

MINNESOTA BOARD OF PHARMACY



An Equal Opportunity Employer

2829 University Ave. SE., #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (612) 617-2262

MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:

October 10, 2016

Metro and Non-Metro; 800-627-3529

E-Mail Address: Pharmacy.Board@state.mn.us

Web Site: www.pharmacy.mn.gov

Legislative Reference Library
645 State Office Building
100 Constitution Avenue
St. Paul, Minnesota 55155

Re: In the Matter of the Proposed Rule Amendments Relating to Pharmacy Practice, including Pharmacy Work Conditions Related to the Safety of the Public, proposing amending Minnesota Rules 6800.2150 and adoption of a new rule part, Minnesota Rules [6800.2160]; Revisor's ID Number RD4355

Dear Librarian:

The Board of Pharmacy intends to adopt rule amendments relating to the above mentioned topic.

We published a Notice of Hearing in the September 19, 2016 issue of the *State Register* and have mailed the Notice under section 14.14. The Board has prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes, sections 14.131 and 14.23, the Board is sending the Library an electronic copy of the Statement of Need and Reasonableness. We have separately mailed the SONAR and other documents to Senators Lourey, Rosen, Sheran and Benson and Representatives Dean, Liebling, Mack and Mullery.

If you have any questions about these rules, please contact me at (651) 201-2830.

Sincerely,

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

**BEFORE THE MINNESOTA
BOARD OF PHARMACY**

In the Matter of the Proposed Rule Amendments
Relating to Pharmacy Practice, including Pharmacy
Work Conditions Related to the Safety of the Public,
proposing amending Minnesota Rules 6800.2150
and adoption of a new rule part,
Minnesota Rules, [6800.2160]

**STATEMENT OF NEED
AND REASONABLENESS**

I. INTRODUCTION

The Minnesota Board of Pharmacy (Board), pursuant to Minnesota Statutes §§ 14.22 through 14.28 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 amendment the Board's rules relating to pharmacy practice. As explained below, the Board proposes to add a new rule part [6800.2160] to establish standards for work conditions that have a direct impact on public safety.

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 (612) 617-2262, or e-mail at cody.wiberg@state.mn.us. TTY users may call (800) 627-3529.

III. STATUTORY AUTHORITY

Minnesota Statutes, section 151.06 Subd. 1 (b), authorizes *and makes it the duty* of the Board to adopt rules for carrying out the provisions of the Pharmacy Practice Act.

IV. NEED FOR AND REASONABLENESS OF THE RULES

The Board is proposing to adopt a new rules part [6800.2160] to address pharmacy work conditions that have a direct impact on the safety of the public. The Board originally proposed to adopt this rule as a portion of a large package of rules changes that was adopted in 2011. The Board withdrew the rule after receiving feedback from the Office of the Governor. However, the Board remains convinced that this proposed rules part is both necessary and reasonable.

6800.2160 PHARMACY WORK CONDITIONS.

The Board is proposing to promulgate work condition rules that, in the judgement of the Board, will 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 as much as 14 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 becoming stressed and fatigued and therefore more likely to make errors, resulting in harm to members of the general public. Consequently, the Board views this proposed rule change as being allowed within its authority and duty under Minnesota Statutes §151.06 to regulate the practice of pharmacy. The Board takes seriously the requirement in Minnesota Statutes §214.001. subd. 2 that no rule shall be imposed unless, among other factors, it is “required for the safety and well being of the citizens of the state.” In the judgment of the Board, the proposed rule is, in fact, required for the safety and well-being of the citizens of the state.

This proposed change is reasonable for several reasons. First, there are at least fourteen other states (including the District of Columbia) that have promulgated rules concerning breaks and/or work conditions 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 dissenting 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.

Other courts have acknowledged that dispensing conditions affect the safe dispensing of drugs. A couple of examples are provided here. 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.”

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. 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. Consequently, in the Board’s judgment, many pharmacies *are* “high intensity settings.” Inspection reports issued by the Board’s surveyors commonly include remarks such as “the staffing for this very busy pharmacy does not appear to be adequate.” Consequently, the Board finds it reasonable to limit the number of continuous hours that a pharmacist can be required to work to twelve and to afford pharmacy staff the opportunity to take breaks.

Research involving other types of healthcare professionals has also been conducted in regards to the impact of prolonged work shifts on patient safety. For example, an article published in the *Joint Commission Journal on Quality and Patient Safety* titled “Effects of Health Care Provider Work Hours and Sleep Deprivation on Safety and Performance” describes studies involving nurses as follows (emphasis added):

In two separate studies, Rogers, Scott, and colleagues have demonstrated that **nurses working greater than 12.5 consecutive hours are at significantly increased risk of making a medical error**. In the first study, 393 randomly selected members of the American Nurses Association logged their work hours daily and reported all medical errors in which they were involved; data were collected on a total of 5,317 work shifts. Thirty-nine percent of all shifts exceeded 12.5 hours, and **working > 12.5 hours was associated with a threefold increased risk (OR = 3.29, p = .001) of making an error**.

In the second study, Scott et al. conducted a similar evaluation of a random sample of nurses drawn from the membership of the American Association of Critical-Care Nurses. In this study of 502 nurses and 6,017 work shifts, **it was found that 67% of critical care nurses’ work shifts exceeded 12 hours and that working 16-hour shifts was common. Nurses working more than 12.5 hours had twice the risk of making a medical error (OR = 1.94, p = .03).**

When the Board last considered adoption of this rule in 2011, it 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 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 large number of patients admitted to a hospital (perhaps after some disaster that caused widespread injuries).

The Board also 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. As explained below, the proposed rule does not even require a pharmacy to be closed while the pharmacist is on break – it simply requires that pharmacist breaks be uninterrupted, which could be accomplished by means other than closing the pharmacy.

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 change are the members of the general public who have prescriptions filled, pharmacies (including their owners), pharmacists, pharmacy technicians, and pharmacist interns. Of these, pharmacies and their owners *might* have to bear some additional costs (see section 5 for an analysis).

Pharmacists, pharmacy technicians and pharmacy interns will benefit by being afforded breaks that should help reduce the stress and fatigue that results from long shifts and no breaks. That may have a positive impact on their personal health. The public will benefit as well, since the Board expects that errors attributable to fatigue will decrease. Since such errors can be life-threatening, some members of the public might avoid hospitalizations or even death. Pharmacy owners may benefit from this change by enjoying better morale, less staff turnover and lower healthcare costs (to the extent that their employees do experience a positive impact on their own health). They may also see a reduction in malpractice suits brought against them by persons harmed by dispensing errors.

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 minimal costs if this rule change is adopted. It is possible that the Board might receive complaints from pharmacists, pharmacy technician or pharmacy interns alleging that a pharmacy is violating the rule. Such complaints would have to be investigated. However, the Board does not anticipate that it would receive a large enough number of new complaints to justify hiring additional staff.

There would be no impact at all on most other state agencies. The Minnesota Department of Human Services, Minnesota State Colleges and Universities, and at least one of the Minnesota Veteran's Homes employ pharmacists and technicians that work in pharmacies. The Board believes that none of those pharmacies are currently opened longer than 12 hours per day and staff at those pharmacies are already afforded lunch and rest breaks. Consequently, there would most likely be no increased costs for those agencies.

It is unlikely that adoption of this proposed rule would have any impact on state revenues that are deposited into the general fund. As with any rule enforced by the Board, a violation *might* result in the Board issuing a disciplinary order. The Board sometimes assesses a civil penalty when issuing a disciplinary order, which would be deposited in the state government special revenue fund. However, the Board expects that there will be few complaints related to this rule and, therefore, little to no impact on Board revenues.

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

As mentioned in section 5 below, whether or not certain pharmacies will bear significant costs if this rule is adopted is not known. Pharmacies may very well be able to adjust staff schedules in a manner that results in no increased costs. To the extent that pharmacies feel compelled to reduce the hours during which they are open, any costs due to decreased sales might be offset by decreased operating costs.

As described in section 4 below, other alternatives were considered by the Board. Pharmacies owners would most likely consider those other alternatives to be more intrusive and costly than the rule that is being proposed by the Board. For example, limiting the number of prescriptions that a pharmacist can certify per hour would most likely require pharmacy owners to hire additional pharmacists. The same is probably true for the other alternatives mentioned.

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;”

The Board seriously considered alternatives to the rule, as originally proposed in the past, as the result of comments received. As mentioned above, the Board rejected a proposal to allow pharmacies to remain open while the only pharmacist on duty went on break after finding no compelling reason to do so. However, the Board did add an exception that would allow pharmacy staff to work shifts of greater than 12 hours in the event of an emergency.

Other alternatives that were more informally considered by the Board were:

- Promulgation of a rule that would limit the number of prescriptions that a pharmacist could certify per hour. Few states have rules or policies of this type.
- Promulgation of a rule that would create grounds for discipline related to unsafe work conditions. For example, the Oregon Board of Pharmacy adopted the following rule:
 - **OR BReg 855-041-1170 Grounds for Discipline.** The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:
 - (3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:
 - (a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.
 - (c) Adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to: (A) Drug Utilization Review; (B) Immunization; (C) Counseling; (D) Verification of the accuracy of a prescription; and (E) All other duties and responsibilities of a pharmacist as specified in Division 19 of this chapter of rules.
- Promulgation of a rule that would create a general requirement to operate pharmacies with reasonable safety. For example, the Oklahoma Board of Pharmacy adopted the following rule:
 - **OK BReg 535:15-3-2. Pharmacy responsibilities.** (a) Pharmacy staffing responsibility. Each pharmacy shall employ an adequate number of pharmacists to perform the practice of pharmacy as defined by the Oklahoma Pharmacy Act with reasonable safety.

These alternatives most likely would help achieve the same purpose as the rule that the Board is proposing – namely, to reduce errors attributable to fatigue and stress. However, as mentioned above, pharmacy owners might also consider these alternatives to be more costly and intrusive than the rule currently being proposed.

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;”**

Whether or not pharmacies will bear an increased cost is unknown. As mentioned above at least two of the major chains operating in Minnesota already close down their pharmacies in order to provide lunch breaks from pharmacy staff members. Many pharmacies currently do not require their staff to work shifts that are longer than 12 hours. However, the Board is aware of pharmacies that are open for longer than 12 hours per day and that currently require pharmacists to work shifts that are as long as 14 hours. The Board does not know if adoption of this rule would somehow result in increased costs for those pharmacies, but acknowledges that it is possible.

- 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, this proposed rule change will reduce the likelihood that dispensing errors will occur. That should help reduce 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 change and existing federal regulations.

- 8. “an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. The statement must describe how the agency, in developing the rules, considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002. For purposes of clause (8), "cumulative effect" means the impact that results from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.”**

The Board has adopted no other rules directly related to work conditions. The federal Fair Labor Standards Act (FLSA) does *not* require employers to provide rest or lunch breaks. However, if an employer chooses to provide rest breaks of less than 20 minutes duration, the breaks must usually be counted as hours worked. Under the FLSA, bona fide meal breaks are usually 30 minutes or more and the employee is completely relieved from duty during the meal period. Bona fide meal breaks do not have to be counted as hours worked. The FLSA does not set a maximum number of hours that an employee can be required to work during a 24-hour period of time. Also, pharmacists are often considered to be exempt employees under the FLSA. (Meaning the provisions of the FLSA do not apply to them). Since the FLSA does not *require*

breaks and does not set limits on the maximum number of hours worked per day, the Board's proposed rule has no effects that are cumulative to the provisions of the FLSA.

The Minnesota Fair Labor Standards Act (§§177.251 – 177.35) does not set a maximum number of hours that an employee can be required to work during a 24-hour period of time. Minn. Stats. §177.253 requires an employer to allow each employee adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom. Minn. Stats. §177.254 requires an employer to permit an employee who is working for eight or more consecutive hours sufficient time to eat a meal. However, professionals such as pharmacists are excluded from the definition of the word “employee” that is found in Minn. Stats. §177.23 and are not therefore entitled to a meal break under §177.254.

As noted above, the provisions of the MLSA do not apply to pharmacists. Consequently, for pharmacists, adoption by the Board of its proposed work conditions rule would have no effects that were cumulative with the MLSA. The Board is not proposing that its work condition rules *replace* the requirements of the MLSA for non-exempt employees such as pharmacy technicians. The MLSA already requires employers to at least provide restroom breaks to non-exempt employees during each four hour period of work. Pharmacy employers providing 15 minute breaks to non-exempt employees, under the Board's proposed work conditions rule, could have such employees combine those breaks with the restroom breaks required under Minn. Stats. §177.253. Similarly, the meal breaks required under the Board's proposed work condition rules could satisfy the meal requirements found in Minn. Stats. §177.254.

In developing this rule, the Board did consider the flexibility that pharmacy owners would have in meeting the proposed new requirements. In order to meet the 12-hour maximum shift requirement, pharmacy owners have the option of reducing the number of hours that their stores are open or of altering work schedules for pharmacists, pharmacy interns and pharmacy technicians. In order to meet the requirements for breaks, pharmacy owners could alter work schedules by reducing the length of shifts or by providing more hours for “crossover” shifts (i.e. periods of time during which more than one pharmacist is on duty). In addition, the proposed rule does **NOT** require that the pharmacy be closed during a pharmacist's breaks – it merely requires that the break be uninterrupted. If the pharmacist were to take a break within the licensed pharmacy space, the pharmacy could remain open and other pharmacy staff members could continue to perform duties that do not require interrupting the pharmacist's break.

The Board notes that Section 14.002 includes the statement (emphasis added): “Therefore, **whenever feasible**, state agencies must develop rules and regulatory programs that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.” For the reasons outlined in this statement, the Board believes that this proposed rule will help meet the Board's regulatory objective of protecting the public from preventable dispensing errors. Except for the flexibility mentioned in the previous paragraph, the Board can think of no other feasible ways to provide more flexibility.

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 Notice of Hearing 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 Notice of Hearing 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, pharmacy technician, and pharmacy for whom the Board has an e-mail address.
4. The Board will make copies of the aforementioned documents available in alternative formats, as requested.
5. The Board may issue a press release – in hopes that media coverage might prompt members of the general public to submit comments.

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, Pharm.D., M.S., R.Ph. 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 Kathy Sheran and Michelle R. Benson, Chair and Ranking Minority Member, respectively, of the Health, Human Services and Housing Committee; Senators Tony Lourey and Julie A. Rosen, Chair and Ranking Minority Member, respectively, of the Health and Human Services Budget Division; Representatives Tara Mack and Joe Mullery, Chair and DFL Lead, respectively, of the Health and Human Services Reform Committee; and Representatives Matt Dean and Tina Liebling, Chair and DFL Lead (Healthcare), respectively, of the Health Human Services Finance Committee. 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 rule 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 originally proposed this rule change as part of a much larger rules package that was adopted in 2011. In developing that package, the Board worked hard to develop proposed rule changes that would 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 for each of the proposed rule changes, including the one that is the subject of this current effort. The Board also used three advisory committees to assist it in the development of this rules package, with the current proposed rule being considered by the General Rules Advisory Committee. 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, including changes to the proposed work condition rules.

Since 2011, the Board has continued to receive many requests from pharmacists and pharmacy technicians to once again try to promulgate work condition rules. These individuals have expressed the opinion that, by working long hours without breaks, they are more likely to make errors that will harm patients. Some of these individuals have also expressed concerns about the negative impact that such work conditions is having on their own health. Some of them are concerned about the impact of the work conditions on their health in general. Some have specific health-related concerns, such as the difficulty of managing diabetes – given that they can't take consistent lunch breaks.

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

Dated: October 2, 2015