

STATE OF MINNESOTA  
OFFICE OF ADMINISTRATIVE HEARINGS  
FOR THE MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed Amendments to  
Rules Governing Pharmacy Practice and  
Drug Wholesaling, Minnesota Rules, Chapter  
6800

**REPORT OF THE  
ADMINISTRATIVE LAW JUDGE**

The rules proposed to be amended concern Definitions, Applications for Pharmacy Licenses, Pharmacy License Categories, Transfers of Pharmacy Ownership, Pharmacy Counseling Areas, Supervision of Pharmacy Areas, Automated Counting Devices, Closing a Pharmacy, Applications for Pharmacist Licensure, Drug Manufacturer and Wholesaler Licensure, Registration of Pharmacy Technicians, Training and Educational Requirements for Pharmacy Technicians, Unprofessional Conduct, Answering Machines and Electronic Voice Recording Devices, Compounding, Prospective Drug Reviews, Patient Profiles, Transfer of Prescriptions between Pharmacies, Prepackaging and Labeling, Radiopharmaceutical Labeling, Veterinary Prescription Drug Labels, Interns and Preceptors, Consulting Services to Licensed Nursing Homes, Emergency Kits, Pharmaceutical Services Policies, Variances, and Medical Gas Distributor Registrations.

The rules proposed to be repealed are about Community Satellites, Minnesota Rules 6800.0100, subpart 2a; Licensure Transfer, Minnesota Rules 6800.1300, subpart 6; Patient Medication Profiles, Minnesota Rules 6800.3110, subpart 6; Definitions, Minnesota Rules 6800.5100, subparts 1, 7, 8, 9, and 10; Registration and Reporting, 6800.5300, subpart 4; and Consulting Services to Licensed Nursing Homes, 6800.6500, subpart 3.

Administrative Law Judge Eric L. Lipman of the Office of Administrative Hearings conducted a hearing on Wednesday, March 3, 2011. The hearing commenced at 9:00 a.m., in the University Room, University Park Plaza, 2829 University Avenue Southeast, Minneapolis, Minnesota 55414-3251.

The hearing and this Report are part of a larger rulemaking process under the Minnesota Administrative Procedure Act.<sup>1</sup> The Minnesota Legislature has designed this process so as to ensure that state agencies have met all of the requirements that the state has specified for adopting rules.

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<sup>1</sup> See, Minn. Stat. §§ 14.131 through 14.20.

The hearing was conducted so as to permit agency representatives and the Administrative Law Judge to hear public comment regarding the impact of the proposed rules and what changes might be appropriate. Further, the hearing process provides the general public an opportunity to review, discuss and critique the proposed rules.

The agency must establish that the proposed rules are necessary and reasonable; that the rules are within the agency's statutory authority; and that any modifications that the agency 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.<sup>2</sup>

Cody Wiberg, Executive Director of the Minnesota Board of Pharmacy (Board), appeared at the rule hearing on behalf of the Board. Also present on behalf of the Board were Pat Eggers, Office Manager, Candace Fleming, Compliance Officer; Karen Schreiner, Les Kotek, Stu Vandenberg and Michelle Matilla, Board Surveyors; and Laura Schwartzwald, Jim Koppem, Kay Hanson, Stacey Jassey and Karen Bergrud, Pharmacy Board Members.

Approximately 37 people attended the hearing and signed the hearing register. The proceedings continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed rules. In addition to Mr. Wiberg, 20 members of the public made statements or asked questions at the hearing.

After the hearing ended, the Administrative Law Judge kept the administrative record open for another 20 calendar days – until March 23, 2011 – to permit interested persons and the Board to submit written comments. Following the initial comment period, the hearing record was open an additional five business days so as to permit interested parties and the Board an opportunity to reply to earlier-submitted comments.<sup>3</sup> The hearing record closed on March 30, 2011.

## **SUMMARY OF CONCLUSIONS**

With five exceptions listed below, the Board has established that it has the statutory authority to adopt the proposed rules and that the rules are necessary and reasonable.

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

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<sup>2</sup> Minn. Stat. §§ 14.05, 14.131, 14.23 and 14.25.

<sup>3</sup> See, Minn. Stat. § 14.15, subd. 1.

## FINDINGS OF FACT

### I. Nature of the Proposed Rules

1. The Board is charged with adopting rules for the conduct of its business; and with making and publishing uniform rules for carrying out the provisions of Minnesota Statutes, chapter 151 governing the Board of Pharmacy.<sup>4</sup>

2. With this rulemaking process, the Board seeks to amend numerous provisions of its rules relating to pharmacy licensure, ownership, operations, staffing and dispensing practice.

3. The Board's purpose follows from changes in the professional practice of pharmacy, along with actions of the United States Congress, the Food and Drug Administration and the Drug Enforcement Administration and other federal agencies that oblige changes in Minnesota's Rules for pharmacy and drug wholesaling.<sup>5</sup>

4. In addition, the Board used this rulemaking to respond to requests from certain licensees and registrants regarding technician registration requirements and the proper use of automated counting and distribution devices.<sup>6</sup>

### II. Procedural Requirements of Chapter 14

5. On July 21, 2008, the Board published in the *State Register* a Request for Comments seeking comments on its possible amendment to rules governing pharmacy practice and drug wholesaling. The Request for Comments was published in the *State Register* at 33 S.R. 174.<sup>7</sup>

6. On December 27, 2010, the Board requested approval of its Dual Notice of Intent to Adopt Rules With or Without a Hearing (Dual Notice, or Notice of Intent to Adopt), Additional Notice Plan and asked for permission to omit the text of the proposed rule changes in the *State Register*.

7. By letter dated January 11, 2011, the undersigned Administrative Law Judge approved the Board's Dual Notice and Additional Notice Plan.

8. The Dual Notice of Intent to Adopt Rules, published in the January 18, 2011 *State Register*, set February 17, 2011 as the deadline for comments or to request a hearing.<sup>8</sup>

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<sup>4</sup> Minn. Stat. § 151.06, subd. 1(a)(8) and 1(c)(2010).

<sup>5</sup> Notice of Intent to Adopt Rules With or Without a Public Hearing (Notice of Intent or Dual Notice) at 3.

<sup>6</sup> *Id.* at 3-4.

<sup>7</sup> Ex. A.

<sup>8</sup> Ex. F.

9. Also by letter dated January 11, 2011, the Chief Administrative Law Judge approved the Board's request to omit the text of the proposed rule changes from the publication of the Dual Notice of Intent to Adopt Rules in the *State Register* as unduly cumbersome and expensive, subject to the following conditions:

(a) the Board will post the Dual Notice of Intent to Adopt Rules on its website and include an embedded link directly to the proposed rules on the Board's website; and,

(b) the Board will maintain the link to the proposed rules on the Board's website for 30 days following publication of the Board's Notice of Adoption.

10. On January 18, 2011, the Board sent by U.S. mail a copy of the Dual Notice of Hearing to all persons and associations who had registered their names with the Board for the purpose of receiving such notice and to all persons and associations identified in the additional notice plan.<sup>9</sup>

11. Minn. R. 1400.2080, subp.6 requires a dual notice to be mailed "at least 33 days before the end of the comment period . . . ."

12. The Board mailed its Dual Notice to all persons and associations who had registered their names with the Board for the purpose of receiving such notice and to all persons and associations identified in the additional notice plan 30 days before the end of the comment period. Accordingly, the mailing was made three days late.

13. On January 21, 2011, the Board mailed a copy of the SONAR to the Legislative Reference Library as required by Minn. Stat. §§ 14.131 and 14.23.<sup>10</sup>

14. 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.

15. The Board mailed the SONAR to the Legislative Reference Library three days after the Notice of Intent to Adopt was mailed. Accordingly, this mailing was made six days after it should have occurred.

16. Also on January 21, 2011, the Board sent a copy of the Notice of Hearing and the Statement of Need and Reasonableness to Legislators as required by Minn. Stat. § 14.116.<sup>11</sup>

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<sup>9</sup> Exs. G and I.

<sup>10</sup> Ex. C.

<sup>11</sup> Ex. M.

17. Minn. Stat. § 14.116 requires the agency to send a copy of the Notice of Intent to Adopt and the SONAR to certain legislators on the same date that it mails its Notice of Intent to Adopt to persons on its rulemaking list and pursuant to its additional notice plan.

18. The Board mailed the Notice of Intent to Adopt and the SONAR to the required legislators three days after the Notice of Intent to Adopt was mailed. Thus, this mailing was likewise made six days after it should have occurred.

19. 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 . . . .”

20. The Administrative Law Judge finds that the Board’s three late mailings did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process and that these errors were harmless errors.

21. The Notice of Hearing identified the date and location of the hearing in this matter.<sup>12</sup>

22. The Notice of Hearing included electronic links to the Revisor’s draft of the rules as well as an electronic link to the SONAR, along with instructions for obtaining copies of these documents from the Board.<sup>13</sup>

23. As required by Minn. Stat. § 14.131, by letter dated January 4, 2011, the Commissioner of Minnesota Management and Budget (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 rule and concluded:

I believe the proposed rules may have a fiscal impact on a small number of local government units that own public hospitals containing pharmacies, but any costs would be limited to meeting requirements for private counseling areas, something that many pharmacies have already implemented under previous rules.<sup>14</sup>

24. At the hearing on March 3, 2011, the Board filed copies of the following documents as required by Minn. R. 1400.2220:

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<sup>12</sup> Exs. E. and F.

<sup>13</sup> Exs. E. and F.

<sup>14</sup> Ex. I.

- a. the Board's Request for Comments as published in the *State Register* on July 21, 2008;<sup>15</sup>
- b. the proposed rules dated January 7, 2011, including the Revisor's approval;<sup>16</sup>
- c. the Board's Statement of Need and Reasonableness (SONAR);<sup>17</sup>
- d. the Certificate of Mailing the SONAR to Legislative Reference Library on January 21, 2011<sup>18</sup>
- e. the Dual Notice as mailed and as published in the *State Register* on January 18, 2011;<sup>19</sup>
- f. the Certificate of Mailing the Dual Notice to the rulemaking mailing list on January 18, 2011, and the Certificate of Accuracy of the Mailing List;<sup>20</sup>
- g. the Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan on January 18, 2011;<sup>21</sup>
- h. the written comments on the proposed rules that the Board received during the comment period that followed the Dual Notice;<sup>22</sup>
- i. the written comments on the proposed rules that the Board received after the close of the comment period but before the rules hearing;<sup>23</sup>
- j. the January 11, 2011 letter from Chief Administrative Law Judge Krause approving the Board's request to omit the text of the proposed rules changes from the publication of the Dual Notice of Intent to Adopt Rules in the *State Register* as unduly expensive and burdensome.<sup>24</sup>

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<sup>15</sup> Ex. A.

<sup>16</sup> Ex. B.

<sup>17</sup> Ex. C.

<sup>18</sup> Ex. D.

<sup>19</sup> Exs. E and F.

<sup>20</sup> Exs. G and H.

<sup>21</sup> Ex. I.

<sup>22</sup> Ex. J.

<sup>23</sup> Ex. K.

<sup>24</sup> Ex. L.

- k. the Certificate of Sending the Dual Notice and the Statement of Need and Reasonableness to Legislators on January 21, 2011.<sup>25</sup>
- l. January 4, 2011 memorandum from Minnesota Management and Budget;<sup>26</sup>
- m. the Certificate of the Board of Pharmacy Authorizing Resolution authorizing Cody Wiberg to act as the Board's representative in the Notice and Hearing phases of the rulemaking;<sup>27</sup>
- n. the Board Analysis of and Response to Comments Received during the 30-day Comment Period that Followed Publication of the Dual Notice.<sup>28</sup>

### III. Statutory Authority

25. The Board cites Minn. Stat. § 151.06 as its source of statutory authority for these proposed rules. Minn. Stat. § 151.06, subdivision 1(a)(8) grants the Board authority “to . . . adopt rules for the conduct of its business;” and subdivision 1(c) requires the Board “to make and publish uniform rules for carrying out and enforcing the provisions of this chapter. The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists.”<sup>29</sup>

26. The Administrative Law Judge concludes that the Board has the statutory authority to adopt rules governing pharmacy practice and drug wholesaling.

### IV. Impact on Farming Operations

27. Minn. Stat. § 14.111 imposes additional notice requirements when the proposed rules affect farming operations. The statute requires that an agency provide a copy of any such changes to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rules in the *State Register*.

28. The proposed rules do not impose restrictions or have an impact on farming operations. The Administrative Law Judge finds that the Board was not required to notify the Commissioner of Agriculture.

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<sup>25</sup> Ex. M.

<sup>26</sup> Ex. N.

<sup>27</sup> Ex. O.

<sup>28</sup> Ex. P.

<sup>29</sup> Minn. Stat. § 151.06, subd. 1; see also SONAR at 1.

## V. Additional Notice Requirements

29. Minn. Stat. §§ 14.131 and 14.23 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.

30. On January 18, 2011, the Board provided the Dual Notice of Intent to Adopt in the following manner, according to the Additional Notice Plan approved by the Office of Administrative Hearings:<sup>30</sup>

- The Dual Notice of Intent to Adopt Rules was posted on the Board's website, <http://www.phcybrd.state.mn.us/rulemake2010.htm>. The Dual Notice included embedded links directly to the proposed rules and the SONAR on the website. The Board has maintained the links continuously since they were posted, pursuant to the Chief Administrative Law Judge's direction as part of the approval to omit publication of the rules with the Dual Notice in the *State Register*.
- A notice of the website posting of the Dual Notice of Intent to Adopt was sent, via e-mail, to every licensee and registrant for whom the Board has an e-mail address. These individuals were also notified that the Request for Comments, the SONAR and other relevant documents were posted on the Board's website.
- A notice of the website posting of the Dual Notice and related documents was posted on the Board's Facebook page.

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

## VI. Statutory Requirements for the SONAR

32. The Administrative Procedure Act obliges an agency adopting rules to address seven factors in its Statement of Need and Reasonableness.<sup>31</sup> Those factors are:

- (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;

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<sup>30</sup> Ex. I; see SONAR at 51-52.

<sup>31</sup> Minn. Stat. § 14.131 (2010).

- (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;
- (3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
- (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;
- (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;
- (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; and
- (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.

#### **A. Regulatory 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.**

33. The Board states that the following groups will be affected by the proposed rules:<sup>32</sup>

- Individuals or businesses that are licensed or registered by the Board, including pharmacists, pharmacy technicians, pharmacist interns, pharmacy owners, drug wholesalers and manufacturers, controlled substance researchers and medical gas manufacturers and distributors.
- Staff in hospitals, long-term care facilities and home health agencies will be affected by some of the proposed changes that relate to drug distribution and pharmacy services in those settings.

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<sup>32</sup> SONAR at 45-47.

- The public will benefit from the proposed regulatory changes because the updates will result in safer and better pharmacy practice.

The Board asserts the following particular costs of the proposed rules:

- Some pharmacies will be obliged to upgrade their counseling areas and thus will bear a cost.
- Pharmacies may incur new costs to ensure that temperature-sensitive drugs are delivered in appropriate containers and handled according to appropriate procedures.
- Some Pharmacy Technicians may experience slightly increased costs when meeting the new continuing education standards.
- Applicants for pharmacy, wholesaler and manufacturer, controlled substance researcher, and medical gas distributor licenses or registrations will face an increased cost if they fail to complete the application process within 12 months of the date in which the application was originally submitted.
- Wholesalers and manufacturers that currently license only the primary location of the parent entity will experience increased costs to the extent that they seek to license additional facilities to receive shipments in Minnesota.
- A pharmacy that is slated to close and the pharmacy that purchases its prescription files *may* bear a cost if the closing pharmacy has to notify the public in advance about the closing. The pharmacy purchasing the files may find them to be less valuable because patients may transfer their prescriptions to a third pharmacy before the closing date.

The Board asserts the following particular benefits of the proposed rules:

- Individuals wanting to open “limited service” pharmacies will benefit by having a more formal process for gaining Board approval.
- Individuals who are purchasing a pharmacy will benefit by having an additional time period during which they can operate under the existing license.
- The public will benefit by not having their pharmacy unexpectedly close if there is some last-minute problem during the ownership transfer process.
- Members of the public who obtain prescriptions from certain pharmacies will benefit when those pharmacies improve their counseling areas.
- Members of the public will benefit from this proposed rule change because there will be better notice of a pharmacy closure. As the Board argues, with

more notice, pharmacy patrons will likely have less trouble refilling prescriptions and greater choices in selecting another pharmacy.

- Pharmacists who apply for licensure transfer (reciprocity) and the pharmacies that want to hire these professionals will benefit from the elimination of the requirement that pharmacists must practice in another state for at least 12 months before they can obtain reciprocal licensure in Minnesota.
- Pharmacists who are also registered preceptors will benefit from a wider selection of preceptor Continuing Education programs.
- Pharmacists and pharmacies operating under a variance will benefit because, under the revised rules, certain practices will be approved by rule – thus reducing the need for submitting a request for a variance to the Board.
- Members of the public will benefit from authorizations to pharmacies to deliver filled prescriptions to a customer’s place of employment.
- Members of the public relying upon temperature-sensitive medications will benefit from more stringent handling practices and a reduction in the likelihood of adverse reactions from improperly delivered drugs.
- Members of the public, pharmacists and pharmacy owners will benefit from more stringent standards for registration of pharmacy technicians. The Board predicts that the new standards will raise the quality of technicians.

**(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.**

34. The Board states it will incur some costs because of the proposed changes – most notably, associated with upgrades to the systems for registering technicians and licensing of pharmacies. The Board has anticipated those costs and included them in its biennial budget request. None of the other Board proposals result in any costs to the Board. To the extent that any pharmacy has increased costs due to these proposed changes, pharmacies operated by state agencies (DHS, MnSCU, Veteran’s Homes, etc.) may have similar increased costs. No other state agencies should have any increased costs.

35. There may be a slight increase in the amount of fees collected from drug wholesalers and manufacturers, on account of the licensing of additional locations.<sup>33</sup>

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<sup>33</sup> SONAR at 47.

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

36. The Board asserts that most of its proposed changes do not involve any costs to licensees, registrants or the Board.

37. In other instances, the Board redrafted its originally-proposed rule so as to meet its regulatory objective in ways that involved fewer compliance costs to regulated parties.

**(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.**

38. Most of the Board's proposed changes do not involve costs, new burdens or features that are not part of widely accepted pharmacy practice.

39. Where the proposed changes did prompt additional compliance costs the Board engaged stakeholders – including the major trade groups and its own advisory panels – to develop cost-effective, consensus solutions to regulatory problems. For example, the proposed changes to the technician registration system were developed through consultation with an advisory group of associations from within the pharmacy profession.<sup>34</sup> The proposed registration rules reflect the consensus, but not unanimous view, that emerged from the meetings of the Minnesota Pharmacists Association Technician Task Force and the Board's Technician Rules Advisory Committee.<sup>35</sup>

**(5) The probable costs of complying with the proposed rules.**

40. Pharmacies that need to remodel their facilities in order to have adequate counseling areas will incur costs associated with the upgrades. The Board predicts that these costs may range from hundreds of dollars to thousands of dollars.

41. Individuals that do not complete applications for pharmacy, wholesaler, manufacturer, medical gas distributor and controlled substance researcher licenses or registrations within 12 months of the original submission date will have to submit a new application. The new application fees range from \$50 to \$180.

42. Manufacturers and wholesalers that have only licensed the primary location of their business will need to pay a fee ranging from \$130 to \$180 for each

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<sup>34</sup> See, SONAR at 2 (“The Technician Rules Advisory Committee (TRAC) included representatives of the Minnesota Pharmacists Association (MPhA), the Minnesota Society of Health-System Pharmacists (MSHP), the National Association of Chain Drug Stores, the Minnesota Retailer’s Association, and the University of Minnesota College of Pharmacy”).

<sup>35</sup> *Id.*, at 48-49.

additional location that is licensed. A location from which the manufacturer or wholesaler ships products to Minnesota needs the accompanying license.

43. Those closing a pharmacy will incur costs associated with notifying the public about the closure.

44. Because some, but not all, technician continuing education courses require an enrollment fee, some Pharmacy Technicians may experience slightly increased costs when meeting the new continuing education standards.

**(6) 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.**

45. The Board contends that the proposed rule changes will promote safer use of medications, reduce medication errors and reduce drug-related morbidity and mortality.

46. It further asserts that if the changes are not adopted, Minnesota patients will be more likely to experience these problems. Such outcomes will result in increased costs to patients, insurers, employers, federal, state and local governments and society at large.<sup>36</sup>

**(7) 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.**

47. The Board is unaware of any differences between the proposed rule changes and existing federal regulations.<sup>37</sup>

**B. Performance-Based Regulation**

48. The Administrative Procedure Act<sup>38</sup> also 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.<sup>39</sup>

49. In developing these rules, the Board has allowed flexibility in meeting the requirements in several areas. For example, as noted above, pharmacies will be

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<sup>36</sup> SONAR at 49-50.

<sup>37</sup> SONAR at 50.

<sup>38</sup> Minn. Stat. § 14.131.

<sup>39</sup> Minn. Stat. § 14.002.

allowed to propose designs for counseling areas other than ones that utilize the partitions that most pharmacies use. Likewise, technicians will be able to choose from several training options and most will have up to one year to complete the required training. The owners of pharmacies that will be closed will be allowed to choose from several different options for notifying customers of the closure. Preceptors will be able to choose from a wider selection of preceptor continuing education programs than before. The Board has responded to calls for regulatory flexibility from its regulated parties.<sup>40</sup>

### **C. Consultation with the Commissioner of Minnesota Management and Budget (MMB)**

50. The Board consulted with Minnesota Management and Budget. It received a written evaluation from MMB on January 4, 2011. MMB concluded that:

- The changes proposed cover a wide range of topics in pharmacy practice.
- There would be no impact on most local governments because these entities do not provide pharmacy services.
- In a small number of instances, a city or a county owns a public hospital that contains a pharmacy.
- The rule changes specify guidelines for patient counseling areas in pharmacies. The proposed changes provide further clarification and specificity to the existing counseling area standards. If a pharmacy does not now have such a counseling area, costs for making the required additions ranges from hundreds to thousands of dollars. A more precise estimate of potential costs is not available.
- Other proposed rule changes are not anticipated to have a fiscal impact on pharmacies in public hospitals operated by local governments.<sup>41</sup>

51. 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.

### **D. Cost to Small Businesses and Cities under Minn. Stat. § 14.127**

52. 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

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<sup>40</sup> SONAR at 50.

<sup>41</sup> Ex. N.

Administrative Law Judge must review the determination and approve or disapprove it.<sup>42</sup>

53. The Board determined that the cost of complying with the proposed rule changes will not exceed \$25,000 for any business or any statutory or home rule charter city. A business or a city that owns a pharmacy might have to remodel in order to have a counseling area that provides a reasonable assurance of privacy. However, the cost of such a remodeling project – particularly after the Board’s most recent set of clarifying amendments – is not likely to exceed \$25,000. The probable costs, if any, associated with the proposed technician registration requirements are unknown – because claims of increased labor costs (following from more stringent education requirements) and reduced labor costs (as technicians assume some duties now only performed by higher-paid pharmacists) are both grounded in this record. Because these requirements will be phased in over several years, it is unlikely that the thresholds in Minn. Stat. § 14.127 will be met in any one year.<sup>43</sup>

54. The Administrative Law Judge finds that the agency has made the determination required by Minn. Stat. § 14.127 and approves that determination.

#### **E. Adoption or Amendment of Local Ordinances**

55. Under Minn. Stat. § 14.128, the agency 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 agency 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.<sup>44</sup>

56. The Board concluded that no local government will need to adopt or amend an ordinance or other regulation to comply with the proposed rules. The Board is unaware of any local governments that adopt ordinances and regulations concerning the operation of pharmacies. Local governments might have ordinances and regulations that apply to all retail businesses – such as zoning restrictions. The Board’s proposed rule should not require local governments to adopt or amend those more general ordinances and regulations.<sup>45</sup>

57. The Administrative Law Judge finds that the agency has made the determination required by Minn. Stat. § 14.128 and approves that determination.

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<sup>42</sup> Minn. Stat. § 14.127, subs. 1 and 2.

<sup>43</sup> SONAR at 51.

<sup>44</sup> 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, subs. 2 and 3.

<sup>45</sup> SONAR at 51.

## VII. Rulemaking Legal Standards

58. The Administrative Law Judge must make the following inquiries: Whether the agency has statutory authority to adopt the rule; whether the rule is unconstitutional or otherwise illegal; whether the agency has complied with the rule adoption procedures; whether the proposed rule grants undue discretion to government officials; whether the rule constitutes an undue delegation of authority to another entity; and whether the proposed language meets the definition of a rule.<sup>46</sup>

59. Under Minn. Stat. § 14.14, subd. 2, and Minn. R. 1400.2100, the agency must establish the need for, and reasonableness of, a proposed rule by an affirmative presentation of facts. In support of a rule, the agency may rely upon materials developed for the hearing record,<sup>47</sup> “legislative facts” (namely, 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),<sup>48</sup> and the agency’s interpretation of related statutes.<sup>49</sup>

60. 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.”<sup>50</sup> 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.”<sup>51</sup>

61. 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.<sup>52</sup> 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.<sup>53</sup>

62. Because both the Board and the Administrative Law Judge suggest changes to the proposed rule language after the date it was originally published in the *State Register*, it is also necessary for the Administrative Law Judge to determine if this

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<sup>46</sup> See, Minn. R. 1400.2100 (2009).

<sup>47</sup> See, *Manufactured Housing Institute v. Petterson*, 347 N.W.2d 238, 240 (Minn. 1984); *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. App. 1991).

<sup>48</sup> Compare generally, *United States v. Gould*, 536 F.2d 216, 220 (8th Cir. 1976).

<sup>49</sup> See, *Mammenga v. Board of Human Services*, 442 N.W.2d 786, 789-92 (Minn. 1989); *Manufactured Housing Institute v. Petterson*, 347 N.W.2d 238, 244 (Minn. 1984).

<sup>50</sup> *Manufactured Hous. Inst.*, 347 N.W.2d at 244.

<sup>51</sup> 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).

<sup>52</sup> *Peterson v. Minn. Dep’t of Labor & Indus.*, 591 N.W.2d 76, 78 (Minn. App. 1999).

<sup>53</sup> *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. App. 1991).

new language is substantially different from that which was originally proposed. The standards to determine whether any changes to proposed rules create a substantially different rule are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if:

“the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice;”

the differences “are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice;” and

the notice of hearing “provided fair warning that the outcome of that rulemaking proceeding could be the rule in question.”

63. In reaching a determination regarding whether modifications result in a rule that is substantially different, the Administrative Law Judge is to consider:

whether “persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests;”

whether the “subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing;” and

whether “the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing.”

## **VIII. Rule by Rule Analysis**

64. Several sections of the proposed rules were not opposed by any member of the public and were adequately supported by the SONAR. Accordingly, this Report will not necessarily address each comment or rule part. Rather, the discussion that follows below focuses on those portions of the proposed rules as to which commentators prompted a genuine dispute as to the reasonableness of the Board’s regulatory choice or otherwise requires closer examination.

65. The Administrative Law Judge finds that the Board has demonstrated by an affirmative presentation of facts the need for and reasonableness of all rule provisions that are not specifically addressed in this Report.

66. Further, the Administrative Law Judge finds that all provisions that are not specifically addressed in this Report are authorized by statute and that there are no other defects that would bar the adoption of those rules.

## 6800.0100 - DEFINITIONS

### A. Subp. 2a. Community Satellites

67. The Board had originally proposed to repeal the regulatory definition and category for “community satellite” pharmacies.

68. In response to stakeholder comment, the Board has decided to withdraw its proposed repeal of this regulation so that it might have the opportunity to more fully assess the continued viability of this category.

69. The Board’s action in maintaining the existing regulation is needed and reasonable.

### B. Subpart 11b. Chart orders

70. At the suggestion of certain commentators the Board proposes to modify its definition of chart orders to require the inclusion of an identifier in addition to the patient’s name. The Board proposes to revise Revisor’s Draft RD3900 as follows:

Subp. 11b. Chart order. “Chart order” means a prescription drug order for a drug that is to be dispensed by a pharmacist, or by a pharmacist-intern under the direct supervision of a pharmacist, and administered by an authorized person only during the patient's stay in a hospital or long-term care facility. The chart order shall contain the name of the patient, **another patient identifier such as a birth date or medical record number**, the drug ordered, and any directions as the practitioner may prescribe concerning strength, dosage, frequency, and route of administration. The manual or electronic signature of the practitioner shall be affixed to the chart order at the time it is written or at a later date in the case of verbal chart orders.

Many hospitals and long-term care facilities already use birth dates, medical record numbers or other identifiers for such purposes.<sup>54</sup> Requiring the use of the second identifier in chart order would prevent medical errors, is a needed and reasonable alternative and would not be a substantial change from the rule as originally proposed.

### C. Subpart 14. Nonsterile product compounding Subpart 15. Sterile product compounding

71. The Board proposes to revise the definition of “nonsterile product compounding” to harmonize it with the terminology used in United States Pharmacopeia Chapter 795. The Board proposes to revise Revisor’s Draft RD3900 as follows:

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<sup>54</sup> SONAR at 51.

Subp. 14. Nonsterile **preparation** compounding. “Nonsterile **preparation** compounding” means the preparation, mixing, assembling, *altering*, packaging and labeling of a nonsterile drug **preparation**, according to United States Pharmacopeia Chapter 795.

Subp. 15. Sterile **preparation** compounding. “Sterile **preparation** compounding” means the preparation, mixing, assembling, *altering*, packaging and labeling of a drug **preparation** that achieves sterility, according to United States Pharmacopeia Chapter 797.

Using the same terminology that is found in the referenced source would avoid confusion by regulated parties, is a needed and reasonable alternative and would not be a substantial change from the rule as originally proposed.

**D. Subpart 18. High-alert drug.**

72. In the rules as originally proposed, the Board used both the terms “high-risk drug” and “high-alert drug,” without distinguishing or defining the two terms of art.

73. To clarify the rules, the Board proposes to eliminate the term “high-risk drug” from the regulatory text<sup>55</sup> and to define “high alert drug.” Defining the term as the Institute for Safe Medication Practices does, the Board proposes to add the following definition to Part 6800.0100:

Subp. 18. High-alert drug. “High-alert drug” means a drug that bears a heightened risk of causing significant patient harm when it is used in error.

The addition of the missing definition, and deletion of the potentially conflicting term, are needed and reasonable and would not be a substantial change from the rule as originally proposed.

**6800.0350 - LICENSE CATEGORIES**

74. The Board proposes to revise the rule providing for pharmacy license categories and renewal of licensure so as to clarify the rule, simplify the renewal and inspection process, and list the key regulated activities that are permitted at a licensed facility.

75. Following the receipt of public comments, the Board proposes to further revise Revisor’s Draft RD3900 as follows:

A pharmacy must be licensed in one or more of the following categories:

A. community/~~retail~~outpatient;

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<sup>55</sup> See, e.g., Revisor’s Draft RD3900 at page 32, line 4.

- B. hospital;
- C. ~~parenteral-enteral~~/home health care;
- D. long-term care;
- E. nuclear;
- F. central service;
- G. non-sterile **preparation** compounding;
- H. sterile **preparation** compounding;
- I. veterinary; and
- J. limited service.

Licensing of a pharmacy in more than one category shall not result in an increase in the license fee.

No pharmacy may engage in providing products or services in categories for which it is not licensed. A pharmacy must designate its category or categories on license renewal or application for an initial license. **Effective July 1, 2012, an initial or renewed license issued by the Board shall list each license category for which the pharmacy has received Board approval; a pharmacy must receive Board approval before providing services in a license category not listed on its license; a pharmacy must notify the Board if it no longer provides services in a license category; and the Board shall issue a revised license, without imposing an additional fee, if it approves a pharmacy's request to provide services in additional license categories or if a pharmacy no longer provides services in one or more license categories.**

The Board may establish special conditions for licensure, appropriate to the situation, before approving a license application for a pharmacy with a limited service license category. Such pharmacies must also apply for and receive any necessary variances, pursuant to part 6800.9900, before an application for licensure will be approved.

The revised rule will improve the Board processes, reduce the numbers of variances requested, is a needed and reasonable alternative, and would not be a substantial change from the rule as proposed.

## **6800.0700 - PHARMACY, SPACE AND SECURITY**

76. A key component of this rulemaking is the establishment of new and more rigorous standards for pharmacy consulting areas.

77. The Board proposes to further revise its original proposal to clarify that partitions, computer terminals or solid enclosures are not mandated by the new standards.<sup>56</sup> The Board proposes to revise Revisor's Draft RD3900 as follows:

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<sup>56</sup> See, Board's Post-Hearing Comments, at 11-12.

E. in the case of a ~~community/retail~~ community/outpatient pharmacy, contains an area where consultation between the patient and the pharmacist must be conducted with an reasonable assurance of privacy. ~~Community/retail pharmacies in existence on February 1, 1999, have until February 1, 2001, to comply with this item; and~~ All new and remodeled community/outpatient pharmacies must meet the standards of this paragraph. A pharmacy licensed before January 1, 2011, must meet the standards within two years of that date, unless the pharmacy has an existing counseling area that **has been** deemed by the Board to provide a reasonable assurance of privacy. **If** pharmacies **use** partitions to create a consultation area in which the patient will typically remain standing, the partitions must be sound-dulling and at least 7 feet high and 24 inches deep. The patient must be able to **enter** into the area created by the partitions so that the partitions are on each side of the patient. Consultation areas not involving the use of partitions may be approved if the Board deems that they will provide a reasonable assurance of privacy. Consultation areas must not contain any item for sale apart from the articles needed for counseling sessions. **Pharmacists must have access to patient profiles in order to comply with part 6800.0910.** Consultation areas must be accessible to the patient from the outside of the prescription dispensing area and be open at all times when the pharmacy is open.

These revisions reduce the compliance costs associated with a more robust privacy rule. The revised rule will improve patient privacy, is a needed and reasonable alternative and would not be a substantial change from the rule as proposed.

#### **6800.1010 - CLOSING A PHARMACY**

78. As part of its original proposal, the Board established a requirement that the public be given notice in advance of a planned closing of a pharmacy. In response to stakeholder comment, the Board proposes to clarify the rule still further by making the following additions, at Page 9, Line 19 of Revisor's Draft RD3900:

In the case of patients who are residents of long-term care facilities, the pharmacy shall provide a written notice to the patients, the caregivers of the patients or to the long-term care facilities in which the patients reside at least 30 days prior to the date on which the pharmacy will be closed.

The proposed rule and modifications are needed and reasonable and would not be a substantial change from the rule as proposed.

#### **6800.1250 - APPLICATIONS FOR LICENSURE**

79. The Board proposes to promulgate the licensure requirements for graduates of colleges approved by the Accreditation Council for Pharmacy Education,

graduates of Canadian colleges of pharmacy and graduates of other foreign pharmacy schools.

80. The proposed rule is consistent with the standards of the National Association of Boards of Pharmacy and the Foreign Pharmacy Graduate Examination Committee. Likewise, the proposed rule codifies the Board's existing (but as yet unpromulgated) practices regarding licensure of foreign graduates.<sup>57</sup> Accordingly, the rule is needed and reasonable.

#### **6800.1440 - REQUIREMENTS FOR WHOLESALE DRUG DISTRIBUTORS.**

81. The Board proposes to correct a reference to the publisher of the United States Pharmacopeia / National Formulary and to withdraw the formulary-related mandate proposed at page 19, lines 19 and 20 of the Revisor's Draft RD3900.

82. Both adjustments are needed and reasonable and do not make a substantial change from the rule as originally proposed.

#### **6800.1500 - CONTINUING EDUCATION**

83. The Board proposes to establish a new continuing education standard for pharmacy technicians. Once fully implemented, the Board would require 20 hours of approved continuing education as a condition of receiving the annual registration as a pharmacy technician.

84. Several stakeholders urged the Board to soften the new requirement – either by accepting a technician's initial certification in lieu of the required credit hours or by permitting technicians to meet the requirement by attending course work aimed at, and accredited for, licensed pharmacists. Concerned that these modifications would undermine its regulatory objectives (particularly as to cost and quality of the program), the Board declined these invitations.<sup>58</sup>

85. The proposed rule is needed and reasonable.

#### **6800.2600 - AUTOMATED COUNTING AND DISTRIBUTION**

##### **A. Subparts 1, 2 and 3**

86. In response to a number of Board investigations of complaints involving the improper loading of automated counting devices (and the dispersal of drugs in error), the Board proposed new rules regulating the operation of automatic counting and distribution devices.

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<sup>57</sup> See, *id.*, at 13-14.

<sup>58</sup> *Id.*, at 16-19.

87. Several commentators suggested that the rule originally proposed by the Board was unduly restrictive and prohibited safe and familiar pharmaceutical practice. Specifically, the commentators suggested that it unnecessarily restricted the deployment of these machines, re-stocking of dispensed but unused drugs, certification of device accuracy after a prescription had been filled and labeling that was appropriate to such devices.<sup>59</sup>

88. Agreeing, the Board proposes to modify Revisor's Draft RD3900, beginning on Page 27, line 9, as follows:

The pharmacy responsible for the control of the automated counting device or automated drug distribution system may proceed with its use unless the Board has provided written notification to the pharmacy that the device or system may not be used. The Board must provide such written notification within 60 days of receiving the documents required under this paragraph. The written notification must specify the steps that the pharmacy must take in order to use the system.

....

**Subp. 2. Automated counting devices.** In addition to the requirements in subpart 1, the following requirements apply to automated counting devices.

A. ~~The filling of cells or cassettes is **considered to be prepackaging** subject to the requirements of Part 6800.3200, subp. 1, paragraphs A, B, E, G, F and H, except that paragraph F shall only apply if the pharmacy's policies and procedures are such that a pharmacist must verify the accuracy of the filling of the cell or cassette.~~ Only one cell or cassette may be filled at a time. ~~Drugs previously removed from a manufacturer's stock container may not be used to fill a cell or cassette. No drug may be distributed from an automated counting device unless a pharmacist has certified the accuracy of the filling of each cell or cassette. All manufacturer stock containers used to fill a cell or cassette must be available for the pharmacist to check during the certification process.~~

B. The labeling of cells and cassettes is subject to the requirements of Part 6800.3200, Subp. 2, paragraphs A, B, C and F. The requirements of Part 6800.3200, Subp. 2, paragraphs D and E also apply unless the information required under those paragraphs is maintained in the packaging control record.

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<sup>59</sup> *Id.*, at 20-25.

Subp. 3. Automated drug distribution systems.

....

D. The pharmacy and therapeutics or **relevant** committee shall develop and regularly review a list of drugs or categories of drugs that are prohibited from being distributed through an automated distribution system....

E. The use of an open matrix drawer that allows access to one drug at a time must be limited to noncontrolled substance drugs, unless the entire drawer contains only one controlled substance product....

(1) large bulky items such as intravenous infusion bags;

(2) nonlegend drugs that are safely **arranged** ....

The revised rule balances the pharmacist's need to use automated counting devices as they were designed while still holding licensed professionals accountable for the accuracy of their dispensing activities.

89. For added clarity, the Board may wish to further revise the first sentence of subpart 2 (A) so that it reads: "The filling of cells or cassettes is subject to the requirements of Part 6800.3200, subp. 1, paragraphs A, B, E, G, F and H, except that paragraph F shall only apply if the pharmacy's policies and procedures are such that **require** a pharmacist to ~~must~~ verify the accuracy of the filling of the cell or cassette." The revised rule as written is not defective. Accordingly, the Board may elect to make this technical correction if it sees fit.

90. The modifications to the proposed rules are needed and reasonable and do not make a substantial change from the rules as they were originally proposed.

**B. Subpart 3 (F)**

91. As part of its original proposal, the Board proposed a requirement that obliged pharmacists to have the removal of a high-alert drug verified by a second licensed health care professional "whenever possible."

92. A number of stakeholders objected to the proposal on the grounds that the requirement was potentially burdensome, particularly when a pharmacist had earlier reviewed the order<sup>60</sup> Agreeing that medical errors are far less likely to occur following review of an order by a pharmacist, the Board proposed to revise the Revisor's Draft RD3900, beginning on page 32, line 21, as follows:

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<sup>60</sup> *Id.*

F. Whenever possible, removal of a high-alert drug from the system, **when a pharmacist has not reviewed the order for the drug**, should be checked by a second licensed health care professional to ensure that the prescription drug order is being correctly interpreted and followed.

93. While the revision perhaps addresses some of the stakeholders' concerns, it does not cure the defect in the original proposal – namely, that regulated parties cannot discern from the text when a review by a second licensed health care professional is required. In order to comply with the rule as proposed, the regulated party will need to guess as to what the Board will regard as “possible.” Likewise, the standards that the Board’s inspectors might use in making this determination are neither stated, nor a part of common understanding, so as to make the intended meaning clear.<sup>61</sup>

94. If a proposed rule fails to provide a reasonable notice of when the regulatory standards will apply, the proposed rule is defective.<sup>62</sup>

95. One possible cure to this defect is to state that among the factors the Board will consider when imposing regulatory discipline for improper removal or dispensing of a high-alert drug, is whether a licensed pharmacist had earlier reviewed the order and whether a second licensed health care professional had reviewed the order. In this way, the Board might encourage the best and safe practices for dispensing these drugs, while removing confusion as to when the obligation to follow these practices applies.

96. Alternatively, the Board could specify the circumstances when it is “possible” for an order to be checked by a second licensed health care professional.

97. Modifying the proposed rules in these ways is needed and reasonable and would not make a substantial change from the rules as they were originally proposed.

### **C. Subpart 3 (J)**

98. In its original draft of the new rules, the Board proposed a requirement that obliged licensees with automated distribution devices to undertake monthly inspection of the machines so as to ensure safe and accurate operation. Several stakeholders commented that, because licensed staff may be in frequent contact with these devices – in effect, continually assessing them – a monthly inspection requirement was burdensome and ineffective.

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<sup>61</sup> Compare, e.g., *In the Matter of the Proposed Rules Governing the Licensure of Treatment Programs for Chemical Abuse and Dependency and Detoxification Programs, Minnesota Rules, Chapter 9530*, OAH Docket No. 3-1800-15509-1 (2004) (“The Administrative Law Judge finds the requirement that a program have a particular licensure, and ‘any additional certifications required by the department,’ to be impermissibly vague and a defect in the rule”) (<http://www.oah.state.mn.us/aljBase/180015509.rr.htm>).

<sup>62</sup> See, *In the Matter of Proposed Amendments to Rules Governing Apprenticeship Wages*, OAH Docket No. 7-1900-17022-1, slip op. at 36 (2006) (<http://www.oah.state.mn.us/aljBase/190017022.rr.htm>).

99. Agreeing in part, the Board proposes to remove the requirement for monthly evaluation and substitute a requirement that licensees conduct “[r]outine evaluations of automated distribution devices ....”

100. As before, with subpart 3F above, the Board’s addition introduces ambiguity into the proposed regulation. If a proposed rule fails to provide a reasonable notice of when the regulatory standards will apply, it is defective.

101. One possible cure to this defect is to re-introduce the concept of a monthly inspection as the regulatory minimum. Accordingly, page 31, line 10 of Revisor’s Draft RD 3900 might read:

“~~J. A monthly Routine inspection~~ evaluations of automated distribution devices must be performed, at least monthly, to ensure, at a minimum, that:”

Modifying the proposed rules in this way is needed and reasonable and would not make a substantial change from the rules as they were originally proposed.

#### **D. Subpart 3 (N)**

102. As part of its original proposal, the Board proposed to codify its existing guidelines for automated medication storage and distribution systems<sup>63</sup> into a formal rule – including the practice that pharmacies use failure mode effect analysis, or some other process, to resolve failures in the dispensing system. As part of the new requirement, the Board proposed:

An ongoing failure mode effect analysis or quality assurance process should be developed that addresses possible system failures, process failures, high-risk drugs, medication errors and controlled substance discrepancies.

To the extent that this language sets forth an aspirational standard that a licensee should, but is not required to meet, it is not a rule.<sup>64</sup>

103. One possible cure to this defect is to require such processes as regulatory minimum. Accordingly, page 32, line 2 of Revisor’s Draft RD 3900 might read:

An ongoing failure mode effect analysis or quality assurance process ~~should be developed that addresses~~ **must be in place and address**

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<sup>63</sup> See, *Guidelines for Automated Medication Storage and Distribution Systems* (Minnesota Board of Pharmacy, March 1, 2001) (<http://www.phcybrd.state.mn.us/forms/autohosp.pdf>).

<sup>64</sup> See, Minn. Stat. § 14.02 (“Rule means every agency statement of general applicability and future effect, including amendments, suspensions, and repeals of rules, adopted to implement or make specific the law enforced or administered by that agency or to govern its organization or procedure”).

possible system failures, process failures, high-risk drugs, medication errors and controlled substance discrepancies.

Alternatively, the Board could delete the sentence that begins at page 32, line 2. Modifying the proposed rules in either of these ways would be needed and reasonable and would not make a substantial change from the rules as they were originally proposed.

## **6800.3000 - PRESCRIPTIONS AND DISTRIBUTION OF DRUGS**

104. In its original draft of the new rules, the Board proposed a requirement that permitted pharmacies, with proper authorization, to deliver prescribed drugs to a patient's place of employment.

105. While the authorization of this practice is welcomed by the stakeholders who commented, some suggested that the phrasing of Revisor Draft RD3900 obliged licensed entities to obtain authorization in writing before the materials are dispensed – a requirement that these stakeholders regarded as impractical and burdensome in many instances. Still other commentators argued that to the extent that the draft rule obliged mail order pharmacies to document that each of its customers refused pharmaceutical counseling, it was unnecessarily costly and burdensome. Lastly, one commenter suggested that the requirement that pharmacies follow both the “recommendations of the manufacturer and the United States Pharmacopeia Chapter 1079,” was unduly restrictive.

106. Agreeing in part, the Board proposes to modify Revisor's Draft 3900 to make the following changes.

A pharmacy may deliver filled prescriptions at the place of employment of the patient or a designated caregiver of the patient only if the pharmacy

(1) obtains **and documents the** authorization of the patient or patient's caregiver for delivery at the place of employment;

(2) ensures the filled prescription order is delivered directly to the patient **or the patient's caregiver as authorized;** and

(3) ensures the security of protected health information.

B. Direct prescription delivery. A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient must, based on the judgment of the pharmacist:

(1) use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes must include the use of appropriate packaging material

and devices, according to the recommendations of the manufacturer **or** the United States Pharmacopeia Chapter 1079, in order to ensure the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

....

(4) provide for an electronic, telephonic or written communication mechanism for a pharmacist or a pharmacy intern working under the direct supervision of a pharmacist, to offer counseling to the patient, ~~unless the patient refuses the consultation. Refusal of consultation by patients must be documented.~~ The patient must receive information indicating what the patient should do if the integrity of the packaging or medication has been compromised during shipment.

These revisions reduce the costs of complying with the proposed rules, are needed and reasonable and do not make a substantial change from the rules as they were originally proposed.

#### **6800.3100 - COMPOUNDING AND DISPENSING**

107. In its original draft of the new rules, the Board proposed revisions to clarify the licensed professional's role in assuring that the correct drug is dispensed.

108. Several stakeholders commented that the proposed clarifications, while helpful, did not clearly recognize current hospital practice or the practice under variances that are now often granted by the Board. Agreeing, the Board proposes to modify Revisor's Draft 3900 to make the following additional changes:

Subp. 3. Certiifcation. In certifying the ~~completed~~ filled prescription ~~order~~ under subpart 1, item F, an individual pharmacist, practitioner or pharmacist-intern shall ~~include~~:

A. ~~checking of~~ check the original labeled container from which the medication was withdrawn, except as provided in part 6800.2600, or when the pharmacy uses a computerized process to identify oral, solid drugs through the use of images;

B. ~~checking of~~ check the labeling on the ~~prescription~~ medication container that will be dispensed;

C. ~~checking~~ check the contents of the ~~prescription~~ medication container that will be dispensed and the appearance of the total product to ensure that all of the doses that are dispensed are of the correct drug, strength and dosage form prescribed.

These modifications maintain widespread practices, are needed and reasonable and do not make a substantial change from the rules as they were originally proposed.

### **6800.3200 - PREPACKAGING AND LABELING**

109. As part of its original proposal, the Board modified the standards for labeling pre-packaged drugs. So as to make clear that the revised standards apply both to repackaging drugs to unit-dose containers, as well as other types of pre-packaging drugs into containers, the Board proposed the following addition to its rules:

Subpart 1. **Prepackaging.** Pharmacies may prepackage and label drugs in convenient quantities for subsequent complete labeling and dispensing according to. **Pre-packaging into unit-dose containers shall be done according to United States Pharmacopeia, chapter 1146.**

The addition is consistent with the Board's enforcement practice, is needed and reasonable, and would not make a substantial change from the rules as they were originally proposed.

### **6800.3300 - PHARMACY COMPOUNDING PRACTICES**

110. In its original draft, the Board proposed a new rule requiring a pharmacist to certify elements of the compounding procedure for certain drugs.

111. Several stakeholders questioned whether the drugs subject to the certification procedure would be the same across pharmacy settings and whether the new certification procedures could be implemented by the planned effective date of the rules.

112. Agreeing, the Board proposes to further modify the proposed rule so as to require the drugs subject to the procedure to be listed in advance and to extend the effective date of the rule by eighteen months. The Board proposes to revise the rule as follows:

**Subp. 6. Certifying compounding procedure. A pharmacy must develop a list of high-risk compounded preparations for which a pharmacist shall certify that each component used in the compounding of the drug preparation has been accurately weighed, measured or subdivided as appropriate, at each stage of the compounding procedure in order to verify conformance with the formula being prepared. Subsequent stages of the compounding process may not be completed until this certification occurs. This subpart shall become effective on January 2, 2013.**

Because the revised rule carefully balances the need for protection of the public with the needs of the regulated parties in achieving compliance it is needed and reasonable.

113. Yet, mindful that the Board seeks to eliminate the term “high-risk drug” from its regulations, and instead use the terms “high-alert drug,”<sup>65</sup> the Administrative Law Judge urges the Board to consider whether the reintroduction of this phrase into its rules is consistent with its intent. Further, without a regulatory definition of “high-risk,” use of this term might render the regulation ambiguous.

114. The changes proposed by the Board, with the further addition of the terms “high-alert,” would not make a substantial change from the rules as they were originally proposed.

### **6800.3850 - PHARMACY TECHNICIANS**

115. As part of a move to improve the quality and capabilities of pharmacy technicians, the Board proposed new minimum age and education requirements for these registrants.

116. While there were a number of stakeholders in support of the proposals, the new standards drew sharp criticism from other commentators. These commentators asserted that the new requirements imposed genuine barriers to entry into the pharmacy profession, established costly and burdensome certification requirements, would negatively impact pharmacy staffing in rural areas, and would sharply reduce the pool of persons who could remain compliant with the Board’s registration standards.<sup>66</sup>

117. Finding merit in these comments, the Board proposes to revise its earlier draft to reduce the number of required hours of “theoretical and practical instruction” (in subpart 1 (B) (4)) from 480 to 240 hours, and to withdraw the proposed staffing ratio in subpart 6 (D). Additionally, so as to mitigate the costs of compliance, the Board proposed the following addition to Minn. R. 6800.3850, subpart 4:

Subp. 4. Written procedures. Written procedures for the use of pharmacy technicians in a pharmacy shall be prepared by the pharmacist-in-charge. A copy of the procedures must be given to each technician and a copy must be kept on file in the pharmacy. The written procedures must be made available for inspection by the board upon request. These procedures must comply with the standards in this chapter and will be reviewed for compliance on that basis.

These procedures must indicate in detail the tasks performed by the pharmacy technician; the name, address, and registration number of the pharmacy technician; and the certification steps performed by the licensed pharmacist in verifying the technician's work. Procedures ~~shall~~ must be updated at least every five years- and whenever a significant change in the way in which pharmacy technicians are utilized occurs. The pharmacist-in-charge shall ~~document~~ ensure that each technician has

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<sup>65</sup> See, Board’s Post-Hearing Comments, at 22.

<sup>66</sup> See, e.g., Hearing Transcript, at 30 - 40.

reviewed the procedures when he or she is first employed by the pharmacy as a technician, and when any substantial changes to the procedures have been made. and at least annually. The pharmacist-in-charge must ensure that proper documentation of such training is maintained in the pharmacy for a period of at least two years after the training occurs.

118. In general, the Board's proposals to upgrade the standards for pharmacy technicians are needed, reasonable and in line with the practices of other states. Additionally, the recent changes proposed by the Board would not make a substantial change from the rules as they were originally proposed.

119. However, the Board's proposed changes to Minn. R. 6800.3850, subpart 1 (B) (4) are ambiguously phrased and confer too much discretion upon the Board. Those proposed revisions state in part:

The Board may renew the registration of a pharmacy technician who has not completed this training requirement provided that: less than six months has elapsed between the date of initial registration as a pharmacy technician and the date of the pharmacy technician's first renewal of registration; or the pharmacy technician shows satisfactory evidence of being enrolled in a pharmacy technician training program offered by a board approved, accredited vocational/technical institution or college, when such program is longer than six months in length.

(Emphasis added). Because the phrasing "the Board may renew the registration" does not provide reasonable notice of the standards that will apply to renewals, it is defective.

120. One possible cure to this defect would be to re-phrase the rule so as to emphasize the technician's option to reapply, in certain circumstances, notwithstanding the more general requirement for 240 hours of professional instruction. Accordingly, page 52, line 8 of Revisor's Draft RD 3900 might read:

The Board may renew the registration of a A pharmacy technician who has not completed this training requirement, **but is otherwise eligible for renewal of his or her registration, may apply for renewal** provided that: less than six months has elapsed between the date of initial registration as a pharmacy technician and the date of the pharmacy technician's first renewal of registration; or the pharmacy technician shows satisfactory evidence of being enrolled in a pharmacy technician training program offered by a board approved, accredited vocational/technical institution or college, when such program is longer than six months in length.

In this way, the rule makes clear that a pharmacy technician who otherwise would not be eligible for renewal may be permitted to apply under the circumstances set forth in the remainder of the paragraph. Yet, such a phrasing does not imply that the Board has unrestricted discretion to reject a conforming application for renewal. Modifying the

proposed rules in this way is needed and reasonable and would not make a substantial change from the rules as they were originally proposed.

### **6800.5350 - PRECEPTORS**

121. As part of an effort to improve the professional training and educational opportunities of pharmacy interns, the Board proposed a new rule that would oblige an intern's professional mentor – known as a preceptor – to meet with the intern at least weekly.

122. While agreeing that a strong and collaborative intern-preceptor relationship is an important goal, several stakeholders asserted that the requirement to meet weekly was overly rigid and impracticable. Agreeing, the Board proposes to revise its earlier draft to provide:

C. they will provide time on a regular basis for the purpose of helping the ~~intern~~ their interns meet the competencies of the internship requirement;

123. In general, the Board's proposal to make the supervision requirement more flexible is needed and reasonable. Additionally, these changes would not make a substantial change from the rules as they were originally proposed.

124. However, the Board's proposed changes to Minn. R. 6800.5350, subpart 2 (C) are ambiguously phrased and fail to provide a reasonable notice of when the regulatory standards will apply. It is not clear from the text whether preceptor-intern meetings that occur monthly, quarterly or yearly, would meet the requirement of "time on a regular basis." Accordingly, the rule is defective.

125. One possible cure to this defect is to re-introduce a time-based standard as the regulatory minimum. Accordingly, page 62, line 24 Revisor's Draft RD 3900 might read:

C. they will provide time on a regular basis, at least three times each month, for the purpose of helping ~~the intern~~ their interns meet the competencies of the internship requirement;

Modifying the proposed rules in this way is needed and reasonable and would not make a substantial change from the rules as they were originally proposed.

### **6800.5400 - TRAINING**

126. In order to improve the supervision of pharmacy interns who undertake compounding or dispensing tasks, the Board proposed minimum staffing ratios between licensed pharmacists and interns.

127. Several stakeholders associated with the University of Minnesota's College of Pharmacy argued that the proposed standard was inappropriate when applied to college experiential educational programs and at odds with the standards of

the Accreditation Council for Pharmaceutical Education (ACPE). Agreeing, the Board proposes to establish an exception, and higher intern to pharmacist ration, for interns who are participating in the experiential education program of colleges of pharmacy. The Board proposes to revise its earlier draft to provide:

Subp. 4a. Supervision, dispensing and compounding. An intern performing tasks associated with dispensing or compounding shall be immediately and personally supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the actions of the intern. **Except in the case of internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy,** a licensed pharmacist may not supervise more than one intern who is performing tasks associated with dispensing or compounding. **In the case of an internship experience conducted as part of the experiential education program of an accredited college or school of pharmacy, a licensed pharmacist may supervise two interns who are performing tasks associated with dispensing or compounding.** The ultimate responsibility for the actions of an intern performing tasks associated with dispensing or compounding shall remain with the licensed pharmacist who is supervising the intern.

Modifying the proposed rules in this way is needed and reasonable and would not make a substantial change from the rules as they were originally proposed.

## **IX. Additional Actions Urged By Stakeholders**

128. As part of the public comment process, a number of stakeholders urged the Board to adopt still other revisions to Chapter 6800 – specifically, requests to modify rule parts 6800.0100, subpart 16 (Limited Service Pharmacy); 6800.0300 (Pharmacy License and Fee Required); 6800.0910 (Patient Access to Pharmacists); 6800.1050 (Required References); 6800.1400 (Drug Manufacturer or Wholesale License); 6800.2160 (Pharmacy Work Conditions); and 6800.7100 (Prescription Labeling). 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.

## **CONCLUSIONS**

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

2. The Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule, with the exceptions noted in Findings 12, 15 and 18. The Administrative Law Judge concludes that these omissions are harmless errors under Minn. Stat. § 14.15, subd. 5.

3. 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; 14.15, subd. 3; and 14.50 (i) and (ii), except as noted in Findings 93, 94, 100, 102, 119 and 124.

4. The Administrative Law Judge has suggested action to correct the defects cited in Conclusion 3, as noted in Findings 95, 96, 101, 103, 120 and 125.

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

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 and 14.50.

7. The modifications to the proposed rules suggested by the Administrative Law Judge after publication of the proposed rules in the *State Register* are not substantially different from the proposed rules as published in the *State Register* within the meaning of Minn. Stat. § 14.05, subd. 2, and 14.15, subd. 3.

8. Due to Conclusion 3, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. § 14.15, subd. 3.

9. 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, the Administrative Law Judge makes the following:

### **RECOMMENDATION**

IT IS HEREBY RECOMMENDED that the proposed amended rules be adopted, except as otherwise noted.

Dated: April 29, 2011

s/Eric L. Lipman  
ERIC L. LIPMAN  
Administrative Law Judge

Reported: Transcript Prepared (1 Volume).

## NOTICE

The Board must make this Report available for review by anyone who wishes to review it for at least five working days before it may take any further action to adopt final rules or to modify or withdraw the proposed rules. If the Board makes changes in the rules, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings contained in this Report, he will advise the Board of actions that will correct the defects, and the Board may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected.

If the Board elects to adopt the actions suggested by the Chief Administrative Law Judge and make no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, it may proceed to adopt the rules. If the Board makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, it must submit copies of the rules showing its changes, the rules as initially proposed, and the proposed order adopting the rules to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Board must submit the final version to the Revisor of Statutes for a review as to its form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review the same and file them with the Secretary of State. When the final rules are filed with the Secretary of State, the Administrative Law Judge will notify the Board, and the Board will notify those persons who requested to be informed of their filing.