

Practice Direction Sub-Committee

Report to the Manitoba Pharmaceutical Association Council

September 15, 2008

(Final Vote 9:0 in favour of report)

Respectfully submitted by:

Scott McFeetors (Chair) on behalf of the committee

MPhA Practice Directions Sub- Committee Report

Foreword: The MPhA Practice Directions Sub-Committee was formed as a direct result of a motion that was carried at the MPhA Special General Meeting that took place on May 4, 2008. The motion stated: Council establish Sub-Committees to analyze the issues specifically identified by the Manitoba Society of Pharmacists and consult with the membership on:

- A. Distance Care Component
- B. Practice Directions and Other Enhanced Delegated Authority Under the Draft Regulations
- C. Pharmacy Technicians
- D. Record Keeping Requirements
- E. Inducements
- F. Pharmacist Manager Qualifications

There were a number of background documents that were available regarding Practice Directions prior to the Sub-Committee meetings that directly influenced the outcome and recommendations of the meetings and those documents have been included in this report.

1. MPhA Practice Directions Sub-Committee Recommendations

2. Summary of Meetings

- i. July 7th, 2008
- ii. July 16th, 2008
- iii. Aug. 26th, 2008

3. Attachments

- 1) Competition Bureau 2007- Self Regulated Professions, Balancing Competition and Regulation
- 2) Manitoba Society of Pharmacists Practice Directions Survey Results
- 3) Manitoba Society of Pharmacists Practice Directions Position Statement
- 4) Manitoba Society of Pharmacists Practice Directions Legal Opinion
- 5) Manitoba Society of Pharmacists Bill 41 Annotated Document – Practice Directions

1. MPhA Practice Directions Sub-Committee Report Recommendations:

The MPhA Practice Directions Sub-Committee was formed as a direct result of a motion that was carried at MPhA Special General Meeting that took place on May 4, 2008. The committee recognizes that a Practice Direction carries the legal weight of a Regulation, and thus it is important that the formation of a Practice Direction must be made with great diligence and care, and be subject to scrutiny and review.

The committee discussed the process of creating a *practice direction* rather than defining any specific practice direction. There was a general consensus amongst the committee that it would not be practical for the entire membership to vote on every single change and implementation of each practice direction. However, there was much discussion on establishing a specific protocol which would allow interest groups, stakeholders and membership to present possible practice directions to the MPhA Council.

The MPhA Practice Directions Sub-Committee recommends that the following process be used to develop practice directions:

1. Identification of practice directions

A proposed Practice Direction may be submitted to MPhA Council by any stakeholder, committee, member, by the Government, or by any other party. Any proposed Practice Direction must:

a) State objective of the practice direction

- i. must state clearly and define outcome (ie. to reduce abuse of drugs)
- ii. It was recommended to adopt Sheridan Scott's competition bureau report (except possibly change the last point) p37 (see Attachment 1) which identifies the principles which must be considered before making a regulation, or, in this case, a Practice Direction. These principles are:

- 1. Regulation should have clearly defined and specific objectives**
- 2. Restrictions should be directly linked to clear and verifiable outcomes**
- 3. Regulation should be the minimum necessary to achieve stated objectives**
- 4. The regulatory process must be impartial and not self-serving**
- 5. A regulatory scheme should allow for periodic assessment of its effectiveness and be subject to regular reviews**

b) Be presented to Council in writing on a form to be developed

c) The Practice Direction should not negatively affect business practices and give unfair advantage—should be achievable by all.

d) Notwithstanding the process outlined in this report for creation of a Practice Direction, Practice directions can be brought forth on an urgent basis by Council in response to a pandemic or public health crisis

2. Consultation and development

The committee felt that this was clearly the most important step involved in the process for creation of a Practice Direction. It is critical that at this point, every effort is made to involve the membership and all stakeholders.

- a) First refer to appropriate committee(s) or adhoc committee(s)
- b) Identify stakeholders
- c) Active efforts to inform members stating the objective of practice directions and given an appropriate time line for feedback and response.
- d) Practice directions are developed in conjunction with feedback received
- e) Return to Council for review and receive legal consultation if necessary

3. Implementation

The intent of this step was to ensure that an appropriate length of time was given before a practice direction was required to be enforced, in order to allow time for compliance. Education of the membership at this point was considered imperative.

- a) Establish an appropriate implementation period and
- b) Notification of the membership via appropriate means, restating the objective of the practice directions.
- c) Education of the membership as appropriate

4. Review and Feedback process

- a) Assessment of the effectiveness of the practice directions
- b) Following the final implementation period date, a review by Council will be conducted to ensure effectiveness and appropriateness of the practice directions
- c) An appropriate time period for review will be determined by Council and no less than 90 days from the final implementation date.

5. Formal Appeals

- a) All formal appeals must be presented to Council in writing
- b) An appeal can be presented at anytime
- c) Subsequent appeals can be made by the general membership according to Bill 41 section 75(3) or similar to it (see below).

75(3) *After notice is given in accordance with the by-laws, a by-law made under subsection (1) may be amended or repealed by a majority of the members of the College*

(a) present and voting at a general meeting or a special general meeting; or

(b) voting in a mail vote or other method of voting conducted in accordance with the by-laws.¹

This committee also recommends that any potential Practice Directions, that have already been identified, be included with the draft regulations for voting on at the same time as the regulations.

¹ Bill 41 The Pharmaceutical Act

2. Summary of Meetings

i. **July 7th, 2008**
Practice Directions Sub-Committee
Location: Victoria Inn

Attendees:

- Mel Baxter
- Lois Cantin
- Greg Harochaw
- Carey Lai
- Scott McFeetors
- Penny Murray
- Tim Pattern
- Gayle Romanetz
- Marilyn Sidhu
- Randy Stephanchew
- Tobi Tse

Regrets:

- Antoine Abi-Khalil
- Jeremy Cockerill
- Al Eros

The first meeting convened on July 7, 2008 with eleven members in attendance. The committee discussed the process of creating a *practice direction* rather than defining any specific practice direction. There was a general consensus amongst the committee that it would not be practical for the entire membership to vote on every single change and implementation of each practice direction. However, there was much discussion on establishing a specific protocol which would allow interest groups, stakeholders and membership to present possible practice directions to the MPhA Council. If Council intends to establish a new practice protocol, the protocol may include a consultation period, a vote or even a possible “probationary” period. It was also suggested that feedback may be collected at the annual Issues Forum held at the Manitoba Pharmacy Conference.

Future meeting dates were considered and possible meeting locations were also discussed.

The committee selected:

- Scott McFeetors as Chairperson
- Carey Lai as Scribe
- Mel Baxter as Report Writer

Two motions were made at the meeting:

1. **Motion 1:** moved by Mel Baxter / seconded by Gayle Romanetz

That Troy Harwood-Jones be allowed to take part in the committee's next meeting as a resource for information, in a non-voting capacity. The motion was carried.

2. **Motion 2:** moved by Carey Lai / seconded by Randy Stephanchew

That a Pharmacy Student (TBA) from the Faculty of Pharmacy at the University of Manitoba be allowed to participate in the committee's next meeting in a non-voting capacity. The motion was carried.

ii. July 16, 2008
Practice Directions Sub Committee
Norwood Hotel 7:00-9:00pm
Rm. 302

Meeting called to order 7: 10 pm

Attendees:

- Mel Baxter
- Lois Cantin
- Greg Harochaw
- Carey Lai
- Scott McFeetors
- Penny Murray
- Gayle Romanetz
- Tobi Tse
- Ola Norrie
- Tim Pattern
- Advit Shah

Regrets:

- Marilyn Sidhu
- Randy Stephanchew
- Antoine Abi-Khalil

1. Al Eros and Jeremy Cockerill withdrew from the committee
2. Quorum: It was determined that a majority of the committee members were present.
3. Introductions:
4. Review of last meeting's notes
 - modify previous notes to mention that some practice directions are necessary due to urgency
 - feed back period
 - some form of period that can challenge the practice direction

Process of Creating Practice Directions:

1. Identification of practice directions
2. Consultation and development
3. Implementation
4. Review and feedback
5. Formal appeal

1. Identification of practice directions

- a) State objective of the practice direction
 - i. must state clear and define outcome (ie. to reduce abuse of drugs) It was recommended to adopt Sheridan Scott's competition bureau report (except possibly change the last point) p37
 - ii. Practice directions can be brought fourth due to pandemic or public health crisis

-Additional Discussion:

Perhaps a form created to submit to a PD request on a form which states the needs and objectives; defines clearly verifiable outcomes.

-Minimum standards necessary to achieve objective

The Practice Direction should be impartial and not self-serving; should not affect business practices and give unfair advantage—should be achievable by all.

2. Consultation and development

- a) First refer to appropriate committee(s) or adhoc committee(s)
- b) Identify stakeholders
- c) Active efforts to inform members stating the objective of practice directions and given an appropriate time line
- d) Practice directions is developed in conjunction with feedback received
- e) Return to Council for review and receive legal consultation if necessary

3. Implementation

- a) Establish an appropriate implementation period and
- b) Notification of the membership via appropriate means, restating the objective of the practice directions. Education of the membership as appropriate

4. Review and Appeals process

- a) Assessment of the effective of the practice directions
- b) Following the final implementation period date, formal reviews will be conducted to ensure effectiveness and appropriateness of the practice directions

5. Formal Appeals

- investigate current appeal process

Motion 1: moved by Carey Lai/seconded by Tim Pattern

Advit Shah, a pharmacy student from the Faculty of Pharmacy at the University of Manitoba be allowed to participate in the committee meetings in a voting capacity.

Motion tabled.

It was determined that the 3rd meeting will be held on August 26, 2008. (7:00pm).

**iii. Aug. 26, 2008
Practice Directions Sub Committee
Norwood Hotel 7:00-9:00 pm
Rm. 302**

Meeting called to order: 7:20pm

Attendees:

- Tobi Tse
- Randy Stephanchew
- Scott McFeetors
- Mel Baxter
- Penny Murray
- Carey Lai
- Lois Cantin

1. Identification of practice directions

a) State objective of the practice direction

- i. must state clearly and define outcome (ie. to reduce abuse of drugs) It was recommended to adopt Sheridan Scott's competition bureau report (except possibly change the last point) p37
- ii. Practice directions can be brought fourth due to pandemic or public health crisis

-Additional Discussion:

Perhaps a form created to submit to a PD request on a form which states the needs and objectives; defines clearly verifiable outcomes.

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3. Implementation

- a) Establish an appropriate implementation period and
- b) Notification of the membership via appropriate means, restating the objective of the practice directions. Education of the membership as appropriate

4. Review and Feedback process

- a) Assessment of the effectiveness of the practice directions
- b) Following the final implementation period date, a review by Council will be conducted to ensure effectiveness and appropriateness of the practice directions
- c) An appropriate time period for review will be determined by Council and no less than 90 days from the final implementation date

5. Formal Appeals

- a) All formal appeals must be presented to Council in writing
- b) Any appeals can be presented at anytime
- c) Any subsequent appeals can be made according to Bill 41 section 75(3) or similar to it (see below).

75(3) After notice is given in accordance with the by-laws, a by-law made under subsection (1) may be amended or repealed by a majority of the members of the College

- (a) present and voting at a general meeting or a special general meeting; or
- (b) voting in a mail vote or other method of voting conducted in accordance with the by-laws.²

Motion: To accept the work that has been completed by the sub-committee and to move into the report writing phase. A completed draft will be circulated amongst those who participated during the sub-committee process.

(Randy/Carey)- **Carried unanimously**

Motion: A vote will be conducted electronically to accept the final report

(Lois/Randy)- **Carried unanimously**

Motion: Advit Shah, a pharmacy student from the Faculty of Pharmacy at the University of Manitoba be allowed to participate in the committee meetings as a voting capacity.

(Carey/Tim) **Defeated**

The point was raised that the initial set of practice directions should be voted on at the same time as the regulations or as a package once they are developed soon thereafter.

3. Attachments:

1) Self-regulated Professions, Balancing Competition and Regulation Competition

Bureau 2007 The following excerpt was taken from the Self-regulated Professions, Balancing Competition and Regulation Competition Bureau 2007 The actual document can be accessed at: [http://www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/vwapj/Professions%20study%20final%20E.pdf/\\$FILE/Professions%20study%20final%20E.pdf](http://www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/vwapj/Professions%20study%20final%20E.pdf/$FILE/Professions%20study%20final%20E.pdf)

2. Effective regulation

The Competition Bureau recognizes that regulating professional services can be important for protecting consumers. It does not argue blindly for competition at the expense of all other policy objectives, since there may be legitimate public interests at issue other than the efficient functioning of markets. The Bureau does, however, advocate that to be effective, regulatory decisions must be fully informed, keeping in mind the many direct and indirect effects they may have on consumers through reduced competition. Regulation that is excessive or restricts competition more than an equally effective alternative can come at great cost and should be removed or modified. In this chapter, the Bureau puts forward six guiding principles to help regulators— comprising provincial and territorial governments and self-regulating organizations—develop and maintain strong, efficient regulation that maximizes consumer welfare. The chapter also outlines a framework for regulators to detect and assess the impact on competition of restrictions under development or review.

² Bill 41 The Pharmaceutical Act

Principles

Regulation should have clearly defined and specific objectives

If regulation is to be effective, it must be premised on clearly defined and specific objectives. A regulatory scheme should state the reasons for its existence and the outcomes it intends to achieve. Rather than simply presenting broad general principles, the scheme should address specific problems. Clearly defined and specific objectives will improve transparency and reduce the likelihood that regulation will be used to pursue private interests under the guise of public protection.

Restrictions should be directly linked to clear and verifiable outcomes

Specific restrictions chosen to achieve regulatory objectives should be directly linked to intended outcomes. To this end, a regulatory scheme should include performance standards that tie restrictions to outcomes through evidence rather than theory alone.

Regulation should be the minimum necessary to achieve stated objectives

Regulation should only comprise what is reasonably required to protect the public and should not restrict competition any more than is necessary to achieve the desired objectives. When considering regulatory options, regulators should look to regulatory schemes that exist across the country or elsewhere that have been shown to meet the intended policy objectives, while not compromising the quality of professional services or competition.

It is often the case that multiple restrictions aim to achieve the same objective. Such overlap may indicate that there is more than the minimum necessary regulation in place. For example, regulators often justify restrictions on advertising as a form of quality assurance; however, this may be unnecessary when high minimum entry qualifications and licensing, also intended to ensure quality, already exist.

The regulatory process must be impartial and not self-serving

In order to achieve the public policy objectives of regulation in the most effective manner, professional organizations must ensure they have the best possible governance structure. To this end, professional organizations must broadly represent all aspects of the profession being regulated, with independent public members at the table alongside professionals. Such representation helps ensure that self-regulatory activities are in the public interest by providing a window on the profession's operations. With broad representation, no one market participant or group of participants can control the regulatory process and manipulate it to its advantage.

While the Bureau recognizes the need for professional organizations to be informed by the expertise of the profession, it is likely overrepresentation to have an overwhelming majority of the members be professionals themselves, which may lead to their pursuing the profession's private interests. Since regulation of the professions is most commonly justified in terms of consumer protection, it seems appropriate that the points of view of consumers be effectively represented in professional organizations.

A regulatory scheme should allow for periodic assessment of its effectiveness and be subject to regular reviews

Regulators should produce annual reports on their activities and regularly review the regulatory scheme to ensure it effectively meets *current* needs. In light of ever-changing technology and market conditions, regulators must continually question the effectiveness of current restrictions. For example, as discussed

in Chapter 1, restrictions on the entry and conduct of professional service providers are often justified as addressing instances of asymmetric information, when consumers are unable to make informed decisions about professional services. The appropriate regulatory response to this has likely changed in recent years, with consumers increasingly using the Internet to find out about services before they buy them. Moreover, regulators must regularly review restrictions to identify those that have undue costs or those whose goals could be better achieved through less intrusive approaches. Without a dynamic review mechanism, regulatory schemes run the risk of losing their relevancy and becoming suboptimal responses to policy objectives.

- 2) **MSP Practice Directions Survey Results:** The following excerpt was taken from the MSP Various Topics Questionnaire Results that are posted on the MSP website. The actual document can be accessed at <http://www.msp.mb.ca/files/Questionnaire%2013%20Various%20Regulatory%20Topics.pdf>

"Practice Directions" is defined in Bill 41, which was passed in December, 2006 as follows: "Practice Direction" means a written statement made by the council for the purpose of giving direction to members and owners about the conduct of their practices or pharmacy operations. As per the following section of Bill 41, Council has the authority to make practice directions. Practice Directions are identified some twenty four times in the Discussion Document of July 30th, 2007, thereby providing Council with the ability to make Practice Directions in a wide range of areas.

Council to govern and administer 6(3) Without limiting subsection (2), the council may, by resolution, take any action consistent with this Act, including the following: (c) making practice directions.

22. Do you support MPhA's authority to make Practice Directions?

Yes	39	55%
No	32	45%
Total	71	100%

23. Should MPhA Council take reasonable steps to develop Practice Directions, prior to members approving the regulations?

Yes	57	80%
No	14	20%
Total	71	100%

24. Please provide additional comments:

17 Responses

- practice direction provides Council with too much discretionary powers
- This is far too vague and should provide more detail, because this can give council more power than the act really intends.
- We need to know EVERYTHING MPhA does If it directly affects the way we practice. If it's a "non-issue" to us at the grass-roots level, then they can issue directives regarding patient safety, or other "red-tape" issues.
- MPhA should prepare the Practice Directions with input from the members. The final draft should be subjected to approval by members too.
- we cannot vote blindly and allow MPhA to decide what are future will be a that there own whim and fancy. all details must be worked out so that we are all playing on a level field. this is why I feel the entire process must be scrapped and started again from scratch
- The regulations development and adoption should be top priority for all organizations, especially MPhA
- Discussion and consultation with the membership should be done, prior to the issuing of Practice Directions by Council.
- MPhA should always take some direction and votes from it's members who are using and implementing the directives so we all have the opportunity to participate in the formulation of directives that we would have to follow.

Are these "suggestions" to help improve practice or guidelines that will cripple it? They must be defined before we vote (unless they are to be done on a pharmacy to pharmacy basis?)
If "practice directions" are basically suggestions, fine. otherwise notice would be important
Practice directions should be presented to members for discussion & voting.
membership should be involved.
Yes, MPhA Council should take reasonable steps to develop Practice Directions, prior to members approving the regulations. The good will the membership shows to MPhA probably shouldn't extend to this. We should have some limitations in place first.
Hopefully pharmacists will also be consulted regarding the practice directions
I need much more information re the type of "practice direction" we are referring to.
We should see the Practice Directions as they are intended, prior to the vote.
Any practice directions should be approved by the membership before becoming regulation/requirement. A minimum amount of notice (3 months) should be given to the memberships about the new suggested directions before being voted on.

- 3) MSP Practice Directions Position Statement:** The following excerpt was taken from the Manitoba Society of Pharmacists Practice Directions Position Statement. The actual document can be accessed at:

<http://www.msp.mb.ca/files/Practice%20Directions%20Position%20Statement.pdf>

The Manitoba Society of Pharmacists recognizes that Bill 41 provides MPhA Council with the authority to make practice directions. The impact that practice directions will have on pharmacy practice in Manitoba is unknown. Clarification will be achieved if MPhA Council takes reasonable steps to develop practice directions and circulate same prior to the approval of the regulations. Circulating practice directions with Manitoba pharmacists in advance of the regulation approval process may increase the probability of the passage of the regulations.

- 4) MSP Practice Directions Legal Opinion:** The following excerpt was taken from the Manitoba Society of Pharmacists Legal Opinion on Practice Directions provided by Robert Dawson of Dawson Law Chambers. The actual document can be accessed at: http://www.msp.mb.ca/files/2008-02-18_msp_practice-directions.pdf

Preliminary matters

Documents consulted

In addition to those materials listed in his earlier opinion letter of 8 May 2007 and the revised draft regulations of 3 December 2007, you have also provided an annotated version of the draft regulations and excerpts from that draft as they relate to practice directions.

Facts and assumptions

The facts and assumptions are the same as those set out in the writer's opinion letter of 8 May 2007, and this new opinion letter states the law as of 15 February 2008.

Citation and references

All references to *The Pharmaceutical Act* refer to the new legislation, and references to the draft regulations refer to the revised version dated 3 December 2007.

Practice directions

Under the new *Act*, practice directions are to be made by resolution and approved by Council: s. 6(3)(c). By the excerpt that you provided to me, you already recognize the frequent reference to practice directions in the draft regulations. By way of comparison, there is no provision for practice directions under the current *Act*, and as a result the current regulations make no reference to them.

Unlike future amendments to the regulations, practice directions do not require approval from the membership. Even though practice directions may introduce substantive changes to the way in which pharmacy is practiced in Manitoba, their implementation requires only approval by Council. Some members are therefore concerned about what they would describe as the potential misuse or abuse of practice directions by Council, allowing it to introduce changes to the practice of pharmacy by way of mere practice directions instead of seeking approval from the membership. If these concerns are valid, the result would be an increase in the power of Council and the reduced role of the membership in defining the rules by which the profession is governed. Of course, such concerns are predicated upon an assumption that practice directions have the same force and effect as the provisions of the *Act* and the regulations.

Enforceability of practice directions

Practice directions are provisions that augment legislation, clarifying ambiguity, presenting an interpretation, or providing details on legislative application. Their use is widespread and almost always authorized by statute. They break down into two categories: directions relating to procedure before courts and tribunals, and standards against which to judge the conduct of professionals.

There is little argument on the enforceability of practice directions that relate to procedural issues before courts and tribunals. In fact, in the Ontario case of *Cessland Corp. v. Fort Norman Explorations Inc.* (1979), 100 D.L.R. (3d) 378 (S.C.), the principle was thought to be so well-established that the enforceability of a practice direction was simply assumed (para. 18). However, it is probably wrong to extend this reasoning to instances in which a practice direction defines a standard against which to judge professional conduct. Whereas the failure to comply with a procedural practice direction gives rise only to procedural penalties, a breach of a practice direction that defines professional conduct may trigger disciplinary consequences, including the expulsion of the offending member from the profession. For this reason, there should be no obvious presumption that such practice directions would be enforceable in the absence of some authority.

In *MacDonald Estate v. Martin*, [1990] 3 S.C.R. 1235, the Supreme Court of Canada held at para.18 that a code of professional conduct will have the same force and effect as regulations and that a court will therefore enforce its provisions. Like a practice direction, a code of professional conduct is adopted by a professional governance body pursuant to delegated authority deriving from the legislation that governs the profession. It seems to follow that, because their statutory basis is the same, a practice direction would be as enforceable as a code of professional conduct.

However, where a practice direction lacks such a statutory basis, it cannot have any binding effect. In *Sherman v. Botan* (2002), 165 Man.R. (2d) 288, the Manitoba Court of Queen's Bench considered the effect of a practice direction that the Law Society of Manitoba had issued at a time when the governing legislation made no reference to practice directions. The applicant sought a court order to reduce the fee that her former lawyer had charged under a contingency agreement, and part of her argument was based upon the substance of a practice direction. Beard J. wrote at para. 9 that the practice direction

... is neither a statutory provision nor a regulation, so it is not binding on the court. It is a practice direction passed by the Law Society as part of its mandate to

regulate the practice of law. It indicates what that governing body finds to be appropriate conduct on the part of a lawyer, and the level of conduct that a member is obligated to meet to remain in good standing.

Beard J. was quite correct, because the now-repealed *The Law Society Act*, C.C.S.M. c. L100, made no provision for practice directions (but see the current *Legal Profession Act*, C.C.S.M. c. L107, at s. 43(a)).

Nevertheless, the court in the *Sherman* case went on at para. 9 to note the usefulness of the practice direction, even though it lacked any statutory basis:

While it is not binding, it is relevant to a determination of what is fair and reasonable under s. 58(4) of the *Law Society Act*. This is especially true here, where the practice direction is exactly on point with the issue before me.

In *Sherman*, the practice direction assisted the court by setting out the considered opinion of the professional governance body on the manner in which members should conduct themselves in such circumstances. Even though lacking a statutory basis that would make the practice direction binding upon members, the pronouncement carried great weight and influenced the court in assessing the usual principles that apply to fees under contingency agreements.

By way of summary on this point, the Supreme Court of Canada *MacDonald Estate* case strongly suggests that practice directions published pursuant to the explicit authority set out in the new *Act* would likely have the same binding effect as actual regulations.

Even if a court rejected that approach, the reasoning in the *Sherman* case shows the weight that a court will attribute to practice directions that reflect the considered opinion of a professional governance body. As a result, either by way of express authority or through weighty influence, practice directions under the new *Act* would have a significant effect upon the practice of pharmacy in Manitoba.

As a qualification to the preceding, it is important to note that, in concluding that a practice direction has the same effect as a regulation, the assumption is made that all practice directions would fall within the intent and purpose of the new *Act*. In *Banks v. British Columbia (Workers' Compensation Board)*, (1988) 51 D.L.R. (4th) 379 (B.C. S.C.), an administrative tribunal published a practice direction that did not coincide with the aims of the statute that authorized its creation. Applying that practice direction, the tribunal denied workers' compensation benefits to an applicant. On review, the decision was struck down by the court, which held at para. 18 that the tribunal had no jurisdiction to enforce a practice direction that had not been made within the scope and extent prescribed by the legislation. Accordingly, so long as a practice direction falls within the intent and purpose of the enabling legislation, a court would likely enforce its provisions in the same way that it would the regulations.

Impact of practice directions

The draft regulations expressly anticipate the publication of practice directions, whose substance would be an extension on equal footing of the regulations and code of ethics.

In some instances, practice directions are merely listed as a required source of knowledge that members of the profession must know. See, for example, s. 3(e) of the new regulations, which requires applicants for registration as pharmacists to demonstrate "knowledge of the Act, Regulations, by-laws, code of ethics, and practice directions applicable to the practice of pharmacy in Manitoba". The same requirement exists for conditional registrations (s. 4(1)(f)), temporary registrations (s. 5(f)), students (s.

8(1)(j)), and interns (s. 9(1)(f)). The message to take away here is that practice directions are important – indeed, as important as the code of ethics and all the other provisions that members currently accept as governing their practice of pharmacy.

Beyond this general requirement that members should be familiar with the practice directions, the drafters of the regulation have structured practice directions so that they would be an independent head by which to commence disciplinary proceedings. Section 49 requires that members follow “applicable practice directions”. In addition, practice directions are intended to be part of the governance of pharmacy technicians (s. 52(4)), students (s. 53(2)), and those entrusted with the supervision of interns, technicians, and students (s. 55). Specific disciplinary offences also rely upon practice directions in the definition of what constitutes unprofessional conduct: requirement for a counseling record (s. 58(2.1)(a)), central-fill records (s. 61(f)), M3P drug dispensing limits (s. 65(2)(c), 65(3), and 65(4)); limits on dispensing other drugs (s. 72(1)); dispensing requirements in general (s. 77(2)); general prescribing procedures (s. 87(e)), and, continued care prescriptions (s. 90(1)). Furthermore, by relying upon practice directions, s. 68(3) creates a defense against a charge of changing a prescription without consent. The draft regulations also anticipate at Schedule A, Standard 13, that Council may adopt the practice directions of other bodies, and there is no limit on which bodies or the scope or extent of those other practice directions.

Because of their equal footing with the other provisions that govern the practice of pharmacy, practice directions have the potential to create new and sweeping grounds by which to commence disciplinary proceedings. The concern is further compounded by the unavailability of such practice directions at this stage of consideration of the draft regulation. Whereas under the current *Act* new heads of disciplinary complaints may be introduced, the consent of the governed membership is required. The new *Act* contemplates that practice directions need only the approval of Council.

5) Manitoba Society of Pharmacists Bill 41 Annotated Document – Practice Directions

The following document was provided by the MSP and documents all references to Practice Directions in the second Bill 41 Draft Regulations Discussion Document.

Annotated DRAFT Pharmaceutical Regulations

Practice Directions



Practice Directions Position Statement - Practice Directions are referenced in many sections throughout the document. The Position Statement has been linked here for ease of reference.

Registration of pharmacists

3 In addition to the requirements set out in s.11(1) of the Act, an applicant for registration as a pharmacist must, prior to registration:

- (a) complete an application in the form prescribed in the by-laws;
- (b) satisfy the board that the applicant does not have a physical or mental condition which, in the opinion of the board, makes the applicant unsuitable for registration as a pharmacist;

~~(e)~~(b) satisfy the board that the applicant does not have an addiction to alcohol, drugs or illegal substances which, in the opinion of the board, makes the applicant unsuitable for registration as a pharmacist;

~~(d)~~(c) satisfy the board that the applicant has not been convicted of an offence or been subject to professional discipline which, in the opinion of the board, makes the applicant unsuitable for registration as a pharmacist;

~~(e)~~(d) demonstrate fluency, satisfactory to the board, in one of the official languages of Canada;

~~(f)~~(e) demonstrate, to the satisfaction of the board, knowledge of the Act, Regulations, by-laws, code of ethics, and **practice directions** applicable to the practice of pharmacy in Manitoba;

~~(g)~~(f) where the applicant is licenced as a pharmacist in another jurisdiction, provide a letter of standing from that jurisdiction satisfactory to the board;

~~(h)~~(g) serve a period of internship as determined by the board; and

~~(i)~~(h) provide a recent passport size image of the applicant in a manner approved by the board.

Conditional register

4(1) Where an applicant for registration as a pharmacist does not yet meet all the requirements for registration, the board may direct the registrar to place the applicant on the conditional register, if in addition to the requirements of s.12(1) of the Act, the applicant:

- (a) completes an application in the form prescribed in the by-laws;
- (b) satisfies the board that the applicant does not have a physical or mental condition which, in the opinion of the board, makes the applicant unsuitable for conditional registration as a pharmacist;
- (c) satisfies the board that the applicant does not have an addiction to alcohol, drugs or illegal substances which, in the opinion of the board, makes the applicant unsuitable for conditional registration as a pharmacist;
- (d) satisfies the board that the applicant has not been convicted of an offence or been subject to professional discipline which, in the opinion of the board, makes the applicant unsuitable for conditional registration as a pharmacist;
- (e) demonstrates fluency, satisfactory to the board, in one of the official languages of Canada;
- (f) demonstrates, to the satisfaction of the board, knowledge of the Act, Regulations, standards of practice, by-laws, code of ethics, and **practice directions** applicable to the practice of pharmacy in Manitoba;
- (g) where the applicant is licenced as a pharmacist in another jurisdiction, provides a letter of standing from that jurisdiction satisfactory to the board;
- (h) serves a period of internship as determined by the board; and
- (i) provides a recent passport size image of the applicant in a manner approved by the board.

Temporary Certificate of Registration **Removed - Temporary Registration**

5 In addition to the requirements of s.18(1) of the Act, an applicant for a temporary certificate of registration must:

- (a) provide evidence satisfactory to council that the applicant is licenced to practice pharmacy and actively practices in another jurisdiction acceptable to council;
- (b) advise council as to all the jurisdictions in which the applicant is licenced to practice pharmacy;
- (c) provide a letter of standing, satisfactory to council, from the jurisdiction in which the applicant is currently licenced and actively practicing pharmacy;
- (d) complete the application forms specified in the by-laws;
- (e) provide a work history satisfactory to council;
- (f) provide an undertaking that the temporary practice will be conducted in accordance with the Act, by-laws, code of ethics, standards of practice, and all relevant **practice directions**; and
- (g) pay any fee specified in the by-laws.

Registration of students

8(1) In addition to the requirements of s.19 of the Act, an applicant for registration as a student must:

- (a) provide evidence satisfactory to the registrar that the applicant is registered as a student in a pharmacy education program approved by the council;
- (b) submit an application to the registrar:
 - (i) where the applicant is registered in the Faculty of Pharmacy at the University of Manitoba, by December 31, in the year the applicant enters the Faculty or such other date as the registrar will permit; or
 - (ii) where the applicant is registered in any other pharmacy education program, at least 30 days prior to the intended date to commence working as a student;
- (c) refrain from working as a student in a pharmacy until registered, which registration can be delayed by failure to comply with (b);
- (d) pay any late filing fee provided for in the by-laws if the applicant fails to comply with (b);
- (e) satisfy the registrar that the applicant does not have a physical or mental condition which, **Removed - in the opinion of the registrar**, as determined by Council, makes the applicant unsuitable for registration as a student;
- (f) satisfy the registrar that the applicant does not have an addiction to

alcohol, drugs or illegal substances which, **Removed - in the opinion of the registrar,** as determined by Council, makes the applicant unsuitable for registration as a student;

- (g) satisfy the registrar that the applicant has not been convicted of an offence which, in the opinion of the Registrar, makes the applicant unsuitable for registration as a student;
- (h) provide to the registrar a recent passport size image of the applicant; and
- (i) satisfy the registrar that the applicant is fluent in one of the official languages of Canada; and
- (j) provide an undertaking that his or her practice as a student will be conducted in accordance with the Act, the by-laws, the code of ethics, the standards of practice and all relevant **practice directions**.

Registration of interns

9(1) In addition to the requirements of s.20 of the Act, an applicant for registration as an intern must:

- (a) provide evidence satisfactory to the registrar that the applicant
 - (i) has completed or will complete within 12 months a pharmacy education program approved by the council;
 - (ii) intends to intern for an educational purpose of a type approved by council; or
 - (iii) is serving an internship as required by the Board under section 3. **Removed - or the registrar under section 14 (1).**
- (b) satisfy the registrar that the applicant does not have a physical or mental condition which, **Removed - in the opinion of the registrar,** as determined by Council , makes the applicant unsuitable for registration as an intern;
- (c) satisfy the registrar that the applicant does not have an addiction to alcohol, drugs or illegal substances which, **Removed - in the opinion of the registrar,** **New – As determined by Council** makes the applicant unsuitable for registration as an intern;
- (d) satisfy the registrar that the applicant has not been convicted of an offence which, in the opinion of the registrar, makes the applicant unsuitable for registration as a pharmacist;
- (e) provide to the registrar a recent passport size image of the applicant .; and
- (f) provide an undertaking that his or her practice as an intern will be conducted in accordance with the Act, the by-laws, the code of ethics, the standards of practice and all relevant **practice directions**.

Standards to be followed

49 The standards set out in Schedule A, and applicable **practice directions** issued by council from time to time, under s.6(3)(c) of the Act, must be followed by:

- (a) members in practicing their profession, directly or through delegation;
- (b) owners in operating the pharmacies for which they are responsible;

- (c) pharmacy managers in supervising the staff of the pharmacies for which they are responsible;
- (d) students, interns, pharmacy technicians and other persons ; and
- (e) persons operating under the authority of Part 10 of these regulations.

Duties of pharmacy technicians

52(4) In addition to the duties described in 54(2), the following duties supporting the practice of pharmacy may be performed by a pharmacy technician, under supervision of a member **Removed – with a section 12 pharmacist licence** and in accordance with applicable **practice directions**:

- (a) reviewing the information on the prescription for legibility and compliance with federal and provincial regulations;
- (b) replenishing drug storage containers and dispensing machines;
- (c) performing a final check on the packaging or pre-packaging of drugs, container selection, and labelling performed by another technician, student or intern, prior to dispensing;

Removed - Allowing the technician to perform the final check of the prepared drugs pursuant to a prescription would be an option for the practice site and not an obligation.

Council acknowledges many of the responses that expressed concern that technicians would not be able to perform this function safely or this role might be exploited by unscrupulous employers wanting to decrease the role of the pharmacist. However, Council felt that technicians doing this check is not a requirement under these proposed regulations, but it is an option that enables the practice site to use qualified technicians to perform the final check of this technical function and free-up the pharmacist to perform the professional task of ensuring patients are receiving the right medication and therapy.

Quoted from Regulations Discussion Document 2 – July 30, 2007

- (d) entering prescription information into a pharmacy database ;
- (e) providing instruction to a person on how to operate a medical device but not provide any explanation involving the interpretation of the results or value of the device;
- (f) inquiring of the practitioner, and receiving the instruction, of whether an existing prescription can be refilled as previously prescribed and without any changes to the prescription;
- (g) collecting information from a patient for a patient profile; and
- (h) entering the pharmacy when it is closed and, with the exception of (e), (f) and (g), perform the duties listed under this section.

Duties of students

53(2) In addition to the duties described in 52(4) and 54(2), the following duties supporting the practice of pharmacy may be performed by a pharmacy student, under supervision of a member **Removed – with a section 12 licence** and in accordance with applicable **practice directions**:

- (a) educating a patient about their drug or drug therapy;
- (b) receiving and recording verbal prescriptions;

Pharmacy manager to arrange supervision

55(1) A pharmacy manager must take reasonable steps to ensure that supervision is provided to interns, pharmacy technicians, students and other persons in accordance with this part, the standards of practice and any relevant **practice directions**.

Member to supervise

55(2) A member must take reasonable steps to ensure that his or her supervision of interns, pharmacy technicians, students and other persons is provided in accordance with this part, the standards of practice and any relevant **practice directions**.

Counselling Record

58(2.1) Not including inpatients of a hospital, no drug may be dispensed unless a counselling record of the following is made and retained:

- (a) **Removed –confirmation of the drug being dispensed and that** the applicable standards of practice and **practice directions** related to the counselling of the patient, or their agent, have been met, indicated by:
 - (i) the signature or initials of the member or intern providing the counselling; and
 - (ii) where the person counselling is a student, the signature or initials of the member supervising the student.
- (b) where the counselling has been refused by the patient or their agent, the name of the person refusing counselling and the signature or initials of the member being advised of the refusal.

Central-fill pharmacy records

61 Where the pharmacy from which the drug is dispensed to a patient is other than the pharmacy in which the drug was prepared for dispensing:

- (a) the pharmacy dispensing to the patient is responsible for retaining the prescription record, prescription label record, and patient profile required under this part;
- (b) the pharmacy preparing the drug for dispensing must retain the prescription record and the prescription label record required under this part;
- (c) the prescription label must, in addition to the requirements of s.59.(1), be marked with the name of the pharmacy in which the medication was prepared for dispensing;
- (d) the prescription record must, in addition to the requirements of s.58(3), contain the name of the pharmacy in which the medication was prepared for dispensing;
- (e) the patient profile must, in addition to the requirements of s.60(1), include written authority from the patient to share the patient's personal and personal health information with the pharmacy in which the medication is to be prepared for dispensing; and
- (f) the involved pharmacies must meet any other requirements of the standards of practice, or applicable **practice directions**.

Limits on dispensing

65(2) A drug listed in the M3P schedule must not be dispensed unless:

- (a) the person dispensing the drug has taken reasonable steps to satisfy himself or herself that there are no questions or issues as described in s.68(4) of these regulations;
- (b) the prescription meets all the requirements of subsection (1);
- (c) the prescription is entered into DPIN in accordance with any applicable **practice directions**; and

Removed - Veterinary prescriptions would not be entered into DPIN and out of province patients would be entered in a pseudo-PHIN as it occurs now for M3P prescriptions.

Quoted from Regulations Discussion Document 2 – July 30, 2007

- (d) the prescription is dated by the authorized practitioner within three days of the date it is presented at the pharmacy for filling.

65(3) Subject to subsection (4), before dispensing a drug on the M3P schedule, prescription and patient information must be entered into DPIN in accordance with any applicable **practice directions**.

65(4) If the requirements of subsection (2) are not met, the person requested to dispense must:

- (a) refuse to fill the prescription and advise the patient or his or her designate and the authorized practitioner or other person who issued the prescription, of the refusal;
- (b) record the refusal to fill the prescription
 - (i) on the prescription form, and
 - (ii) in DPIN, in accordance with any applicable **practice directions**;
- (c) retain the prescription form, unless the patient or that patient's designate requests the prescription be returned, in which case a copy of the prescription form must be retained.

Changing prescriptions

68(3) Except as permitted by any applicable **practice directions**, no change must be made to a prescription without the consent of the practitioner or extended practice pharmacist issuing the prescription, in which case:

- (a) a revised written prescription must be issued by the practitioner or extended practice pharmacist; or
- (b) a verbal prescription recorded.

Limitations on sale of particular drugs

72(1) The following drugs may only be sold by retail from a dispensary to a patient (or his or her designate), and only after complying with any applicable standards of practice or **practice directions** and assessing that the drugs are appropriate in the circumstances of the patient:

- (a) any drug listed in Schedule 2 of the manual; or
- (b) a drug with pseudoephedrine as the single active ingredient.

Requirements of dispensing

77(2) A dispensing practitioner must practice under this designation in accordance with the obligation of members under the Act, including the regulations and any applicable **practice directions**.

Duties of committee

85(5) The committee must, on at least an annual basis:

- (a) review this regulation as it relates to included practices;
- (b) review standards of practice, **practice directions**, and the code of ethics as they relate to included practices;
- (c) review the outcomes of inspections and audits which relate to included practices;
- (d) formulate recommendations regarding the qualification of specialists;
- (e) formulate recommendations regarding improvements or changes which could be made to these regulations, standards of practice, practice directions and the code of ethics in regard to included practices;
- (f) formulate recommendations regarding the appropriateness of included practices being exercised outside of a collaborative practice ; and
- (g) present the recommendations to council.

Criteria for prescribing

87 A member may only prescribe where:

- (a) the member has made a reasonable inquiry to assess whether the drug will be safe and effective in the circumstances of the patient, including:
 - (i) the patient's symptoms;
 - (ii) the patient's medical history or information;
 - (iii) the patient's allergies;
 - (iv) other medications the patient may be taking; and
 - (v) any other inquires reasonably necessary in the circumstances.

(b) the member has assessed the patient in person, **New – in compliance with the standards of practice or practice directions;**

- (c) the drug is prescribed in a circumstance which is within the member's usual scope of practice or specialty;
- (d) the member has complied with any policies or rules related to prescribing at the pharmacy at which the member practices;
- (e) the member has complied with any applicable **practice directions**;

- (f) the member has determined that the prescription is reasonably necessary or desirable to treat the patient;
- (g) except where the prescription is being issued for an in-patient of a facility under the Health Services Insurance Act, the member has discussed with the patient, or his or her agent, reasonable and available therapeutic options and costs.
- (h) the device is needed to meet the care needs of the patient.

Continued care prescriptions

90(1) Subject to this section, a member **Removed – with a section 12 practicing licence** may authorize an additional refill of a prescription, beyond those authorized by the original practitioner issuing the prescription, where:

- (a) the patient has a continuing need or chronic condition;
- (b) the prescribing practitioner or extended practice pharmacist has died or retired within the previous six months or has not responded to an inquiry for refill authorization and it would be onerous or impossible for the patient to contact or attend with the original practitioner issuing the prescription in a timely manner;
- (c) the history of the patient with the subject drug has not changed ;
- (d) the patient advises that they have not recently experienced any adverse drug reactions to the subject drug;
- (e) the prescription was previously filled at the same pharmacy; and
- (f) the member complies with any applicable **practice directions**.

Notice through newsletter

100 Subject to any applicable by-laws, the newsletter may be used to provide notice to members and owners of matters concerning:

- (a) annual or special general meetings;
- (b) regulations or consultation regarding regulations;
- (c) by-laws;
- (d) the code of ethics or consultation regarding the code of ethics;
- (e) **practice directions**;
- (f) council resolutions; and
- (g) any other matter of concern to the profession.

SCHEDULE "A" Part 6 of Regulations

STANDARDS OF PRACTICE AND OPERATION OF PHARMACIES

New - Standard 1 – Collaborative practice

Members, in partnership with patients and other health care providers, use their unique knowledge and skills to meet patient's drug related needs and to achieve positive patient outcomes by maintaining or improving the patient's quality of life.

Removed – Standard 6 **New – Standard 2** – Dispensing and sale

Members must only dispense or sell drugs where it is **New – therapeutically appropriate**
Removed – safe, legal and ethical to do so.

Removed – Standard 2 **New – Standard 3** – Patient counselling

Members must counsel the patient, or their agent, providing specific information required for safe and effective drug therapy **Removed – pursuant to each prescription**.

Removed – Standard 15 **New – Standard 4** - Drug Information

Members must provide accurate, unbiased and pertinent drug information.

Removed – Standard 1 **New – Standard 5** – Drug acquisition and handling

Members are responsible **New - to ensure the safety, accuracy and quality of**
products and services they supply. **Removed – for the purchase, receipt, storage, and disposal of drugs in a safe,**
legal and ethical manner

Removed – Standard 8 **New – Standard 6** – Prescribing

Members must only issue prescriptions to patients where it is
New – therapeutically appropriate **Removed – safe**, legal and ethical to do so.

Removed – Standard 9 **New – Standard 7** – Administration of drugs

Members must only administer drugs to patients upon informed consent and where it is **New – therapeutically appropriate** **Removed – safe**, legal and ethical to do so.

Removed – Standard 10 **New – Standard 8** – Test interpretation

Members interpreting patient-administered automated tests must do so in a competent and accurate manner.

Removed – Standard 11 **New – Standard 9** – Test orders

Members may only order screening and diagnostic tests where it is
New – appropriate **Removed – safe**, legal and ethical to do so.

Removed – Standard 3 **New – Standard 10** – Incidents and Discrepancies

Members must expeditiously **New - address, document and report incidents,**
discrepancies and adverse events in dispensing and provision of patient care.

Removed – correct, document and report incidents and discrepancies in dispensing and provision of patient care.

Removed – Standard 13 **New – Standard 11** – Scope of Practice or Operation

New - Members must practice or operate a pharmacy in a safe and ethical
manner and within the provision of the act. **Removed – Members can only practice within the provision of the act**

Removed – Standard 17 **New – Standard 12** - Extemporaneous Compounding

Members must ensure that all extemporaneous compounding is done in a safe, legal and ethical manner.

New - Standard 13 – Additional practice direction

Members must practice in compliance with **practice directions** drafted by other organizations when adopted by Council.

Removed – Standard 16 **New – Standard 14** - **Documentation**

Members must ensure all documentation is clear, comprehensive and readable.

Removed – Standard 5 **New – Standard 15** – **Records**

Members and owners must ensure records required under the act and regulations are stored in a secure and readily retrievable manner and, when it is appropriate, destroy and dispose of in a manner that would protect the confidentiality of patient information.

Removed – Standard 14 **New – Standard 16** – **Pharmacist to staff ratio**

New – Members **Removed – Pharmacy managers** and owners must ensure that a pharmacy is operated with a ratio of members to pharmacy technicians, interns, students, and other staff or workers that insures the practice of pharmacy which is conducted in a safe, legal and ethical manner.

Removed – Standard 7 **New – Standard 17** – **Pharmacy hours**

Members and Owners must ensure pharmacist services are available to patients during reasonable hours of operation.

Removed – Standard 12 **New – Standard 18** – **Policies for staff**

Pharmacy managers must develop, implement and maintain current written polices and procedures for the training of pharmacy staff clearly stating the scope and limitations of their functions for the safe, legal and ethical operation of the pharmacy.

Removed – Standard 4 **New – Standard 19** – **Pharmacy facilities**

Pharmacy managers and owners must ensure the facilities are suitable for the pharmacy practice conducted.

New - Standard 20 – Technology

Pharmacy managers and owners must develop, implement and maintain written policies for the assessment and incorporation of technology into the safe, legal and ethical operation of the pharmacy.

New - Standard 21 – High risk practices

Pharmacy managers and owners must develop, implement and maintain written policies and procedures to:

- (a) identify, mitigate and avoid situations that expose patients and staff to inappropriate risk; and,
- (b) require all staff to participate in this undertaking.