



The Manitoba Pharmaceutical Association

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REGULATIONS ADVISORY COMMITTEE MEETING MINUTES, April 2nd & 4th, 2007

April 2nd: Convene at 11:00 am adjourn at 5:00 pm

April 4th: Convene at 8:30 am and adjourn at 8:30 pm

Members:

Kevin Hall, (Absent April 4th, from 1:00 pm to 5:30 pm)
Dr. Bill Pope (attended only April 2nd, 11:00 am to 1:00 pm),
Angie Wierzbicki,
Kris Thorkelson,
Joanne Johnson,
Tim Pattern,
Mel Baxter,
Norma Drosdowech,
Lavern Vercaigne

Ex officio:

Pat Trozzo (Absent April 4th)

Resource:

David Marr, legal counsel
Graeme Young, legal counsel (for April 2nd only)
Ronald Guse, Registrar (recording secretary)

President Pat Trozzo welcomed the Regulations Advisory Committee (RAC) members and thanked them for attending the meeting. Regrets were acknowledged from Sue Neilson (College of Registered Nurses) and Olaf Koester (Manitoba Health).

Mr. Trozzo advised the committee members that per diems were available and arrangements for such could be made directly with the Registrar. He reminded the committee of the Terms of Reference and that the committee's progress should not be slowed by "word smithing". He indicated it was important to be thorough in reviewing the document and raise issues deemed important for discussion. The RAC suggestions will be forwarded to Council for consideration at the April 13th meeting. The Registrar, in consultation with the Chair, will prepare the report and minutes for review and approval by the RAC members prior to it being forwarded to Council.

Mr. Trozzo opened nominations for Chair of the committee. The Committee agreed the Chair would have voting and speaking privileges as consistent with all other members of the Committee. Two committee members were nominated and Dr. Lavern Vercaigne was elected through a private balloting process.

Mr. Trozzo handed over the Chair to Dr. Vercaigne.

After a brief discussion with the Committee, it was decided that a two-thirds majority of members would be needed to approve a suggestion to Council. However, the committee could agree that a strong opposing view of the recommendation could be noted. There were no objections expressed for this process.

Tim Pattern circulated a letter, addressed to the MPhA President, and “cc”ed to all Committee members at the beginning of the first meeting. The letter expressed concern about the process MPhA has proposed for the consideration of the new regulations. Another committee member expressed concern that the Committee was not advised they could prepare, in advance, opinions for circulation as the mandate of the Committee was to review the draft Regulations Discussion Document during the discussions at the meeting. The Chair suggested the letter be forwarded to the President for his consideration and possible referral to Council. In a similar manner, Kris Thorkelson asked the Chair about circulating a letter of his opinions. The Chair advised Mr. Thorkelson to forward his letter to the President as well.

As Dr. Pope needed to leave the meeting at 1:00 pm (April 2nd), the Chair received the Committee’s approval for Dr. Pope to identify and comment on specific areas of the Regulations Discussion Document. Dr. Pope’s comments were noted and will be included in the suggestions to Council, where applicable.

Dr. Vercaigne noted that any suggestions to Council were not final decisions, but rather, simply information for Council to consider in their deliberations. Dr. Vercaigne requested that the RAC review the document, section by section, and committee members were welcome to raise issues in the section under review. As an issue is raised and discussion ensues, it can be followed by a request for a specific “suggestion” to Council. The “suggestion” needs to be moved, seconded, discussed and then voted upon by the voting members.

The committee began reviewing the document and the following “suggestions” were considered and voted upon:

Suggestions to council:

1. Regulation 5 (c) should be reviewed and revised where necessary to facilitate the ability to acquire a temporary registration.
Moved by Kevin Hall Seconded by Kris Thorkelson Vote: 8/8 in favor

A purpose of the “temporary registration” is to register a pharmacist that is urgently needed. Regulation 5(c) requires an applicant to provide a letter of standing, satisfactory to council, from all the jurisdictions in which the applicant

is licensed to practice pharmacy. It was thought this would be too cumbersome in matters requiring a quick registration process, such as a public health emergency, where pharmacists from other jurisdictions might volunteer to assist in Manitoba.

2. Regulation 8 (1) h should remove the word “moral”.
Moved by Norma Drosdowech Seconded by Mel Baxter Vote: 8/8 in favor

The committee indicated that it would be too difficult to make judgements on a person’s morals.

3. Regulation 8 (2) b should be reviewed and revised as necessary to clarify if a student is not currently participating in a pharmacy education program (e.g. prolonged illness, temporary suspension, etc) are they considered to still be “enrolled” in the Faculty?
Moved by Kevin Hall Seconded by Joanne Johnson Vote: 8/8 in favor

It was felt that if a student is not currently registered in courses because of a prolonged illness, suspension, or issue of that nature, that he/she really shouldn’t be on the MPhA register of students. It was also suggested that there should be a mechanism in place to insure that employers are aware when students are no longer “enrolled” in the Faculty.

4. Regulation 11(1) should also include a similar subsection as regulation 3 (c) to make application criteria for registration and licensure more consistent.
Moved by Kevin Hall Seconded by Kris Thorkelson Vote: 8/8 in favor

The committee indicated that a statement such as “satisfy the registrar that the applicant does not have an addiction to alcohol, drugs or illegal substances which, as set out by the board, makes the applicant unsuitable for license as a pharmacist” would also be appropriate here. There will need to be clarification of what criteria are considered to make the applicant “unsuitable”.

5. *DEFEATED*
Regulation 11 (1) a should remove the word “investigation”.
Moved by Tim Pattern Seconded by Kris Thorkelson Vote: 2 in favor, 5 against, 1 did not vote

Although the committee voted against the removal of "investigation", there was a strong opinion by one member that “investigation” be removed as the applicant may not have been found guilty of anything at the time of application. In the event Council decides to leave it in, a definition of “investigation” should appear in the regulations.

6. Regulation 11 (1) should have an additional subsection (f) that requires the applicant to disclose whether he or she has a license to practice pharmacy in another jurisdiction.
Moved by Joanne Johnson Seconded by Mel Baxter Vote: 6 in favor, 1 against, 1 did not vote

7. Regulation 11 (2) should change the wording from applying under “either” Section 12 or Section 13, to applying under Section 12, Section 13, or both.
Moved by Kevin Hall Seconded by Angela Wierzbicki Vote: 6 in favor, 1 against, 1 did not vote

This clarification was requested to acknowledge that a pharmacist working in both areas should be able to keep licenses in both areas and it should not be a choice of one over another. One committee member was concerned about the potential unintended consequences of making the change.

8. In Regulations 12 (2) and 13 (2), regarding requirements for licensure, Council should consider potential further requirements for moving from one practice area to another.
Moved by Kevin Hall Seconded by: Joanne Johnson Vote: 7 in favor, 1 did not vote

For example, a community pharmacist may take a job working on a hospital ward, or vice versa, a hospital pharmacist may want to switch to a community practice. Although the pharmacist would still have a Section 12 license in both scenarios, there may be concerns for public safety, which could be addressed in the regulations by way of a requirement for a minimal period of training/supervision under a Section 12 pharmacist with experience in the new practice setting.

This may not be applicable to all cases, such as where a community pharmacist already provides service to a hospital (i.e. smaller communities), or vice versa. Some flexibility should be considered, but section 12 pharmacists should not be automatically considered to be competent to practice safely in a new practice environment.

9. Regulation 19 (1) specifies how pharmacist profiles must be made available, and council should consider methods to track and analyze how frequently the profiles are being accessed.
Moved by Norma Drosdowech Seconded by Joanne Johnson Vote: 8/8 in favor

This should help to address regulation 28. Some Committee members were concerned the profile system would be used for unwanted solicitation of pharmacists.

10. Regulation 21 (b) should be removed and in 21 (c) “availability of interpretation” should be removed.
Moved by Mel Baxter Seconded by Joanne Johnson Vote: 8/8 in favor

The committee did not want regulation 21 to be used as a marketing tool for pharmacies to describe services available.

11. Regulation 24 (4) should be revised to indicate that if a member's profile is being revised, the member should be notified of the significant changes prior to posting. Moved by Kris Thorkelson Seconded by: Tim Pattern Vote: 5 in favor, 2 against, 1 did not vote

Some Committee members felt strongly that members should be notified of significant changes to their profile prior to posting because of the potential negative effect of posting incorrect information. However, for minor or "cosmetic" changes, prior notification was not needed.

12. Regulation 29 (1) should be reviewed and revised as necessary to allow for flexibility of licensing practice sites and clarify whether one site needs one license or several sites can have one license. Also, there may be a need to define "facility". Moved by Kevin Hall Seconded by Mel Baxter Vote: 8/8 in favor

13. Regulation 29 (1) e should have further clarification of the term "affiliated". Moved by Kris Thorkelson Seconded by Angela Wierzbicki Vote: 8/8 in favor

Consideration should be given to require all names the pharmacy knows is part of their business plan and provides a transparent open description of the business links. A change might include the word "main" before URL as listing "any" affiliated websites could be burdensome for some businesses.

14. Regulation 29 (3) should be reviewed and revised as necessary to clarify how the components will apply to all areas of practice. Moved by Kevin Hall Seconded by Tim Pattern Vote: 8/8 in favor

For example, if a practice site has a central fill component, but the pharmacists working there are also care for patients in the facility, are they considered to be working at a central fill facility, and thus working hours do not count toward maintaining a Section 12 license?

15. Regulations 29(4) The Committee recommends that a section be added that allows pharmacies to provide one of the specified components without having declared the component on the application if in an emergent situation arises and to meet the immediate needs of the patient. Moved: Joanne Johnson Seconded: Mel Baxter Vote: 8/8 in favor

This should be documented to describe the event and the reasons.

16. Regulation 29 (6) should clarify how a facility is defined and what is meant by "adjoining"? Moved by Kevin Hall Seconded by Joanne Johnson Vote: 8/8 in favor

For example, clarification is required to determine if pharmacies in a large hospital, joined by a tunnel system, are considered to be the same facility or adjoining?

17. Regulation 30(a) The Committee recommends to remove "ethical" from section 30(a), as the inspector or registrar cannot determine ethical in a pre-opening inspection.

Moved by Kris Thorkelson Seconded by Kevin Hall Vote: 7 in favour, 1 against

18. Regulation 32(2b) The Committee recommends this section has the following works added, "Unless the Council determines that the service may be made available for a specified lesser amount of time."

Moved by Joanne Johnson Seconded by Kevin Hall. Vote: 8/8 in favor

The Committee felt that in certain situations that it might be appropriate for the pharmacy to be open less than 25 hours per week, and that opportunity would be left to the discretion of council.

19. DEFEATED Regulation 33 The Committee recommends that section 33 be removed and a committee be formed of MPhA, IPS, government and other stakeholders to review Distance Care.

Moved by Tim Pattern Seconded by Kris Thorkelson Vote: 4 in favor and 4 against

Note: Four strong opinions that section 33 prevents IPS from continuing in Manitoba and, as reported in the italicized introduction to this section, the Minister of Health wants this business to remain.

20. Regulations 33(3b)i The Committee requests that Council review this section to clarify what would be required for implementation, suggested time lines and the willingness of jurisdictions to participate.

Moved by Lavern Vercaigne Seconded by Kevin Hall Vote: 8/8 in favor

There is concern that section 33(b)i would not be possible to implement immediately upon the regulations being passed and an implementation date should be considered. Further information is needed regarding the receptiveness of the State Boards, for example, to participate in such agreements.

21. Regulation 37(1) The Council needs to consider the application of tele-pharmacy practice in populated urban areas where this section would only allow it to occur in remote and under serviced areas.

Moved by Kevin Hall Seconded by Angela Wierzbicki Vote: 8/8 in favour

If it is to be expanded, the tele-pharmacy requirements need to be reviewed and revised.

22. Regulation 38 Council should clarify whether clinical pharmacy practice is only section 12 and whether members under 38(1)c need section 12 or can section 13 pharmacists be allowed.
Moved by Kevin Hall Seconded by Norma Drosdoweck Vote: 8/8 in favor

Kevin Hall left at this point in the meeting.

23. Regulation 39(a) Council should consider this section be changed to "member" to allow for both section 12 and section 13 practicing pharmacists.
Moved Lavern Vercaigne Seconded by Kris Thorkelson Vote: 7/7 in favor

24. Regulation 39(b) The Committee recommends the 4000 hour requirement be removed as this would prevent a newly registered and licensed pharmacist to purchase a pharmacy or become a manager upon graduation.
Moved by Angela Wierzbicki Seconded by Kris Thorkelson Vote 8/8 in favour
(*Kevin Hall was at the meeting for this vote)

Council should consider more flexible requirements than a 4000 hour requirement. If there is concern that a newly licensed pharmacist cannot perform as a manager, then that needs to be incorporated into a suitable training program, either at the University or the internship program or pharmacy manger training program developed.

25. Regulation 40(1)b Recommend that Council remove the part b as this will be reported on the annual basis though the filing of the annual return with the pharmacy license application.
Moved by Kris Thorkelson Seconded by Angela Wierzbicki Vote: 7/7 in favor

26. Regulation 41(2) Council should consider only a change in partnership of 50% or more for this section.
Moved by Kris Thorkelson Seconded by Tim Pattern Vote: 7/7 in favour

27. DEFEATED Regulation 43 The Committee suggested that components can be added to an existing license instead of surrendering the license and reapplying.
Moved by Tim Pattern Seconded by Kris Thorkelson Vote: 2 in favour, 5 against

The Committee advises Council that changes to components included in this section should not be an onerous process.

28. Regulations 45(b) The Committee recommends to Council the section be changed to "additional business names" instead of "second business name".
Moved by Kris Thorkelson Seconded by Tim Pattern Vote: 7/7 in favor

This would facilitate the continued use of an established pharmacy name that is already familiar to the public.

29. Regulation 50(d) The Committee recommends that Council clarify this section whether it includes refills in hospital practice.
 Moved by Joanne Johnson Seconded by Kris Thorkelson Vote: 6 in favor, 1 against
- At present, refills may not be checked by the pharmacist in some hospital practice.
30. Regulation 51 The Committee recommends changing this section to read "...or any other task supporting the practice of pharmacy..."
 Moved by Lavern Vercaigne Seconded by Norma Drosdowech Vote: 7/7 in favor
31. Regulation 52(2) The Committee recommends that Council does set a sunset clause in order to allow persons working as technicians to meet the requirements of section 52(2).
 Moved by Lavern Vercaigne Seconded by Mel Baxter Vote: 7/7 in favor
- Council was asked to provide an opinion as to when this may come into effect.
32. Regulation 52(3) and 52(4) The Committee recommends that Council remove section 12 pharmacist from 52(3) and 52(4) and it should just read under supervision of a "member".
 Moved by Joanne Johnson Seconded by Angela Wierzbicki Vote: 7/7 in favor
- The Committee suggests clarification is needed as to what tasks can be delegated by section 12 and section 13 pharmacists (including in a central fill component) and these sections adjusted according.
33. Regulation 52(4) The Committee recommends that Council include a section that continues the ratio of 1 to 1 plus 1 for pharmacists to technicians in community pharmacy.
 Moved by Mel Baxter Seconded by Tim Pattern Vote: 5 in favor, 2 against
34. Regulation 52(4) The Committee recommends that technicians be allowed to demonstrate and explain medical devices under the supervision of members and Council needs to review and revise this section.
 Moved by Angela Wierzbicki Seconded by Kris Thorkelson Vote: 7/7 in favor
35. Regulation 52(4)a The Committee recommends that Council needs to provide clarification regarding the meaning of technicians "interpreting" prescriptions.
 Moved by Joanne Johnson Seconded by Tim Pattern Vote: 7/7 in favor
36. Regulation 52(4)c The Committee raised concerns regarding section 52(4)c and the impact upon patient safety and liability.
 Moved by Norma Drosdowech Seconded by Mel Baxter Vote: 7/7 in favor
37. DEFEATED It was suggested that Committee members could seek external advice on the draft regulations discussion document and forward the information to Council prior to the April 13th meeting, but it must be noted the information forwarded is not on behalf of the RAC.

Moved by Kris Thorkelson Seconded by Tim Pattern Vote: 2 in favor, 5 against

Two members felt strongly in favor of the motion.

38. Part 8 Regulations 57 through 67(3) The Committee recommends that Council review the implications of Part 8 on hospital pharmacy practice setting.
Moved by Laverne Vercaigne Seconded by Mel Baxter Vote: 7/7 in favor
 39. Regulation 58(2)a The Committee recommends that Council change 58(2)a to allow for signature or initials of the member.
Moved by Joanne Johnson Seconded by Kris Thorkelson Vote: 7/7 in favor
 40. Regulations 60(1)c The Committee recommends that Council remove the requirement of recording the PHIN where the person refuses to provide the information.
Moved by Tim Pattern Seconded by Kris Thorkelson Vote: 7/7 in favor
 41. Regulations 62(5) The Committee recommends Council consider removing 62(5) for all medication, but maintain the requirement for CDSA products, because this would be difficult and too labour intensive to administer in both hospital and community pharmacy settings.
Moved by Joanne Johnson Seconded by Kris Thorkelson Vote: 7/7 in favor
 42. Regulation 63. The Committee recommends Council consider removing 63 for all medication, but maintain the requirement for CDSA products, because this would be difficult and too labour intensive to administer in the pharmacy.
Moved by Angela Wierzbicki Seconded by Mel Baxter Vote: 7/7 in favor
 43. Regulations 64(1)c The Committee recommends that section 64(1)c is removed as it would be onerous to maintain and would not provide the needed information to ensure the communication was occurring.
Moved by Kris Thorkelson Seconded by Angela Wierzbicki Vote: 7/7 in favor
 44. Regulations 68(4)f The Committee is concerned that all medications may lack "some therapeutic value" and the wording should be changed by removing the word "may".
Moved by Norma Drosdowech Seconded by Angela Wierzbicki Vote: 7/7 in favor
- The Committee also suggests that scenarios be included to provide some practice applications of this section.
45. Regulations 69(2) The Committee recommends the section be changed to not require DPIN entry, where the patient has requested the information not be entered, until Manitoba Health has created a pseudo-PHIN system (that would enable the information to be entered in a general file).
Moved by Tim Pattern Seconded by Kris Thorkelson Vote: 5 in favor, 2 against

One member had a strong objection to the motion.

46. Regulations 70(2a)i and 70(2b)i The Committee recommends these sections be changed to add "and the declaration is documented" and remove the corresponding subsections ii.
Moved by Norma Drosdowech Seconded by Mel Baxter Vote: 7/7 in favor

Kevin Hall rejoined the meeting.

47. DEFEATED Regulations 73 There was a motion that Council remove section 73.
Moved by Angela Wierzbicki Seconded by Kris Thorkelson Vote: 4 in favor, 4 against

Four members strongly supported the removal of this section.

48. Regulations 74(1) The Committee recommends that a section be added that will allow the dispensing practitioners committee to consult other health professions and individuals as it may deem important to do so.
Moved by Mel Baxter Seconded by Kevin Hall Vote: 8/8 in favor

49. DEFEATED Regulations 74(2) and 85(2) There was motion that a member would be appointed for two years and renewed at the discretion of the appointing body.
Moved by Kevin Hall Seconded by Mel Baxter Vote: 5 in favor, 3 against

Five members felt that more than two terms may be beneficial

50. Regulations 75(4) and 79(4) The Committee recommends that these sections be removed and an appeal process developed.
Moved by Kris Thorkelson Seconded by Angela Wierzbicki Vote: 8/8 in favor

51. Regulations 86(1.1) The Committee recommends that section 86(1.1) be reworked and moved to section 68 in order to recognize that this is not prescribing, per se and should not, therefore, be covered by section 87.
Moved by Kevin Hall Seconded by Lavern Vercaigne Vote: 8/8 in favor

Therapeutic interchange in the hospital setting is based on prior approval by the medical staff and occurs automatically; therefore the prescribing criteria listed in section 87 could not be met in the hospital setting. The Committee did recognize that moving this regulation to section 68 might conflict with the authority permitted for interchangeable pharmaceutical products described in Part 9 of the act, but Regulation 86(1.1) should not be considered prescribing and therefore should not be left in Part 12 of the regulations.

52. Regulations 89(1) The Committee recommends that Council remove the requirement of recording the PHIN where the person refuses to provide the information.
Moved by Kris Thorkelson Seconded by Tim Pattern Vote: 7 in favor, 1 against

53. Regulations 91(2) The Committee recommends that the training program as established by Council includes training in enhanced safety measures and emergency resuscitation.

Moved by Kevin Hall Seconded by Joanne Johnson Vote: 8/8 in favor

54. Regulations 94(1) The Committee recommends that Council review and revise this section to allow for routine tests, like blood pressure, pregnancy, blood glucose, be exempt from the record keeping required under this section.

Moved by Joanne Johnson Seconded by Mel Baxter Vote: 7 in favor, 1 against

One member felt that documentation was necessary from a liability perspective.

55. Regulations 95(4) The Committee recommend that Council change section 95(4) to include all the sections (1,2,3) and not just limited to 95(3), with the appropriate wording change.

Moved by Kris Thorkelson Seconded by Kevin Hall Vote: 8/8 in favor

The Committee concluded their review of the Regulations Discussion Document.

The Committee then considered general motions from the members.

Motion #1 Moved by Kris Thorkelson and seconded by Tim Pattern that Council consider providing a copy of this Committee's Meeting Minutes along with the Regulations Discussion Document when it is circulated to the MPhA membership.

Carried Vote 8/8

Motion #2 Moved by Tim Pattern and seconded by Kris Thorkelson that Council consider doing a Regulatory Impact Assessment of the Regulations Discussion Document and prepare a report for the MPhA membership.

Defeated Vote 5 in favor, 3 against (did not meet the two third majority)

Motion #3 Moved by Kris Thorkelson and seconded by Tim Pattern that the Regulations Advisory Committee convene another meeting to further discuss the results as reported in the minutes.

Defeated Vote: 4 in favor, 4 against (did not meet the two third majority)

Notwithstanding the Committee was asked to review the draft Regulations Discussion Document as prepared by and forwarded from the Executive Committee, two Committee members felt there was not enough time to seek external consultations or perform a thorough review of the document.

The committee members felt that any further communication could occur through e-mail.