

# Minnesota Board of Pharmacy

## EIGHT HUNDRED AND FORTY FIRST MEETING

At approximately 9:00 a.m., on December 10, 2014, the Minnesota Board of Pharmacy met in Conference Room A, at the University Park Plaza Building, 2829 University Avenue Southeast, Minneapolis, Minnesota, for the purpose of conducting a general business meeting. All members of the Board were in attendance with the exception of Ms. Kay Hanson. Also in attendance were the Board's Executive Director, Dr. Cody Wiberg; Deputy Director, Dr. Beth Ferguson; Legal Counsel, Mr. Bryan Huffman and Ms. Sara Boeshans; and Board of Pharmacy staff, Ms. Candice Fleming, Ms. Michele Mattila, Ms. Karen Schreiner, Mr. Steven Huff, Mr. Tim Litsey, Ms. Barb Carter, Ms. Katrina Howard, and Ms. Patricia Eggers.

President Stuart Williams called the meeting to order.

The Board went into a closed session to discuss matters regarding disciplinary cases.

At the conclusion of the closed session, the meeting was reopened to the public.

The Board next discussed the minutes of the October 29, 2014 business meeting with a correction. The minutes of the October 29, 2014 meeting were adopted with the correction.

Ms. Karen Bergrud moved and Mr. Rabih Nahas seconded to approve the items on the Consent Agenda. The motion passed.

The Consent Agenda for the meeting was as follows:

- Variance Committee Report – Approve
- CE Report – Approve
- Membership and Licensure Issues for 2015 – Approve
  - ◆ Continue Membership in NABP
  - ◆ Continue to require graduates of foreign pharmacy schools to pass the FPGEE and to receive FPGEC certification
- Continue to require graduation from an approved college of pharmacy and continue to approve and adopt the accreditation standards of the Accreditation Council on Pharmacy Education (ACPE) and the list of approved colleges of pharmacy established by ACPE as the list of colleges from which the Board will accept graduates as candidates for licensure.

Mr. Bob Goetz moved and Ms. Laura Schwartzwald seconded to approve the remainder of the agenda. The motion passed.

The Board next turned its attention to election of officers and designation of officials for the year of 2015.

For the office of President, Mr. Bob Goetz nominated Mr. Stu Williams. Ms. Laura Schwartzwald seconded the nomination. There being no further nominations, the nominations were closed and Mr. Stu Williams was elected to the office of President by a unanimous ballot.

For the office of Vice President, Mr. Bob Goetz nominated Ms. Laura Schwartzwald. Ms. Karen Bergrud seconded the nomination. There being no further nominations, the nominations were closed and Ms. Laura Schwartzwald was elected to the office of Vice President by a unanimous ballot.

For the office of Secretary (Executive Director), Ms. Karen Bergrud nominated Dr. Cody Wiberg. Ms. Laura Schwartzwald seconded the nomination. There being no further nominations for the position, the nominations were closed and Dr. Wiberg was elected as the Secretary (Executive Director) by a unanimous ballot.

For the position of Deputy Director, Ms. Karen Bergrud nominated Ms. Beth Ferguson. Ms. Laura Schwartzwald seconded the nomination. There being no further nominations for the position, the nominations were closed and Ms. Ferguson was designated as the Deputy Director by a unanimous ballot.

For the position of Associate Director for Compliance, Ms. Karen Bergrud moved that Ms. Candice Fleming be continued in that position. Ms. Laura Schwartzwald seconded the motion. The motion prevailed and Ms. Candice Fleming was continued in the position of Associate Director for Compliance by a unanimous ballot.

For the position of Assistant Director for Administrative Affairs, Ms. Karen Bergrud moved that Ms. Patricia Eggers be continued in that position. Ms. Laura Schwartzwald seconded the motion. The motion prevailed and Ms. Patricia Eggers was continued in the position of Assistant Director for Administrative Affairs by a unanimous ballot.

President Williams next began a discussion of appointments to the Board's standing committees for 2015. After a brief discussion, the following committee appointments were made:

President Williams made the appointments as follows:

Ms. Kay Hanson and Ms. Laura Schwartzwald are appointed to the Continuing Education Advisory Task Force (CEATF) committee.

Ms. Laura Schwartzwald and Mr. Bob Goetz are appointed to the Internship Advisory Committee.

All members of the Board will rotate through the Committee on Professional Standards (COPS, formerly CRP) with two members present at each meeting.

All members of the Board will rotate through the Complaint Review Panel (CRP, formerly COPS) with two members present at each meeting.

All members of the Board will rotate through the Variance and Policy Review Committee, with two members present at each meeting and with the Board's Pharmacy Surveyors rotating as well, two Surveyors present at each meeting.

Ms. Laura Schwartzwald, Mr. Bob Goetz, and Dr. Beth Ferguson will serve on the Internship Advisory Committee. The motion passed.

Mr. Stu Williams will be the Board's representative and Ms. Kay Hanson will be the alternate to the Program Committee of the Health Professionals Services Program. The motion passed.

Ms. Betty Johnson is the Board's representative on the Prescription Monitoring Program Advisory Committee.

Mr. Rabih Nahas and Ms. Beth Ferguson will be the representatives and Ms. Kay Hanson will be the alternate to the Minnesota Alliance for Patient Safety.

The first variance and policy review issues to come before the Board were from Guidepoint Pharmacy #108 and #109. Ms. Laura Schwartzwald and Mr. Stuart Williams excused themselves from the meeting. These variance requests are in regard to the use of tele-pharmacies. The Variance and Policy Review Committee recommended a six month approval of the variance request with conditions. Mr. Justin Barnes moved and Mr. Bob Goetz seconded that the recommendations of the Variance and Policy Review Committee be approved. The motion passed.

The second variance and policy review issue to come before the Board was from Guidepoint Pharmacy #108. This policy review and variance request was for them to allow the delivery of prescriptions to the nursing staff of Assisted Living Facilities and/or home health care offices. The Variance and Policy Review Committee recommended approval until June 11, 2016 with conditions. Mr. Justin Barnes moved and Mr. Bob Goetz seconded that the recommendations of the Variance and Policy Review Committee be approved. The motion passed.

Ms. Schwartzwald and Mr. Williams returned to the meeting and Mr. Goetz excused himself from the meeting.

The third variance and policy review issues to come before the Board was from ten Walgreen Pharmacies. Mr. Bob Goetz excused himself from the meeting. Present at the meeting were Ms. Michele Aytah, Walgreens; Mr. Bill Cover, Corporate Manager of Pharmacy Affairs; Mr. Greg Boll, District Pharmacy Supervisor; and Mr. Richard

Engleka, Pharmacy Director. There were ten policy requests for the Fully Rx automation unit for the “Well Experience” locations. The Variance and Policy Review Committee recommended that the policy be denied. Mr. Cover stated that since they have no Fully Rx units in operation in Minnesota this policy request will be withdrawn until the summer of 2015 until they are able to address the “unique ID” per Board regulations. At this time they will bring the policy back to the Board for approval.

The fourth variance and policy review issues to come before the Board were from all Walgreen Pharmacy (153) locations. These policy review requests were for unique identifiers. The Variance and Policy Review Committee recommended denial of the policy request because each step of the dispensing process must be documented with unique identifiers. Mr. Rabih Nahas moved and Ms. Laura Schwartzwald seconded that the revised policies and procedures, submitted by Walgreens after the VPRC meeting, be approved. The motion passed.

The fifth variance and policy review issues to come before the Board were from several Walgreen Pharmacies. The Variance and Policy Review Committee made recommendations in its report. These variances are before the Board to allow Mr. Goetz to recuse himself. Ms. Karen Bergrud moved and Ms. Laura Schwartzwald seconded that the recommendations of the Variance and Policy Review Committee be approved. The motion passed.

Mr. Goetz returned to the meeting and Ms. Karen Bergrud excused herself from the meeting.

The sixth variance and policy review issues to come before the Board were from variance Mayo Clinics. The Variance and Policy Review Committee recommended one year approval with conditions. Ms. Laura Schwartzwald moved and Mr. Justin Barnes seconded that the recommendations of the Variance and Policy Review Committee be approved. The motion passed.

The seventh variance and policy review issue to come before the Board was from Mayo Clinic Pharmacy in Rochester. This variance request is to allow one pharmacist to supervise four plus one technicians in the communication center areas. The Variance and Policy Review Committee recommended one year approval to allow one pharmacist to supervise three technicians in the communication center subject to the following conditions that the technicians not be allowed to collect health information such as medication histories and allergies and that non-technician support personnel cannot enter refill requests or accept them from patients and the other three points raised by staff. Mr. Justin Barnes moved and Ms. Laura Schwartzwald seconded that the recommendations of the Variance and Policy Review Committee be approved. The motion passed.

Ms. Bergrud returned to the meeting.

Dr. Wiberg next began a discussion of pharmacist participation for lethal injection. Present at the meeting were Mr. Jeremy Schroeder a former board member of Amnesty International USA and Ms. Rosalind Park, Research Director at Advocates for Human Rights. After much discussion, it was deemed that pharmacist participation in executions is already addressed in the Board of Pharmacy laws and rules. The petition failed for the lack of a motion.

Dr. Wiberg next began a discussion of a rule-making petition from Mr. Kurtis Hanna and the video record is Ms. Cassie Trumm. After some discussion, Mr. Justin Barnes moved and Ms. Laura Schwartzwald seconded that the petition be denied due to the fact that the Board does not have the authority to engage in the rule-making and that Dr. Wiberg's document entitled "Rule-making petition of Kurtis Hanna" serve as the Board's response. The motion passed.

Dr. Wiberg next presented the Board with three reports to the legislature. They are the Obsolete Rules Report, the Controlled Substances Report, and the Pharmaceutical Waste Report. Ms. Laura Schwartzwald moved and Ms. Karen Bergrud seconded that the reports be approved and submitted. The motion passed.

Dr. Wiberg next discussed possible legislation concerning pharmacy technicians and immunizations. Mr. Jeff Lindoo, on behalf of the Task Force, and Ms. Michele Aytay, from Minnesota Pharmacist Association (MPhA) spoke at the meeting. Mr. Bob Goetz moved and Mr. Justin Barnes seconded that the Board authorizes Dr. Wiberg to work with stakeholders and the legislature to seek an increase to a three to one ratio as at least a starting point and report back to the Board at the next board meeting as to how things are going. The motion passed with Mr. Rabih Nahas abstaining.

Dr. Cody Wiberg next discussed increasing pharmacist involvement in immunizations. Ms. Laura Schwartzwald moved and Mr. Bob Goetz seconded that they authorize Dr. Wiberg to work with stake holders and the legislature in seeking the proposed changes in immunization on the condition that mandatory participation in Minnesota Immunization Information Connection (MIIC) is a condition. The motion passed.

Ms. Barb Carter next gave an update on the Prescription Monitoring Program (PMP). She also presented the Board with a copy of the Report to the Legislature. Mr. Rabih Nahas moved and Ms. Karen Bergrud seconded that the reports be approved and submitted. The motion passed.

The NABP Interactive Member Forum was held on December 2 & 3, 2014. Mr. Stuart Williams presented the Board with information that they received at this meeting. No action was taken at this time.

Mr. Williams also spoke about how District V put forth a resolution to the National Association of Boards of Pharmacy (NABP) regarding not accepting grants or sponsorships from any entities that the Boards regulate. NABP informed Mr. Williams

that the Executive Council uniformly opposes that. NABP will draft a resolution for District V to consider that they believe that the Executive Council will support that will call on the creation of a task force that will study the issue that will find a way that will provide the necessary funding for travel grants. No action was taken at this time.

At this time the Board went back into closed session to discuss an additional disciplinary case.

The Board reconvened at 1:56 PM.

There being no further business, requiring action by the Board, President Stuart Williams adjourned the meeting at approximately 1:58 PM.

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PRESIDENT

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EXECUTIVE DIRECTOR

**Minnesota Board of Pharmacy  
841<sup>st</sup> Board of Pharmacy Meeting  
Wednesday, December 10, 2014**

Statutes, Rules and Guidances

*Rule-making petition of Kurtis Hanna*

Mr. Hanna has submitted a request entitled: “**PETITION IN SUPPORT OF RULE MAKING OR ACTION**” (hereinafter “**petition**”). His stated goal is the “Removal Of Cannabis From Schedule I Of Minnesota’s Controlled Substance Act”. In his petition, Mr. Hanna asks that the Board:

- Engage in the rule-making process to “specifically exempt plants of the genus Cannabis or material naturally originating from them, including tetrahydrocannabinols (THC) and cannabidiol (CBD), from the list of substances classified as Schedule I in Minnesota Rules § 6800.4210 (C).”
- “(I)nclude language in their two upcoming end of year reports to the legislature that says that the current Rules are Obsolete and request that the legislature either fix The Problem in the statutes or give the Board the ability to use the expedited rule change process to remove them from the Rules yourself.”
- “(P)ass upon the validity of Minnesota Rules § 6800.4210 (C)(17) and § 6800.4210 (C)(25), pursuant to 14.44, because Petitioner alleges that the rules would then subsequently violates constitutional provisions of Equal Protection and Due Process.” (If the Board decides not to engage in the rule-making process).

Petition to engage in rule-making

Minn. Stat. §14.09 states, in part:

Any person may petition an agency requesting the adoption, amendment, or repeal of any rule. The petition shall be specific as to what action is requested and the need for the action. Upon receiving a petition an agency shall have 60 days in which to make a specific and detailed reply in writing as to its planned disposition of the request and the reasons for its planned disposition of the request.

However, Minn. Stat. §14.05, subd. 1 states, in part (emphasis added):

***Each agency shall adopt, amend, suspend, or repeal its rules*** in accordance with the procedures specified in sections 14.001 to 14.69, and ***only pursuant to authority delegated by law*** and in full compliance with its duties and obligations.

The Board of Pharmacy does not have the authority to remove marijuana, tetrahydrocannabinols, or cannabidiol from Schedule I by amending Minn. R. 6800.4210. Petitioner bases his petition on Minn. Stat. §152.02, subd. 7, asserting that the Board has a duty

under that subdivision to “delete or reschedule” substances that no longer meet certain criteria listed in that subdivision. However, subdivision 7 begins with the phrase (emphasis added):

The Board of Pharmacy is authorized to regulate and define *additional* substances which contain quantities of a substance possessing abuse potential in accordance with the following criteria: . . . .

Subdivision 7 grants the Board authority to add controlled substances to the schedules, not to remove them. The criteria in subdivision 7 are used by the Board when it is considering the use of the normal rule-making process to add controlled substances to the schedules. (Note that the Board uses more stringent criteria, found in subd. 8b, when considering the use of the expedited rule-making process to place additional substances into Schedule I).

In Subdivision 8, the Legislature expressly states that “[t]he Board may not delete or reschedule a drug that is in Schedule I, except as provided in subdivision 12.”

Subdivision 12 states that (emphasis added):

**Coordination of controlled substance regulation with federal law and state statute.** *If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the state Board of Pharmacy, the state Board of Pharmacy shall similarly control the substance under this chapter*, after the expiration of 30 days from publication in the Federal Register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance. Such order shall be filed with the secretary of state. If within that 30-day period, the state Board of Pharmacy objects to inclusion, rescheduling, or deletion, it shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the state Board of Pharmacy shall publish its decision, which shall be subject to the provisions of chapter 14.

In exercising the authority granted by this chapter, the state Board of Pharmacy shall be subject to the provisions of chapter 14.

The state Board of Pharmacy shall annually submit a report to the legislature on or before December 1 that specifies what changes the board made to the controlled substance schedules maintained by the board in Minnesota Rules, parts 6800.4210 to 6800.4250, in the preceding 12 months. The report must include specific recommendations for amending the controlled substance schedules contained in subdivisions 2 to 6, so that they conform with the controlled substance schedules maintained by the board in Minnesota Rules, parts 6800.4210 to 6800.4250.

Since marijuana, tetrahydrocannabinols and cannabidiol have not been rescheduled or deleted as controlled substances by either Congress or the U.S. Drug Enforcement Administration and, in fact, remain in the federal Schedule I, subdivisions 8 and 12 prohibit the Board from deleting or rescheduling them at this time. If Congress or the DEA ever reschedules

these substances (or deletes them from the federal schedules) the Board may consider whether the federal changes should be reflected in the State schedules.

The petitioner seems to contend that the following sentence, found in subdivision 12, can be read without reference to the other language found in subdivision 12 and, therefore, allows the Board to engage in the rule-making that he requests: “In exercising the authority granted by this chapter, the state Board of Pharmacy shall be subject to the provisions of chapter 14.”

This contention is incorrect. First, the sentence cannot be read without reference to the rest of the language in subdivision 12. Minn. Stat. §152.02, subd. 8 requires the Board to abide by the requirements of all three paragraphs of subd. 12. Consequently, the Board:

- Cannot delete or reschedule a controlled substance found in Schedule I unless the federal government deletes or reschedules it;
- Must follow the rule-making provisions found in MN Stats. Chapter 14 whenever it makes any change to the controlled substances rules; **and**
- Must report to the Legislature about the changes that it does make.

Second, the sentence petitioner refers to in subdivision 12 (*supra* preceding paragraph) simply requires the Board to follow the rule-making provisions found in Chapter 14 when amending the controlled substances rules found in Minn. R. chapter 6800. As noted above, Minn. Stat. §14.05, subd. 1 states that an agency can engage in rule-making only pursuant to authority delegated by law. That same subdivision further states that: “(e)xcept as provided in section 14.06, sections 14.001 to 14.69 shall not be authority for an agency to adopt, amend, suspend, or repeal rules.” In other words, Minn. R. chapter 14 does not grant authority to the Board to engage in rule-making. Instead, the Board’s rule-making authority regarding controlled substances is derived from Minn. Stat. §152.02, subs. 7, 8, 8b, 9 and 12.

Since the Board has no authority to engage in the requested rule-making, the Board must deny the petition for rule-making.

#### Including requested language in Board reports

Per Minn. Stat. §14.05, subd. 5, the obsolete rules report must list “rules or portions of rules that are obsolete, unnecessary, or duplicative of other state or federal statutes or rules.” For reasons discussed below, the rule part in question, MN Rules 6800.4210, is not obsolete or unnecessary. The apparent intent of Minn. Stat. §152.02, subd. 12 is to ensure that the controlled substance schedules found in the rules are coordinated with the schedules found in Minnesota and federal statutes. Consequently, Minn. R. 6800.4210 through 6800.4250 are, necessarily, going to be duplicative of the schedules found in state statutes and federal regulations.

During the 2014 Session, the Legislature passed legislation that established a medical cannabis program. In doing so, the Legislature effectively excluded the cannabis plant, in raw form, from the definition of “medical cannabis.” The Legislature also declined to reschedule marijuana and tetrahydrocannabinols, leaving them in Schedule I. Petitioner offers no support

for his contention that the Legislature “overlooked completely” the rescheduling of marijuana and tetrahydrocannabinols during its “deliberative process.” Since the Legislature declined to reschedule the substances that are the subject of this petition, their inclusion in MN Rules 6800.4210 is appropriate and not “obsolete” or “unnecessary”. Consequently, the Board should not include the requested language in its obsolete rules report.

Per Minn. Stat. §152.02, subd. 12, the controlled substances report must include specific recommendations for amending the controlled substance schedules contained in subdivisions 2 to 6, so that they conform with the controlled substance schedules maintained by the board in Minn. R.6800.4210 to 6800.4250. As explained above, the Board cannot remove “plants of the genus Cannabis or material naturally originating from them, including tetrahydrocannabinols (THC) and cannabidiol (CBD)” from Minn. R. 6800.4210. While not prohibited, there is no requirement that the Board include in its controlled substance report any recommendations beyond those necessary to conform the schedules found in the statutes with those found in the rules.

#### Passing upon the validity of Minn. R. 6800.4210

Minn. Stat. §§ 14.44 and 14.45 concern the determination of the validity of rules by the Minnesota Court of Appeals. These sections do not require an agency to pass on the validity of its rules - and there would appear to be no need for the Board to do so. Section 14.45 states, in part, “the court shall declare the rule invalid if it finds that it violates constitutional provisions or exceeds the statutory authority of the agency or was adopted without compliance with statutory rulemaking procedures.” In May of this year, the Minnesota Court of Appeals found that “Minnesota's classification of marijuana does not violate the right to equal protection of the law.” In doing so, the Court of Appeals noted that the Minnesota Supreme Court had previously reached the same conclusion. Note that one of the Supreme Court decisions that was referenced by the Court of Appeals states (emphasis added) “the *legislative* classification of marijuana in Schedule I does not violate the constitution.” This indicates that the courts are not relying on the belief that “the Board of Pharmacy can still remove substances from Schedule I” but are also considering actions of the Legislature. Given these court decisions, and the fact that the Office of Administrative Hearings reviews all rules promulgated by the Board to determine if the Board has exceeded its statutory authority or failed to comply with required rule-making procedures, there is no need for the Board to pass on the validity of the rule language in question.

#### Staff Recommendation

Based on the foregoing, the Executive Director recommends: (1) denial of Mr. Hanna’s petition because the Board does not have the authority to engage in the rule-making that he is requesting and (2) that this document serve as the Board’s response.