December 16, 2016

VIA E-FILING ONLY
Cody C. Wiberg
Executive Director
Minnesota Board of Pharmacy
2829 University Ave SE, Ste 530
Minneapolis, MN 55414
Cody.Wiberg@state.mn.us

Re: In the Matter of Proposed Permanent Rules Relating to Pharmacy Work Conditions
OAH 10-9026-33753; Revisor 4355

Dear Mr. Wiberg:

Enclosed herewith and served upon you is the ORDER ON REVIEW OF RULES UNDER MINN. STAT. § 14.15 in the above-entitled matter. The Administrative Law Judge has determined there are no negative findings in these rules.

The Office of Administrative Hearings has closed this file and is returning the rule record so that the Minnesota Board of Pharmacy can maintain the official rulemaking record in this matter as required by Minn. Stat. § 14.365. Please ensure that the agency’s signed order adopting the rules is filed with our office. The Office of Administrative Hearings will request copies of the finalized rules from the Revisor’s office following receipt of that order. Our office will then file four copies of the adopted rules with the Secretary of State, who will forward one copy to the Revisor of Statutes, one copy to the Governor, and one to the agency for its rulemaking record. The Board will then receive from the Revisor’s office three copies of the Notice of Adoption of the rules.

The Board’s next step is to arrange for publication of the Notice of Adoption in the State Register. Two copies of the Notice of Adoption provided by the Revisor’s office should be submitted to the State Register for publication. A permanent rule with a hearing does not become effective until five working days after a Notice of Adoption is published in the State Register in accordance with Minn. Stat. § 14.27.
If you have any questions regarding this matter, please contact Katie Lin at (651) 361-7911 or katie.lin@state.mn.us.

Sincerely,

[Signature]

PERRY WILSON
Administrative Law Judge

Enclosure
cc: Office of the Governor
    Legislative Coordinating Commission
    Revisor of Statutes
Sheena Denny certifies that on December 16, 2016, she served a true and correct copy of the attached REPORT OF THE ADMINISTRATIVE LAW JUDGE; by courier service, by placing it in the United States mail with postage prepaid, or by electronic mail, as indicated below, addressed to the following individuals:

<table>
<thead>
<tr>
<th>VIA E-FILING ONLY</th>
<th>Merone Melekin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cody C. Wiberg</td>
<td>Office of Governor Mark Dayton</td>
</tr>
<tr>
<td>Executive Director</td>
<td><a href="mailto:Merone.Melekin@state.mn.us">Merone.Melekin@state.mn.us</a></td>
</tr>
<tr>
<td>Minnesota Board of Pharmacy</td>
<td></td>
</tr>
<tr>
<td>2829 University Ave SE, Ste 530</td>
<td></td>
</tr>
<tr>
<td>Minneapolis, MN  55414</td>
<td></td>
</tr>
<tr>
<td><a href="mailto:Cody.Wiberg@state.mn.us">Cody.Wiberg@state.mn.us</a></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Legislative Coordinating Commission</th>
<th>Paul Marinac</th>
</tr>
</thead>
<tbody>
<tr>
<td>(<a href="mailto:lcc@lcc.leg.mn">lcc@lcc.leg.mn</a>)</td>
<td>Office of the Revisor of Statutes</td>
</tr>
<tr>
<td></td>
<td><a href="mailto:paul.marinac@revisor.mn.gov">paul.marinac@revisor.mn.gov</a></td>
</tr>
</tbody>
</table>
In the Matter of the Proposed Permanent Rules Relating to Pharmacy Working Conditions

REPORT OF THE ADMINISTRATIVE LAW JUDGE

This matter came before Administrative Law Judge Perry M. Wilson for a rulemaking hearing on October 19, 2016. The public hearing was held at 9:30 a.m. in Courtroom 11 at the Office of Administrative Hearings in Saint Paul, Minnesota.

The Minnesota Board of Pharmacy (Board or Agency) proposes new rules governing working conditions at pharmacies located in Minnesota.\(^1\) The Agency's objective for these new rules is to increase safety in pharmacy practice:

- By prohibiting pharmacies licensed and located in Minnesota from requiring pharmacists, pharmacist interns, and pharmacy technicians to work more than 12 hours in one continuous 12 hour period;
- By requiring that pharmacies licensed and located in Minnesota to permit pharmacists, pharmacist interns, and pharmacy technicians working more than six uninterrupted hours to take one 30 minute uninterrupted break;
- By requiring that pharmacies licensed and located in Minnesota to permit pharmacists, pharmacist interns, and pharmacy technicians working more than four hours sufficient time to use the nearest restroom;
- By allowing pharmacies licensed and located in Minnesota flexibility as to whether to remain open when pharmacists are on a 30 minute break required by the new rules;
- By providing an exception to the break rules in the case of emergency.

The hearing and this Report are part of a larger rulemaking process conducted under the Minnesota Administrative Procedure Act (Act).\(^2\) The Minnesota Legislature has designed this process to ensure that state agencies have met all of the requirements that the state has specified for adopting rules.

---

\(^1\) See Exhibit (Ex.) 1 Statement of Need and Reasonableness (SONAR).
The hearing was conducted to permit Board representatives and the Administrative Law Judge to hear public comment regarding the impact of the proposed rules and what rule changes might be appropriate. The hearing process provided the general public an opportunity to review, discuss, and critique the proposed rules.

The Board must establish that: 1) the proposed rules are necessary and reasonable; 2) the rules are within the Board’s statutory authority; and 3) any modifications that the Board may have made after the proposed rules were initially published in the State Register are within the scope of the matter that was originally announced.\(^3\)

The Board was represented at the public hearing by Cody Wiberg, its Executive Director.

Approximately 25 people attended the hearing and 13 signed the hearing register. The proceedings continued until all interested persons, groups and associations had an opportunity to be heard concerning the proposed rules.

After the close of the hearing, the Administrative Law Judge kept the rulemaking record open for another 20 calendar days – until November 8, 2016 – to permit interested persons and the Agency time to submit written comments. Following the initial comment period, the hearing record was held open an additional five business days to permit interested parties and the Board an opportunity to reply to earlier-submitted comments.\(^4\) The hearing record closed on November 16, 2016.

**SUMMARY OF CONCLUSIONS**

The Board has established that it has the statutory authority to adopt the proposed rules and that the proposed rules are needed and reasonable.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

**FINDINGS OF FACT**

I. **Background to the Proposed Rules**

1. The Board was created by the legislature to regulate the practice of pharmacy in the State of Minnesota.\(^5\) The Board has the authority to adopt rules for the purpose of carrying out its authority under the Pharmacy Practice Act.\(^6\) The practice of pharmacy includes “offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management, and control of a

---

\(^3\) Minn. Stat. §§ 14.05, .131, .23, .25 (2016).
\(^4\) See Minn. Stat. § 14.15, subd. 1.
\(^5\) See Minn. Stat. §§ 151.01-.302 (2016).
\(^6\) See Minn. Stat. § 151.06, subd. 1(b).
pharmacy…” Since public safety is an important purpose for the Board’s regulation of the practice of pharmacy, it follows that the Board has the authority to adopt rules for the safe operation, management and control of pharmacies by pharmacists.

2. The proposed rules were originally part of a larger set of new rules the Board adopted in 2011. The proposed rules were withdrawn from consideration by the Board after it received feedback from the office of the Governor. The Board believes that the proposed rules are reasonable and necessary to promote safety in the pharmacy practice in Minnesota.

II. Rulemaking Authority

3. Minn. Stat. § 151.06, subd. 1(b), authorizes the Board to adopt rules to regulate the practice of pharmacy.

III. Procedural Requirements of Chapter 14 (2016)

A. Publications

4. On September 19, 2016, to comply with the Act, the Board published in the State Register a Request for Comments, seeking comments on its possible rules governing pharmacy working conditions.

5. On August 23, 2016, the Board requested approval of its Additional Notice Plan.


7. Pursuant to the Additional Notice Plan, the Board:

- Had published a Request for Comments in the State Register and mailed or e-mailed a copy of it to all persons on the Board’s rulemaking list;
- Would publish the Notice of Hearing in the State Register and mail copies of it to all persons on the Board’s rulemaking list. The Board would also mail or e-mail copies of the proposed rules to all such persons;

---

7 Minn. Stat. § 151.01, subd. 27 (9).
8 See SONAR at 1.
9 See id. at 2.
10 41 State Register 355 (Sept. 19, 2016).
11 Letter from Cody Wiberg, Executive Director, Board of Pharmacy, to The Honorable Tammy L. Pust, Chief Administrative Law Judge (Aug. 23, 2016).
12 Order on review of notice of hearing and additional notice plan (Sept. 7, 2016).
• Posted the Request for Comments and the Revisor’s draft of the proposed rule changes on its Web site. The SONAR, the Notice of Hearing and other relevant documents would be posted on the Board’s Web site;

• Would notify all pharmacists, pharmacist interns, pharmacy technicians, and pharmacies for whom the Board has an e-mail addresses on file of the Board’s posting of the Request for Comments and Revisor’s draft of the proposed rule changes on its Web site. Copies of the Request for Comments, the Revisor’s draft, and the SONAR would be attached to these e-mails;

• Would make copies of the aforementioned documents available in alternative formats, as requested;

• Might issue a press release about the hearing to notify the public.

8. Before the hearing, the Board demonstrated that it complied with the terms of the Additional Notice Plan.\textsuperscript{13}

9. On October 10, 2016, the Board sent a copy of the SONAR to certain legislators and the Legislative Coordinating Commission, either by depositing them in the United States mail with postage prepaid or by sending an electronic copy via e-mail in an effort to comply with Minn. Stat. § 14.116.\textsuperscript{14}

10. On October 10, 2016, the Board sent by e-mail a copy of the SONAR to the Legislative Reference Library to meet the requirement set forth in Minn. Stat. §§ 14.131, .23.\textsuperscript{15}

11. The Notice of Hearing identified the date and location of the hearing in this matter.\textsuperscript{16}

12. At the hearing on October 19, 2016, the Board filed copies of the following documents as required by Minn. R. 1400.2220 (2015):

   a. Proposed rules dated June 29, 2016, including the Revisor’s approval;\textsuperscript{17}

   b. Agency’s Statement of Need and Reasonableness;\textsuperscript{18}

\textsuperscript{13} See Certificate of giving additional notice under additional notice plan and press release, filed Oct. 13, 2016.
\textsuperscript{14} See attachments to Letter from Cody Wiberg to Judge Wilson (Oct. 11, 2016).
\textsuperscript{15} See id.
\textsuperscript{16} Amended Notice of Hearing, undated, filed Aug. 30, 2016.
\textsuperscript{17} Ex. 2.
\textsuperscript{18} Ex. 1.
Before the hearing the Board filed the following documents with the Office of Administrative Hearings:

a. Letter mailing the SONAR to the Legislative Reference Library on October 10, 2016;\(^{19}\)

b. Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan;\(^ {20}\)

c. Written comments on the proposed rules that the Agency received during the comment period that followed the Notice;\(^ {21}\)

d. Certificate of Mailing the Notice of the Hearing to the Rulemaking Mailing List on September 19, 2016;\(^ {22}\) and,

e. December 1, 2015 memorandum from Minnesota Management and Budget;\(^ {23}\)

B. Additional Notice Requirements

13. Minn. Stat. §§ 14.131, .23 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule; or alternatively, the agency must detail why these notification efforts were not made.

14. Pursuant to the Additional Notice Plan approved by the Office of Administrative Hearings on September 7, 2016, the Board used the following methods to deliver notification to persons or classes of person who may be affected by the proposed rules:

- Posted the Request for Comments and the Revisor’s draft of the proposed rule changes and the SONAR on its Web site;

- Notified all pharmacists, pharmacist interns, pharmacy technicians, and pharmacies for whom the Board had an e-mail addresses on file of the Board’s posting of the Request for Comments and Revisor’s draft of the proposed rule changes on its Web site. Copies of the Request for Comments, the Revisor’s draft, and the SONAR were be attached to these emails;

\(^{19}\) Letter from C. Wiberg to Legislative Reference Librarian (Oct. 21, 2016).
\(^{21}\) Filed Oct. 12, 2016.
\(^{22}\) See attachments to Letter from C. Wiberg to Judge Wilson (Oct. 11. 2016).
\(^{23}\) Id.
• Issued a press release describing the proposed rules and hearing.24

C. Notice Practice

1. Notice to Stakeholders

15. On September 19, 2016, the Board provided a copy of the Notice of Hearing to its official rulemaking list maintained under Minn. Stat. § 14.14.25

16. The hearing on the proposed rules was held on October 19, 2016.26

17. There are 31 days between September 19, 2016 and October 19, 2016.

18. The Administrative Law Judge concludes that the Board did not fulfill its responsibility to mail the Notice of Hearing “at least 33 days before the ... start of the hearing.”27

2. Notice to Legislators

19. On October 10, 2016, the Board sent a copy of the Notice of Hearing and the SONAR to legislators and the Legislative Coordinating Commission as required by Minn. Stat. § 14.116.28

20. Minn. Stat. § 14.116 requires the Board to send a copy of the Notice of Hearing and the SONAR to certain legislators on the same date that it mails its Notice of Hearing to persons on its rulemaking list and pursuant to its Additional Notice Plan.

21. The Administrative Law Judge concludes that the Board did not fulfill its responsibilities to mail the Notice of Hearing “at least 33 days before the . . . start of the hearing”29 and did not provide timely notice to legislators and the Legislative Coordinating Commission.

3. Notice to the Legislative Reference Library

22. On October 10, 2016, the Board e-mailed a copy of the SONAR to the Legislative Reference Library.30

---

24 Certificate of giving additional notice pursuant to additional notice plan, Oct. 13, 2016.
25 See Certificate of mailing the notice of hearing to the rulemaking list, attached to Letter from C. Wiberg to Judge Wilson (Oct. 11, 2016).
26 Notice of Hearing.
27 Minn. R. 1400.2080, subp. 6 (2015).
29 Minn. R. 1400.2080, subp. 6.
30 See Certificate of mailing the statement of need and reasonableness to the Legislative Reference Library, attached to Letter from C. Wiberg to Judge Wilson (Oct. 11, 2016).
23. Minn. Stat. § 14.23 requires the agency to send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt is mailed.

24. The Administrative Law Judge concludes that the Board did not fulfill its responsibilities to “send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt [was] mailed.”

4. Assessment of Agency’s Notice Practice

25. Minn. Stat. § 14.15, subd. 5, requires an administrative law judge to disregard an error or defect in the proceeding due to an “agency’s failure to satisfy any procedural requirement” if the administrative law judge finds “that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process . . . .”

26. An agency must place into the hearing record “any other document or evidence to show compliance with any other law or rule which the agency is required to follow in adopting this rule.”

27. By letter dated October 11, 2016, the Board stated that it did not mail the Notice of Hearing to its rulemaking list at least 33 days before the hearing.

28. By letter dated October 11, 2016, the Board stated that it did not timely mail the Notice of Hearing and SONAR to the Legislative Reference Library, the Legislative Coordinating Council, and the statutorily required list of legislators as required by law.

29. The Administrative Law Judge concludes that the Board’s failure to timely provided a copy of the Notice of Hearing to its official rulemaking list maintained under Minn. Stat. § 14.14, and to timely provide the Notice of Hearing and SONAR to the Legislative Reference Library, the Legislative Coordinating Council, and the statutorily required list of legislators, did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process. To assure that all persons desiring to comment on the proposed rules were able to do so, the Administrative Law Judge extended the comment period to 20 days after the date of the hearing, upon receiving the Board’s letter indicating that it had failed to timely comply with the notice procedures stated above. For these reasons, the procedural errors constituted harmless error under Minn. Stat. § 14.15, subd. 5(1).

D. Statutory Requirements for the SONAR

30. The Administrative Procedure Act obliges an agency adopting rules to address certain factors in its SONAR. Those factors are:

---

31 Minn. R. 1400.2220, subp. 1(K).
33 Id.
a. 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;

b. 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;

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

d. 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;

e. 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;

f. 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;

g. 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; and

h. an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

1. The Agency’s Regulatory Analysis

(a) 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.

31. The Board believes that, because the proposed rules pertain to the operation of pharmacies in Minnesota, the proposed rules could affect a variety of people
and entities. Most immediately, the proposed rules would affect pharmacists, pharmacy technicians, pharmacy interns, and the owners and operators of pharmacies. The Board believes that the public would also be affected by increased safety in the practice of pharmacy resulting from implementation of the proposed rules.

32. The following stakeholders would be potentially affected by the proposed rules:

- Pharmacists, pharmacy technicians, and pharmacy interns would be affected by the proposed rule because they would be able to choose whether to take breaks and would not be required to work more than twelve continuous hours in one day. These changes would relieve stress and fatigue;

- Pharmacy owners and operators would be affected by the proposed rules because they would be required to allow the breaks in the work day required by the rules, if elected by pharmacists, pharmacy technicians, and pharmacy interns. In addition, they would have the option to elect to close their pharmacies during the breaks required by the proposed rules and allowed to continuously operate in case of emergency. They may benefit from decreased employee turnover and decreased malpractice claims resulting from claims arising from drug dispensing errors;

- The public would be affected implementation of the proposed rules because drug dispensing errors resulting from pharmacist fatigue would decrease.

(b) 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.

33. The Board anticipates there will be minimal additional costs to it or any other agency to implement or enforce the proposed rules. The Board has staff in place to enforce the existing rules and the Board will require no additional revenues to implement and enforce the proposed rules. The Board asserts the proposed rules will not affect state revenues because the Board will not require additional state funds to implement and enforce the proposed rules and no other state agencies will be affected by implementation of the proposed rules.

35 SONAR at 5.
36 Id.
37 Id.
38 Id.
39 Id. at 6.
34. The Board did not provide an analysis of whether the proposed rules would result in increased costs to state-operated health care facilities that operate pharmacies.

(c) The determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

35. The Board does not believe there are less costly or less intrusive methods of achieving the purpose of the proposed rules. It reviewed other state’s regulations of pharmaceutical practice. The Board carefully considered whether the costs and potential burdens of the proposed rules could be lessened by adoption of other states’ regulatory approaches. The Board concluded that there would be no lesser costs or burden achieved by adopting these other approaches.

(d) 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.

36. The Board considered three alternatives to the proposed rules. One alternative considered was to limit the number of prescriptions that a pharmacist could certify in an hour. A second alternative was to create a disciplinary rule that covered “failure to prevent fatigue, distraction, or other conditions that interfere with a pharmacist’s ability to practice with reasonable competency and safety.” This rule would also have required “[a]dequate time for a pharmacist to complete professional duties and responsibilities.” The third alternative would have required pharmacies to operate, in general, safely.

37. The Board believes that each of the three alternatives it considered would operate to reduce errors attributable to fatigue and stress. The Board rejected these alternatives because they might be more costly and intrusive to the operators of pharmacies than the proposed rules.

\[\text{Id. at 6-7.}\]
\[\text{Id.}\]
\[\text{Id. at 7.}\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id.}\]
\[\text{Id.}\]
(e) The probable costs of complying with the proposed rules, 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.

38. The Board stated that it does not know if the operators of pharmacies will incur additional costs as a result of the promulgation of the new rules.\textsuperscript{48} The Board believes that pharmacies that have operated with pharmacist work time in excess of twelve hours may incur additional costs.\textsuperscript{49}

39. Other than operators of pharmacies, the Board does not expect other affected parties to incur cost increases related to complying with the proposed rules.\textsuperscript{50}

40. The Memorandum supplied by the Minnesota Management and Budget Office analyzing the cost impact of the proposed rules states that pharmacies operated by local units of government will only be impacted if they currently operate in a way that does not conform to the proposed rules and that the nonconforming pharmacies would likely be able implement low or no cost options such that there would be no significant cost impact on local units of government from implementation of the proposed rules.\textsuperscript{51}

(f) The probable costs or consequences of not adopting the proposed rule, including those costs borne by individual categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

41. The Board states that the consequences of not adopting the proposed rules are that prescription errors will:

- Result in an increase in the morbidity and mortality of patients;
- Result in increased costs to patients, insurers, employers, federal, state and local governments and the public in general;
- Result in increased costs to pharmacies arising from more costly malpractice premiums and legal judgments from malpractice cases.\textsuperscript{52}

\textsuperscript{48} Id. at 8.
\textsuperscript{49} Id.
\textsuperscript{50} Id.
\textsuperscript{51} Memorandum from Paul Moore, Office to Management and Budget to Cody Wiberg, (Dec. 1, 2015), filed Oct. 11, 2016, located between pages 14 and 15 of Executive Director comments.
\textsuperscript{52} See SONAR at 8.
(g) An assessment of any differences between the proposed rules and existing federal regulation and a specific analysis of the need for and reasonableness of each difference.

42. The Board states that there are no differences between the proposed rules and existing federal regulations.53

(h) Assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

43. The Board states that both federal and Minnesota workplace laws govern various aspects of the operation of pharmacies, but asserts that there are no state or federal laws or regulations conflict with the proposed rules.54

2. Performance–Based Regulation

44. The Administrative Procedure Act55 requires an agency to describe how it has considered and implemented the legislative policy supporting performance-based regulatory systems. A performance-based rule is one that emphasizes superior achievement in meeting the agency’s regulatory objectives, and maximum flexibility for the regulated party and the agency in meeting those goals.56

45. The Board states that, since the proposed rules do not conflict with federal or Minnesota law, and because pharmacies are free to meet the requirement of the rules in various ways, the proposed rules provide superior achievement of its objective of decreasing errors in prescription dispensing while providing maximum flexibility to pharmacy operators.57

46. As an example of the flexibility the Board believes is provided by the proposed rules, it states that pharmacy operators may meet the 12-hour work limit by reducing hours of operation, by changing work shift hours, or by increasing staff.58

3. Consultation with the Commissioner of Minnesota Management and Budget (MMB)

47. As required by Minn. Stat. § 14.131, and by means of the Office Memorandum dated December 1, 2015, the Commissioner of MMB responded to a request by the Board to evaluate the fiscal impact and benefit of the proposed rules on local units of government. MMB reviewed the Board’s proposed rules and concluded

53 Id.
54 Id. at 8-9.
57 See SONAR at 8-9.
58 Id.
that: “[i]n all, no significant state mandated costs on units of local government are likely to result...[from the proposed rules].”^59

48.  The Administrative Law Judge finds that the Board has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems, and the fiscal impact on units of local government.


49.  Minn. Stat. § 14.127 requires the Board 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.” The Board must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.^

50.  The Board did not attempt to comply with the requirements of Minn. Stat. § 14.127, except to note that whether increased costs will be incurred by pharmacies to comply with the proposed rules is unknown.^

51.  The Administrative Law Judge disapproves the Board’s cost calculation under Minn. Stat. § 14.127.


52.  As provided in Minn. Stat. § 14.127, subd. 1, qualifying small businesses and small cities may be able to claim a temporary exemption from compliance with the proposed rules. The statute states:

any business that has less than 50 full-time employees or any statutory or home rule charter city that has less than ten full-time employees may file a written statement with the agency claiming a temporary exemption from the rules. Upon filing of such a statement with the agency, the rules do not apply to that business or that city until the rules are approved by a law enacted after the agency determination or administrative law judge disapproval.^

53.  Importantly, however, the “safe harbor” provisions will not apply if the Governor waives application of these provisions, sends notice of the waiver “to the

^59 Memorandum from Paul Moore, MMB, to Cody Wiberg, (Dec. 1, 2015), filed Oct. 11, 2016, located between pages 14 and 15 of Executive Director comments (emphasis in original).
^60 Minn. Stat. § 14.127, subds. 1, 2.
^61 See SONAR at 8.
^62 Minn. Stat. § 14.127, subd. 3.
speaker of the house and the president of the senate” and publishes “publish notice of this determination in the State Register.”

6. Adoption or Amendment of Local Ordinances

54. Under Minn. Stat. § 14.128, the Board must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The Board must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.

55. The Board has not made the determination required by Minn. Stat. § 14.128.

56. The Administrative Law Judge disapproves the Board’s determination required by Minn. Stat. § 14.128.


57. Minn. Stat. § 14.128, subd. 2, provides:

If the agency determines that the proposed rule requires adoption or amendment of an ordinance or other regulation, or if the administrative law judge disapproves the agency’s determination that the rule does not have this effect, the rule may not become effective until:

1. the next July 1 or January 1 after notice of final adoption is published in the State Register; or

2. a later date provided by law or specified in the proposed rule.

58. A significant exception to section 14.128, subdivision 2, is provided in Minn. Stat. § 14.128, subd. 3(4), which states that the governor may waive the application of Minn. Stat. § 14.128, subd. 2.

IV. Rulemaking Legal Standards

59. The Administrative Law Judge must inquire as to whether: (1) the Agency has statutory authority to adopt the rule; (2) the rule is unconstitutional or otherwise illegal; (3) the Agency has complied with the rule adoption procedures; (4) the proposed rule grants undue discretion to government officials; (5) the rule constitutes an undue

---

63 Minn. Stat. § 14.127, subd. 4.
64 Minn. Stat. § 14.128, subd. 1. Moreover, a determination that the proposed rules require adoption or amendment of an ordinance may modify the effective date of the rule, subject to some exceptions. Minn. Stat. § 14.128, subds. 2, 3.
delegation of authority to another entity; and (6) the proposed language meets the
definition of a rule.65

60. Under Minn. Stat. § 14.14, subd. 2, and Minn. R. 1400.2100, an agency
must establish the need for, and reasonableness of, a proposed rule by an affirmative
presentation of facts. In support of a rule, an agency may rely upon: materials developed
for the hearing record”66 “legislative facts” including general and well-established
principles that are not related to the specifics of a particular case but which guide the
development of law and policy;67 and the agency’s interpretation of related statutes.68

61. A proposed rule is reasonable if the agency can “explain on what evidence
it is relying and how the evidence connects rationally with the agency’s choice of action
to be taken.”69 By contrast, a proposed rule will be deemed arbitrary and capricious where
the agency’s choice is based upon whim, devoid of articulated reasons or “represents its
will and not its judgment.”70

62. An important corollary to these standards is that when proposing new rules
an agency is entitled to make choices between different possible regulatory approaches,
so long as the alternative that is selected by the agency is a rational one.71 Thus, while
reasonable minds might differ as to whether one or another particular approach
represents “the best alternative,” the agency’s selection will be approved if it is one that
a rational person could have made.72

V. Rule by Rule Analysis

A. Proposed rule 6800.2160, subpart 1

63. Proposed rule 6800.2160, subpart 1, prohibits a pharmacy licensed and
located in Minnesota from requiring that a pharmacist, pharmacist-intern, or pharmacist
technician work more than 12 continuous hours per day, inclusive of the breaks required
by subpart 2 of the proposed rule. This subpart of the proposed rules was the subject of
comments at the hearing and written comments.

64. Opposition to subpart 1 of proposed rule 6800.2160 came from Mayo Clinic
Midwest Pharmacy leadership group, which includes the Mayo Clinic and eleven other
Mayo Clinic Health System hospitals operating in Minnesota (Mayo Clinic).73

66 See Manufactured Hous. Inst. v. Pettersen, 347 N.W.2d 238, 240 (Minn. 1984); Minn. Chamber of
Commerce v. Minn. Pollution Control Agency, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991).
68 See Mammenga v. Dept’ of Human Servs., 442 N.W.2d 786, 789-92 (Minn. 1989); Manufactured Hous.,
347 N.W.2d at 244.
69 Manufactured Hous. Inst., 347 N.W.2d at 244.
70 See Mammenga, 442 N.W.2d at 789; St. Paul Area Chamber of Commerce v. Minn. Pub. Serv. Comm’n;
312 Minn. 250, 260-61, 251 N.W.2d 350, 357-58 (1977).
72 Minn. Chamber of Commerce v. Minnesota Pollution Control Agency, 469 N.W.2d at 103.
73 Letter to Cody Wiberg from Mayo Clinic Midwest Pharmacy Leadership Group (Oct. 11, 2016).
expressed concern about the broad sweep of this proposed rule, including all pharmacists, pharmacist-interns, and pharmacy technicians. In written comments, Mayo Clinic suggested that the proposed rule be narrowed to apply to “dispensing” pharmacists and technicians or those pharmacists “providing direct patient care.”74 According to these comments, the suggested limitation would exclude pharmacists in management or supervisory roles and those pharmacists and technicians who are not involved in direct patient care.75

65. In oral comments, a representative of Mayo Clinic noted at the hearing that the proposed rule should focus on retail pharmacies and not those operated in conjunction with a hospital, because closing a hospital-based pharmacy to comply with the proposed rule would not be safe for patients.76 The Mayo Clinic representative also noted that the proposed rule conflicts with the work hours standards of the American Society of Health System Pharmacists (ASHP).77 ASHP promulgated “Duty-Hour Requirements for Pharmacy Residencies 2012.”78 ASHP rules apply to pharmacy residents in health care systems, like the Mayo Clinic.79 These rules limit pharmacy residents to 80 hours of work per week, averaged over a four-week period, and limit a resident’s continuous duty hours to 16 and the maximum duty assignment to 24 hours, even when breaks for napping are available.80 The Mayo Clinic requested that hospital pharmacies in Minnesota be governed by the ASHP rules, rather than the proposed rules.81

66. A number of practicing pharmacists provided written comments regarding subpart 1 of the proposed rule.82 The majority of the practicing pharmacists supported the subpart.83 One pharmacist expressed concern that the subpart would complicate scheduling of their work shifts and, perhaps, require them to work additional days composed of fewer hours.84 Two of the pharmacists who submitted written comments also appeared at the hearing and provided comments supporting subpart 1.85

67. The Board considered these comments and concluded that the evidence it cited in the SONAR showed that longer pharmacist work hours made dispensing errors more likely and that the safety of patients fully supported and justified subpart 1 of the proposed rule.86 The Board also stated that patient safety would not be implicated because the emergency exception provided in subpart 3 of the proposed rule would

---

74 Id.
75 Id.
76 Comments of Karen Bergrud.
77 Id.
78 See Ex. 3.
79 Id.
80 Id.
81 Comments of K. Bergrud.
82 See e-Comments Report.
83 Id.
84 Id.
85 Statement of Amy Rahm; Statement of Gary Clausen.
86 Statement of Cody Wiberg.
permit a pharmacy to remain open if patient safety was implicated by a closure that would otherwise be required by the proposed rule.\textsuperscript{87}

B. Proposed rule 6800.2160, subpart 2

68. Subpart 2(A) of proposed rule 6800.2160 requires pharmacies to allow pharmacists and pharmacy technicians working more six continuous hours to take an uninterrupted 30 minute break. Subpart 2(B) of proposed rule 6800.2160 requires pharmacies to allow pharmacists and pharmacy technicians to have adequate time to utilize the nearest convenient restroom once during each continuous four-hour period they work. Subpart 2(C) of proposed rule 6800.2160 permits pharmacies to remain open while a pharmacist is on a break, but requires that, if the pharmacy remains open, the pharmacist must be in the establishment in which the pharmacy is located.

69. Subpart 2 of proposed rule 6800.2160 is opposed by pharmacy operators, represented by the Minnesota Grocers Association, the Minnesota Retailers Association, and the National Association of Chain Drug Stores. This opposition is based on the assertion that this subpart will operate to require pharmacies to close multiple times during the day or employ a second pharmacist to cover on breaks required by the subpart.\textsuperscript{88} They also state that pharmacy closures during the day will disrupt patient care, when the pharmacist is not available to dispense prescription drugs or provide advice to patients.\textsuperscript{89} Finally, the pharmacy operators state that current pharmacy operations provide break opportunities for pharmacists, who can rest during the daily ebb and flow of the work day.\textsuperscript{90}

70. Pharmacists supported the rule as conducive to work place and patient safety.\textsuperscript{91} One pharmacist expressed concern that allowing the pharmacy to remain open while the pharmacist is on a break would implicated safety and advocated that pharmacies be required to close during a pharmacist break.\textsuperscript{92}

71. The Board considered these comments and concluded that the evidence it cited in the SONAR showed that longer pharmacist work hours made dispensing errors more likely and that the safety of patients fully supported and justified subpart 1 of the proposed rule. The Board also stated that patient safety would not be implicated if the pharmacy remained open during a pharmacist break because of the conditions stated in subpart 3 the emergency exception provided in subpart 2(C) that a pharmacy must meet in order to remain open.\textsuperscript{93}

\textsuperscript{87} Id.
\textsuperscript{88} Letter from Jamie Pfuhl, President, Minnesota Grocers Association, to Judge Perry Wilson (Oct. 17, 2016) (Pfuhl letter); Statement of Bruce Nustad, Minnesota Retailers Association; Statement of Joel Kurzman, National Association of Chain Drug Stores.
\textsuperscript{89} See Pfuhl letter.
\textsuperscript{90} Id.
\textsuperscript{91} See e-Comments report.
\textsuperscript{92} Id. comments of Seth Runkle.
\textsuperscript{93} Statement of C. Wiberg.
72. The Board started the rulemaking process on September 28, 2015, when it published a request for comments on the proposed rules. During this comment process, the Board received 80 comments on the proposed rules. These comments and the Board’s analysis of the comments it received were compiled in December of 2015. The comments and the Board’s analysis resulted in changes and additions to the proposed rules leading to the form of the proposed rules that are the subject of this report.

VI. The Administrative Law Judge’s Determinations Regarding the Proposed Rules

73. The proposed rules have received comments both for and against them during the hearing process. The Board has considered the comments and, in the case of comments it received in 2015, made changes and additions to the proposed rules. The comments received during the hearing process were addressed by the Board and the Administrative Law Judge concludes that the Board has reasonable and rational responses to the comments made during the hearing process.

74. The Administrative Law Judge concludes that the Board has shown there is a rational basis for the proposed rules. In compliance with Minnesota law, the Board considered the advice of members of the public, pharmacists, and, health care facilities. As described in the SONAR and the summary of comments, the Board engaged in an extensive outreach program. The process afforded significant opportunities for input from members of the public, organizations, businesses, and others.

75. The Board’s SONAR, comment summary analysis, hearing statements and and post-hearing submissions provide an adequate explanation of the need for and reasonableness of the proposed rules and the rule falls within the broad authority the legislature has given to the Board to create the proposed rules. The Administrative Law Judge concludes that, in accordance with applicable case law, the Board has provided ample explanation of the facts on which it is relying and shown how those facts connect rationally with the approach it has taken in creating the proposed rules.

76. Accordingly, the Administrative Law Judge finds that the Board has demonstrated that:

   a) the proposed rules are needed and reasonable;
   b) there are no other impediments to preclude their adoption; and
   c) there are no defects found in the rules as proposed.

---

94 See Minnesota Board of Pharmacy Staff Analysis of Comments Received during Comment Period, filed Oct. 11, 2016.
95 Id. at 2.
96 Id.
97 Manufactured Hous. Inst., 347 N.W.2d at 244.
Based upon the Findings of Fact and the contents of the rulemaking record, the Administrative Law Judge makes the following:

**CONCLUSIONS OF LAW**

1. The Minnesota Board of Pharmacy gave notice to interested persons in this matter.

2. Except as noted in Findings 19 to 24 and 49 to 56, the Board has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule. The Administrative Law Judge concludes that the cited omissions constitute either harmless error under Minn. Stat. § 14.15, subd. 5, or are addressed by self-executing remedies provided by applicable statute.

3. The Administrative Law Judge concludes that the Board has fulfilled its additional notice requirements.

4. The Board has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1, .15, subd. 3, .50(i), (ii).

5. The Notice of Hearing, the proposed rules, and SONAR complied with Minn. R. 1400.2080, subp. 5 (2015).

6. The Board has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, .50.

7. As part of the public comment process, a number of stakeholders urged the Board to adopt other revisions to the proposed rules. In each instance, the Board’s rationale in declining to make the requested revisions to its rules was well grounded in this record and reasonable.

8. A finding or conclusion of need and reasonableness with regard to any particular rule subsection does not preclude and should not discourage the Board from further modification of the proposed rules based upon this Report and an examination of the public comments, provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions of Law, the Administrative Law Judge makes the following:
RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules be adopted.

Dated: December 16, 2016

__________________________
PERRY M. WILSON
Administrative Law Judge

 Reported: Digitally recorded, no transcript prepared.

NOTICE

This Report must be available for review to all affected individuals upon request for at least five working days before the agency takes any further action on the rules. The agency may then adopt the final rules or modify or withdraw its proposed rule. If the agency makes any changes in the rule, it must submit the rule to the Chief Administrative Law Judge for a review of the changes prior to final adoption. Upon adoption of a final rule, the agency must submit a copy of the Order Adopting Rules to the Chief Administrative Law Judge. After the rule’s adoption, the Office of Administrative Hearings will file certified copies of the rules with the Secretary of State. At that time, the agency must give notice to all persons who requested to be informed when the rule is adopted and filed with the Secretary of State.
MINNESOTA BOARD OF PHARMACY

Staff Analysis of Comments Received during the Comment Period that Followed Publication of the Dual Notice in the September 28, 2015 Issue of the State Register; with Recommendations for Changes to the Proposed Rule.

In the Matter of the Possible Adoption of Rules Governing Pharmacy Practice, Including Pharmacy Work Conditions Related to the Safety of the Public, Proposing Adoption of a New Rule Part Minnesota Rules 6800.2160; Revisor’s ID Number RD4355.

INTRODUCTION

In the September 28, 2015 Issue of the State Register, pages 393 - 394, the Board of Pharmacy published a Request for Comments which stated, in part:

“The Minnesota Board of Pharmacy requests comments on its possible Adoption of Rules Governing Pharmacy Practice, including Pharmacy Work Conditions Related to the Safety of the Public. The Board is considering adopting a new rule that would prohibit a pharmacy that is licensed under Minnesota Statutes §151.19, subd. 1, and that is located within the State of Minnesota, from requiring a pharmacist, pharmacy intern or pharmacy technician to work for more than twelve continuous hours per day. The rule would also require that pharmacists, pharmacy interns and pharmacy technicians, working longer than six continuous hours per day, be allowed during that time period to take a 30 minute, uninterrupted meal break and one additional uninterrupted 15 minute break.”

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. Work on that package of rule changes began several years earlier. The Board withdrew the rule after receiving feedback in 2010 from the Office of Governor. However, the Board remains convinced that this proposed rules part is both necessary and reasonable.

As noted in the Statement of Need and Reasonableness (SONAR) for this proposed rule:

“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.”

In hindsight, an additional observation should have been included. Based on routine pharmacy inspections conducted by Board Surveyors, and on spontaneous communications from pharmacists, it appears that staffing levels have been reduced in many pharmacies, in some cases to the point that a single pharmacist is on duty, with no overlap of pharmacists. It also appears that the frequency with which a pharmacist is required to work for greater than eight hours, as the only pharmacist on duty, is increasing.

Note that “staff”, as used in this document, refers to the Executive Director of the Board of Pharmacy unless otherwise noted.

SUMMARY AND ANALYSIS OF COMMENTS

As of December 14, 2015, the date on which the drafting of this document was completed, the Board had received official comments from approximately 80 individuals, businesses, health care systems and trade or professional associations. The total number of comments received was slightly larger because a few commenters submitted more than one document that contained comments. About a half dozen pharmacists talked directly with staff but declined to submit written comments after they were told that the comments are considered public documents.

Slightly more than half of the comments were in favor of adoption of the proposed rule. Nearly all comments in favor of the rule came from pharmacists. Many of the pharmacists were staff pharmacists but nearly a dozen were community pharmacy managers. A few comments in favor of the rule came from pharmacy technicians and one came from a physician who was the spouse of a pharmacist. A number of comments were considered to be in favor of the rules, even though the commenter expressed concerns. In those cases, the commenters clearly favored the concepts of allowing breaks and placing limits on the maximum number of continuous hours worked. However, they felt that the Board’s proposed rule did not go far enough.

In reviewing the comments in preparation for the drafting of this document, staff considered the commenter to be “against” adoption if concerns were expressed about the concepts of allowing breaks and limiting hours worked – even if the commenter did not explicitly state an opposition to the rule. In addition, many commenters considered to be against the rule stated opposition only to the breaks that would be required; not to the limitation on the maximum number of continuous hours worked. Nearly all of the comments considered to be against the adoption of part or all of the rule came from trade and professional associations, health care systems, pharmacy owners or pharmacy managers. For example, nine pharmacists (eight of whom were pharmacy managers) who work for a regional chain submitted comments in opposition to the rule. A technician working for that chain also submitted comments in opposition to the rule, as did the chain itself.

Five comments could not be classified as either “for” or “against” adoption. For example, a pharmacist licensed by the Board but currently working in Ohio expressed interest in the rule and
indicated he would be following its progress, but didn’t clearly state whether he supports or opposes it.

Comments in Support of the Proposed Rule

Some commenters expressed support for adoption of the proposed rule without elaborating on their reasons. Some commenters expressed support because, at least in part, they view breaks and a limit on continuous hours worked as employee benefits that pharmacists should be entitled to. Other commenters viewed breaks and a limit on continuous hours worked not so much as an employee entitlement, but as a necessity so that pharmacists can tend to basic “bodily needs” and not have their own health jeopardized by stress and fatigue. However, most commenters who support the rule expressed the opinion that, if adopted, the rule would increase safety for patients. Here are a few examples of comments in support of the rule. The first two comments are from pharmacists, while the third is from a physician who is the husband of a pharmacist.

“I have been a licensed pharmacist in this state since I graduated from pharmacy school in 1998. I am writing to show my support for this rule change. I spent the first 10 years of my career working in a grocery-store pharmacy that did not have any pharmacist overlap; the pharmacy was open 10 hours a day, and as the only pharmacist on duty, it was rare that I got an uninterrupted lunch break, and never got an additional 15-minute break. It has always been downright baffling to me that in a profession where errors can endanger the lives of others that employers do not place more emphasis on making sure pharmacy staff have adequate meal breaks and that extended working hours are avoided. Fatigue and hunger have a dramatic effect on my ability to concentrate on the task at hand, so I am very pleased that the Board is proposing this rule. This will be greatly beneficial to pharmacy staff and the general public, in my opinion. As pharmacists continue to take on advanced roles without additional staff being added (such as vaccinations and MTM services, which I do fully support), it is more important than ever that safe working conditions are maintained.”

“I have been a licensed pharmacist in the state of MN since 1995. In that time, I have endured countless retail shifts for which I have been denied the opportunity to eat a meal and/or use the restroom. I have had numerous concerns for patient safety while distracted by the physical signs of hunger; shakiness, lightheadedness, and sweating. I’ve been denied the opportunity to use the restroom, even during menses, for which on one devastating occasion, led to leaking a pool of blood all over the pharmacy floor. Public safety is without doubt at risk when pharmacists are not allowed time to satisfy basic human needs.”

“My wife is employed as a pharmacist for a major retailer and over a number of years I have had the opportunity to observe what I consider to be potentially unsafe workplace practices. Working consecutive 11 to 13 hour shifts with inadequate or nonexistent breaks, being forced to stand during this entire period is by no means conducive to the mental alertness necessary for the competent conduct of the pharmacist’s professional responsibilities. The medical literature is replete with objective documentation of the deleterious effects of prolonged physician work hours on clinical decision making. The
practicing pharmacist is at risk for suffering the same degradation of professional competence in such work situations. These are of course conditions that would be deemed unacceptable to the vast majority of the American workforce charged with far less demanding occupations. Thus, I would vigorously request the Board’s considering correction of this egregious and potentially unsafe situation.”

The commenters who support the concepts of breaks and limits on continuous hours worked, but who believe that the proposed rule does not go far enough, make arguments such as:

- The word “emergency” found in subpart 3 should be “given some definition or at least some examples to ensure that these new rules are not being intentionally skirted.”
- “Language regarding how these new rules will be enforced in practice and/or consequences for failure to adequately adopt these work place conditions also seems prudent at this time.”
- Pharmacy owners should be required to pay a pharmacist for all time worked, including time spent on duty above the number of hours on which the pharmacist’s salary is based. Otherwise pharmacists may feel compelled to work longer than 12 hours “off the clock” in order to keep up with unreasonable workloads. Pharmacy owners would be incentivized to adequately staff pharmacies if they had to pay pharmacists for all of the extra hours that pharmacists are now working without compensation.
- The rule should state employees working longer than four continuous hours be allowed one uninterrupted 15-minute break and that it be required for employees working at least six continuous hours per day to be given a 30-minute, uninterrupted meal break.
- Pharmacists should be required to take breaks, rather than just being allowed to take breaks. Otherwise, some pharmacists may feel compelled to not take breaks in order to keep up with a very busy workload. Alternatively, pharmacy owners may “punish” pharmacists who choose to take breaks by assigning them to shifts that are shorter than six hours or transferring them to undesirable stores.
- The rule should clarify that “consistent staffing issues such as scheduling, understaffing, low budgeting, or low prescription volume are not considered emergencies.” For example, deliberate failure by a hospital pharmacy to employ a sufficient number of pharmacists, so that the need for pharmacists to work double shifts occurs on a routine basis, should not be allowed.
- If the proposed rule is not adopted, then trying to get pharmacists included as non-exempt employees under the Fair Labor Standards Act should be considered.
- The rule should clarify that pharmacists either can or must take breaks away from the pharmacy.
- The rule should limit the maximum number of hours that a pharmacist, intern or technician can be required to work to eight, rather than 12.

Analysis and response to comments in support of the proposed rule

A few commenters seem to view breaks and a limit on continuous hours worked as employee benefits to which pharmacists should be entitled. However, as noted in the SONAR, the “Board is proposing to promulgate work condition rules that, in the judgement of the Board, will have a positive impact on patient safety.” The Board’s intent is not to confer employee benefits on
pharmacists, pharmacy interns or pharmacy technicians. The proposed rules may benefit these individuals in that they may be subject to less stress and there may be a positive impact on their own health, particularly if they have certain conditions such as diabetes or disorders of the back legs or feet. However, the Board’s primary mission is to promote, preserve, and protect the health, safety, and welfare of the general public.

Similarly, one commenter suggested that pharmacy owners should be required to pay a pharmacist for all time worked, including time spent on duty above the number of hours on which the pharmacist’s salary is based. Attempting to promulgate a rule addressing salaries or wages, and whether or not pharmacists should be paid for overtime hours, would most likely be an ultra vires act on the part of the Board. (i.e. the Board would be exceeding its statutory authority). The compensation of pharmacists does not directly relate to public safety.

In regards to the emergency exception found in subp. 3 of the proposed rule, there is no need to define the term “emergency.” As drafted, the rule creates an exception to the requirements of the rule for situations involving “immediate health risks for patients.” That phrase was included so that, for the purpose of this rule, emergencies must be related to immediate risks to the health of patients. In addition, the Board included this comment in the SONAR:

“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).”

Some comments suggest that the rule should clarify that pharmacists either can or must take breaks away from the pharmacy and that pharmacists be required to take breaks. Minn. Stats. §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.” By not requiring pharmacists to take breaks and allowing breaks to be taken either within the pharmacy or away from it, the Board is allowing for flexibility on the part of both the employees involved and the businesses that employ them.

**Comments Expressing Concern About and/or Opposition to the Rule**

Some commenters expressed opposition to the proposed rule without elaborating on their reasons. A few commenters expressed opposition to the rule based on their fear that pharmacy owners would somehow “override” the rules in ways that make things even worse – at least from the perspective of the commenters. For example, one commenter stated that the company for which he works has already changed schedules so that pharmacists work 6.5 hour shifts rather than 13 hour shifts, resulting in pharmacists working six days per week. (A district pharmacy manager for one of the chains told a Board Surveyor that the chain was splitting up 13 hour shifts in this manner – for safety reasons). Other commenters did not expressly state an opposition to the proposed rule but did express concerns or raise questions.
Comments primarily related to community pharmacy practice

The National Association of Chain Drug Stores (NACDS) and the Minnesota Retailers Association (MNRA) submitted comments which they state are on “behalf of the approximately 751 chain pharmacies operating in the State of Minnesota.” However, it is not clear from the document whether all chains operating in Minnesota were consulted about the comments that were submitted, consequently staff does not know if the comments are endorsed by all chains. The following is a summary of the comments submitted by NACDS and MNRA:

- “pharmacists are professionals and as professionals, they should be allowed the autonomy to determine the amount of time needed to adequately complete their workload and when to take breaks. Limiting a pharmacist’s working hours and requiring that breaks be uninterrupted may go against the professional judgment of a pharmacist for certain situations.”
- “we are in favor of rules that permit, but do not mandate, pharmacist meal and rest breaks, and allow pharmacists to choose when to take a meal or rest break. We also believe that the rules should allow pharmacy personnel to continue to perform the permitted responsibilities during the temporary absence of the pharmacist.”
- “Our pharmacies have dedicated pharmacists who routinely come in early to set up for the day and stay late to complete administrative tasks they were unable to complete while attending to patients’ needs. Our pharmacists possess an excellent work ethic and take these extra measures to ensure that patients receive timely service and the best care possible. Limiting the shift of a pharmacist to 12 hours will not decrease their workload. If the flexibility of coming in early and staying late is eliminated, the pressure of unfinished work may lead to more errors in dispensing, thus harming patients.”
- “the two breaks proposed under Subpart 2 may restrict patient access to the pharmacy and may therefore be detrimental to patient care” and “may lead to considerable confusion for our patients.”
- “As independently licensed health professionals, pharmacists have significant latitude within which to practice at the pharmacies where they are employed. Pharmacies must defer to the professional judgment of their pharmacists in matters such as the validity of controlled substance prescriptions, the appropriateness of a medication for a patient who reports relevant drug allergies; the type of information to convey to patients receiving risky medications, and other situations where weighing pros and cons requires professional expertise. Similarly, pharmacies must defer to pharmacists when deciding if and when to take breaks during their shifts and how long those breaks should be. Therefore, we encourage the Board to eliminate specifying both the lunch break and the additional 15 minute break from the Rule and leave these decisions to the pharmacists. However, if the Board is unwilling to eliminate both breaks, we request that the additional 15 minute uninterrupted break be removed so as to avoid harm and disruption of care to patients. Additionally, we requests that the 6 hour shift criteria be amended to 9 hours.”
- NACDS and MNRA request some clarifications from the Board regarding this Rule and suggest the following alternative language:
The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions: (a) The pharmacist shall be considered present and on duty during any such meal break and must provide adequate notice to patients assuring that a pharmacist is available on the premises for consultation regarding emergency matters upon request during a meal break. (b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered. (c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break. (d) Nothing in this section shall prevent the pharmacy from being closed to the public during a ½ hour meal break.

A representative of the Walgreen Company submitted the following comment: “The Walgreen Company has been actively engaged in the discussion and proposed alternative language in the recently submitted comments from the Minnesota Retailers Association and the National Association of Chain Drug Stores related to the proposed new rule section 6800.2160. Walgreens stands in support of these joint comments, alternative language and background provided in the submitted comments.”

A representative of CVS Health submitted comments that are similar to the comments submitted by NACDS and MNRA. For example, “CVS Health strongly believes that a pharmacist should continue to manage their own work schedule and not rely on a Board rule to dictate work conditions.” The recommendations of CVS Health for alternative language is identical to the alternative language submitted by NACDS and MNRA, except that CVS Health suggests that employees should not be entitled to lunch breaks unless they work at least ten continuous hours.

A representative of Thrifty-White Pharmacy submitted comments that are, in part, similar to the comments submitted by NACDS and MNRA. The e-mail submitted by the representative expresses the support of Thrifty-White for the alternative language proposed by NACDS and MNRA. However, the comments submitted make other suggestions as well:

- “State and federal laws and regulations already place requirements on employers for meals and rest periods for hourly employees. We suggest that only salaried technicians, interns, and pharmacists be covered under this regulation.”
- Consider dropping the requirement for a second, 15-minute break.
- Employees should not be entitled to breaks unless they work at least ten continuous hours.
• The Board should develop a “valid tool” to measure the impact of the rule on medication errors and include a sunset period for the rule, affording the Board the opportunity to evaluate whether or not the permanently adopt the rule.

The Minnesota Grocers Association, which represents grocery stores that operate pharmacies, expressed the following concerns:

• “Scheduling consistent pharmacy hours will be near impossible if different pharmacists choose to take different breaks at different times on different days each week. This will cause customer confusion and a lack of schedule continuity. Regardless of whether the pharmacist would like to voluntarily break or not, in order to provide consistency for patients about when the pharmacy is open or closed, pharmacies will likely have to close for 30 minutes and for 15 minutes every day.”
• If only one pharmacist is on duty and chooses to take both breaks at some time during the day, the pharmacy will have to unexpectedly close business to customers and stop all pharmacy operations because technicians would not be monitored during the uninterrupted break time. An uninterrupted break would mean that a pharmacy must close to business during the breaks which would substantially harm business for smaller and independent pharmacies that only have one pharmacist on duty.”
• “Forcing retail pharmacies to close down operation multiple times in one day is bad for patient access and bad for customer service.”

The individual pharmacists and pharmacy technicians who work in community pharmacies and who submitted comments in opposition to the rule, either gave no basis for their opposition or expressed some of the same concerns given by the trade associations and pharmacy owners mentioned above.

Analysis and response to comments primarily related to community pharmacy practice

The comments suggesting that “pharmacists are professionals and as professionals, they should be allowed the autonomy to determine the amount of time needed to adequately complete their workload and when to take breaks” are well-taken. Pharmacists should, indeed, have that autonomy. However, it is not at all clear that pharmacists are actually allowed that autonomy by their employers, at least not as a practical matter. The understanding of staff, based on the observations made by Board of Pharmacy Surveyors during inspections and on conversations with pharmacists, is that it is rare for the pharmacist-in-charge (PIC) of a pharmacy to have the authority to set staffing levels, determine the hours that a pharmacy is open, or to close a pharmacy so that staff can takes breaks. (Unless, of course, the PIC owns the pharmacy). Some of the comments submitted in support of the rules came from pharmacists who state that they have been denied breaks or that breaks are inadequate or non-existent. Those comments echo remarks that have been made to staff, including the Pharmacy Surveyors and the Executive Director, by pharmacists.

Even the statement that pharmacies “must defer to the professional judgment of their pharmacists in matters such as the validity of controlled substance prescriptions,” which touches upon clinical decision making, may not be entirely accurate. After some pharmacy chains reached settlements
with the U.S. Drug Enforcement Administration (DEA) that required them to pay civil penalties of up to $80 million, many chains established internal policies and procedures that pharmacists must follow when filling prescriptions for controlled substances. The policies that staff has seen do include statements that pharmacists may use their professional judgment for some, but not all, of the procedures that must be followed. This is not meant to be a criticism of those policies. The controlled substance policies that staff has seen contain procedures that pharmacist should follow when they are considering whether or not to dispense controlled substances. However, a policy that contains the statement that pharmacists who fail to meet their corresponding responsibility obligations may be disciplined, up to and including termination, might have an impact on how pharmacists exercise their professional judgment.

The comment that seems to suggest that pharmacists routinely and voluntarily “come in early to set up for the day and stay late to complete administrative tasks they were unable to complete while attending to patients’ needs” solely because they have excellent work ethics is debatable. As health care professionals, most pharmacists do have good work ethics and they do end up taking those extra measures - because they are concerned for the welfare of their patients. However, given the cutbacks in staffing that have been reported to and observed by the Pharmacy Surveyors, many pharmacists may feel they have no choice but to work those additional hours. Pharmacists have told the Pharmacy Surveyors and the Executive Director that they routinely have to work one or more additional hours every shift, without pay, in order to keep up with their workload. The tasks that they perform when they work these additional hours are not always “administrative.” For example, one of the most common duties that pharmacists appear to be performing when working beyond the end of their shift is quality assurance, which is not an administrative task.

Several of the comments suggest increasing the minimum amount of time that an individual would have to work before getting any type of break from six to either nine or ten hours. The Board is proposing this rule due to concern that requiring pharmacy staff to work long hours without adequate breaks poses a risk to the public. If the Board adopted this suggestion, pharmacy staff members might be required to work as long as ten hours with no break. That is not much better than having them work 12 hours without a break.

Some of the comments seem to mistakenly assume that the rule, as proposed, would require pharmacies to close when pharmacists take breaks. As noted in the SONAR, the rule does not require pharmacies to close in order for pharmacists to take breaks – it simply requires that pharmacist breaks be uninterrupted, which could be accomplished by means other than closing the pharmacy. However, the Executive Director recommends that additional language be added to the rule to clarify that a pharmacy does not have to be closed when a pharmacist is on break. (See recommend changes to the proposed rule language at the end of this document).

A comment from NACDS and MNRA states: “we are in favor of rules that permit, but do not mandate, pharmacist meal and rest breaks, and allow pharmacists to choose when to take a meal or rest break.” The proposed rule, as originally drafted, does permit pharmacist meal and rest breaks. It does not mandate that pharmacists take breaks, it allows them to. It does prohibit pharmacies from denying them breaks, unless an emergency exists.
Several comments suggest that the rule should allow pharmacy personnel to continue to perform the permitted responsibilities during the temporary absence of the pharmacist. As pointed out in the SONAR, the “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.”

Several comments suggest dropping the additional 15 minute break. Removing the additional 15 minute break, without having some sort of provision requiring at least restroom breaks, seems ill-advised. Staff recommends that if the additional 15 minute break is removed, language should be included that affords pharmacy staff adequate time from work, within each four consecutive hours of work, to utilize the nearest convenient restroom. (See recommend changes to the proposed rule language at the end of this document).

One comment states: “State and federal laws and regulations already place requirements on employers for meals and rest periods for hourly employees. We suggest that only salaried technicians, interns, and pharmacists be covered under this regulation.” The federal Fair Labor Standards Act (FLSA) does not require employers to provide rest or lunch breaks. The Minnesota Fair Labor Standards Act (§§177.251 – 177.35) (MFLSA) requires an employer to allow each non-exempt employee adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom. It also requires an employer to permit a non-exempt employee who is working for eight or more consecutive hours sufficient time to eat a meal. The purpose of the state and federal Fair Labor Standards Act is to protect employees. However, the Board is proposing work condition rules in order to protect the public from errors that may occur when pharmacy staff are required to work long hours without breaks. There is no reason to believe that pharmacy technicians and interns are any less susceptible than pharmacists to the problems that working under such conditions can cause.

Comments primarily related to hospital pharmacy practice

The Minnesota Hospital Association (MHA) submitted comments on behalf of its 143 members. The submitted document states that these members were consulted and that many provided feedback to MHA about the Board’s proposed rule. However, staff does not know whether all of the members were consulted. The following are the major points made by MHA:

- MHA members do not dispute that “pharmacists and their staff perform critical functions in the overall care delivery process, otherwise avoidable mistakes in these functions can cause significant harm to patients and/or decrease the effectiveness of corresponding treatments, and one step in avoiding such harm or suboptimal outcomes is being focused and alert.”
- Given that “existing laws, regulations and restrictions that already govern many of the issues and proposals contained in the potential rule, some members questioned the need for additional state regulations in light of the existing, long-standing and well understood federal law.”
• Comments from MHA members indicate concern about “the potential rule’s lack of clear recognition of the need to maintain flexibility and to make adjustments as needed to best serve patients.”
• “Some members requested modifications to the potential rule to allow a pharmacist to work up to 16 hours in cases when another pharmacist calls in sick and the one on duty needs to work a double shift to maintain access to medications for patients.”
• “Many pharmacies in rural communities are staffed with one pharmacist and one technician during weekend and evening shifts. The potential rule would make this staffing model impossible or extremely challenging to maintain.”
• “Given the 24/7/365 nature of the services our members provide, there are . . . variations in the level of activity from one time of day to another or even one hour to another. These volume fluctuations are unpredictable and . . . it is unavoidable that there will be spikes in demand or urgent needs for medications at unexpected times. As the potential rule currently reads, it would appear that hospital pharmacies will need to close and deny access to medications or medication adjustments in order to comply with the rigid break mandates.”
• “Just as the underlying goals of the potential rule are to advance safer care for patients, the Board should consider and adjust any future rule drafting to recognize that closing a hospital pharmacy even for 30 minutes can pose significant risks to certain patients.”
• MHA acknowledges that the draft rule contains exceptions for emergency situations, but notes that “emergency” isn’t defined and opines that: “the exception for emergency situations is extremely narrow given that once a pharmacist begins a break it has to be uninterrupted, meaning that s/he will not be aware of the pharmacy receiving a request for pharmaceuticals or other service on an emergency basis.” MHA encourages the Board to “further clarify what constitutes an emergency and explicitly recognize that breaks are subject to interruption to rule out the existence of or respond appropriately to emergency situations.”

The Minnesota Society of Health-System Pharmacists submitted comments that expressed concerns or raised questions about the proposed rule. The following is a summary of the concerns and questions:

• “The proposed work condition restrictions will limit patient access to pharmacy services and pharmacy staff participation on the patient care team. Patient safety is improved when pharmacy services and pharmacy staff are readily available.”
• “The CMS Conditions of Participation (CoP) for Pharmaceutical Services stipulate that hospital policies and procedures for pharmaceutical services must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice issued by nationally recognized organizations such as the American Society of Health-System Pharmacists (ASHP). The American Society of Health-System Pharmacists has gone on record with a Position Statement on Pharmacy Staff Fatigue and Medication Errors (0504). The position of ASHP is to oppose state or federal laws or regulations that mandate or restrict work hours for pharmacy staff. ASHP has also published duty-hour requirements for pharmacy residents (licensed pharmacists) that specify duty hours must be limited to 80 hours per week averaged over a four-week period. The proposed
Minnesota work conditions rule is inconsistent with accepted national standards of practice in health-system pharmacy.”

- The proposed rule is “inconsistent with Minnesota law as the Minnesota Fair Labor Standards Act does not set a maximum number of hours that an employee can be required to work during a 24-hour period of time. We believe hospitals and health-systems should continue to follow current MN law and their local policies on work conditions to assure patient safety.”

- “The requirement for ‘uninterrupted’ breaks would limit patient access to pharmacy services and pharmacy staff participation on the patient care team” and “It is simply not feasible to close a 24-hour inpatient pharmacy department to allow a pharmacist to take an uninterrupted break. Further, even if the hospital was large enough to staff at least two pharmacists at all times, if one is on an uninterrupted break it is possible the other pharmacist may need to attend an emergent patient code or other emergent care situation necessitating their collaboration with the patient care team.”

- “We acknowledge that the emergency exception can be applied to minimize immediate health risks for patients, but we believe that further definition may be necessary. For example, there are emergency situations, such as a sick call that cannot be filled, which may require a staff member to work more than 12 hours. However, there are also work situations in which a pharmacy staff member may choose to sign up for additional open shifts which will put them over the 12 hour limit. These open shifts may occur due to unplanned medical leaves of absence, personal leaves of absence, unfilled or open positions in recruitment and other scheduling situations.”

- “This rule also does not address the employer’s or employee’s responsibility to enforce the 12 hour limit for employees working multiple jobs.”

The Mayo Clinic Midwest Pharmacy Leadership Group submitted comments that expressed concerns or raised questions about the proposed rule language. It is not clear from the documented submitted if the concerns and questions were also submitted on behalf of Mayo Clinic itself. The following is a summary of the concerns and questions:

- Does “pharmacist” include all individuals with a license to practice pharmacy regardless of their role? Indicating “dispensing pharmacists” or “pharmacists providing direct patient care” would provide clarification if the intent is to only include such pharmacists.

- The American Society of Health-System Pharmacists (ASHP) has well-defined requirements specified for pharmacy residencies that address maximum duty-period lengths. Those requirements are “in conflict” with the Board’s proposed rule.

- A pharmacist may be on-call in case a patient need arises or a co-worker calls in sick. Would on-call hours be included in the 12-hour limit, or would they be handled under the emergency exceptions?

- The statement “12 continuous hours, inclusive of breaks” appears to contradict itself. “If there is an uninterrupted break then the work hours would not be continuous.”

- The rule does not address the situation where a pharmacist works a full 8-10 hour day and then moonlights at another pharmacy. Is it the intent of the Board to hold individual pharmacists accountable for compliance with the proposed rule?

- There are situations where pharmacists or technicians voluntarily pick up additional shifts, resulting in them working longer than 12 hours.


- In a small hospital or on the night-shift, the pharmacy can’t close down for a lunch break – nor can a pharmacist be guaranteed uninterrupted breaks – given the unpredictable need for stat patient medications. (emphasis added)
- If a pharmacy has to shut down for a lunch break, the work will continue to accumulate, resulting in more stress for staff and interruptions for customers.
- While other states have workload restrictions for pharmacists, there are no such restrictions for other healthcare professionals in Minnesota.

A representative of Allina Health submitted comments that expressed concerns and asked questions about the proposed rules. The following is a summary of the concerns and questions:

- Allina Health “could not support language that would mandate a maximum twelve hour shift.”
- Staff sometimes voluntarily agree to work double shifts. However, Allina does not require its staff to work double shifts. In the event that nobody volunteers to work an extra shift, the least senior staff member is assigned to work the shift, in accordance with union contracts. It is unclear if the emergency exceptions of the proposed rule would cover this situation.
- Uninterrupted breaks would negatively impact patient care because pharmacies would have to close in order for staff to have uninterrupted breaks.
- Since the proposed rule does not have a definition of the word “emergency,” Allina Health has concerns over how the emergency exceptions in subp. 3 would be “mandated and executed.” Specific situations mentioned were staff that voluntarily pick up additional hours and individuals who moonlight for other employers. In addition to staff calling in sick for shifts, other situations mentioned include: unplanned medical leaves, maternity leaves, and vacation leaves.
- The comments mention the section of the Board’s SONAR that references the federal and state Fair Labor Standards Acts (FSLA) and opines that, since the state FSLA applies to “non-exempt” employees, the Board erred in stating that the state FSLA does not apply to pharmacists.
- Well-controlled studies that demonstrate an association between mandated breaks and a decrease in errors, specific to pharmacy, are virtually non-existent. The Institute for Safe Medicine Practices suggests multiple strategies to minimize fatigue beyond rest and meal breaks. “Allina Health maintains that care for oneself is the professional accountability of the staff in order to care for patients.”

The Essentia Health Corporate Director of Pharmacy submitted comments that expressed significant concerns regarding the proposed rules. The comments also made recommendations for changes to the proposed rule. The concerns and proposed changes are as follows:

- “Additional guidance is necessary regarding staff requests to volunteer to work additional hours available on the work schedule when this would result in staff working greater than 12 continuous hours.”
- “Essentia Health is seeking documentation from the Minnesota Board of Pharmacy that is specific to pharmacy practice that relates hours worked to error rate. This would include specifically a review of errors made in a 12 hour work day as well as a 16 hour work day
and would include information on both technicians as well as pharmacists.” And “Essentia Health requests that the Board of Pharmacy commission a practice based study on error rates immediately following the re-opening of a pharmacy pursuant to a break as opposed to other periods of time throughout a work shift or day in both the ambulatory and acute care settings.”

- “Are there other elements related to patient safety that could be evaluated for providing guidance on pharmacy practice? This might include workload volumes and interruptions as opposed to only the number of hours worked.”
- “It is our recommendation that employees not work greater than 16 continuous hours.”
- “It is difficult to define a standard 30 minute uninterrupted lunch time for pharmacists and or technicians in smaller acute care hospitals where a limited number of staff work in the department . . . We are concerned that this uninterrupted break may adversely affect patient care if a pharmacist is unavailable for urgent situations that occur during this time period.”
- “We have concerns regarding the volume of work that would accumulate during the uninterrupted break time and therefore create a bottle-neck of patient care needs that could result in patient delay or therapy or increase the risk of error.”
- “It is our concern that patients who may experience a delay in receiving their medication in ambulatory pharmacy settings due to the uninterrupted break may result in reduced patient adherence which could negatively impact patient outcomes.”
- “Additional guidance from the Minnesota Board of Pharmacy is necessary to further define emergency specifically - and are there time parameters around ‘last moment’?”

The individual pharmacists and pharmacy technicians who worked in hospitals or health care systems who submitted comments in opposition to the rule, either gave no basis for their opposition of expressed some of the same concerns given by the associations and health care systems mentioned above.

Analysis and response to comments primarily related to hospital pharmacy practice

Staff concurs with the MHA statement: “pharmacists and their staff perform critical functions in the overall care delivery process, otherwise avoidable mistakes in these functions can cause significant harm to patients and/or decrease the effectiveness of corresponding treatments, and one step in avoiding such harm or suboptimal outcomes is being focused and alert.” That is why the Board is proposing work condition rules.

In regards to the comments concerning the federal and state FLSA, please see the third paragraph on page 10. The Board did not err when it stated that the MFSLA does not apply to pharmacists. Pharmacists are exempt from the provisions of that act. Consequently, for pharmacists, adoption by the Board of its proposed work conditions rule would have no effects that were cumulative with the MFSLA. The Board is not proposing that its work condition rules replace the requirements of the MFSLA for non-exempt employees such as pharmacy technicians. The MFSLA already requires employers to at least provide restroom breaks to non-exempt employees during each four hour period of work. Under the Board’s proposed rule, as originally drafted, pharmacy employers providing 15 minute breaks to non-exempt employees 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. However, staff recommends that if the additional 15 minute break is removed, language should be included that affords pharmacy staff adequate time from work, within each four consecutive hours of work, to utilize the nearest convenient restroom. That requirement is taken directly from the MFLSA. (See recommend changes to the proposed rule language at the end of this document).

One comment suggested “modifications to the potential rule to allow a pharmacist to work up to 16 hours in cases when another pharmacist calls in sick and the one on duty needs to work a double shift to maintain access to medications for patients.” As noted in the SONAR, that situation would be covered by the exceptions for emergency subpart.

Although the rule, as originally drafted, actually did not prohibit the interruption of a pharmacist’s break in the event of an emergency, staff recommends changes to clarify that breaks can be interrupted when an emergency occurs. (See recommend changes to the proposed rule language at the end of this document).

Some of the comments seem to mistakenly assume that the rule, as originally proposed, would require pharmacies to close when pharmacists take breaks. As noted in the SONAR, the rule does not require pharmacies to close in order for pharmacists to take breaks – it simply requires that pharmacist breaks be uninterrupted, which could be accomplished by means other than closing the pharmacy. However, staff recommends that additional language be added to the proposed rule to clarify that a pharmacy does not have to be closed when a pharmacist is on break. (See recommend changes to the proposed rule language at the end of this document).

The rule does not prohibit pharmacists from working longer than 12 consecutive hours, nor does it require pharmacy employers to monitor work that a pharmacist may perform for another employer. The Board already has statutes and rules in place that allow it to discipline licensees for engaging 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 harms or could harm a patient. (See Minn. Stats. §151.071, sub. 2(9) and MN Rules 6800.2250, subp. 1(K)). The Board evaluates every complaint on a case-by-case basis, based on the facts uncovered during an investigation, but is possible that the Board could hold a pharmacist accountable for practice deficiencies caused by working repeated shifts in excess of twelve hours. However, it seems unlikely that very many pharmacists would actually engage in such behavior.

The Center for Medicare and Medicaid Services (CMS) Conditions of Participation for Pharmaceutical Services (CoP) state, in part, that “pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations. Agencies and organizations could include FDA, NIH, American Society of Health-System Pharmacists, etc.” The CoP do not require a hospital pharmacy to follow every standard or recommendation made by every professional organization. At any rate, the position of ASHP to oppose state or federal laws or regulations that mandate or
restrict work hours for pharmacy staff is not a “professional principle” or practice standard – it is a policy position.

The Board’s proposed rule is not in conflict with the ASHP requirements for pharmacy residencies that address maximum duty-period lengths. Those requirements state that duty hours *must be limited* to 80 hours per week, averaged over a four-week period, inclusive of all inhouse call activities and all moonlighting. They *do not* state that pharmacy residency programs must require residents to work 80 hours per week – or that they must work more than 12 hours per day. Staff has not conducted research to determine how ASHP developed its requirements for duty hours, but wonders how 80 per week was selected. Given that residents must be allowed to have one duty free day per week, working 80 hours per week equates to working in excess of 13 hours per day, six days per week.

Several commenters suggest that the Board should study the impact that the proposed rule would have on error rates. That is not a viable option. The Board cannot compel its licensees to provide data on errors – not even aggregate data on error rates. In fact, when the Board has requested error data from certain licensees, they have refused to provide the data, claiming that: 1) the data was proprietary; and 2) the data was protected under the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA). That latter claim, at least, is probably correct because the PSQIA states that “patient safety work product” is not subject to subpoena, discovery, and disclosure pursuant to federal or state Freedom of Information Acts. Nor can it be admitted as evidence in civil, criminal or administrative proceedings; nor used in a professional disciplinary proceeding. It seems likely that most pharmacy owners would not agree to voluntarily provide such data. In addition, pharmacy owners may not even have historical error data that is sufficiently detailed to allow an assessment of when errors occur in relation to the length of time that a pharmacist had worked prior to an error.

Furthermore, as noted in the SONAR, data does exist that shows that other health care professionals who work greater than 12.5 hour shifts are at significantly increased risk of making a medical error. There is no reason to believe that pharmacists, pharmacist interns and technicians are somehow more immune to the effects of fatigue and stress. The SONAR also provides information about court cases involving pharmacy errors in which working long shifts was determines to be a contributing factor to an error.

**Comments primarily related to long-term care pharmacy practice**

A representative of Merwin LTC Pharmacy expressing the following concerns:

- “No other health care provider in Minnesota has regulatory requirements imposing limitations on hours worked or requirements for rest periods."
- Due to Minnesota Department of Health rules, long-term care pharmacies “face real deadlines related to the processing and deliveries of prescriptions.”
- The proposed rule does not specify that a pharmacy must close in order for a pharmacist to take an uninterrupted break and it allows for exceptions for emergency situations. However, nurses at the facilities serviced by a LTC pharmacy would consider timely access to a pharmacist to be an “emergency.”
• Breaks may actually increase stress because pharmacists would have to play “catch up” for the “imposed” break time, rather than taking a break when time allows.
• Patients in LTC facilities are often higher acuity patients that may require changes in prescriptions on a frequent basis. Pharmacists need to be available to authorize the release of a drug from an emergency kit or from an automated drug distribution system. Nurses don’t have the ability to override these systems to obtain an emergently needed drug. Consequently, the proposed rule’s requirement that pharmacists be allowed to take an uninterrupted break could result in harm to patients.
• Currently, pharmacists take breaks when time allows and/or when it is needed. “An imposed mandatory break time will also limit the ability of an employee to self-assess their need for a break and to step away when they need to, as it will be a prescribed break time.”
• If the Board is committed to moving forward, consider:
  o Make the required breaks interruptible in “certain situations,” such as hospital and long-term care pharmacies.
  o Consider dropping the requirement for a second 15 minute break period.
  o Consider making the break requirement apply only to individuals who work ten or longer hours.

Analysis and response to comments primarily related to long-term care pharmacy practice

For the reasons mentioned in other sections, staff is recommending changes that clarify the pharmacists breaks can be interrupted in the case of emergencies. In addition, staff is recommending that the language requiring a second, uninterrupted break, be modified to align with the MFLSA requirement that individuals be allowed a reasonable period of time during each four hours worked to use a restroom. (See below).

The statement that pharmacists need to be available to authorize the release of a drug from an emergency kit is not true. MN Rules 6800.6700 does not require pharmacists to review orders for drugs that are removed from an emergency kit. The drugs in an emergency kit are meant to be used in emergency situations, where waiting even minutes for a pharmacist review could result in serious consequences for the patient, up to and including death.

The statement that implies that pharmacists need to be available to authorize the release of a drug from an automated drug distribution system (ADDS) when the drug needs to be given “urgently” is also not true. To the contrary, Minn. Stats §151.58, subd. 5(d) states (emphasis added): “access to drugs when a pharmacist has not reviewed and approved the prescription drug order is permitted only when a formal and written decision to allow such access is issued by the pharmacy and the therapeutics committee or its equivalent. The committee must specify the patient care circumstances in which such access is allowed, the drugs that can be accessed, and the staff that are allowed to access the drugs.” Clearly, drug can be removed from an ADDS without the need for a pharmacist to authorize the removal, provided that the relevant facility committee allows it.
The statement that, due to Minnesota Department of Health rules, long-term care pharmacies “face real deadlines related to the processing and deliveries of prescriptions” is essentially true. However, staff’s understanding is that the Minnesota Department of Health, Health Regulation Division, under a cooperative agreement with the Centers for Medicare and Medicaid (CMS), is responsible for ensuring that facilities accepting Medicare and Medicaid payment for services provided to program beneficiaries meet federal regulations and certification rules. The CMS State Operations Manual, Appendix PP (Guidance to Surveyors for Long Term Care Facilities) states, in relation to timing errors (emphasis NOT added, it is in the original document):

Count a wrong time error if the medication is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT’S HEALTH AND SAFETY.

If delay in administering a medication would lead to “resident discomfort or jeopardize the resident’s health and safety,” that would constitute an “emergency” for the purpose of the proposed rule and a pharmacist’s break could therefore be interrupted. In addition, staff understands that specialty long-term care pharmacies typically work with LTC facilities and prescribers so that orders for medications that are not needed on an urgent or emergency basis are written with administration times that take into account the length of time it will take for the pharmacy to get the medication delivered to the facility.

RECOMMENDATIONS

Based on the comments received, and assuming that comments heard at the Board’s December 16, 2015 meeting are not substantially different than the written comments received to date, the Board’s Executive Director recommends that the proposed rule language be amended as follows:

6800.2150. PHARMACIST ON DUTY.

A. Subpart 1. REQUIREMENT TO HAVE A PHARMACIST ON DUTY. A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except that for brief absences of the pharmacist arising out of and in the course of pharmacy practice, are allowable;

B. Subp. 2. LIMITING ACCESS TO PHARMACIES. When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as
provided in part 6800.7530. In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period.

6800.2160 PHARMACY WORK CONDITIONS.

Subpart 1. Limitation on continuous hours worked. A pharmacy licensed under Minnesota Statutes §151.19, subd. 1, which is located within the state of Minnesota, shall not require a pharmacist, pharmacist-intern or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subpart 2.

Subp. 2. Requirements for breaks. (a) A pharmacist, pharmacist-intern or pharmacy technician working longer than six continuous hours per day shall be allowed during that time period to take a 30 minute, uninterrupted meal break, and one additional uninterrupted 15 minute break.

(b) A pharmacist, pharmacist-intern or pharmacy technician shall be allowed adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.

(c) A pharmacy may, but is not required to, close when a pharmacist is on a meal break. If the pharmacy does not close, the pharmacist shall remain within the licensed pharmacy in order to be available for emergencies. If the licensed pharmacy comprises the entire establishment in which the dispensing area is located, the pharmacist shall remain in close proximity to the dispensing area. In addition, the following apply:
(1) Pharmacy technicians, pharmacist-interns and other supportive staff authorized by the pharmacist on duty may continue to perform duties as delineated by that pharmacist while the pharmacist is on break;

(2) No duties reserved to pharmacists and pharmacist-interns under any part of this chapter, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians; and

(3) Only prescriptions that have been certified by a pharmacist, as required by part 6800.3100, may be dispensed while the pharmacist is on break; except that prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may not be dispensed while the pharmacist is on break.

(d) In pharmacies staffed by two or more pharmacists, the pharmacists shall stagger their breaks so that at least one pharmacist remains on duty at all times that the pharmacy remains open for the transaction of business.

Subp. 3. Exceptions for emergencies. Subp. 1 and subp. 2, paragraph (a) 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 meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.
<table>
<thead>
<tr>
<th>Name and address</th>
<th>Organization represented (if any)</th>
<th>Email</th>
<th>Telephone</th>
<th>Speak at hearing</th>
<th>Receive ALJ's report</th>
<th>Receive notice of filing with Secretary of State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cody Wiberg, MN Board of Pharmacy,</td>
<td>Board of Pharmacy</td>
<td><a href="mailto:cody.wiberg@state.mn.us">cody.wiberg@state.mn.us</a></td>
<td>(651) 201-2830</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2824 University Ave SE #530, Mpls, MN 55414</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karen Berglund, 55902</td>
<td>Mayo Clinic</td>
<td><a href="mailto:berglund.karen@mayo.edu">berglund.karen@mayo.edu</a></td>
<td>(507) 244-6831</td>
<td>Y</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Joel Kurzman, 2550 Crawford Ave., St Paul, MN 55101</td>
<td>NACDS</td>
<td><a href="mailto:jakuzman@nacds.org">jakuzman@nacds.org</a></td>
<td>(767) 905-0655</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Bruce Myron, 4600 Essentis Ave, St Paul, MN 55104</td>
<td>Minnesota Hospital Foundation</td>
<td><a href="mailto:bruce_myrton@ug.essentis.com">bruce_myrton@ug.essentis.com</a></td>
<td>(612) 223-2391</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Michelle Alvay, 575 Twin Oaks Circle, Hudson, WI 53016</td>
<td>Walgreens</td>
<td><a href="mailto:michelle.alvay@walgreens.com">michelle.alvay@walgreens.com</a></td>
<td>(608) 251-0508</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Jeff Lindo, 207/208/210 Dr. New Alexandria Ave,</td>
<td></td>
<td>jefflindo@com</td>
<td>(507) 853-8612</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Amy Panin, 240 St Paul St, Apt 350, St Paul, MN 55102</td>
<td>CVS</td>
<td><a href="mailto:amypanin@gmail.com">amypanin@gmail.com</a></td>
<td>(612) 469-3458</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mary Foss, 3300 3rd Ave. N, N. Minneapolis, MN 55403</td>
<td>North Memorial Hospital</td>
<td><a href="mailto:fess@mn.northmemorial.edu">fess@mn.northmemorial.edu</a></td>
<td>(612) 207-1299</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Samantha Saunders, 1516 N. Inverness Ave. W, Chicago, IL 60614</td>
<td>Board of Pharmacy (Public Member)</td>
<td><a href="mailto:javierg@ilchamps.org">javierg@ilchamps.org</a></td>
<td>773-306-892</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Andrew Belna, 6809 Virginia Ave S, Eden Prairie, MN 55344</td>
<td>Board of Pharmacy (Public Member)</td>
<td><a href="mailto:andrew.belna@express-scripts.com">andrew.belna@express-scripts.com</a></td>
<td>(952) 837-7410</td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RULE HEARING REGISTER

Docket No: 10-9026-33753

Hearing Date: 10/19/2016

Check here if you wish to:

<table>
<thead>
<tr>
<th>Name and address</th>
<th>Organization represented (if any)</th>
<th>Email</th>
<th>Telephone</th>
<th>Speak at hearing?</th>
<th>ALJ's report</th>
<th>Notice of filing with Secretary of State</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gary Clausen</td>
<td>Maple Grant</td>
<td><a href="mailto:Clausen@vmin.net">Clausen@vmin.net</a></td>
<td>763-2360</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>Jessica Andrus</td>
<td>Rosemann</td>
<td><a href="mailto:androff@min.nm.com">androff@min.nm.com</a></td>
<td>651-329-3535</td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
<tr>
<td>Mary Phipps</td>
<td>St. Cloud, MN</td>
<td>Board of Pharmacy</td>
<td><a href="mailto:phipps@costume.com">phipps@costume.com</a></td>
<td>☑</td>
<td></td>
<td>☑</td>
</tr>
</tbody>
</table>
October 17, 2016

The Honorable Perry Wilson, Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street
PO Box 64620
Saint Paul, MN  55164-0620

Dear Judge Wilson:

On behalf of our members, we are reaching out to express concern over the proposed work condition rule from the Board of Pharmacy. We have two primary concerns as it relates to pharmacists. We are fearful that the rule, which mandates the availability of an uninterrupted 30-minute meal break followed by an additional uninterrupted 15-minute break at some later time if a pharmacist works more than six continuous hours, will produce the following problems:

- Under the proposed rule, pharmacies would be required to either shut down or employ a second pharmacist to be available during the mandated meal and additional break. This mandate would be especially cumbersome to locations in Greater Minnesota where there are already challenges to adequately staff pharmacies to meet the medical needs of the communities they serve.

- The rule potentially requires a pharmacist to take a break at the expense of their patient. It assumes that a patient has the time and flexibility to return at a later period for consultation and service. The unintended consequence could result in a health risk for that patient. This rule eliminates the flexibility to balance the needs and care of your patients versus timely breaks.

In addition, the proposed new rules would limit patient accessibility to the pharmacy and greatly disrupt pharmacy scheduling operations. The result of these new rules could mean a drop in patient care and a rise in customer dissatisfaction.

Retail pharmacies provide flexible work environments for pharmacists that maximize customer interaction with effective and safe patient care. Current practices already provide rest time opportunities for pharmacists. Often times during the daily ebb and flow of business, pharmacists are afforded opportunities to rest or take breaks at their own discretion. Forcing retail pharmacies to close down operation multiple times in one day is bad for patient access and bad for customer service.

Please strongly consider these concerns while moving forward in the rule making process.

Sincerely,

Jamie Pfuhl
President
Minnesota Grocers Association

OAH-046
Introduction. This rulemaking hearing is being conducted by an Administrative Law Judge from the Minnesota Office of Administrative Hearings. The Office is an independent agency of state government and is independent of the agency proposing to adopt rules today.

This hearing is part of the process by which agency rules are adopted under the Minnesota Administrative Procedure Act. During this rulemaking proceeding, the agency must document its statutory authority to adopt the proposed rule, demonstrate that it has fulfilled all relevant legal and procedural requirements of law, and demonstrate the need for and reasonableness of each portion of the proposed rule with an affirmative presentation of facts.

Agenda.

1. Explanation of hearing procedure by Administrative Law Judge.
2. Submission of written exhibits by the agency.
3. Oral presentation by agency.
4. Questions and statements by the public.

If you have a time problem today, please notify the Administrative Law Judge, who will make every effort to accommodate you.

Hearing Procedure.

1. Everyone attending the hearing is requested to sign the hearing register to ensure an accurate record of the number of people in attendance. The hearing register is located on the registration table. If you wish to speak, you must sign the register.

2. If you wish to make an oral statement, please place a check mark in the appropriate column on the hearing register. When you go to the designated speaker’s area, please state and spell your name, address, and the interest or group you represent, if any. It is very helpful if you can identify the specific rule part you are addressing either by rule number (e.g. Minn. R. 1400.2200), or by page number. Any speaker may ask questions of the agency panel and, in turn, may be questioned by the agency panel, the Administrative Law Judge, or other persons. The Administrative Law Judge may limit repetitive or immaterial statements or questioning. If you are able to simply identify with the remarks of a prior speaker, please do so.

3. The hearing is being recorded on tape or by a court reporter for possible later transcription. Therefore, speakers should remember the following:
   (a) It is important that you speak loudly, clearly and slowly.
   (b) All statements must be clearly verbalized – a nod cannot be recorded.
   (c) All technical terms and proper names must be spelled out the first time they are mentioned.
   (d) Only one person may speak at a time.

If you have a written copy of your oral remarks that you can leave as an exhibit, please do so.
4. Anyone who desires to submit written comments may do so at this hearing or within five days of the close of the hearing. The Administrative Law Judge may, during the hearing, extend the period for receipt of comments up to 20 calendar days. Comments may be submitted to the Administrative Law Judge electronically through the Office of Administrative Hearings’ e-Comments website at https://mn.gov/oah/forms-and-filing/e-comments/; you will find step-by-step instructions at that site. Comments may also be submitted by facsimile to (651 539-0310), or by U.S. mail directed to the address listed below:

Office of Administrative Hearings
Attn: Katie Lin
PO Box 64620
St. Paul, MN 55164-0620

Comments must be RECEIVED before 4:30 p.m. on the date on which the comment period closes in order to be considered timely.

5. After the period for submission of written comments ends, you will have an additional five-working-day period for filing a written response to any comments that were submitted during the initial 20-day comment period. Additional or new evidence may not be submitted during this rebuttal period. The responses must be RECEIVED at the Office of Administrative Hearings before 4:30 p.m. on the fifth working day.

Report of Administrative Law Judge. The Administrative Law Judge will complete a report addressing the issues of statutory authority, compliance with substantive and procedural requirements, whether any changes proposed to the published rules are substantially different, and the need for and reasonableness of each section of the rule. The report may also summarize comments made and suggest changes to the proposed rule. The report will be available to members of the public upon request. To request a copy of the report, please email Katie.Lin@state.mn.us or check the box on the Hearing Register indicating you wish to receive a copy of the Administrative Law Judge’s report. Rule reports are also available on our website at http://mn.gov/oah/. In accordance with the Americans with Disabilities Act, the report can be made available in alternative format upon request (for example, large print or digitally). Please contact Katie Lin at 651/361-7911 if you need this service.

Rule Adoption. After receiving the Administrative Law Judge’s report, the Chief Administrative Law Judge’s report if there is an adverse finding, and the entire hearing record, the agency will decide whether to adopt, withdraw or modify the proposed rule based upon a consideration of the comments made during this rule hearing proceeding. The agency must wait at least five days after issuance of the Administrative Law Judge’s report, and the Chief Administrative Law Judge’s report if applicable, before taking any action.

Thank you for attending and participating in this hearing.
Hello,

Thanks much. I actually did not want Judge Wilson to make a ruling in advance of the hearing – sorry if I did not make that clear in my letter. I know that he has to consider that issue as part of the rule-making process. Extending the comment period seems quite fair.

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director
MINNESOTA BOARD OF PHARMACY

Mr. Wiberg,

Judge Wilson has received and reviewed your letter to him dated October 11, 2016. In that letter you request that the Judge rule on certain procedural and notice problems you describe in the letter. Your letter implies that you would like a ruling on these issues in advance of the rule making hearing. Judge Wilson asked me to tell you that since the Pharmacy Board’s compliance with notice and procedural rules is a part of the rule making process, he will not rule in advance of the hearing on the matters described in your letter.

Judge Wilson will extend the comment period on the proposed rules from 14 to 20 days.

If you have any questions, please let me know.

Katie Lin
State Program Administrator Intermediate
Office of Administrative Hearings
600 Robert St N
PO Box 64620
St. Paul, MN  55164-0620
P: 651-361-7911
F: 651-539-0310
mn.gov/oah
Mr. Wiberg,

Judge Wilson has received and reviewed your letter to him dated October 11, 2016. In that letter you request that the Judge rule on certain procedural and notice problems you describe in the letter. Your letter implies that you would like a ruling on these issues in advance of the rule making hearing. Judge Wilson asked me to tell you that since the Pharmacy Board's compliance with notice and procedural rules is a part of the rule making process, he will not rule in advance of the hearing on the matters described in your letter.

Judge Wilson will extend the comment period on the proposed rules from 14 to 20 days.

If you have any questions, please let me know.

Katie Lin
State Program Administrator Intermediate

Office of Administrative Hearings
600 Robert St N
PO Box 64620
St. Paul, MN 55164-0620
P: 651-361-7911
F: 651-539-0310
mn.gov/oah
Minnesota Board of Pharmacy

CERTIFICATE OF GIVING ADDITIONAL NOTICE UNDER THE ADDITIONAL NOTICE PLAN

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.

I certify that on September 21, 2016, at Minneapolis, Hennepin County, Minnesota, I gave notice according to the Additional Notice Plan approved by the Office of Administrative Hearings on September 7, 2016. Specifically, I sent out an e-mail to all pharmacists, pharmacist interns, pharmacy technicians and pharmacies for whom we have an e-mail address on file, alerting them to the fact that the Notice of Hearing had been published in the State Register. I attached a copy of the Revisor’s Draft of the rule, the Statement of Need and Reasonableness (SONAR) and the Notice of Hearing (Notice). In addition, the Board has placed the Notice, the SONAR, the Revisor’s Draft and the Docket on its Web site. The Docket contains a link to the Notice as published in the State Register. On October 12, 2016, I sent a press release concerning the proposed rule and the hearing to various news outlets around the state.

Cody Wiberg
Executive Director
October 11, 2016

Cody Wiberg  
Executive Director, Minnesota Board of Pharmacy  
2829 University Avenue, #530  
Minneapolis, MN  55414-3251

Dear Cody,

The Mayo Clinic Midwest Pharmacy Leadership Group is submitting comments regarding the draft rule revision to 6800.2160 regarding Pharmacy Work Conditions. Mayo Midwest includes the Mayo Clinic Hospital- Rochester, plus eleven other Mayo Clinic Health System hospital sites in Minnesota, six of which are Critical Access Hospitals with only one pharmacist and technician on duty.

**Rule draft Lines 1.17 – 1.18 “...shall not require a pharmacist, pharmacist intern, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks...”**

- Does the category of “pharmacist” and “technicians” include any and all individuals under that licensure/registration regardless of their role? I.e. pharmacists in supervisory/management roles, pharmacy residents, technicians serving in non-dispensing roles. Perhaps indicating “dispensing pharmacists/technicians” or “pharmacists providing direct patient care” would provide clarification, if that is the intent.
- The statement “12 continuous hours, inclusive of the breaks,” appears to contradict itself. If there’s an uninterrupted break then the work hours would not be continuous. If there was not a break, then the term “continuous” fits the intent. When staff are scheduled a 12 hour shift, it may actually be a 12.5 hour shift to allow for a 30 minute, unpaid meal break. Since the 30 minutes is not work time (unpaid), this scheduling approach should meet the intent of not working more than a 12 hour shift.
- There are concerns that the draft rules, if accepted as final, will have unanticipated consequences that may in some instances worsen pharmacy work conditions, specifically in regards to restrictions for pharmacy residents work hours. The draft rules are in conflict with the National ASHP Duty Hour Requirements for Pharmacy Residents.
  - Per [Standard 1: Requirements and Selection of Residents](#), ASHP requires pharmacy residents to be licensed or eligible for licensure as a pharmacist in the state or jurisdiction in which the program is conducted. The current draft rule does not clearly differentiate pharmacist from pharmacy resident, creating disconnect between the
Board of Pharmacy draft rule 6800-2160 and the existing ASHP Duty-Hour Requirements for Pharmacy Residencies. We outline the following background:

- Per ASHP, resident duty hours must be limited to 80 hours per week, averaged over a four-week period, inclusive of all in-house call activities and moonlighting.
- ASHP requires programs to implement mandatory time free of duty where residents must have a minimum of one day in seven days free of duty (when averaged over four weeks), residents should have 10 hours free between scheduled duties, and must have at a minimum 8 hours between scheduled duty periods.
- ASHP states that continuous duty periods of resident should not exceed 16 hours, with a maximum allowable duty assignment that does not exceed 24 hours even with built in strategic napping or other strategies to reduce fatigue and sleep deprivation.
- ASHP states that the duty hour standards must be enforced by the Residency Program Director (RPD). ASHP also requires that the RPD must educate residents and preceptors about professional responsibilities, importance of rest and fit for duty to provide services required by patients, and education on signs of fatigue and sleep deprivation.

The aforementioned ASHP duty hour requirements would conflict with the proposed draft rules for pharmacist work conditions. ASHP pharmacy residency accreditation standards and duty hour requirements were adopted by programs across the US to ensure fitness for pharmacy resident duty and to ensure patient safety is not endangered. If pharmacy residents are included in the classification of pharmacists per the Minnesota Board of Pharmacy draft rule, the potential implication of this would further worsen workload requirements of staff pharmacists.

Based on this rationale, we propose the draft rule be modified to specifically state that postgraduate pharmacy residents who participate in an ASHP-accredited program be required to follow the ASHP duty-hour requirements for pharmacy residencies and are exempt from the Minnesota Rules 6800.2160

Rule draft lines 2.16 – 2.18, Subpt 2, (3) (a): “the pharmacy develops a list of drugs that may not be dispensed while a pharmacist is taking an allowed break, without the patient receiving counseling from a pharmacist, when counseling would normally be required.”
To develop a list of specific drugs would be very difficult and not meet the intent. Limiting the drugs that can be dispensed without counseling should be determined by the pharmacist when certifying the prescription. There are several variables that weigh into that determination other than the specific drug. For example; consider the age/cognitive state of the patient, multiple drug therapies that may interact, a change in the manufacturer/product appearance or handling, etc. A patient may have been on a high risk drug for some time without any changes in therapy or patient condition. Counseling may not be required in that case. That should be determined on a case by case basis. We recommend deleting Subpt. 2,(3) (a).

Lines 2.22 – 2.24 (c) and (d): regarding lack of counseling for prescriptions dispensed while a pharmacist is on break. Suggested edits/additions are underlined:

(c) if the patient or caregiver declines to wait, but requests counseling a telephone number at which the patient or a caregiver can be reached is obtained.
(d) after returning from break and if counseling has been requested, the pharmacist makes a reasonable effort to contact the patient or caregiver by telephone and provides counseling;

**Rule draft lines 1.19 – 1.25, Subp. 2: Requirement for breaks.**

As indicated in the SONAR, there are other states that have work-hour restrictions on pharmacists, however we are unaware of any other Healthcare professions in Minnesota that are regulated in this regard by the state. The Pharmacy Leadership Group for Mayo Midwest requests the Board reconsider these restrictions as written.

Thank you for your willingness to consider these comments when finalizing the rule draft revision.

Mayo Midwest Pharmacy Leadership Group
NOTICE OF HEARING

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

Public Hearing. The Minnesota Board of Pharmacy intends to adopt rules after a public hearing following the procedures in the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2200 to 1400.2240, and the Administrative Procedure Act, Minnesota Statutes, sections 14.131 to 14.20. The agency will hold a public hearing on the above-named rules at the Office of Administrative Hearings, 600 Robert Street North, St. Paul, MN 55164-0620 starting at 9:30 A.M. on October 19, 2016 and continuing until the hearing is completed. The agency will schedule additional days of hearing if necessary. All interested or affected persons will have an opportunity to participate by submitting either oral or written data, statements, or arguments. Statements may be submitted without appearing at the hearing.

Administrative Law Judge. Administrative Law Judge Perry Wilson will conduct the hearing. Judge Wilson’s Legal Assistant Katie Lin can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone 651-361-7900 and FAX 651-539-0310 or katie.lin@state.mn.us. The rule hearing procedure is governed by Minnesota Statutes, sections 14.131 to 14.20, and by the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2000 to 1400.2240. You should direct questions about the rule hearing procedure to the administrative law judge.

Subject of Rules, Statutory Authority, and Agency Contact Person. The proposed rules are about pharmacy work conditions that have an impact on public safety. The Board is proposing to limit the number of continuous hours that pharmacists, pharmacist interns and pharmacy technicians can be required to work and to require that they be given breaks in certain circumstances. The proposed rules are authorized by Minnesota Statutes, §151.06, subd. 1(b). A copy of the proposed rules is published in the State Register. A copy is also attached to this notice as mailed or e-mailed and is available at the agency’s website at http://mn.gov/boards/pharmacy/statutes/rules.jsp, under the Rule-Making Docket heading.

The agency contact person is: Cody Wiberg at Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, MN 55414. Phone: (651)201-2825, FAX: (612)617-2262, and e-mail: cody.wiberg@state.mn.us.

Statement of Need and Reasonableness. The statement of need and reasonableness contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. A copy of the Statement of Need and Reasonableness is available on the agency’s website at http://mn.gov/boards/pharmacy/statutes/rules.jsp, under the Rule-Making Docket heading. You may also obtain a copy by contacting the agency contact person.
Public Comment. You and all interested or affected persons, including representatives of associations and other interested groups, will have an opportunity to participate by attending and commenting at the hearing and by submitting written comments, as described below. All written comments and other written materials must be submitted to the administrative law judge through the Office of Administrative Hearings e-Comments system that is available on the following Web page: https://minnesotaoah.granicusideas.com/. The administrative law judge will accept your views either orally at the hearing or in writing at any time before the close of the hearing record. All evidence that you present should relate to the proposed rules. You may also submit written material to the administrative law judge to be recorded in the hearing record for five working days after the public hearing ends. At the hearing the administrative law judge may order this five-day comment period extended for a longer period but for no more than 20 calendar days. Following the comment period, there is a five-working-day rebuttal period during which the agency and any interested person may respond in writing to any new information submitted. No one may submit additional evidence during the five-day rebuttal period. The Office of Administrative Hearings must receive all comments and responses submitted to the administrative law judge no later than 4:30 p.m. on the due date. All responses received are public and will be available for review at the Office of Administrative Hearings.

The agency requests that any person submitting written views or data to the administrative law judge before the hearing or during the comment or rebuttal period also submit a copy of the written views or data to the agency contact person at the address stated above.

Alternative Format/Accommodation. Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

Modifications. The agency may modify the proposed rules as a result of the rule hearing process. It must support modifications by data and views presented during the rule hearing process. The adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under Minnesota Rules, part 1400.2110. If the proposed rules affect you in any way, the agency encourages you to participate.

Adoption Procedure after the Hearing. After the close of the hearing record, the administrative law judge will issue a report on the proposed rules. You may ask to be notified of the date when the judge’s report will become available, and can make this request at the hearing or in writing to the administrative law judge. You may also ask to be notified of the date that the agency adopts the rules and files them with the Secretary of State, or ask to register with the agency to receive notice of future rule proceedings. You may make these requests at the hearing or in writing to the agency contact person stated above.

Lobbyist Registration. Minnesota Statutes, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions regarding this requirement to the Campaign Finance and Public Disclosure Board at:
Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone 651-539-1180 or 1-800-657-3889.

Order. I order that the rulemaking hearing be held at the date, time, and location listed above.

9/7/2016

__________________________  ___________________________
Date              Cody Wiberg
                  Executive Director
Cody,

Just a few comments, is this worth sending to Administrative Law Judge, Perry Wilson? Have not sent yet. Not sure it is worth doing at this point?

Thanks

Gary Clauson

---

I would fear large chains/hospitals would have overnight shifts run longer than 12 hours and claim that they are ‘separate’ days. Not the spirit of the rule, re-wording would eliminate this concern.

Same reasoning as above.

Do you want required, or optional to take if wanted? In my experience most techs will want break. Most pharmacists won’t unless paid or shift is longer than 8 hours. Also see MN statute 177.254 noted below.

Nothing in this rule would require the employer to pay the employee for this break period.

Dear proximity

We almost opened a retail location in the Mall of America. Would not want to allow someone within a strip mall or large establishment to be too far away. Reachable by cellphone, yes, but not the spirit of the rule?? Near proximity does open the door for interpretation issues, but does give cause to educate upon survey or complaint.
2015 Minnesota Statutes

177.253 MANDATORY WORK BREAKS.

Subdivision 1. Rest breaks.

An employer must allow each employee adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.

Subd. 2. Collective bargaining agreement.

Nothing in this section prohibits employers and employees from establishing rest breaks different from those provided in this section pursuant to a collective bargaining agreement.

177.254 MANDATORY MEAL BREAK.

Subdivision 1. Meal break.

An employer must permit each employee who is working for eight or more consecutive hours sufficient time to eat a meal.

Subd. 2. Payment not required.

Nothing in this section requires the employer to pay the employee during the meal break.

Subd. 3. Collective bargaining agreement.

Nothing in this section prohibits employers and employees from establishing meal periods different from those provided in this section pursuant to a collective bargaining agreement.

Minnesota Administrative Rules

5200.0120 HOURS WORKED.

Subp. 2.

On-call time.

An employee who is required to remain on the employer's premises or so close to the premises that the employee cannot use the time effectively for the employee's own purposes is working while on call. An employee who is not required to remain on or near the employer's premises, but is merely required to leave word at the employee's home or with company officials where the

Meals.

Bona fide meal periods are not hours worked. Bona fide meal periods do not include rest periods such as coffee breaks or time for snacks. The employee must be completely relieved from duty for the purpose of eating regular meals. Thirty minutes or more is ordinarily long enough for a bona fide meal period. A shorter period may be adequate under special conditions. The employee is not completely relieved from duty if required to perform any duties, whether active or inactive, while eating. It is not necessary that an employee be permitted to leave the premises, if the employee is otherwise completely freed from duties during the meal period. If the meal period is frequently interrupted by calls to duty, the employee is not relieved of all duties and the meal periods must be considered as hours worked.
October 11, 2016

The Honorable Perry Wilson
Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620
Saint Paul, Minnesota 55164-0620

Re: In the Matter of the Proposed Rule of the Minnesota Board of Pharmacy 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]; Request to Schedule a Rules Hearing and Request to Review Additional Notice Plan; OAH Docket No. 10-9026-33753; Revisor’s ID Number RD4355.

Dear Judge Wilson:

I am writing to disclose that I have inadvertently made three, related procedural errors in regards to the above-mentioned proposed rule.

Minn. Stat. §§ 14.131 and 14.23 require a copy of the Statement of Need and Reasonableness (SONAR) to be sent to the Legislative Reference Library (LRL) and §14.23 requires that the SONAR be sent to the LRL when the Notice of Intent to Adopt is mailed.

Minn. Stat. §14.116 requires an agency to send a copy of the Notice of Intent to Adopt and the SONAR to certain legislators and to the Legislative Coordinating Commission (LCC) on the same date that it mails the Notice of Intent to Adopt to persons on its rule-making list.

Minn. R. 1400.2080, subp. 6 states:

“A notice of hearing or notice of intent to adopt rules must be mailed at least 33 days before the end of the comment period or the start of the hearing, and must be published in the State Register at least 30 days before the end of the comment period or the start of the hearing.”

I have been using the Minnesota Rule-Making Manual as my guide to the rule-making process. Chapter 7 states that the above-mentioned documents must be sent out to the various parties when the agency mails out its Notice of Intent to Adopt. Unfortunately, I was not thinking of our Notice of Hearing as being a Notice of Intent to Adopt. Instead, I was confusing the phrase
“Notice of Intent to Adopt” with the Order Adopting Rules, which would be published at a later date in the State Register and sent out to interested parties.

I did e-mail our Notice of Hearing to the individuals and organizations on the Board’s rule-making list on September 19, 2016, the day that the Notice was published in the State Register. That is 31 days, rather than 33 days, before the hearing date of October 19, 2016. I did not discover my error regarding the sending of documents to legislators, the LCC and the LRL until yesterday, at which time I did e-mail copies of the required documents to them. I will be uploading the required certificates of mailing to the Office of Administrative Hearings e-filing site today.

I regret making these errors and apologize for them but would respectfully request that you find, pursuant to Minn. Stats. §14.15, subd. 5, that the Board's failure to satisfy these specific procedural requirements did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process and that the Board has taken corrective action to cure these errors so that the failures did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process. In support of this request, I offer the following facts and comments:

- This is the second attempt by the Board to promulgate this particular rule. The Board first included a version of this proposed rule in a large package of rule changes that it adopted in 2011. It was included in that package of rules until very late in the process and, consequently, interested parties had a substantial amount of time to comment on the proposal. It was withdrawn from the rules package at the request of the office of Governor Tim Pawlenty.

- The Board officially began the current rule-making process on September 28, 2015 when it published a Request for Comments (RFC) in the State Register. It e-mailed the RFC to the individuals and groups on the Board’s rule-making list and to every pharmacist, pharmacy, pharmacy technician and pharmacist intern for whom we have an e-mail address. As a result, as of December 14, 2015, the date on which I completed the drafting on a document that analyzed the received comments, the Board had received official comments from approximately 80 individuals, businesses, health care systems and trade or professional associations. The total number of comments received was slightly larger because a few commenters submitted more than one document that contained comments. About a half dozen pharmacists talked directly with staff but declined to submit written comments after they were told that the comments are considered public documents. (I will upload a copy of the analysis document for your review).

- The proposed work condition rule was on the agenda for the Board’s December 16, 2015 meeting. The Board reviewed the analysis document and took public testimony concerning the proposed rule. As a result of the written comments received and the testimony heard at the meeting, the Board made changes to the proposed language.

- Board President Stuart Williams and I met with the Governor’s Health Care Policy Advisor on March 8, 2016. As a result of that meeting, we agreed to put the proposed rule on the agenda for the Board’s April 13, 2016 meeting so that the Board could hear additional, oral comments. This was done primarily to afford certain groups who still had
concerns about the rule to offer additional written comments and oral testimony. After considering the comments and testimony, the Board further amended the proposed rule.

In summary, the Board believes that it has offered ample opportunity to all interested individuals and groups to participate meaningfully in the rulemaking process; both when the rule was originally considered back in 2011, and for the past year. In addition, the Board decided to hold the upcoming hearing in order to provide another opportunity for comment.

Thank you for your consideration in this matter.

Sincerely,

Cody Wiberg

Cody Wiberg, Pharm.D., M.S., R.Ph.  
Executive Director  
Minnesota Board of Pharmacy
Thanks Katie. I think the comment period should close 14 days after the hearing is completed.

Judge Wilson,
We already received public comments for the Board of Pharmacy rules. As a result, we will open the e-Comments comment period before the hearing date. However, how many days after the hearing would you like to the comment period to end (5-20 days)?

Thanks!

Katie Lin
State Program Administrator Intermediate
Office of Administrative Hearings
600 Robert St N
PO Box 64620
St. Paul, MN  55164-0620
P: 651-361-7911
F: 651-539-0310
mn.gov/oah

Sounds good, thanks!

Kendra McCausland
State Program Administrator
Office of Administrative Hearings
600 Robert St N
PO Box 64620
St. Paul, MN  55164-0620
P: 651-361-7870
F: 651-539-0310
mn.gov/oah
Kendra,
Good morning! Nothing yet. I can probably draft something. In the past we didn’t normally open these comment periods until the date of the hearing so we don’t have an open comment period for this yet. Since we are already getting comments, I’ll discuss it with Denise to see if we should open it earlier. I’ll get back to you!

Katie Lin
State Program Administrator Intermediate
Office of Administrative Hearings
600 Robert St N
PO Box 64620
St. Paul, MN  55164-0620
P: 651-361-7911
F: 651-539-0310
mn.gov/oah

Hey Katie! Do you have any standardized language that we can send this guy to tell him he has to use e-Comments?

Kendra McCausland
State Program Administrator
Office of Administrative Hearings
600 Robert St N
PO Box 64620
St. Paul, MN  55164-0620
P: 651-361-7870
F: 651-539-0310
mn.gov/oah

Kendra,
Hope your Wednesday is going well. Cody Wiberg at the board of pharmacy recommended I send comments to Judge Wilson. Please let me know if anything is unclear or needs further explanation. Attachment enclosed.
Thank you,

*Gary Clauson RPh*
Affiliated Academic Staff
University of Minnesota
College of Pharmacy
claus016@umn.edu
763-234-2060

Hello,

I would advise anyone who has comments to submit them to the Judge. The Board will consider all of the comments submitted. In the past, the Board has responded to some comments by "tweaking" the language of the proposed rule – and has responded to others by not making changes. But if comments aren't submitted, the Board obviously can't consider them at all. In addition, comments are considered by the Judge as well.

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director
MINNESOTA BOARD OF PHARMACY

---

**From:** Gary Clauson [mailto:claus016@umn.edu]
**Sent:** Wednesday, September 21, 2016 11:38 AM
**To:** Wiberg, Cody (HLB)
**Subject:** Re: Proposed Work Condition Rules - Notice of Hearing.

Cody,

I have not sent this to the administrative law judge yet. Please see attachment and advise if I should bother sending.

Thanks for your time,

*Gary Clauson RPh*
Affiliated Academic Staff
University of Minnesota
College of Pharmacy
claus016@umn.edu
763-234-2060

On Wed, Sep 21, 2016 at 9:30 AM, Wiberg, Cody (HLB) <Cody.Wiberg@state.mn.us> wrote:
Hello,
This e-mail is being sent out to all pharmacies, pharmacist, pharmacist interns and pharmacy technicians for whom we have an e-mail address. It applies to pharmacies located within Minnesota and pharmacists, interns and technicians working within the state. A Notice of Hearing (NOH) was published Monday, September 19th, in the Minnesota State Register. Here is the link:

http://www.comm.media.state.mn.us/bookstore/stateregister/41_12.pdf

Please note that there is a difference in how comments are submitted now that a hearing has been scheduled. The NOH gives full details but, basically, comments need to be submitted on line to the Administrative Law Judge, Perry Wilson. The Board requests that you submit a copy of your comments to me at my e-mail address. I pass on all comments to the Board Members.

I am attaching the Notice of Hearing, the Statement of Need and Reasonableness and a copy of the final rules draft to this e-mail.

Cody Wiberg, Pharm.D., M.S., R.Ph.
Executive Director
Minnesota Board of Pharmacy
--
Gary Clauson
Affiliated Academic Staff
University of Minnesota
College of Pharmacy
claus016@umn.edu
763-234-2060
September 7, 2016

VIA EMAIL ONLY
Cody C. Wiberg
Executive Director
Minnesota Board of Pharmacy
2829 University Ave SE, Ste 530
Minneapolis, MN 55414
Cody.Wiberg@state.mn.us

Re: In the Matter of Proposed Rules Amendments Relating to Pharmacy Practice Including Pharmacy Work Conditions Related to the Safety of the Public
OAH 10-9026-33753; Revisor R-4355

Dear Mr. Wiberg:

Enclosed herewith and served upon you please find the ORDER ON REVIEW OF NOTICE OF HEARING AND ADDITIONAL NOTICE PLAN in the above-entitled matter.

Prior to publishing the Notice of Hearing in the State Register, please notify the Office of Administrative Hearings (OAH) at katie.lin@state.mn.us in order to activate the agency’s e-Comments page on OAH’s website. Please note that if you do not notify us of the publication, the e-Comments site will not be available to receive public comments.

For the convenience of the Office of Administrative Hearings, the Administrative Law Judge requests the Minnesota Board of Pharmacy to change the contact information on page one of the Notice of Hearing, at lines 2-4 of the paragraph titled Notice of Hearing, to read “Judge Wilson’s Legal Assistant Katie Lin can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone 651-361-7900 and FAX 651-539-0310 or katie.lin@state.mn.us.”

If you have any questions regarding this matter, please contact Katie Lin at (651) 361-7911, katie.lin@state.mn.us, or facsimile at (651) 539-0310.

Sincerely,

Perry Wilson
Administrative Law Judge

PMW:klm
Enclosure
STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
ADMINISTRATIVE LAW SECTION
PO BOX 64620
600 NORTH ROBERT STREET
ST. PAUL, MINNESOTA 55164

CERTIFICATE OF SERVICE

In the Matter of Proposed Rules Amendments Relating to Pharmacy Practice Including Pharmacy Work Conditions Related to the Safety of the Public

OAH Docket No.

Kendra McCausland, certifies that on September 7, 2016, she served a true and correct copy of the attached ORDER ON REVIEW OF NOTICE OF HEARING AND ADDITIONAL NOTICE PLAN; by courier service, by placing it in the United States mail with postage prepaid, or by electronic mail, as indicated below, addressed to the following individuals:

VIA EMAIL ONLY
Cody C. Wiberg
Executive Director
Minnesota Board of Pharmacy
2829 University Ave SE, Ste 530
Minneapolis, MN  55414
Cody.Wiberg@state.mn.us
This matter came before Administrative Law Judge Perry Wilson upon the Minnesota Board of Pharmacy’s (Board) request for review of its Notice of Hearing Additional Notice Plan. The Board seeks a legal review of its materials under Minn. R. 1400.2060, .2080 (2015).

Under its Additional Notice Plan, the Board:

- Has published a Request for Comments in the State Register and has mailed or emailed a copy of it to all person’s on the Board’s rulemaking list;

- Will publish the Notice of Hearing in the State Register and will mail copies of it to all persons on the Board’s rule making list. The Board will also mail or email copies of the proposed rules to all such persons;

- 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 be posted on the Board’s Web site;

- Will notify all pharmacists, pharmacist interns, pharmacy technicians, and pharmacies for whom the Board has an email addresses on file of the Board’s posting of the Request for Comments and Revisor’s draft of the proposed rule changes on its Web site. Copies of the Request for Comments, the Revisor’s draft, and the SONAR will be attached to these emails;

- Will make copies of the aforementioned documents available in alternative formats, as requested;

- May issue a press release about the hearing to notify the public.
Based upon a review of the written submissions by the Board,

**IT IS HEREBY ORDERED THAT:**

1. The Additional Notice Plan is **APPROVED**.
2. The Notice of Hearing is **APPROVED**.

Dated: September 7, 2016

PERRY WILSON
Administrative Law Judge
NOTICE OF HEARING

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

Public Hearing. The Minnesota Board of Pharmacy intends to adopt rules after a public hearing following the procedures in the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2200 to 1400.2240, and the Administrative Procedure Act, Minnesota Statutes, sections 14.131 to 14.20. The agency will hold a public hearing on the above-named rules at the Office of Administrative Hearings, 600 Robert Street North, St. Paul, MN 55164-0620 starting at 9:30 A.M. on October 19, 2016 and continuing until the hearing is completed. The agency will schedule additional days of hearing if necessary. All interested or affected persons will have an opportunity to participate by submitting either oral or written data, statements, or arguments. Statements may be submitted without appearing at the hearing.

Administrative Law Judge. Administrative Law Judge Perry Wilson will conduct the hearing. The judge can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone (651)361-7870, and FAX 651-361-7936. The rule hearing procedure is governed by Minnesota Statutes, sections 14.131 to 14.20, and by the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2000 to 1400.2240. You should direct questions about the rule hearing procedure to the administrative law judge.

Subject of Rules, Statutory Authority, and Agency Contact Person. The proposed rules are about pharmacy work conditions that have an impact on public safety. The Board is proposing to limit the number of continuous hours that pharmacists, pharmacist interns and pharmacy technicians can be required to work and to require that they be given breaks in certain circumstances. The proposed rules are authorized by Minnesota Statutes, §151.06, subd. 1(b). A copy of the proposed rules is published in the State Register. A copy is also attached to this notice as mailed or e-mailed and is available at the agency’s website at http://mn.gov/boards/pharmacy/statutes/rules.jsp, under the Rule-Making Docket heading.

The agency contact person is: Cody Wiberg at Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, MN 55414. Phone: (651)201-2825, FAX: (612)617-2262, and e-mail: Cody.Wiberg@state.mn.us.

Statement of Need and Reasonableness. The statement of need and reasonableness contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. A copy of the Statement of Need and Reasonableness is available on the agency’s website at http://mn.gov/boards/pharmacy/statutes/rules.jsp, under the Rule-Making Docket heading. You may also obtain a copy by contacting the agency contact person.
**Public Comment.** You and all interested or affected persons, including representatives of associations and other interested groups, will have an opportunity to participate by attending and commenting at the hearing and by submitting written comments, as described below. *All written comments and other written materials must be submitted to the administrative law judge through the Office of Administrative Hearings e-Comments system that is available on the following Web page: [https://minnesotaoah.granicusidease.com/](https://minnesotaoah.granicusidease.com/). The administrative law judge will accept your views either orally at the hearing or in writing at any time before the close of the hearing record. All evidence that you present should relate to the proposed rules. You may also submit written material to the administrative law judge to be recorded in the hearing record for five working days after the public hearing ends. At the hearing the administrative law judge may order this five-day comment period extended for a longer period but for no more than 20 calendar days. Following the comment period, there is a five-working-day rebuttal period during which the agency and any interested person may respond in writing to any new information submitted. No one may submit additional evidence during the five-day rebuttal period. The Office of Administrative Hearings must receive all comments and responses submitted to the administrative law judge no later than 4:30 p.m. on the due date. All responses received are public and will be available for review at the Office of Administrative Hearings.*

The agency requests that any person submitting written views or data to the administrative law judge before the hearing or during the comment or rebuttal period also submit a copy of the written views or data to the agency contact person at the address stated above.

**Alternative Format/Accommodation.** Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

**Modifications.** The agency may modify the proposed rules as a result of the rule hearing process. It must support modifications by data and views presented during the rule hearing process. The adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under *Minnesota Rules*, part 1400.2110. If the proposed rules affect you in any way, the agency encourages you to participate.

**Adoption Procedure after the Hearing.** After the close of the hearing record, the administrative law judge will issue a report on the proposed rules. You may ask to be notified of the date when the judge’s report will become available, and can make this request at the hearing or in writing to the administrative law judge. You may also ask to be notified of the date that the agency adopts the rules and files them with the Secretary of State, or ask to register with the agency to receive notice of future rule proceedings. You may make these requests at the hearing or in writing to the agency contact person stated above.

**Lobbyist Registration.** *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions regarding this requirement to the Campaign Finance and Public Disclosure Board at:
Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone 651-539-1180 or 1-800-657-3889.

**Order.** I order that the rulemaking hearing be held at the date, time, and location listed above.

__________________________  ____________________________
Date  Cody Wiberg
     Executive Director
Mr. Wiberg,
Good afternoon. We received your request to review the Notice of Hearing and Additional Notice Plan. Unfortunately the Notice of Hearing contains outdated information regarding how to submit public comments to the administrative law judge. The “Public Comment” portion of the Notice of Hearing refers to our rulecomments@state.mn.us mailbox. This mailbox is no longer valid. We are now requiring all comments be submitted through our e-Comments system at: https://minnesotaoah.granicusideas.com/.

Once we receive a corrected Notice of Hearing that includes language about our e-Comments system, Judge Wilson will review the Notice of Hearing and Additional Notice Plan. Please note the five working day review deadline will begin upon receipt of the corrected Notice of Hearing.

If you have any questions, please feel free to get in touch with me.

Best,

Katie Lin  
State Program Administrator Intermediate  
Office of Administrative Hearings  
600 Robert St N  
PO Box 64620  
St. Paul, MN 55164-0620  
P: 651-361-7911  
F: 651-539-0310  
mn.gov/oah
August 23, 2016

The Honorable Tammy L. Pust
Chief Administrative Law Judge
Office of Administrative Hearings
600 North Robert Street
P.O. Box 64620
Saint Paul, Minnesota 55164-0620

Re: In the Matter of the Proposed Rule of the Minnesota Board of Pharmacy 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]; Request to Schedule a Rules Hearing and Request to
Review Additional Notice Plan; OAH Docket No. 10-9026-33753; Revisor’s ID Number
RD4355.

Dear Chief Judge Pust:

The Minnesota Board of Pharmacy has already worked with your staff to schedule a rules
hearing in this matter but submits this formal request for the scheduling of a rules hearing under
Minnesota Statutes, sections 14.131 to 14.20, and assignment of an Administrative Law Judge.
Your staff has informed me that Judge Perry Wilson has been assigned and that the hearing will
be scheduled for 9:30AM on October 19, 2016 at the Office of Administrative Hearings. The
hearing is for the Board’s proposed rule about pharmacy work conditions that are related to the
safety of the public.

Enclosed are the documents for the Judge Wilson’s review, as required by Minnesota Rules, part
1400.2080, subpart 5:

1) The Notice of Hearing proposed to be issued.
2) A copy of the proposed rules, with a certificate of approval as to form by the Revisor of
Statutes attached.
3) The Statement of Need and Reasonableness.

The Board also requests that you approve our Additional Notice Plan. The documents required
for your review by Minnesota Rules, part 1400.2060, include the three documents listed above
for requesting a rules hearing. We are also providing you below with our explanation of why we
believe our Additional Notice Plan reflects reasonable efforts to notify persons or classes of
persons who might be significantly affected by the rules in accordance with Minnesota Statutes, section 14.14, subdivision 1a.

Our Additional Notice Plan is described beginning on page 9 of the Statement of Need and Reasonableness. We believe our Additional Notice Plan complies with the statute for the following reasons. The individuals and businesses most immediately affected by the proposed rule are pharmacists, pharmacist interns, pharmacy technicians and pharmacies. We have already posted the Request for Comments, the original Revisor’s draft of the proposed rule and the Statement of Need and Reasonableness of the Board’s Web site. We will also publish the Notice of Hearing and the latest Revisor’s draft of the proposed rule on the Web site. Whenever we place such documents on our web site, we send out an e-mail to all pharmacists, pharmacist interns, pharmacy technicians and pharmacies for whom we have an e-mail address on file. (We currently have 20,361 e-mail addresses on file). The e-mail alerts the licensees and registrants that we have posted the rule-making documents on the Web site. We also attach copies of the Notice of Hearing, the Revisor’s draft of the rules and the SONAR to the e-mails. This process ensures that the individuals and businesses most directly impacted will receive notice about the rule and the rule-making process and be able to review relevant documents. The public is also affected by this rule and the Board may issue a press release about the hearing in hopes that media outlets will report on the process.

Please call me at (651)201-2830 if you have any questions.

Sincerely,

Cody Wiberg

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

Proposed Permanent Rules Relating to Pharmacy Working Conditions

6800.2150 PHARMACIST ON DUTY.

Subpart 1. Requirement to have a pharmacist on duty. A. A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except that for brief absences of the pharmacist arising out of and in the course of pharmacy practice are allowable.

Subp. 2. Limiting access to pharmacies. B. When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as provided in part 6800.7530. In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period.

6800.2160 PHARMACY WORK CONDITIONS.

Subpart 1. Limitation on continuous hours worked. A pharmacy licensed under Minnesota Statutes, section 151.19, subdivision 1, which is located within Minnesota, shall not require a pharmacist, pharmacist-intern, or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subpart 2.

Subp. 2. Requirements for breaks.

A. A pharmacist, pharmacist-intern, or pharmacy technician working longer than six continuous hours per day shall be allowed during that time period to take a 30-minute, uninterrupted break.

B. A pharmacist, pharmacist-intern, or pharmacy technician shall be allowed adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.
C. A pharmacy may, but is not required to, close when a pharmacist is on a break. If the pharmacy does not close, the pharmacist shall either remain within the licensed pharmacy or within the establishment in which the licensed pharmacy is located in order to be available for emergencies. In addition, the following apply:

(1) pharmacy technicians, pharmacist-interns, and other supportive staff, authorized by the pharmacist on duty, may continue to perform duties as allowed under this chapter;

(2) no duties reserved to pharmacists and pharmacist interns under any part of this chapter, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians or other supportive staff; and

(3) only prescriptions that have been certified by a pharmacist, as required by part 6800.3100, may be dispensed while the pharmacist is on break; except that prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may be dispensed only if the following conditions are met:

(a) the pharmacy develops a list of drugs that may not be dispensed while a pharmacist is taking an allowed break, without the patient receiving counseling from a pharmacist, when counseling would normally be required;

(b) the patient, or other individual who is picking up the prescription on behalf of the patient, is told that the pharmacist is on a break and is offered the chance to wait until the pharmacist returns from break in order to receive counseling;

(c) if the patient or caregiver declines to wait, a telephone number at which the patient or a caregiver can be reached is obtained;

(d) after returning from the break, the pharmacist makes a reasonable effort to contact the patient or a caregiver by telephone and provides counseling; and

6800.2160
(e) the pharmacist documents the counseling that was provided or
documents why counseling was not provided, including a description of the efforts made
to contact the patient or caregiver. The documentation shall be retained by the pharmacy,
and be made available for inspection by the board or its authorized representatives, for a
period of at least two years.

D. In pharmacies staffed by two or more pharmacists, the pharmacists shall
stagger breaks so that at least one pharmacist remains on duty at all times that the
pharmacy remains open for the transaction of business.

Subp. 3. Exceptions for emergencies. Subpart 1 and subpart 2, item A, shall not
apply in the event that an emergency necessitates that a pharmacist, pharmacist-intern, or
pharmacy technician work longer than 12 continuous hours, work without taking required
meal breaks, or have a break interrupted in order to minimize immediate health risks for
patients.
TITLE: Proposed Permanent Rules Relating to Pharmacy Working Conditions

AGENCY: Board of Pharmacy

MINNESOTA RULES: Chapter 6800

The attached rules are approved for publication in the State Register

Lauren C. Bethke
Assistant Revisor
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;”

Page 5 of 12
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 Serviccs, 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 or 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:
  
  o **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:
  
  o **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
Minnesota Board of Pharmacy

NOTICE OF HEARING

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

Public Hearing. The Minnesota Board of Pharmacy intends to adopt rules after a public hearing following the procedures in the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2200 to 1400.2240, and the Administrative Procedure Act, Minnesota Statutes, sections 14.131 to 14.20. The agency will hold a public hearing on the above-named rules at the Office of Administrative Hearings, 600 Robert Street North, St. Paul, MN 55164-0620 starting at 9:30 A.M. on October 19, 2016 and continuing until the hearing is completed. The agency will schedule additional days of hearing if necessary. All interested or affected persons will have an opportunity to participate by submitting either oral or written data, statements, or arguments. Statements may be submitted without appearing at the hearing.

Administrative Law Judge. Administrative Law Judge Perry Wilson will conduct the hearing. The judge can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone (651)361-7870, and FAX 651-361-7936. The rule hearing procedure is governed by Minnesota Statutes, sections 14.131 to 14.20, and by the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2000 to 1400.2240. You should direct questions about the rule hearing procedure to the administrative law judge.

Subject of Rules, Statutory Authority, and Agency Contact Person. The proposed rules are about pharmacy work conditions that have an impact on public safety. The Board is proposing to limit the number of continuous hours that pharmacists, pharmacist interns and pharmacy technicians can be required to work and to require that they be given breaks in certain circumstances. The proposed rules are authorized by Minnesota Statutes, §151.06, subd. 1(b). A copy of the proposed rules is published in the State Register. A copy is also attached to this notice as mailed or e-mailed and is available at the agency’s website at http://mn.gov/boards/pharmacy/statutes/rules.jsp, under the Rule-Making Docket heading.

The agency contact person is: Cody Wiberg at Minnesota Board of Pharmacy, 2829 University Avenue SE, Suite 530, Minneapolis, MN 55414. Phone: (651)201-2825, FAX: (612)617-2262, and e-mail: cody.wiberg@state.mn.us.

Statement of Need and Reasonableness. The statement of need and reasonableness contains a summary of the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. A copy of the Statement of Need and Reasonableness is available on the agency’s website at http://mn.gov/boards/pharmacy/statutes/rules.jsp, under the Rule-Making Docket heading. You may also obtain a copy by contacting the agency contact person.
Public Comment. You and all interested or affected persons, including representatives of associations and other interested groups, will have an opportunity to participate. *The administrative law judge will accept your views* either orally at the hearing or in writing at any time before the close of the hearing record. Submit written comments *to the administrative law judge at the address above or to rulecomments@state.mn.us*. All evidence that you present should relate to the proposed rules. You may also submit written material *to the administrative law judge* to be recorded in the hearing record for five working days after the public hearing ends. At the hearing the administrative law judge may order this five-day comment period extended for a longer period but for no more than 20 calendar days. Following the comment period, there is a five-working-day rebuttal period during which the agency and any interested person may respond in writing to any new information submitted. No one may submit additional evidence during the five-day rebuttal period. The Office of Administrative Hearings must receive all comments and responses submitted to the administrative law judge no later than 4:30 p.m. on the due date. All responses received are public and will be available for review at the Office of Administrative Hearings.

The agency requests that any person submitting written views or data to the administrative law judge before the hearing or during the comment or rebuttal period also submit a copy of the written views or data to the agency contact person at the address stated above.

Alternative Format/Accommodation. Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

Modifications. The agency may modify the proposed rules as a result of the rule hearing process. It must support modifications by data and views presented during the rule hearing process. The adopted rules may not be substantially different than these proposed rules, unless the agency follows the procedure under *Minnesota Rules*, part 1400.2110. If the proposed rules affect you in any way, the agency encourages you to participate.

Adoption Procedure after the Hearing. After the close of the hearing record, the administrative law judge will issue a report on the proposed rules. You may ask to be notified of the date when the judge’s report will become available, and can make this request at the hearing or in writing to the administrative law judge. You may also ask to be notified of the date that the agency adopts the rules and files them with the Secretary of State, or ask to register with the agency to receive notice of future rule proceedings. You may make these requests at the hearing or in writing to the agency contact person stated above.

Lobbyist Registration. *Minnesota Statutes*, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. You should direct questions regarding this requirement to the Campaign Finance and Public Disclosure Board at: Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone 651-539-1180 or 1-800-657-3889.
**Order.** I order that the rulemaking hearing be held at the date, time, and location listed above.

__________________________  ________________________________
Date  Cody Wiberg
      Executive Director
STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

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

NOTICE OF APPEARANCE

PLEASE TAKE NOTICE that:

1. The agency named below will appear at the Rules Hearing and all subsequent proceedings in the above-entitled matter.

2. By providing its email address below, the Agency acknowledges that it has read and agrees to the terms of the Office of Administrative Hearings’ e-Filing policy and chooses to opt into receiving electronic notice from the Office of Administrative Hearings in this matter. **Note: Provision of an email address DOES NOT constitute consent to electronic service from any opposing party or agency in this proceeding.**

3. The Agency agrees to use best efforts to provide the Office of Administrative Hearings with the email address(es) for interested parties.

**Party’s/Agency’s Name:** Minnesota Board of Pharmacy
Email: cody.wiberg@state.mn.us  Telephone: (651)201-2830
Mailing Address: 2829 University Avenue SE #530, Minneapolis, MN 55414

**Interested Parties:** We will provide OAH with our list of Parties Who Want to be Notified About Rule-Making.

Dated: August 19, 2016

Signature of Agency Representative
(Executive Director)

[78328/1] Note: This form must be served upon the opposing party/agency. Counsel may not withdraw from representation without written notice.