result in a drug interaction increased by 3 percent for each additional prescription filled per hour.

The issue of prolonged work shifts has been addressed by organizations that set standards for other healthcare professions. For example, the Association of American Medical Colleges has issued a *Policy Guidance on Graduate Medical Education* that includes the statement (emphasis added): "On typical clinical rotations, residents should not be scheduled to be on duty for more than 24 hours consecutively; **continuous duty in high intensity settings** (e.g., emergency rooms, critical care units) **should, in general, be scheduled for no more than 12 hours**".

According to a report published by the Kaiser Family Foundation in May, 2010, "from 1999 to 2009, the number of prescriptions increased 39% (from 2.8 billion to 3.9 billion), compared to a US population growth of 9%. The average number of retail prescriptions per capita increased from 10.1 in 1999 to 12.6 in 2009". Even though the number of licensed pharmacies in the United States increased as well during that period, the average number of prescriptions filled per day has significantly increased in most pharmacies. In the Board's judgment, many pharmacies are essentially "high intensity settings". Consequently, the Board finds it reasonable to limit the number of continuous hours that a pharmacist can be required to work to twelve.

The Board received comments about the potential negative impacts on patient care that might occur if the twelve hour limit did not allow exemptions for emergency situations. As a result, the Board has added the following to the proposed language:

> "Subp. 3. **Exceptions for emergencies.** Subparts 1 and 2 shall not apply in the event that an emergency necessitates that a pharmacist, intern, or technician work longer than 12

continuous hours, or work without taking required breaks, in order to minimize immediate health risks for patients".

The Board intends for this exception to be used only for true emergencies. Examples might include: having a pharmacist who is scheduled to work call in sick at the last moment, so that a pharmacist working a twelve hour shift would need to remain on duty, or having a sudden and unexpected number of patients admitted to a hospital (perhaps after some disaster that caused widespread injuries).

The Board has received the suggestion that it ought to allow pharmacies to remain open while the only pharmacist on duty is away on a break. However, the Board finds no compelling reason to adopt that suggestion. Two of the largest pharmacy chains operating in Minnesota have a policy of closing their pharmacies so that pharmacists and other staff members can take a lunch break. The Board has not received a single complaint alleging that a patient was harmed by this practice. It is the Board's judgment that patients would be more likely to be harmed if unlicensed staff provided inappropriate services while the pharmacist was away from the pharmacy.

**6800.2250 UNPROFESSIONAL CONDUCT**

Many of the changes proposed in this part substitute the word "legend" for the word "prescription" – and "nonlegend" for "nonprescription". Please see the discussion for Part 6800.0300 for the rationale for making those changes.

In Subpart 1(C), the Board is proposing to insert "prescription drug order" in place of the word "prescription". As noted in the discussion for Part 6800.0100, subpart 11, the Board is proposing that the word "prescription" be used for prescription drug orders that are written for the outpatient setting (i.e. that are written for patients who will be using the drug at home or in some other outpatient setting). The Board is proposing to use the phrase "chart order" to refer to prescription drug orders issued for an inpatient setting (i.e. – prescription drug orders issued for patients admitted to hospitals, nursing homes or other health care facilities). This proposed change would clarify that the Board considers it to be unprofessional conduct for a pharmacist to refuse to fill a prescription drug order that a pharmacist would be reasonably expected to fill – regardless of the treatment setting. It is certainly reasonable to expect a pharmacist to fill a prescription drug order whether the patient is being served in a community pharmacy or is an inpatient in a hospital or long-term care facility. (As long as any pharmacist would be reasonably expected to fill the prescription drug order in question).

Subpart 1(E) makes it unprofessional conduct to discriminate against individuals who have certain characteristics. The proposed change for Subpart 1 (E) adds sexual orientation and marital status to the list of those characteristics. In addition, it substitutes the word "disability" for the word "disease". Disability is the word used throughout Minnesota's Human Rights Act (Minnesota Statutes Chapter 363A). Adding sexual orientation is reasonable in that Minnesota Statutes §363A.17 makes it unfair discriminatory practice for a person engaged in a business, such as a pharmacy, to discriminate against an individual on the basis of sexual orientation. In addition, a pharmacy is also a "place of public accommodation" as defined in Minnesota Statutes §363A.03. Pursuant to Minnesota Statutes §363A.11, it is an unfair discriminatory

practice to deny any person the full and equal enjoyment of the goods, services, facilities, privileges, advantages, and accommodations of a place of public accommodation because of, among other things, marital status and sexual orientation. The Board finds that engaging in unfair discriminatory practice by denying needed pharmaceuticals and pharmacy services to individuals because of the characteristics listed in this part would reasonably be considered unprofessional conduct.

The proposed addition of Subpart 1(K) would make it unprofessional conduct to engage in any pharmacy practice which constitutes a danger to the health, welfare, or safety of a patient or the public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist and which harmed or could have harmed a patient. From time-to-time, the Board receives a complaint about a pharmacist who has done something that, while perhaps not specifically or clearly prohibited by statute or rule, is nevertheless far outside the bounds of what a prudent pharmacist would do. As an example, a couple of years ago the Board investigated two complaints alleging that pharmacists were dispensing drugs based on purported prescriptions that originated from illegitimate Web sites. Most of the drugs are commonly abused and some were controlled substances. At the time, the action of these pharmacists was not as clearly prohibited by law as it is now. Fortunately, the Board was able to get the pharmacists involved to voluntarily agree to sign stipulation and consent orders. If they had not agreed to sign the orders, the Board would've had an easier time pursuing disciplinary action if the language we are proposing now would've been in place then.

This proposed change is reasonable given that other Minnesota health licensing boards have similar provisions in either statute or rule. For example, the state's nursing practice act, Minnesota Statutes §148.261 makes it grounds for disciplinary action to engage in "unprofessional conduct, including, but not limited to, a departure from or failure to conform to board rules of professional or practical nursing practice that interpret the statutory definition of professional or practical nursing as well as provide criteria for violations of the statutes, or, **if no rule exists, to the minimal standards of acceptable and prevailing professional or practical nursing practice,** or any nursing practice that may create unnecessary danger to a patient's life, health, or safety". (Emphasis added). Likewise, the state's medical practice act, Minnesota Statutes §147.091, subd. 1 makes it grounds for disciplinary action to engage in unprofessional conduct, which includes "any departure from or the failure to conform to the minimal standards of acceptable and prevailing medical practice".

**6800.2400 PHARMACIST-IN-CHARGE**

The Board is proposing to require a successor pharmacist-in-charge (PIC) to submit an acknowledgment of an awareness and understanding of any variances that the pharmacy has been granted according to part 6800.9900. The successor PIC would then be responsible for ensuring that any conditions imposed by the board on granted variances continue to be met. This change is reasonable in that it actually decreases both regulatory burden and the Board's workload. Currently, a successor PIC must submit a complete variance request, including supporting documentation, in order for the pharmacy to continue using an approved variance. The Board's staff then has to process the request for review and approval by the Variance

Committee and then the entire Board. This process was put into place after Board Surveyors reported that many successor PICs had no knowledge of the variance requests that had been approved for their pharmacies.

The proposed change will allow the PIC to submit only a brief document acknowledging awareness and understanding of any variances that the pharmacy has been granted. This document will be filed with the pharmacy's records and will not have to be reviewed by the Variance Committee or the full Board. This new procedure will accomplish the same goal as does the current procedure – ensuring that a successor PIC is aware of variances issued to the pharmacy and that he or she acknowledges that the conditions of the variance will be met.

**6800.2600 AUTOMATED COUNTING AND DISTRIBUTION**

The Board believes that this part needs to be amended for two reasons. First, the use of automated counting and distribution devices has increased significantly since this part was first promulgated. There has also been a proliferation in the type of devices that are in use. These changes make it necessary for the Board to update this part to better reflect current usage of these devices. Second, the Board wants to decrease the regulatory burden faced by the pharmacies that use the devices.

Currently, any pharmacy that wants to use an automated counting device must submit a variance request to the Board. Any pharmacy that wants to use an automated distribution system must submit a policies and procedures document to the Board. The Board and its staff then review either the policy and procedure document or the variance request. The Board processes hundreds of policy and procedure documents and variance requests for these devices every year. Virtually all of the requests are approved – although sometimes only after the pharmacy has made recommended changes.

In handling the variance and policy review requests, the Board has made approval conditional upon adherence to guidelines for the use of automated counting and distribution devices. The guidelines were developed by the Board's professional staff (i.e. the Surveyors) and were approved by the Board. They reflect current best practices for the use of such devices and are drawn from extensive consultation with pharmacists who use these devices. The guidelines also reflect relevant U.S. Food and Drug Administration good manufacturing procedures. It should be noted that the Institute for Safe Medication Practices actually based their guidelines for these devices on our Board's guidelines.

These proposed changes are reasonable given that the Board is simply putting into rule these guidelines - which it has long required pharmacies to adhere to as a condition of variance and policy review approval. Thus, pharmacies that use these devices will not face any new requirements. In fact, they will face less regulatory burden because they will not have to submit variance and policy review requests prior to using the devices. The Board, of course, will retain the authority to require a pharmacy to stop using a device if it finds that the pharmacy is not using the device in accordance with this amended part.

**6800.3000 PRESCRIPTIONS AND DISTRIBUTION OF DRUGS**

Several of the changes proposed for this part involve distinguishing between "prescription drug orders" and "filled prescriptions". Please see the discussion for Part 6800.0100, subpart 11 for the rationale for making those changes.

The Board is proposing a change that would allow a pharmacy to deliver filled prescriptions to the place of employment of the patient or of a designated caregiver of the patient. This change would be of most benefit to patients who receive temperature-sensitive drugs by mail or other means of delivery. The Board has received complaints from patients when such drugs are left by delivery personnel in excessively hot or cold environments, such as the front porch of the patient's house. If such drugs were delivered to the patient's workplace, at his or her request, he or she could make sure that the drugs were appropriately stored. (Presumably, if a patient requests delivery at the workplace, he or she will have made sure that drugs that are temperature-sensitive can be stored adequately). The proposed changes will require the delivering pharmacy to take certain steps to ensure that the patient's privacy is protected.

Despite the proposed change that would allow delivery of filled prescriptions at a patient's place of employment, some drugs will still be delivered to the homes of patients. In addition, there can be unexpected delays in the deliveries of filled prescriptions. Consequently, the Board is proposing new language that would require pharmacies to use adequate storage and shipping containers and processes to ensure drug stability and potency during deliveries. In developing these proposed changes, Board staff reviewed the statutes and rules that other states have adopted in this area. Thus, the proposed language is largely based on rules and statutes that pharmacies successfully follow in other states. Given that patients can be harmed if they take temperature-sensitive drugs that have not been properly handled and given that the Board has received complaints about improper handling of delivered drugs, the proposed language is necessary. Given that pharmacies in other states have been able to comply with very similar laws and rules, the proposed language is reasonable.

The proposed changes to Subpart 3 basically require electronic prescribing to be in compliance with Minnesota Statutes §62J.497 and any rules promulgated thereunder by the state Department of Health. In enacting Minnesota Statutes §62J.497, the Legislature established certain standards and requirements that must be adhered to by anyone involved in the electronic prescribing process. The Board is proposing to reference Minnesota Statutes §62J.497 in the chapter of rules that it administers because pharmacists are much more likely to periodically review Chapter 6800 than sections of statute administered by other agencies.

The changes proposed for Subpart 4 are meant to place into rule the Board's policy concerning the use of answering machines and interactive voice recording (IVR) devices. Such devices are now commonly used in pharmacies. Patients can leave messages asking that prescriptions be refilled – or even just punch in the prescription number that they want refilled. In addition, prescribers can leave a voice message in which they issue a new prescription for a patient. Since Part 6800.3100, Subp.1 (B) allows only pharmacists and pharmacist-interns to receive verbal orders for new prescriptions, the Board has taken the position that only pharmacists and pharmacist-interns can take new prescription messages off of answering

machines and IVRs. However, Board Surveyors continue to discover pharmacies where technicians are allowed to take such messages off of these devices.

Some pharmacists have argued that technicians ought to be able to write down new prescriptions that have been left on these devices, as long as a pharmacist listens to the message and double-checks what the technician has written down. The Board disagrees because of the problem of confirmation bias, which is a form of cognitive error based on the tendency to seek out information which supports one's beliefs, while ignoring contradictory information. In this context, a pharmacist who strongly believes in the competency of a technician is more likely to miss an error made by that technician. Given that messages saved on these devices can sometimes be hard to understand, a pharmacist who is just double-checking what a technician has written down may end up misinterpreting an indistinct message in the same manner as the technician.

**6800.3100 COMPOUNDING AND DISPENSING**

Several of the changes proposed for this part involve distinguishing between "prescription drug orders" and "filled prescriptions". Please see the discussion for Part 6800.0100, subpart 11 for the rationale for making those changes.

The change proposed for Subpart 1 (E) will officially allow pharmacies to have technicians assist in extemporaneous compounding, which is the compounding of a drug product for an individual patient pursuant to a prescription drug order. Under a literal reading of the current rule, such compounding may only be done by pharmacists and pharmacy-interns. However, in some settings, the Board has not enforced a literal reading of the rule for years. Most notably, technicians in hospital and home health care pharmacies often participate in the extemporaneous compounding of drugs, including drugs that must be compounded under sterile conditions. In short, the use of technicians in this manner has become widely accepted within the profession. (Note that technicians are tacitly allowed to assist in *bulk c*ompounding pursuant to Part 6800.3850, Subpart 6 – since the Board established a 3:1 technician:pharmacist ratio in that Subpart).

Since this proposed change removes the requirement that all aspects of extemporaneous compounding be done only by pharmacists and pharmacist-interns, technicians will be allowed to assist in such compounding. However, there is a limit to what the Board can allow technicians to do. Minnesota Statutes §151.102, Subdivision 1 states, in part (emphasis added):

> "A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing **nonjudgmental** tasks and works under the personal and direct supervision of the pharmacist".

The Board cannot amend the rules in a way that conflicts with state statutes. Consequently, the Board cannot allow technicians to perform tasks that require the professional judgment of a pharmacist. The Board finds that the establishment and verification of the initial formulation record for a compounded preparation requires the professional judgment of a pharmacist. In

order to properly compound a drug and prepare a formulation record, the pharmacist must answer questions such as the following, which are taken from the USP, Chapter 795:

- Have the physical and chemical properties and medicinal, dietary, and pharmaceutical uses of the drug substances been reviewed?
- Are the quantity and quality of each active ingredient identifiable?
- Will the active ingredients be effectively absorbed, locally or systemically according to the prescribed purpose, from the preparation and route of administration?
- Are there added substances, confirmed or potentially present from manufactured products that may be expected to cause an allergic reaction, irritation, toxicity, or undesirable organoleptic response from the patient?
- Are there added substances, confirmed or potentially present, that may be unfavorable (e.g., unsuitable pH or inadequate solubility)?
- Were all calculations and measurements confirmed to ensure that the preparation will be compounded accurately?

Answering these questions requires the professional training and judgment of a pharmacist. Consequently, under these proposed changes, technicians will not be allowed to establish and validate the initial formulation records for compounded preparations. (See also a proposed change to Part 6800.3300, subpart 6 that formally requires "stage-checking" for compounded products).

One of the changes proposed for Subpart 1 (G) replaces the words "prescribers or their agents" with the phrase "practitioners or other individuals allowed to prescribe legend drugs according to Minnesota Statutes, section 151.37, subdivision 2". The Board believes that this change will clarify that only licensed practitioners and certain "appropriately certified, registered or licensed health professionals" designated by practitioners are allowed to authorize refills. (e.g a registered nurse working under a protocol pursuant to Minnesota Statutes §148.235). A mere "agent" of a practitioner may transmit the practitioner's instructions concerning refills to a pharmacy but cannot authorize a refill. The current language of this rule might be misinterpreted to mean that an agent of a prescriber can independently authorize a refill.

For a discussion of a second proposed change to Subpart 1(G), which substitutes the phrase "unique identifier" for the word initials, please see the discussion for Part 6800.0100, Subpart 17.

For Subpart 1(H), the Board is proposing to change the description of the nonprofessional duties that clerical personnel can perform. At the time that this part was originally promulgated, "looking up" and "filing" refills most likely meant retrieving paper prescriptions from file folders and filing them after the pharmacist was done using them. Currently, nearly all pharmacies utilize computers - and "looking up prescription refills" generally means accessing electronically stored prescription data. The process of accessing the prescription data usually includes a drug utilization review (DUR) process that checks for such things as drug interactions, high dose, low dose, etc. The process of entering data for a new prescription triggers a DUR. Unregistered clerical personnel, who will probably lack the training that the Board is proposing to require of technicians, should not be involved in prescription data entry or retrieval of refill

information. In fact, the Board has long required pharmacies to have policies in place that require even technicians who are doing data entry to have a pharmacist review and handle all DUR alerts. This proposed change is reasonable in that it simply clarifies the language of this Subpart to reflect the Board's long-standing interpretation.

In the first sentence of Subpart 3, the Board is proposing to replace the word "the" with the phrase "an individual". The Board is doing so to clarify its long-standing interpretation that a single, individual pharmacist must certify the accuracy of a filled prescription. The Board continues to find that it is important to have a single pharmacist take responsibility for the accuracy of the entire filling process. The Board may grant a variance to this rule that does allow individual pharmacists to take responsibility for just one portion of the process but will do so only if the pharmacy requesting the variance initially demonstrates, and continues to demonstrate, that its alternative certification process does not result in a significant increase in dispensing errors or missed, significant drug utilization review alerts.

This clarification is reasonable given that the Board has granted variances to this rule and has received complaints about dispensing errors that may have been prevented if only one pharmacist had verified the accuracy of the entire filling process. The Board has required pharmacies to alter their policies and procedures as a condition for continued variance approval in order to minimize the risk of additional errors. Given the receipt of these complaints, it is reasonable for the Board to require pharmacies that want to divide the responsibility for ensuring the accuracy of the filling process between two or more pharmacists to have their procedures periodically reviewed through the variance process.

For a discussion of a second proposed change to Subpart 1(H), which substitutes the phrase "unique identifier" for the word "initialing", please see the discussion for Part 6800.0100, Subpart 17.

For Subpart 3a, the Board is proposing the use of the phrase "unique identifier" in place of the phrase "documentation to identify the names, initials, or identification codes". Please see the discussion for Part 6800.0100, Subpart 17 for the rationale. The Board is also proposing that the documentation required by this Subpart be maintained for a minimum of two years, which is reasonable since it is consistent with the time period required by the Board for the maintenance of other records. It is important for the Board to have access to this data when it investigates complaints that allege that a dispensing error has taken place. Knowing which personnel were involved in the alleged error can help Board staff make recommendations to the pharmacy for minimizing the risk that future errors of the same type will occur. The Board is also proposing the addition of language that clarifies that while more than one individual may be involved in the prescription-filling process, it is important to have a single pharmacist take responsibility for the accuracy of the entire process (as discussed in the previous paragraph).

**6800.3110 PATIENT MEDICATION PROFILES**

Several of the changes proposed for this part involve distinguishing between "prescription drug orders" and "filled prescriptions". Please see the discussion for Part 6800.0100, subpart 11 for the rationale for making those changes.

The changes proposed for the last paragraph of this part clarify the manner in which the Board has long interpreted the requirements for handling drug utilization review alerts. (Namely, that only a pharmacist or pharmacist-intern may override such alerts). Although pharmacy technicians are allowed to do data entry and process refills, they cannot override DUR alerts because doing so is a judgmental task that they are not allowed to perform. It is reasonable to make this clarification since Minnesota Statutes §151.102 allows technicians to perform only nonjudgmental tasks.

The Board is proposing to repeal Subpart 6 which allowed pharmacies to not create patient profiles in circumstances:

- When the patient does not want a profile established; and
- When a hospital pharmacy serving only inpatients prepares discharge prescriptions for a patient.

The information that pharmacies are required to collect and maintain in patient profiles is critical to the proper dispensing of drugs. Date of birth or age, gender, disease states, known drug allergies and adverse reactions, and a list of current medications must all be known by the pharmacist if he or she is to adequately assess the appropriateness of a new prescription drug order. It would be unreasonable for a patient to withhold this information and still expect a pharmacist to provide quality pharmaceutical care. Likewise, if a pharmacist provides care to a patient it is important to maintain a record of the care that is given. In the case of a hospital pharmacy preparing discharge prescriptions, the hospital pharmacy should have collected the information required to be in a patient profile in order to provide care for the patient while he or she was hospitalized.

**6800.3120 TRANSFER OF PRESCRIPTIONS BETWEEN PHARMACIES**

Patients commonly either want or need to have a prescription transferred between pharmacies. This rule spells out in detail the procedures to be followed when a prescription is transferred. The Board is proposing to clarify that a registered intern may transfer prescription information to a licensed pharmacist or another registered intern. The Board has long taken the position that interns can transfer prescriptions so this change is reasonable in that it is simply meant to clarify this in Rule.

As currently written, this part only allows a transfer for the "purpose of *refilling* a prescription". Technically, that means that a pharmacy cannot transfer prescription drug information for the purpose of the *initial* filling of the order. It is not uncommon for a pharmacy to receive a prescription drug order that the patient does not want immediately filled. Such orders are usually "put on hold" or "profiled", meaning the information is entered into the pharmacy's computer but the prescription is not actually filled and dispensed to the patient. Since the pharmacy has never actually filled the prescription, it can't transfer prescription information to another pharmacy because such a transfer would not be for the purpose of refilling the prescription. Similarly, a prescription drug order may be telephoned by the prescriber to the wrong pharmacy. The current wording of this Part would prevent the correct

pharmacy from receiving a transfer from the incorrect pharmacy – again, because it would not be for the purpose of refilling the prescription.

The board is proposing to allow pharmacies to transfer prescription drug order information in such situations provided that the procedures described in the new Subpart 8a are followed. Those procedures should ensure that either the transfer occurs from the original prescription drug order or from computerized records of the prescription that have been double-checked through the quality assurance process required by Part 6800.3950, subpart 4. Note that the quality assurance process would usually have been completed in those cases where a transfer was for the purpose of refilling a prescription. (Because the QA process must be completed within 72 hours of the initial filling of the prescription and most transfers for the purpose of refilling a prescription happen after those 72 hours have elapsed).

In Subparts 3 and 4, the Board is proposing that the transferring and receiving pharmacists or interns exchange names and telephone numbers (rather than just addresses). Requiring the exchange of names is consistent with rules that require a pharmacist to record the name of a practitioner or practitioner's agent that telephones a prescription to the pharmacy. If a complaint alleges that a prescription has been improperly transferred, it is important for the Board to know which individuals were involved in the transfer. Exchanging telephone numbers can expedite communication between the pharmacies should any questions arise after the transfer has occurred. This proposed change is reasonable given that it would take very little extra time to exchange names and phone numbers.

In Subpart 9, the Board proposes language that indicates pharmacists and interns - not pharmacies – can provide informational copies of prescriptions to other interns and pharmacists. The Board further proposes clarifying that drug therapy information may be provided not only to physicians, but to any licensed, registered or certified health professional who is currently providing services to or acting on behalf of the patient. This is necessary and reasonable given that advanced practice nurses, physician assistants, dentists, podiatrists, optometrists and other professionals may need such information in order to appropriately provide services to patients.

The change proposed for Subpart 10 is reasonable and necessary because the U.S. Drug Enforcement Administration recently adopted interim final rules that allow for the electronic transmission of Schedule II controlled substances as long as certain requirements are met. This means that Schedule II prescriptions no longer always have to be "written".

**6800.3200 PREPACKAGING AND LABELING**

The Board is proposing the changes in Subpart 1(B) because sometimes it is a distributor, rather than a manufacturer, that assigns lot numbers and expiration dates to the drugs used by a pharmacy. For the rationale for replacing "initials" with "unique identifier" in Subpart 1(E) and (F), please see the discussion above for Part 6800.0100, Subpart 17. The Board is proposing to add a new part 6800.8550 concerning the labeling of radiopharmaceuticals and thus needs to add Subpart 2(G) in this part to reference that new part. Please see the discussion for the proposed Part 6800.8550 for further information.

**6800.3300 PHARMACY COMPOUNDING PRACTICES**

As mentioned above in the discussion for Part 6800.3100, the Board is proposing to formally allow pharmacies to have technicians assist in extemporaneous compounding, which is the compounding of a drug product for an individual patient pursuant to a prescription drug order. As also noted above, the use of technicians in this manner has become widely accepted within the profession and the Board has not enforced a literal reading of Part 6800.3100 in quite some time.

Having technicians assist in extemporaneous compounding is not without its potential problems, however. The Board has investigated complaints involving errors made by technicians who were assisting in extemporaneous compounding. In the judgement of the Board, at least some of these errors could have been avoided if the process of stage-checking had been used by the pharmacists who supervised the technicians. As the proposed new language describes, stage-checking involves having a pharmacist certify that each component used in the compounding of a drug product has been accurately weighed, measured or subdivided, as appropriate, at each stage of the compounding procedure. This affords the pharmacist the opportunity of checking to make sure that the correct ingredients, in the correct amounts have been added to the compounded preparation in the correct sequence.

The language that the Board is proposing to include in a new Subpart 6 is taken nearly verbatim from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, (Appendix B - Good Compounding Practices Applicable to State Licensed Pharmacies, Subpart F). Nearly identical language is used by at least seven other states, including Iowa. It is reasonable for the Board to adopt language that was developed by NABP and used in many other states.

**6800.3350 BEYOND-USE DATES**

The Board is proposing the change the language in Subpart 4 to clarify its intent. The current language is read by some pharmacists to mean that beyond-use dates *must* be printed on the label of prescription vials. In fact, the Board has only required that *if* the pharmacy chooses to place a beyond-use date on a prescription vial, then the standards described in the subpart must be followed. The proposed language is reasonable in that it should make the Board's long-standing intent much clearer.

**6800.3400 PRESCRIPTION LABELING**

As mentioned above, the Board is proposing the creation of a new Part 6800.8550 that will specifically address the labeling of radiopharmaceuticals. Consequently, the Board is noting at the beginning of Part 6800.3400 that the part no longer applies to radiopharmaceuticals. It is also proposing a new Subpart 5 that states that the labeling of radiopharmaceuticals must be done in accordance with the new Part 6800.8550.

The change proposed for Subpart 1(A) does not actually change the intent of that clause. It merely replaces somewhat confusing verbiage with language that is more precise. The same is true for the change proposed for Subpart 1(J).

The Board is proposing a change to Subpart 1(K) that would extend certain labeling requirements to nonlegend drugs that are not dispensed in the manufacturer's original container. Currently, this part requires that any dispensed prescription medication be labeled with its physical description, including any identification code that may appear on tablets and capsules. This requirement was adopted in 2007 by the Board as a means of reducing the risk of a patient actually consuming an incorrectly dispensed drug. (If the label says, for example, that the drug is a white, oblong tablet but the patient receives a pink and round tablet, he or she will probably contact the pharmacy to verify whether or not the correct drug has been dispensed).

It is reasonable to extend this requirement to nonlegend (over-the-counter) drugs when they are not dispensed in the original manufacturer's container. When they are not dispensed in the original manufacturer's container, the patient has no more information about the appearance of the drug than he or she would have about the appearance of a legend drug. Consequently, the same rationale for requiring a description of the drug on the label prepared by the pharmacy applies.

The Board is also proposing to exempt drugs dispensed as part of an investigational drug study from the requirement found in Subpart 1(K). Blinding is often an essential component of such studies. (i.e. – neither the patient nor the investigator knows which patients receive an active drug and which patients receive a placebo). Labeling a drug with a description of the drug can sometimes interfere with the blinding process.

The Board adopted Subpart 4, concerning the labeling of veterinary prescription drugs, in 2007. Until earlier in this decade, most such drugs were dispensed directly by the veterinarian to the owner of the animal or animals for which the drug was prescribed. However, there are now many pharmacies specializing in dispensing veterinary drugs to animal owners. Since labeling requirements are different for veterinary prescriptions, the Board added this Subpart to describe the minimum necessary information that must be included, by a pharmacy, on a veterinary prescription label. This Subpart was adapted from the labeling requirements enforced by the Minnesota Board of Veterinary Medicine as found in Minnesota Statutes § 156.18, subd. 2. The Board is now proposing to amend this Subpart to also reflect the labeling requirements established by the U.S. Food and Drug Administration (FDA) pursuant to the Animal Medicinal Drug Use Clarification Act (AMDUCA). It is reasonable for the Board to require veterinary prescription labels to conform to the requirements already enforced by the Minnesota Board of Veterinary Medicine and AMDUCA.

**6800.3450 LABELING OF OUTPATIENT INTRAVENOUS ADMIXTURE DRUGS**

Please see the discussion for Part 6800.0100, subpart 17 for the Board's rationale for proposing to use the phrase "unique identifier" in place of the word "initials".

**6800.3510 REFILL LIMITATIONS**

Please see the discussion for Part 6800.0100, subparts 11 and 11a for the Board's rationale for at times using the term "prescription drug order", rather than the word "prescription".

**6800.3750 UNIT DOSE DISPENSING**

Please see the discussion for Part 6800.0100, subparts 11 and 11a for the Board's rationale for using the term "prescription drug order", rather than the word "prescription".

The Board is proposing a change to Subpart 9 that distinguishes between controlled substances and noncontrolled substances in regards to how they are stored when a unit dose system is being utilized. Currently, all drugs must be stored in a locked area or locked cart at all times. The proposed language will still require all controlled substances to be stored in that manner, since such drugs are most likely to be diverted (i.e. stolen). If the proposed language is adopted, noncontrolled substances will have to be stored in a locked area or a locked cart only when the patient care area is not staffed. This change is reasonable in that it will make it easier in certain circumstances for noncontrolled drugs to be administered to patients while still making sure that adequate measures are in place to prevent the diversion of controlled substances.

**6800.3850 PHARMACY TECHNICIANS**

The Board is proposing major changes in the registration requirements for pharmacy technicians. All of the changes will be discussed here, including a proposal to require technicians to complete 20 hours of CE every two years as a condition of being eligible for renewed registration. (See the proposed language change in the Revisor's Draft for Part 6800.1500).

Supportive personnel have assisted pharmacists in the preparation and dispensing of pharmaceutical products for many years (several decades, at least). However, the Board did not begin registering technicians until it was empowered to do so when the Legislature added Subdivision 1(a)(9) to Minnesota Statutes §151.06 in 1997. At the same time, the Legislature also added a definition of "technician" to Minnesota Statutes §151.01 and created Minnesota Statutes §151.102, which describes the manner in which pharmacies may utilize technicians.

Up until now, the registration of technicians has been solely for the purposes of identifying, tracking and, when necessary, disciplining individuals thus registered. The only registration requirements that the Board has established are a minimum age of 16 and an annual fee of $20. The Board is proposing to significantly expand technician registration requirements by:

- increasing the minimum age to 18;
- requiring high school graduation or GED;
- requiring the completion of a formal training program prior to the first time that a technician renews a registration; and
- requiring the completion of 20 hours of continuing education as a pre-requisite for registration renewal.

The Board finds that these changes are necessary at this time for a variety of reasons. Per Minnesota Statutes §151.102, technicians may only assist pharmacists by performing "nonjudgmental tasks" while working "under the personal and direct supervision of the pharmacist". However, even "nonjudgmental" tasks sometimes require a technician to have a great deal of knowledge and training. For example, technicians are routinely used in hospital and home health care pharmacies to prepare complex intravenous admixtures, such as total parenteral nutrition solutions. Technicians are also used by some pharmacies in the bulk compounding of drug products. The consequences of having a technician make a mistake while performing such tasks can be devastating if the supervising pharmacist fails to detect the error while certifying the accuracy of the work. Adopting the increased requirements described above should result in technicians, on average, being better trained and therefore less likely to make errors.

The Board is not alone in its belief that the time has come to increase the registration standards for technicians. As mentioned above, the Technician Rules Advisory Committee (TRAC) that reviewed the proposed changes involving technician registration included representatives of the Minnesota Pharmacists Association (MPhA), the Minnesota Society of Health-System Pharmacists (MSHP), the National Association of Chain Drug Stores (NACDS), the Minnesota Retailer's Association, and the University of Minnesota College of Pharmacy. The TRAC grew out of an earlier task force that was established by MPhA 2005. That earlier task force included even more organizations, including the Minnesota Grocer's Association (representing grocery stores with pharmacies), the then extant Pharmacy Technician Training Program of Century College, and the Board of Pharmacy. While these organizations do not agree on all aspects of this issue, they do all agree that the standards for technician registration must be strengthened.

For example, the Minnesota Society of Health-System Pharmacists, the professional association that has proposed the most rigorous standards for technician registration, published a white paper in 2007 in which stated that the: "following recommendations are the vision of where MSHP believes pharmacy technician education, training and competency need to be set:

I. Require a minimum age of 18 to practice as a pharmacy technician
II. Require Pharmacy Technician Certification within one year of becoming registered as a pharmacy technician and maintaining the certification to maintain registration beginning in 2008

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    a. The certification exam would be a psychometrically sound exam that assesses a pharmacy technician's ability to critical think through problems.

III. Require the employer to have a site based, board approved technician training program and have site based annual competencies by 2010.

    a. This training will be for newly hired pharmacy technicians and the training would occur within 3 months of the hire.
    b. Completing the training would be contingent to register as a pharmacy technician.

c. Competencies would be completed in a calendar year.

IV. Require ASHP Accredited Training Program by 2015 (either employer or college based 15 week training program)
V. Require formal education by 2020".

Other organizations and individuals that participated in the MPhA Technician Task Force and/or served on the TRAC favor less rigorous standards. The rule changes that the Board is proposing for technician registration represent the consensus that was reached by the MPhA task force and the TRAC. No consensus was reached on one issue, namely the certification of technicians. There are two organizations that administer national technician certification programs: The Pharmacy Technician Certification Board (PTCB) and the Institute for the Certification of Pharmacy Technicians (ICPT). Both organizations are accredited and both administer psychometrically validated certification examinations. The Board recognizes both programs for the purposes of Minnesota Statutes §151.102, Subd. 1 which allows a pharmacy to exceed the ratio of pharmacy technicians to pharmacists permitted in that subdivision or in rule by a total of one technician at any given time in the pharmacy, provided at least one technician is certified.

Some members of the MPhA task force and of the TRAC (including MSHP representatives) recommended that the Board set a date by which all technicians would have to be certified. Those individuals, and the groups that they represent, believe that certification is an indication of competency. Other members of the MPhA task force and of the TRAC recommended against requiring all technicians to be certified as a condition of registration. Those individuals, and the groups that they represent, do not believe that certification is necessarily an indication of competency. While the National Association of Boards of Pharmacy has called for all states to require certification of technicians by 2015, no more than a third of the states currently require certification as a condition of registration. Given that there is no consensus within the profession in this state for requiring certification, it is reasonable for the Board to not establish a certification requirement at this time. The Board will continue to study the issue and may adopt a certification requirement in the future.

In contrast to certification, more states (23) do require that an individual be at least 18 years old and/or have a high school diploma or GED before registering as a technician. Since many other states have adopted these requirements and since the consensus among TRAC members favored them, it is reasonable for the Board to adopt these requirements.

Most other states (at least 35) also have some sort of training requirement. Almost all states that have a training requirement allow it to be met through the completion of an on-the-job training program developed by the pharmacist-in-charge or by the pharmacy. A handful of states, at most, require completion of a more formal, accredited training program. Some members of the MPhA Technician Task Force and/or the TRAC recommended that the Board require completion of a formal, accredited training program. However, other members recommended against such a requirement, arguing that rural, independent community pharmacies would find it difficult to attract technicians that had completed a formal, accredited training program.

Given that the majority of states have a technician training requirement and that the consensus of the TRAC was to support such a requirement, it is reasonable for the Board to establish a training requirement at this time. Given that almost no other states require the completion of a formal, accredited training program, it is reasonable for the Board to not require completion of such a program. Note that the Board is proposing language that would recognize completion of a formal, accredited training program as one option for completing the training requirement. The Board will continue to study the issue and may adopt different training requirements in the future.

Please also note that the Board is not proposing to require the completion of a training program prior to initial registration as a technician. Such a requirement would effectively eliminate the option of an employer-developed, Board-approved, on-the-job training program. (Since an individual cannot work as a pharmacy technician without being registered as such). The Board considered establishing a new "technician-in-training" registration category to allow initial registrants to work in a pharmacy while completing training. Unfortunately, the Board does not have the resources at this time to pay for the upgrade to its licensing system that would be required. Consequently, the Board is tying the completion of the training requirement to the first registration renewal. An individual will need to complete the required training before their first technician registration renewal. Note that the Board will probably establish a policy for granting variances to individuals who initially register as technicians in the couple of months prior to the January 1st renewal deadline for technicians. The variances would allow such individuals to have until their second registration renewal to complete the required training. Such variances would be granted due to the fact that it would be difficult to complete the training in just a couple of months.

Only about a third of the states require pharmacy technicians to complete continuing education programs as a condition of renewing registrations. However, given that the consensus among TRAC members was to support a CE requirement, it is reasonable for the Board to adopt such a requirement. The practice of pharmacy is continuously evolving, with new drugs, new technologies and new practices being introduced on a very regular basis. It is important for pharmacy technicians to complete CE programs so that they can try to keep up-to-date with these changes.

The proposed change in Subpart 1 of this Part is meant to reinforce the fact that an individual who works in a pharmacy as a technician must be registered as such. Some pharmacists mistakenly believe that there is a "grace period" during which new employees can work as technicians before they can be registered. At least several times each year, the Board is notified about an individual who has been fired for misconduct (such as the theft of narcotics) and who had not been properly registered as a technician. The Board's ability to identify, track and discipline such individuals is hampered when they have not been properly registered. In other cases, the Board has discovered multiple individuals working in a single pharmacy as technicians who have never been registered. Also, given the above-described proposed changes in registration requirements, it will be even more important to have technicians registered in the future. This proposed change is reasonable in that it simply makes crystal clear the long-standing rule that individuals must be registered as technicians before they are allowed to work as such.

The proposed change in Subpart 1a of this Part, clarifies that the Board may place limitations on the registration of a technician who has been found to be in violation of pharmacy-related laws and rules. At times, establishing a limitation is the most appropriate course of action for the Board to take. For example, if a technician is being disciplined for the theft of a controlled substance, it may be appropriate to limit the places at which the technician may work to facilities that do not handle controlled substances. This change is reasonable in that Minnesota health licensing boards routinely place limitations on the registrations and licenses of the individuals that they discipline. There is no reason that registered pharmacy technicians should not also be subject to limitations, when appropriate.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

In Subpart 1e (A), the Board is proposing an exception to the requirement that a pharmacy technician must wear a name badge while on duty that clearly identifies the person as a technician. The proposed change would exempt technicians assisting in the preparation of sterile compounded products (i.e. complying with the requirements of USP Chapter 797) from wearing a name badge. A name badge worn during the preparation of sterile compounded products would be a possible source of bacterial or viral contamination. In addition, the reason for requiring technicians to wear a name badge is so that they will not be mistaken as a pharmacist by patients or non-pharmacy staff. However, such individuals are typically not present in the work areas in which sterile compounding takes place. Consequently, it is reasonable for the Board to allow this exception.

Notwithstanding the fact that a new, general training requirement is being proposed, the Board still finds that it is necessary for the pharmacist-in-charge of a pharmacy to ensure that technicians have specific training that relates to the tasks that they will be performing. This requirement is made explicit by the addition of a new Subpart 1h (c) to this Part. The duties performed by technicians working in different types of pharmacies (and sometimes even within a single pharmacy) vary widely. For example, technicians working in hospital pharmacies often assist in the preparation of sterile compounded products- something that technicians working in community pharmacies rarely do. The Board finds that it is clearly reasonable to expect that technicians have training that is specific to the tasks that they will be performing. Not requiring such specific training would put patients at risk for receiving improperly prepared drug products.

The change proposed for Subpart 5 would require a pharmacist-in-charge to update technician policies every time a significant change in the way in which technicians are used occurs. The current language requires an update in technician policies only once every five years. Board Surveyors have investigated complaints about errors that involved technicians who were engaged in activities that were not described in the pharmacy's technician policies manual. The errors might have been prevented had the technicians been following clearly defined policies and procedures. Therefore, the Board finds it reasonable to require a pharmacist-in-charge to update technician policies whenever a significant change in the way in which technicians are utilized occurs.

The changes proposed for Subpart 7 clarify, in Rule, the Board's long-standing interpretation of this Subpart. Since filing, billing, completing sales transactions and delivery are not currently mentioned in this Subpart, it is common for Board staff to receive questions about whether individuals engaged in such activities have to be included for the purpose of determining compliance with technician-to-pharmacist ratios. The Board has long held the position that individuals engaged in such activities do not have to be included when determining compliance with the ratios. This change is reasonable in that it is simply a clarification of the rule.

The change proposed for Subpart 9 would make it unprofessional conduct for anyone to falsify any documents pertaining to the training of pharmacy technicians. Given that the Board is proposing a new technician training requirement and will be requiring technicians to show proof of having completed such training, it is reasonable for the Board to adopt this language. By explicitly making falsification of such records unprofessional conduct, the Board hopes to deter those individuals who might be tempted to engage in such conduct. This language is also consistent with similar language making it unprofessional conduct to falsify records pertaining to an application for pharmacist licensure.

**6800.3950 ELECTRONIC DATA PROCESSING; COMPUTER USAGE**

Some of the proposed changes for this Part merely replace antiquated terminology with more up-to-date language. For example, the phrase "electronic data processing" is a more accurate description of the devices that are the subject of this Part than is the word "automated". Likewise, the phrase "system's storage devices and databases" is being used to replace the now seldom-used phrase "data bank".

Please see the discussion above for Part 6800.0100, Subpart 11 for the rationale for making the changes involving the phrase "prescription drug order". Please see the discussion above for Part 6900.0100, Subpart 17 for the rationale for making the changes involving the phrase "unique identifier".

One of the changes proposed for Subpart 4 clarifies that pharmacist-interns are allowed to complete the quality assurance process that is required by that Subpart. The Board has actually been allowing pharmacist-interns to complete the quality assurance process for quite some time. This change makes merely clarifies the Board's long-standing interpretation of this rule. The Board has interpreted the rule in this manner since Part 6800.3100 allows interns to complete the closely related process of certification.

**6800.4075 CENTRALIZED PRESCRIPTION PROCESSING AND FILLING**

Please see the discussion above for Part 6800.0100, Subparts11 for the rationale for making the changes involving the phrase “prescription drug order”.

The change proposed for Subpart C acknowledges that the Legislature substituted its judgment for the Board’s by enacting Minnesota Statutes §151.215.

**6800.4200 INCLUSIONS AND EXCEPTIONS**

Please see the discussion above for Part 6800.0100, Subparts11 for the rationale for making the change involving the phrase “prescription drug order”. Please see the discussion above for Part 6900.0100, Subpart 17 for the rationale for making the changes involving the phrase “unique identifier”.

**6800.4300 DISPENSING SCHEDULE II CONTROLLED SUBSTANCES FOR PATIENTS IN LONG-TERM CARE FACILITIES AND TERMINALLY ILL PATIENTS**

Please see the discussion above for Part 6800.0100, Subparts11 for the rationale for making the changes involving the phrase “prescription drug order”.

**6800.5100 DEFINTIONS**

Many of the changes being proposed for this Part (and for the other Parts that relate to internship) are necessary because of changes made by the University of Minnesota College of Pharmacy (COP) to its curriculum. (Other colleges of pharmacy across the country have made similar changes). Some of those changes, in turn, were necessary because the Accreditation Council for Pharmacy Education (ACPE) modified the accreditation standards that it uses for colleges of pharmacy.

The changes being proposed for Subpart 2 reflect changes in the terminology used by the COP and ACPE. The pharmacy practice experience component of college of pharmacy curricula is now commonly referred to as the “experiential education program”. The word “externship” is less commonly used. This proposed change is reasonable in that it simply reflects the fact that this sort of training is now referred to as “experiential education”.

The Board is proposing the change in Subpart 3 in part to clarify that pharmacy students can’t register as interns until they have completed their first year of pharmacy school. The phrase “fourth, fifth and sixth academic year” was adopted at a time when most pharmacy students completed just two years of pre-pharmacy education. In those days, the “third academic year”, was the first professional academic year (i.e. the first year of pharmacy school). Likewise, the “fourth, fifth and sixth academic years” corresponded to the “second, third and fourth professional academic years”. Now, however, it is extremely common for students admitted to pharmacy school to have completed three or four years of pre-pharmacy coursework. For those students, their first year in pharmacy school is not their “third academic year”. Consequently, the

Board finds it necessary and reasonable to use the phrase "second, third and fourth professional academic years". Using that phrase makes the number of years of pre-pharmacy coursework completed irrelevant for the purpose of this Subpart.

The change proposed for Subpart 5 (D) simply clarifies that an individual participating in a pharmacy residency or fellowship program, who is licensed as a pharmacist in Minnesota, does not also have to be registered as an intern. That has been the Board's long-standing interpretation of this Subpart, since there is no valid policy reason for requiring a licensed pharmacist to register as an intern simply because he/she is participating in a residency or fellowship program.

The change proposed for Subpart 6 will allow a licensed pharmacist serving in a federal health care facility (such as a Veteran's Administration or Indian Health Service hospital) to act as a preceptor. Pharmacists working at federal facilities are not required to be licensed by the Board but are required to be licensed by some state Board of Pharmacy. The Board finds that it is reasonable to allow these pharmacists to serve as preceptors given that they do have to be licensed in at least one state. Also, it would be beneficial for interested students to be allowed to complete internship experiences at the federal facilities, given the unique populations that they serve.

The Board is proposing to repeal Subpart 7, which defines the word "Quarter" because the College of Pharmacy no longer operates on the basis of quarters. Instead, the College now operates on the basis of semesters. It is reasonable to repeal language that refers to something that is obsolete.

The Board is proposing to repeal Subparts 8, 9 and 10 because it makes more sense to deal with the important topic of intern supervision in Subpart 6800.5400, which deals with training, than to include it in a definitions subpart. Please see the discussion for Subpart 6800.5400 for additional information.

**6800.5300 REGISTRATION AND REPORTING**

One of the changes proposed for Subpart 1 clarifies that it is not always necessary for a person who is participating in a residency or fellowship program to register as an intern. Please see the discussion above for Part 6800.5100, Subpart 5 (D) for additional information.

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for

the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The remaining changes being proposed for Subpart 1 better state the procedures that the Board has long followed concerning the submission of certain internship documentation. The Board has required interns to submit notices of employment and progress report affidavits for many years. The Board has not required interns to complete pre- and post-internship examinations for years. Therefore, reference to "examinations" is being removed. These changes are reasonable in that they will not actually result in any change in the procedures that the Board has followed for quite some time.

The change proposed for Subpart 2 would eliminate the requirement for interns to surrender their pocket registration cards on termination of their registration as an intern. The Board has not rigorously enforced this requirement. In addition, the Board now has an online license and registration verification system which is the preferred method for verifying the current license or registration status of an individual or business licensed or registered by the Board.

The Board is proposing the repeal of Subpart 4 because it is obsolete. The Board has not required the submission of any "additional records" of an "intern's professional activities" for years, nor has it required interns to take any internship-related examinations. Since the Board no longer requires the submission of additional records or the completion of examinations, it is reasonable to repeal this Subpart.

The Board requires registered interns who complete at least 240 internship hours within Minnesota to complete an Intern Competency Manual that describes the competencies that interns are expected to master during the course of their practical experience. Each time an intern masters a particular competency, their preceptor initials the competency statement. The Board is proposing a change to Subpart 5, that would allow interns to complete up to 400 internship hours within Minnesota before they would be required to complete the Internship Competency Manual.

Most University of Minnesota College of Pharmacy students complete more than 400 hours of internship within the state, so this change will not have an impact on them. This change will primarily affect students of the North Dakota State University College of Pharmacy, many of whom do complete a substantial number of internship hours in Minnesota. Currently, the experiential education program of the NDSU COP includes eight, five-week Advance Pharmacy Practice Experience (APPE) rotations. (i.e. each APPE rotation consists of 200 hours of experience). Consequently, 240 hours bears no logical relationship to the NDSU rotation structure, whereas 400 hours equal the amount of experience that NDSU students receive in two of their APPE rotations. For this reason, the Board finds the change proposed for Subpart 5 to be reasonable.

The Board is proposing to change Subpart 6 so that individuals who are completing residencies and fellowships will not be allowed to continue their registration as interns if they terminate efforts towards completing their residency or fellowship. Since "pharmacist-intern"

and “intern” are defined to mean, among other things, a participant in a residency or fellowship program, it stands to reason that an individual who is no longer a resident or fellow cannot remain registered as an intern unless he/she meets another part of the definition of “intern”. A person in this situation could retain their internship by submitting the proper applications and fees to become a licensed pharmacist, thereby satisfying Part 6800.5100, subpart 5 (C).

**6800.5350 PRECEPTORS**

In Subpart 1, the Board is proposing to strike the phrase “in licensed pharmacies” to reflect the fact that many pharmacists act as preceptors in settings other than licensed pharmacies. For example, there are preceptors who offer rotations in settings such as poison centers and clinics. If those rotations are not associated with the College of Pharmacy’s experiential education program, the pharmacists should be registered by the Board as preceptors. That helps ensure that only pharmacists who are aware of the Board’s rules concerning internships and who have not been the subject of disciplinary action serve as experiential educators for interns. In addition, interns completing internship experiences outside of the College’s experiential education program are required to submit notices of employment and progress report affidavits signed by a registered preceptor. For these reasons, and because it is desirable for pharmacy students to complete some internship experiences in non-traditional settings, it is reasonable for the Board to make this change. The rest of the changes proposed for Subpart 1 are meant to simply clarify the process through which the Board has issued preceptor certificates. The Board has always required pharmacists to submit an application and supporting documentation before sending them preceptor certificates.

The change proposed for Subpart 2 (B) clarifies the Board’s interpretation of that provision. Individuals sometimes ask if the 2,000 and 4,000 hour requirements for “pharmacy practice” can be met by interns who are participating in residency and fellowship programs without being licensed as pharmacists. The proposed change clarifies that those hourly requirements must be met while working as a licensed pharmacist.

The Board is proposing the change in Subpart 3 (c) because of complaints that it has received from interns concerning the amount of time that their preceptors spend educating them. In some cases, preceptors reportedly meet with students for the purpose of providing educational instruction only once or twice during the internship experience. The Board believes that it is reasonable to expect preceptors to meet at least weekly with interns to provide them with instruction that will help them to meet the competencies of the internship requirement.

**6800.5400 TRAINING**

Due to the changes mentioned in the discussion for Subpart 6800.5100, pharmacy students are now expected to complete what are known as Introductory Pharmacy Practice Experiences (IPPE) earlier in their academic career. This has resulted in the need to have more experiential education “slots” available for students. Unfortunately, there are not always enough preceptors available to accommodate the number of students being placed into the slots. The College of Pharmacy therefore asked the Board to consider changing the intern-to-preceptor ratio found in Subpart 4 from 1:1 to 2:1.

The Board concurs that this would be an acceptable change in regards to the educational component of internships. In other words, the Board believes that a single preceptor can provide adequate educational instruction to two interns at one time. However, the Board firmly maintains that there is a difference between providing educational instruction to interns and supervising the work that they do – especially in regards to intern participation in the dispensing and compounding process. In regards to internships, the Board has two basic goals. The most important goal, as always, is to protect the health, safety and welfare of the public. The secondary goal, which is also important, is to make sure that interns receive adequate experiential training so that they master the competencies that they will need to have when they practice pharmacy on their own.

Given that protection of the public is the most important goal, the Board proposes that a licensed pharmacist continue to be limited to supervising one intern who is performing tasks associated with dispensing and compounding. Given the allowed technician-to-pharmacist ratios, if the Board permitted a 2:1 intern-to-pharmacist ratio for supervision purposes, one pharmacist could be asked to supervise as many as five unlicensed technicians and interns. In regards to unit-dose dispensing, intravenous admixture compounding, bulk compounding and pre-packaging, one pharmacist might be supervising as many as six unlicensed interns and technicians.

Since an intern is permitted to certify the prescriptions that he/she processes or that a technician has processed, pharmacies might end up using interns as if they were actually licensed pharmacists. In fact, the Board has already encountered situations in which pharmacies have replaced licensed pharmacists with registered interns, presumably due to the significant cost-savings involved. In another case, a Board Surveyor walked into one pharmacy where a single pharmacist and five interns were simultaneously on duty. Apparently, the pharmacists at the store believed that the 1:1 ratio applied only to educational activities of the internship and not to the supervision of interns.

In the judgment of the Board, allowing one pharmacist to supervise up to six unlicensed individuals or to replace licensed pharmacists with registered interns pose unacceptable risks to the public. Note that any licensed pharmacist on duty at the internship site can supervise the intern – the intern's preceptor does not have to be on duty at all times that an intern is working. Consequently, one preceptor can have two interns assigned for the purpose of providing educational instruction. However, another licensed pharmacist would be allowed to supervise interns who were involved in compounding or dispensing processes. Thus, the Board's proposed changes will more than likely still increase the number of internship slots that are available. Also note that direct supervision of interns is not required when they are completing medication histories, formulating pharmaceutical care plans, making drug therapy medications, counseling patients, participating in medical rounds or providing education to other staff – provided that all drug therapy and related recommendations must be reviewed by a licensed pharmacist.

The Board is not proposing substantive changes to Subpart 6. Instead, the proposed changes merely "clean up the language" of the Subpart so that it is easier to understand, replaces wording with more current terminology or strikes obsolete material.

**6800.5500 LICENSURE TRANSFER STANDARDS**

Please see the discussion above for Part 6800.1300 for an explanation of the Board's rationale for no longer requiring an applicant for licensure transfer to work as a licensed pharmacist in another state for at least 12 months prior to reciprocating.

**6800.6200 PRESCRIPTION ORDER COMMUNICATION**

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrase "prescription drug order". One of the changes proposed for Subpart 3 clarify that orders for Schedule II controlled substances for residents of long-term care facilities must be manually signed by the prescriber if they are written on paper. This is consistent with the requirements of the federal Controlled Substances Act, as interpreted by the U.S. Drug Enforcement Administration. The other change proposed for Subpart 3 clarifies that Schedule II controlled substance orders can be electronically prescribed. (However, the Board notes "interim final" rules recently adopted by the DEA must be followed).

**6800.6500 CONSULTING SERVICES TO LICENSED NURSING HOMES**

The Board is proposing to clarify in Subpart 2 (H) that only licensed nursing personnel are allowed to prepare up to a 72-hour supply of medications for residents who are temporarily leaving a nursing home. It is the Board's understanding that while unlicensed individuals are involved in administering medications in nursing homes, licensed nursing personnel are still "responsible for overseeing medication administration". Since the current rule language states that personnel responsible for overseeing medication administration are allowed to prepare the 72-hour supply of medications, the Board considers this proposed change to only be a clarification of the rule.

The Board is proposing to add Subpart 2 (I) to require consultant pharmacist to prepare policies and procedures for the disposition of medications that conform to Parts 4658.1350 and 6800.2350. The proper disposition of medications has taken on added importance in recent years because the Minnesota Pollution Control Agency (MPCA) has been more vigorously enforcing laws and rules concerning the handling of pharmaceutical waste. In the Board's judgement, it is reasonable to have the nursing home's consultant pharmacist involved in developing the policies and procedures for drug disposition. The consultant pharmacist is in a better position than facility staff to understand the requirements and limitations for returning drugs to pharmacies that are discussed in Part 4658.1350. The consulting pharmacist is also more likely to understand the process of determining which drugs are considered hazardous pharmaceutical waste (as is required by the MPCA).

The Board is proposing to repeal Subpart 3 because the first paragraph is unnecessary and the second paragraph is obsolete. Part 4658.1350 already requires nursing homes to contact the Board of Pharmacy to obtain the necessary forms (and related instructions) for the disposal of controlled substances. Consequently, paragraph 1 of Subpart 3 of Part 6800.6500 is redundant. Paragraph 2 of Subpart 3 is obsolete in that destroying drugs at the nursing (which has most

commonly been done by flushing down a sink or toilet) is not always allowed under the statutes and rules administered by the MPCA. The Board can't reasonably continue to require witnessed destruction of drugs at a facility when such destruction may be in violation of other statutes and rules.

**6800.6700 DRUGS FOR USE IN EMERGENCY KITS**

In Subpart 2 (A), the Board is proposing to replace the word "expiration" with the phrase "beyond-use". In 2007, the Board adopted rules that replaced "expiration date" with "beyond-use" date, when appropriate, but unfortunately missed this instance. The United States Pharmacopoeia (USP) defines "beyond-use date" as the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. The manufacturer certifies that the product will maintain at least 90% of its original potency until the expiration date. The certification requires the product to be stored according to label directions with the original packaging intact and unopened. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date. It is reasonable for the Board to make this change, since it is merely correcting an oversight that occurred when similar changes were made throughout Chapter 6800 in 2007.

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrase "prescription drug order".

The Board is proposing a change to Subpart 4 that would allow controlled substance sedative drugs to be stored in emergency kits. There are, in fact, emergency situations (such as acute agitation and some types of seizures) for which the administration of drugs classified as "sedatives" is appropriate. The Board has granted quite a few variances to this Subpart to allow sedatives to be stored in emergency kits. Given these facts, the Board finds that this change is reasonable.

**6800.7520 PHARMACEUTICAL SERVICE POLICY**

The Board is proposing changes to Subpart 1 (P) to bring it into accordance with Part 6800.3300, subpart 2. The Board amended Part 6800.3300 in 2007 to require that nonsterile compounding be done in accordance with the United State Pharmacopeia (USP), Chapter 795 and that sterile compounding be done in accordance with USP Chapter 797. This proposed change for Subpart 1 (P) should have been made at that time.

The USP is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States. USP sets standards for the quality of these products and works with healthcare providers to help them reach the standards. USP's standards are also recognized and used in many other countries outside the United States. These standards have been helping to ensure good pharmaceutical care for people throughout the world for more than 185 years. The USP has established updated standards for non-sterile and sterile compounding. (USP Chapters 795 and

797). Since the USP is the official public standards setting authority for pharmaceutical products, it is the judgment of the Board that pharmacists should adhere to these standards when compounding.

The Board is proposing the change to Subpart 1(S)(1)(a) because there are certain situations in which licensed health care professionals other than nurses procure controlled substances. (For example, a physician may sometimes procure a drug). The Board finds no good reason for limiting the procurement of a controlled substance to nurses - so long as it is done by a licensed health care professional. Limiting procurement to only licensed nurses might actually be detrimental to patient care in some circumstances.

The Board is proposing to further modify Subpart 1(S)(1) to allow for the use of a computer system which utilizes electronic distribution records of controlled substance transactions as long as certain conditions are met. Many hospitals have moved from paper-based drug distribution record systems to computerized systems. Provided that the conditions specified in the Board's proposed language are met, these computerized systems can be used to accurately track the distribution of controlled substances and to minimize the risk of diversion. The Board believes that it is reasonable to allow for the use of emerging technologies – provided that they do not pose any increased risks to the public.

The Board is proposing to amend Subpart 1(S)(2) to allow licensed individuals other than nurses or pharmacists to witness the wasting of doses of controlled substances – provided that they are authorized to have access to controlled substances. The Board finds no good reason for limiting the wasting of a controlled substance to nurses and pharmacists - so long as it is done by a licensed health care professional authorized to have access to controlled substances.

The Board is proposing the amendment to Subpart 1(S)(4) because there are instances in which it would be beneficial to allow controlled substances to be stored in patient care areas other than nursing stations. For example, an area where surgeries are performed may not necessarily be on a nursing station and yet there would obviously be a need to have controlled substances stored in such areas. The Board finds that it is reasonable to allow storage of controlled substances in such areas as long as they are stored under lock.

For Subpart 1(T), the Board is proposing to clarify that only registered nurses are allowed to prepare up to a 72-hour supply of medications for residents who are temporarily leaving a facility. This is basically consistent with the requirement, described above, that allows only licensed nursing personnel to prepare similar supplies of medications for patients temporarily leaving nursing homes. The Board believes that allowing unlicensed personnel to prepare such supplies of medication would increase the risk of errors that might adversely affect patients.

**6800.7900 PRESCRIPTION LABELING**

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrases "prescription drug order" and "chart order".

For Subpart 5, the Board is proposing to change the required elements that must be placed on the labels of intravenous admixture products. Since the lot number, the identity of the pharmacist who prepares or certifies the admixture, and the date and time of compounding are contained in the compounding records, there is no need to place them on the label. Including the date and time of administration is not always necessary (e.g. if an admixture is meant to be given immediately after it is compounded).

In Subpart 5 (H), the Board is proposing to replace the word "expiration" with the phrase "beyond-use". In 2007, the Board adopted rules that replaced "expiration date" with "beyond-use" date, when appropriate, but unfortunately missed this instance. The United States Pharmacopoeia (USP) defines "beyond-use date" as the date after which a drug should not be used. The expiration date printed on a drug package is set by the drug manufacturer. The manufacturer certifies that the product will maintain at least 90% of its original potency until the expiration date. The certification requires the product to be stored according to label directions with the original packaging intact and unopened. Drugs dispensed in the original packaging retain the manufacturer's expiration date, but when a pharmacist compounds a drug product or repackages commercially available drugs into consumer containers, the manufacturer's expiration date should no longer be used. Instead, the pharmacist is supposed to assign a beyond-use date. It is reasonable for the Board to make this change, since it is merely correcting an oversight that occurred when similar changes were made throughout Chapter 6800 in 2007.

The change being proposed for Subpart 6 acknowledges that there are some situations for which the labeling of medications is not done by pharmacy staff. In the judgement of the Board, however, the hospital pharmacy service should be responsible for ensuring that labeling not done by pharmacy staff is done in accordance with applicable statutes and rules. (e.g – by developing appropriate policies and procedures). Pharmacy staff is more likely to be aware of those laws and rules than other hospital staff.

**6800.8000 SCOPE AND PURPOSE**

Please see the discussion above for Part 6800.0100, subpart 6 for an explanation of the Board's proposed changes related to the use of "home health care pharmacies" in place of "parenteral-enteral/home health care pharmacies".

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrase "prescription drug order".

**6800.8004 DRUG DISTRIBUTION AND CONTROL**

In Subpart 1, the Board is proposing to replace the word "physician's" with the word "practitioner's". This is reasonable given that "practitioner" is defined in Minnesota Statues §151.01, subd. 23 to include all licensed health care professional who are authorized to issue prescription drug orders – and not just physicians.

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrases "prescription drug order" and "chart order".

The Board is proposing to require home health care pharmacies to delivery medications as required in Part 6800.3000. Please see that part for an explanation of the Board's proposed new delivery requirements. Since a home health care pharmacy might deliver drugs to the home of a patient, just as a community pharmacy might, it is reasonable for the Board to require the same delivery standards be followed.

**6800.8007 PATIENT CARE GUIDELINES**

In several places, the Board is proposing to replace the word "physician" with the word "practitioner". This is reasonable given that "practitioner" is defined in Minnesota Statues §151.01, subd. 23 to include all licensed health care professional who are authorized to issue prescription drug orders – and not just physicians.

Please see the discussion above for Part 6800.0100, subpart 11 for an explanation of the Board's proposed changes related to the use of the phrases "prescription drug order" and "chart order".

**6800.8550 LABELING OF RADIOPHARMACEUTICALS**

A radiopharmaceutical is basically a radioactive pharmaceutical used for diagnostic or therapeutic purposes. Due to potential toxicity, the preparation, distribution and use of such products require special procedures. Having received questions concerning the labeling of radiopharmaceuticals, the Board is proposing to add a new Part 6800.8550 that specifies requirements for such labeling. In developing this new language, the Board researched applicable standards and consulted with pharmacists who specialize in the use of radiopharmaceuticals. The Board believes that the proposed changes are reasonable in that they adhere to the applicable standards and were deemed to be accurate by the specialists that were consulted.

**6800.9900 VARIANCES**

The Board is proposing to require a successor pharmacist-in-charge (PIC) to submit an acknowledgment of an awareness and understanding of any variances that the pharmacy has been granted according to part 6800.9900. The successor PIC would then be responsible for ensuring that any conditions imposed by the board on granted variances continue to be met. This change is reasonable in that it actually decreases both regulatory burden and the Board's workload. Currently, a successor PIC must submit a complete variance request, including supporting documentation, in order for the pharmacy to continue using an approved variance. The Board's staff then has to process the request for review and approval by the Variance Committee and then the entire Board. This process was put into place after Board Surveyors reported that many successor PICs had no knowledge of the variance requests that had been approved for their pharmacies.

The proposed change will allow the PIC to submit only a brief document acknowledging awareness and understanding of any variances that the pharmacy has been granted. This document will be filed with the pharmacy's records and will not have to be reviewed by the Variance Committee or the full Board. This new procedure will accomplish the same goal as does the current procedure – ensuring that a successor PIC is aware of variances issued to the pharmacy and that he or she acknowledges that the conditions of the variance will be met.

**6800.9921 REGISTRATION**

The Board is proposing language that clarifies that it no longer has the authority to set fees through the rule-making process. Minnesota Statutes § 16A.1283 states, in part: "an executive branch state agency may not impose a new fee or increase an existing fee unless the new fee or increase is approved by law". A number of Parts in Chapter 6800 refer to fees that had been set by the Board through the rule-making process, prior to the enactment of M.S. § 16A.1283. The Board is proposing similar changes for each of those Parts, including this one. These changes will **NOT** result in any fee increases. The Board worked with the Office of the Revisor to develop this language and will be drafting proposed legislation that, if enacted, will place the fees now listed in Chapter 6800 of the Rules into Chapter 151 of the Statutes. Since the Board is prohibited by statute from imposing a new fee or increasing an existing fee, it is reasonable for the Board to remove specific fees from the Rules and work with the Legislature to have the fees listed in Statute instead.

The Board is proposing that an application for a medical gas distributor registration which has not been completed within 12 months of the date on which the board received the application will no longer be valid. The Board regularly receives applications for medical gas distributor registrations that are not complete. The applicant sometimes does not submit the information needed to complete the application, even when requested to do so by Board staff. In addition, applicants for medical gas distributor registration sometimes do not make arrangements to have required pre-licensing inspections completed. The longer the delay in completing the application process, the more likely it is that some change in circumstance will occur that would be of concern to the Board. In addition, long delays often results in Board staff having to repeat work (such as repeating inspections). Therefore, it would be reasonable to require that an applicant who has not completed all of the steps necessary for medical gas distributor registration within 12 months, reapply so that the Board can review any changes in circumstances and recover extra costs associated with the delay.

## V. REGULATORY ANALYSIS

Minnesota Statutes § 14.131 sets out several factors that must be considered in the Statement of Need and Reasonableness. Each factor is listed separately and is followed by the Board's analysis.

1. **"a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;"**

The parties most directly affected by the proposed rule changes are the following individuals or businesses that are licensed or registered by the Board: pharmacists, pharmacy technicians, pharmacist interns, pharmacy owners, drug wholesalers and manufacturers, controlled substance researchers and medical gas manufacturers and distributors. Staff in hospitals, long-term care facilities and home health agencies would be more indirectly affected by some of the proposed changes that concern drug distribution and pharmacy services in those settings.

Many of the proposed rule changes will have no discernable impact on anyone. In some cases, the Board is proposing changes simply to clarify its existing interpretation of the rule part in question. In other cases, the Board has already had to make changes to a procedure, usually due to circumstances beyond its control, and the new proposed rule change just reflects those changes. In either instance, the individuals and businesses affected by the rule are already being required to act according the new proposed rule language.

Individuals that want to open "limited service" pharmacies will benefit by having a more formal process for gaining Board approval. Currently, such individuals may not even be aware that the Board has been allowing, through the variance process, the operation of what amount to limited service pharmacies. Some members of the public will benefit from the availability of additional limited service pharmacies.

Individuals who are purchasing a pharmacy will benefit by having an additional, short period time during which they can operate under the existing license. The public will benefit by not having their pharmacy unexpectedly close if there is some last-minute problem during the ownership transfer process.

Members of the public who obtain prescriptions from certain pharmacies will benefit when those pharmacies improve their counseling areas. The pharmacies that need to upgrade counseling areas will bear a cost. However, the reader should keep in mind that many of those pharmacies were supposed to have upgraded their counseling areas by February 1, 2001 under a rule change adopted in the late 1990's.

A pharmacy that closes and the pharmacy that purchases its prescription files *may* bear a cost if the closing pharmacy has to notify the public in advance about the closing. The pharmacy purchasing the files may find them to be less valuable because patients may transfer their prescriptions to a third pharmacy before the closing date. Consequently, the purchasing pharmacy may offer to pay the closing pharmacy less money for the files. The impact is hard to determine, however, because I certain percentage of patients transfer their prescriptions from the purchasing pharmacy to a third pharmacy even when they have not been notified in advance of the closing. In fact, the Board is aware of patients who have transferred their prescriptions specifically because they were upset that they were never told that their pharmacy was closing. Also, members of the public will benefit from this proposed rule change. They will not be caught unawares when their pharmacy closes and should thus be less likely to have trouble refilling prescriptions. In addition, they will have more freedom to choose the pharmacy that they want to use once their original pharmacy closes.

Pharmacists who apply for licensure transfer (reciprocity) and the pharmacies that want to hire them will benefit by having the Board drop the requirement that pharmacist practice in another state for at least 12 months before they can reciprocate into Minnesota.

Pharmacists who are also registered preceptors will benefit by having a wider variety of preceptor CE programs to choose from.

Up until now, the registration of technicians has been solely for the purposes of identifying, tracking and, when necessary, disciplining individuals thus registered. The only registration requirements that the Board has established are a minimum age of 16 and an annual fee of $20. The Board is proposing to significantly expand technician registration requirements by:

- increasing the minimum age to 18;
- requiring high school graduation or GED;
- requiring the completion of a formal training program prior to the first time that a technician renews a registration; and
- requiring the completion of 20 hours of continuing education as a pre-requisite for registration renewal.

The public will benefit as well, since the Board expects that errors attributable to fatigue will decrease. Pharmacy owners will benefit from this change by enjoying better morale and less staff turnover.

Pharmacists and pharmacies will benefit because they will be able to submit fewer variance requests. The Board is replacing guidelines with rules in some areas and new pharmacists-in-charge will not have to resubmit variance requests.

Members of the public will benefit in that pharmacies will be able to deliver filled prescriptions to their places of employment. Pharmacies may possible incur new costs by having to make sure that temperature-sensitive drugs are delivered in appropriate containers, using appropriate procedures. However, members of the public will benefit if such containers and procedures are used since they will be less likely to experience adverse reactions to drugs that were improperly delivered.

Members of the public, pharmacists and pharmacy owners will benefit from having increased standards for technician registration. These new standards should help raise the overall quality of the technician workforce. That should result in fewer dispensing and compounding errors, thereby increasing public safety. Pharmacists may find that they are more comfortable delegating non-professional tasks to better qualified and trained technicians. Pharmacy owners will benefit by having better qualified and trained employees. Some pharmacy owners believe that the new registration standards for pharmacy technicians will drive up their salaries, resulting in increased labor costs. On the other hand, some pharmacists believe that pharmacy owners will replace pharmacists with technicians to the extent possible and actually have decreased labor costs. Technicians may experience some slight costs associated with completing continuing

education. However, there are many CE programs available that are low cost or even free. Technicians will have a cost if they choose to obtain formal training. Pharmacies that do not already have a formal technician training program may incur some costs to develop one if they choose to do in-house training.

Applicants for pharmacy, wholesaler and manufacturer, controlled substance researcher, and medical gas distributor licenses or registrations will face an increase cost if they fail to complete the application process within 12 months. Wholesalers and manufacturers that currently license only the primary location of the parent entity will experience increased costs to the extent that they have to license additional facilities from which drugs are shipped into the State of Minnesota.

Pharmacist-interns and the College of Pharmacy may benefit because there may be an increase in the number of available internship "slots".

Finally, the public will benefit from many of the proposed changes since the changes, in various ways, will result in the safer distribution of drugs and in better standards of pharmacy practice.

**2. "the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule, and any anticipated effect on state revenues;"**

The Board will incur some costs because of changes that will need to be made to its licensing system. (For changes related to the registration of technicians and the licensing of pharmacies). The Board may also have a slight increase in costs related the requirement that technicians complete continuing education. However, those costs can readily be absorbed within the Board's existing appropriation because the Board included these costs when developing the budget for this biennium – in anticipation of adopting these rule changes. None of the other Board proposals result in any costs to the Board. To the extent that any pharmacy has increased costs due to these proposed changes, pharmacies operated by state agencies (DHS, MnSCU, Veteran's Homes) may have similar increased costs. No other state agencies should have any increased costs. There may be a slight increase in the amount of fees collected from drug wholesalers and manufacturers, since some of them will need to license each facility from which they ship drugs into the state – instead of just the primary headquarters.

**3. "a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;"**

Most of the Board's proposed changes don't involve any costs at all – either to licensees/registrants or to the Board. Most of the changes are not intrusive, either.

In regards to counseling areas, the Board did makes some changes to its first proposed draft – and those changes will provide more flexibility to pharmacies that must finally come into compliance with this rule (that was first adopted in the late 1990's). Pharmacies will be allowed to propose designs for counseling areas other than ones that utilize the partitions that most

pharmacies use. For some pharmacies, this may decrease costs by not requiring remodeling as extensive as might be required by using partitions. In the Board's judgment, other less intrusive measures, such as allowing a pharmacy to put up a sign saying something like "Please stand back at least 10 feet to ensure the privacy of other customers", will not be sufficient to adequately achieve the purpose of the proposed rule change.

As noted above in the discussion of Part 6800.1010, some "individuals who represent pharmacies have expressed the concern that the adoption of the proposed subpart 3 might decrease the value of the sale of prescription files when a pharmacy closes. The Board has addressed this concern by allowing pharmacies to select from a variety of notification options and by shortening the notification time frame. The Board considers this to be a reasonable compromise between the desire of the seller of a closing pharmacy's prescription files to maximize the value of the sale and the need to protect the right of patients to chose where to get their prescriptions filled and to be assured that they will be able to get their prescriptions refilled in a timely manner after the pharmacy that they have been frequenting closes". The Board believes that it has compromised as much as it can if the purpose of the rule change is to be achieved.

As noted above in the discussion for Part 6800.2160, with regards to the proposed work condition rules, the Board considered and rejected a "suggestion that it ought to allow pharmacies to remain open while the only pharmacist on duty is away on a break. However, the Board finds no compelling reason to adopt that suggestion. Two of the largest pharmacy chains operating in Minnesota have a policy of closing their pharmacies so that pharmacists and other staff members can take a lunch break. The Board has not received a single complaint alleging that a patient was harmed by this practice. It is the Board's judgment that patients would be more likely to be harmed if unlicensed staff provided inappropriate services while the pharmacist was away from the pharmacy".

In regards to the proposed changes in technician registration requirements, the Board has chosen a middle ground between those individuals see no need for making any changes at all and those individuals and organizations that prefer even more stringent requirements than the Board is proposing. The Board believes that the proposed changes are the least intrusive ones that can be made if the purpose of the proposed rule changes is to be achieved.

**4. "a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;"**

This is actually addressed in the previous section. Most of the proposed changes do not involve any costs, aren't particularly intrusive, are not controversial and, in some cases, will not require licensees and registrants to make any significant changes. The Board did not seriously consider any alternatives for those proposed changes.

The Board seriously considered alternatives in regards to counseling areas, the closing of pharmacies, work condition rules and technician registration requirements. The Board changed its original proposed language in the regards to the closing of pharmacies and counseling areas.

The Board rejected a proposal to allow pharmacies to remain open while the only pharmacist on duty went on break. The proposed technician registration changes were developed through a lengthy process of consultation with the major organizations that represent various aspects of the pharmacy profession. They reflect the consensus that came out of meetings of the Minnesota Pharmacists Association Technician Task Force and the Board's Technician Rules Advisory Committee. The Board has chosen to stick with that admittedly fragile consensus, even though some individuals and organizations would like the Board to move towards their positions.

**5. "the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;"**

Pharmacies that need to remodel in order to have adequate counseling areas will have costs that vary depending on the extent of the remodeling that needs to be done. The costs may range from hundreds to thousands of dollars.

Individuals that do not complete applications for pharmacy, wholesaler, manufacturer, medical gas distributor and controlled substance researcher licenses or registrations within 12 months will have to submit a new application, along with a fee ranging from $50 - $180, depending on the type of business involved. There were presumably be some costs associated with reapplying, such as labor, postage, etc.

Manufacturers and wholesalers that have only licensed the primary location of their business will need to pay a fee ranging from $130 to $180 for each additional location that they need to license. (Which would be any location from which they ship products into the state of Minnesota). There would presumably be some costs associated with processing the additional applications, such as labor, postage, etc.

The probable cost, if any, of requiring a closing pharmacy to notify the public about the closure is unknown.

The probable costs, if any, associated with the proposed technician registration requirements is unknown. As mentioned above, some individuals have expressed the belief that labor costs will increase because technicians will demand higher salaries while other hold that labor costs will go down because pharmacies will have technicians perform some tasks that they currently have much higher paid pharmacists perform.

**6. "the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;**

In the judgment of the Board, many of these proposed rule changes will promote the safer use of medications. They will reduce medication errors and drug-related morbidity and mortality. If these rules are not adopted, patients will be more likely to experience these problems. That will result in increased costs to patients, insurers, employers, federal, state and local governments

and society in general. Pharmacies may also have increased costs due to more costly malpractice insurance premiums and to legal judgments rendered against them

.

7. **"an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference."**

There are no known differences between the proposed rule changes and existing federal regulations.

8. **"… a description of how the Board, in developing the rules, considered and implemented the legislative policies supporting performance--based regulatory systems set forth in Section 14.002."**

Many of the proposed rule changes simply clarify existing interpretations of the relevant Part. Others are putting into rule some of the guidelines that the Board is already requiring pharmacies to follow as a condition of approving variance requests. Still others will actually decrease the regulatory burden faced by licensees and registrants by, for example, decreasing the need to request rule variances. Thus, the regulatory burden of licensees and registrants is not being increased by most of the proposed changes in rule language.

In developing these rules, the Board has allowed flexibility in meeting the requirements in several areas. As noted above, pharmacies will be allowed to propose designs for counseling areas other than ones that utilize the partitions that most pharmacies use. For some pharmacies, this may decrease costs by not requiring remodeling as extensive as might be required by using partitions. Technicians will be able to choose from several training options and most will be given up to one year to complete the required training (longer in some cases). The owners of pharmacies that will be closed will be allowed to choose from several different options for notifying customers of the closure. Preceptors will have a wider selection of preceptor continuing education program to choose from.

## VI. Additional Notice

Minnesota Statutes, Sections 14.131 and 14.23, require the Board to describe the efforts made to provide additional notification to persons or classes affected by the proposed rule or explain why such efforts were not made. The Board proposes the following steps to provide notice to any affected parties:

1. The Board has published a Request for Comments in the State Register and has mailed or e-mailed a copy of it to all persons on the Board's rulemaking list.

2. The Board will publish the Dual Notice in the State Register and will mail copies of it to all persons on the Board's rulemaking list. The Board will also mail or e-mail a copy of the proposed rules to all such persons.

3. The Board has posted the Request for Comments and the Revisor's Draft of the proposed rule changes on its Web site. The Statement of Need and Reasonableness, the Dual Notice and other relevant documents will also be posted on the Board's Web site. A notice of the Web site posting of the aforementioned documents will be sent, via e-mail, to every pharmacist, pharmacist intern, preceptor, pharmacy technician, pharmacy, drug wholesaler and drug manufacturer for whom the Board has an e-mail address. A notice of the Web site posting of the aforementioned documents will also be posted on the Board's Facebook page.

4. The Board will make copies of the aforementioned documents available in alternative formats, as requested.

## VII. List of Witnesses

If the rules go to a public hearing, the Board anticipates having the following witnesses testify in support of the need and reasonableness of the rule:

Cody Wiberg, Executive Director
Minnesota Board of Pharmacy

This individual would testify regarding all aspects of the Board's proposal.

## VIII. Contact with Legislative Sponsors about the Proposed Rule

According to Minnesota Statutes § 14.116, if the mailing of a Notice of Intent to Adopt Rules is within two years of the effective date of the law granting the agency authority to adopt the proposed rules, an agency must make reasonable efforts to send a copy of the Notice and the Statement of Need and Reasonableness to all sitting legislators who were chief house and senate authors of the bill granting the rulemaking authority. Since the law granting the Board of Pharmacy the authority to develop rules to regulate pharmacy practice appears to have been passed in 1937, the requirement to notify the chief authors expired long ago.

Minnesota Statutes § 14.116 also requires an agency to send a copy of the Notice and the Statement of Need and Reasonableness to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules. Therefore, a copy of the Notice of Intent to Adopt Rules and a copy of the Statement of Need and Reasonableness will be sent to: Senators John Marty and Paul E. Koering, Chair and Ranking Minority Member, respectively, of the Health, Housing and Family Security Committee; Senators Linda Berglin and Michelle L. Fischbach, Chair and Ranking Minority Member, respectively, of the Health and Human Services Budget Division; Representatives Paul Thissen and Jim Abeler, Chair and Lead-GOP, respectively, of the Health Care and Human Services Policy and Oversight Committee; Representatives Karen Clark and Dan Severson, Chair and Lead-GOP, respectively, of the Housing Finance and Policy and Public Health Finance Division and Representatives Thomas Huntley and Matt Dean, Chair and Lead-GOP, respectively, of the Health Care and Human Services Finance Division. A certificate of

mailing will be done to acknowledge the mailings and will be included with the documents submitted to the Office of Administrative Hearings as part of the rulemaking record.

## IX. Summation

This rules package is being proposed in order to make changes that are necessary, in the Board's judgment, to better protect the health, safety and welfare of the public. The Board has worked hard to develop proposed rule changes that should also be acceptable to a majority of the members of the profession and to most of the owners of pharmacies, drug wholesalers and drug manufacturers. Board staff conducted background research to assess the current state-of-the-art for pharmacy practice and to identify rules in need of updating. The Board also used three advisory committees to assist it in the development of this rules package. These committees included individuals representing many areas of the pharmacy profession in Minnesota. Included on the committees were representatives of the two major professional associations of pharmacists in Minnesota (MPhA and MSHP) and of the Minnesota Retailer's Association, the National Association of Chain Drug Stores and the College of Pharmacy. The Board also received many comments about the proposed rule language and made many changes as a result of those comments.

From the information contained in this Statement of Need and Reasonableness, the Board has demonstrated that it is fulfilling its responsibility to protect the public's health, safety and welfare Minnesota while also providing flexibility to licensees and registrants in the manner in which they choose to practice or conduct their business.

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director
Minnesota Board of Pharmacy

9/6/2010
Date