

# A Regulations Awareness Campaign: Regulations Discussion Document

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# Background...

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- Bill 41: the *Pharmaceutical Act* passed on December 4<sup>th</sup>, 2006 and received Royal Assent on December 7<sup>th</sup>, 2006
- Major amendment to the Bill was the requirement for approval of the regulations by the members before forwarding to the Minister of Health

# Regulations Approval Process....

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- Work on the regulations started in early summer of 2006 and Council did their first review in September 2006
- Work stopped as the fate of Bill 41 became uncertain
- Council developed a regulations approval process and distributed the document to all members in January 2007.
- Standing Committees, staff, legal counsel, Executive Committee and Regulations Advisory Committee provided input to the drafting of the *Regulations Discussion Document*
- *Regulations Discussion Document* planned release to all members during the week of April 16<sup>th</sup>, 2007

# *Regulations Discussion Document*

## ....what is it?

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- It is not draft regulations.
- It is not the final version of regulations.
- It is not “carved in stone”.
- It is not “wordsmithed”.
- It is not a “light read”.
- It is not a legal document.
- It is not necessarily Council’s opinion.
- It is a document intended to stimulate discussion, opinion, understanding and feedback.

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As you read the Regulations Discussion Document and formulate your thoughts and opinions, you may need to reference the new *Pharmaceutical Act* (Bill 41). (go to [www.napra.org](http://www.napra.org) and see the link)

# ...and then what?

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- Engagement of the members and stakeholders until the end of May, 2007 (A response survey to be developed.)
- June 1<sup>st</sup>, 2007 begin drafting regulations taking into account the feedback received from the *Regulations Discussion Document*.
- June 15<sup>th</sup>, 2007 meeting with the Minister of Health to discuss the points raised by members, controversial and non controversial issues, the Minister's perspective on what was included in the *Regulations Discussion Document* and any direction regarding content and review what might be included in the draft regulations.
- July 2<sup>nd</sup>, 2007 draft regulations are circulated to the members for their review and consideration during the summer months.

# When and under what process will the regulations be approved?

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- A number of options can be considered:
  - Line-by-line approval at a meeting or mail in vote
  - Approval of the entire document in one vote
  - Set aside sections that members need to discuss further, but approve the balance in one vote.
  - or there may be other suggestions come forward...

# The College of Pharmacists of Manitoba

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## **Duty to serve the public interest**

- **5(2)** The college must carry out its activities and govern its members in a manner that serves and protects the public interest.

# Part 1: Definitions

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- In the act “dispense” does not mean to do the final check. It means to provide the drug pursuant to a prescription.
- *Health care setting* definition is enhanced from the former “patient care setting” and includes direct patient care in a pharmacy and other practice settings.

# Part 1: Definitions

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- *Preparing a drug for dispensing* would be the “final check” of the labelling and medication before the drug is dispensed and would include prepackaging.
- *Supportive care setting* allows for the practice of pharmacy without having direct patient contact.

# Part 2: Registration

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In order for a person to be licensed as a pharmacist, their name must appear on the register of pharmacists. Successfully completing the registration process will place the name of the applicant on the “register of pharmacists” forever, unless it is removed voluntarily or under other provisions of the Act. It is the Board of Examiners that oversees the registration process.

# Part 2: Registration

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- Please note the explanation, in the document, for section 3 that describes how these requirements will be met.
- Conditional registration is needed to facilitate graduates that have not met all criteria and when temporary registration is needed. (4,5 & 6)
- The other register will list “extended practice pharmacists”. (7)
- Students and interns will be required to register (8 & 9)
- “Students” become “Interns” when they enter their final year of a pharmacy education program. (9(1))

# Part 3: Licensing of Pharmacists

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- Once a person is on the register of pharmacists or the conditional register, a license can be issued.
- New sections for licensing include a need for insurance, declaration of mental and physical fitness, absence of addiction, conviction revealed and notification of licences currently held in other jurisdictions. (11(1))

# Part 3: Licensing of Pharmacists

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- Two types of licences are proposed as described under section 12 and section 13, but have changed from the current patient care and non-patient care categories.
- Section 12 practice is directly with patients and section 13 will have other health care professionals between them and the patient.

# Part 3: Licensing of Pharmacists

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- Section 13 licence will be issued with the condition the pharmacist will not perform any of the functions described under section 50 and would not provide patient specific information directly to a patient.
- Section 13 licence is really a section 12 license with conditions (13(3))
- Proposal allows for conversion of licence (14(2)) and a temporary conversion (14(3))
- Licence renewal uses the same wording for competence programs and learning portfolio as appears now in the regulations. (16)

# Part 4: Pharmacist Profile

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- This is new and the regulation making authority rests with Council, not with the members.
- Council is looking for the input from the members on this part.
- MPhA was advised to use the same wording from the regulations to the Medical Act, and did so.

# Part 5: Pharmacy Licences

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- Proposal for Community, Hospital and Clinical practice pharmacy licences
- Clinical pharmacy sites would be “drugless pharmacies”.
- Components could be added to a licence for distant care, tele-pharmacy and satellites, long term care, secondary hospital, central fill and lock & leave.
- Information would be declared on the application, and can be changed with 30 days notice (43(1)), temporarily (43(2)) or for an urgent need (29(9.1))

# Part 5: Pharmacy Licences

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- Distant care component would include mail order businesses and the International Prescription Service (IPS) practice.(33)
- Distant care sections address concerns regarding safe, legal and ethical care through inter-jurisdictional agreements and minimum number of hours.

# Part 5: Pharmacy Licences

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- Secondary Hospital component would facilitate hospitals with pharmacies, and community pharmacies, to provide services to a hospital without a pharmacy. (35(1.1))
- Central fill component is needed when a pharmacy packages medication, pursuant to or in anticipation of a prescription, for another pharmacy. (36)
- Tele-pharmacy uses technology to provide pharmacy services in under serviced areas. (37)

# Part 5: Pharmacy Licences

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- Clinical Pharmacy is new and allows pharmacy practice to occur without the distribution of drugs, and could include a drug information site or a pharmacy for educational purposes only.(38)
- As pharmacy managers will have enhanced responsibilities under the proposal, additional qualifications and/or experience would be required, as well as on site supervision.(39)

# Part 5: Pharmacy Licences

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- Changes in ownership, partnership, pharmacy manager, pharmacy name and premises will require 14 days notice.
- “surrender” the licence does not mean the pharmacy will not have a licence, it means the return of the paper document.
- A new licence document will be issued depending upon the change.

# Part 6: Standards

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- The standards of practice will be included in an attached schedule.
- Standards can be further defined through Council's ability to make practice directions. (49)

# Part 7: Duties and Delegation

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- Section 50 describes practices that can be performed only by a pharmacist licensed under section 12, or an intern under the supervision of a section 12 pharmacist (50 & 51)
- Technicians are defined and can be delegated acts included under the practice of pharmacy definition and other duties. (52)

# Part 7: Duties and Delegation

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- Students and interns can be delegated acts included under the practice of pharmacy definition and other duties. (51 & 53)
- Technicians and interns can work under supervision, while students require direct supervision.
- Other persons can be given tasks to do in a pharmacy (54(2))

# Part 7: Duties and Delegation

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- Dispensing can be delegated to another health care professional, once the filling of the prescription has been approved by the pharmacist (54(3))
- Supervision requirements and responsibilities rest with the pharmacy manager and individual pharmacists (55)

# Part 8: Prescriptions & Records

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- “Dispensing” records are broken into authorization, preparation, counselling and prescription. (58)
- They can be kept separately or all together.
- Medication label is the same with the addition of the number of refills or part-fills remaining (59(1)) and requirements under central fill (61).

# Part 8: Prescriptions & Records

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- Acquisition records are required now, but further details are described. (62(2))
- “Disposal” of drugs is interpreted to mean “distribution” outside of the prescription or the retail sale and could include the selling of drugs to doctor’s offices or returning to a wholesale. (63(2))
- Destruction records are to be kept. (63(3))
- The intention of section 62 and 63 are to verify the current inventory against acquisitions and the sale, dispensing, disposal and destruction.

# Part 8: Prescriptions & Records

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- Communication records are to be developed and maintained and includes billing statements. 64(1)
- Multiple prescription program (M3P) requirements are similar (65)
- Enhanced retention of records reflect the enhanced scope of practice permitted under the definition of practice. (67(1))

# Part 9: Dispensing of Drugs

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- Practice directions could allow pharmacists to make changes to a prescription. (68(3))
- Questionable prescriptions supports the judgment of pharmacists to refuse to dispense a drug pursuant to a prescription (68(4))
- Proper patient safety and care would be supported by having all dispensing information entered into the DPIN, exceptions can be made by Council through a practice direction. (69(2))
- Child resistant container section is similar to present regulations, but refusal needs to be documented

# Part 9: Dispensing of Drugs

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- Sale of expired drug sections and scheduled drugs is the same as it is now (71 & 72), with the addition of it is “unlikely the drug will be fully consumed before the expiry date”.
- Inducements would not be permitted when selling a drug pursuant to a prescription or for an activity included under the “practice of pharmacy”. (73)

# Part 10: Dispensing by Persons who are not members

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- The Dispensing Practitioners Committee will include a representative from the nursing and medical colleges. (74)
- The Committee may approve and revoke privileges (75(2) & 79)
- Registrar can interim suspend (79(3))
- Dispensing practitioners have the same record keeping requirements as pharmacies, but are not required to obtain a pharmacy licence (77)

# Part 11: Extended Practice Pharmacists & Specialty Practice

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- Except where specified, only Extended Practice Pharmacists (“EPPh”) can engage in “included practices” (80(1)) and be qualified as a specialist. (81(1) & 82)
- EPPh must be licensed under section 12 and practice in a collaborative setting.
- Clinical assistants under the regulations to the *Medical Act* qualify as EPPh (83)
- Specialty Practice qualifications would be more than an enhanced knowledge. (84(2))

# Part 11: Extended Practice Pharmacists & Specialty Practice

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- An interdisciplinary advisory committee will be established to review extended practice pharmacists and make recommendations to Council. (85)

# Part 12: Prescribing by Members

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- Section 12 pharmacists can prescribe schedule 2 and 3 drugs, natural health products (86(1)) and continued care refills (90)
- Section 12 pharmacists working in hospitals may have additional prescribing ability (86(1.1))
- Section 12 or section 13 pharmacists can prescribe, as approved by Council, under a public health emergency. (86(4))

## Part 12: Prescribing by Members

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- Extended practice pharmacists can prescribe within their scope of specialty practice (86(2)) or through delegation as a clinical assistant. (86(3))
- Criteria for prescribing established and a record maintained (87 & 89(1))

# Part 13: Administration of Drugs

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- Section 12 pharmacists may administer drugs orally, topically or via inhalation without further qualifications. (91(1))
- Section 12 or section 13 pharmacists, with additional training (91(2)), may administer drugs “sub Q”, IM or IV through an established line. (91(4))
- Clinical Assistant specialists (EPPh) may administer drugs in accordance with the regulations to the *Medical Act*. (91(5))
- Drug Administration records must be kept (92(1))

# Part 14: Test Interpretation

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- Section 12 pharmacists may interpret and advise patients regarding the results and implications of patient administered automated tests. (93)
- Records must be made and kept (94(1) & 94(2))

# Part 15: Ordering and Receipt of Test Reports

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- Ordering of tests under Part 15 may require that a list of tests be developed.
- Section 12 pharmacists may order any test with the approval of the patient's practitioner and receive a copy of the report. (95(1))
- Section 12 pharmacists working in hospital may have authority to order tests as permitted by the institution. (95(2))
- When results are known, the pharmacist cannot independently speak with the patient about the results, with respect to the diagnosis or treatment. Collaboration and delegation needs to occur before the pharmacist speaks with the patient. (95(4))

# Part 16: Insurance

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- All pharmacists will be required to have professional liability insurance (97(1))
- All pharmacies will be required to have commercial general liability insurance (97(2))

## Part 17: Publication

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- Publication of newsletter will include Discipline Committee decisions, Complaint Committee decisions to suspend, Registrar decisions to suspend and various other items described in section 100.

# Standards of Practice

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- Important for members to review the proposed standards.
- The standard may stand on its own or be subject to further description and clarification through practice directions, similar to the process now in effect.

# Regulations made by the Minister

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- The Minister has the sole responsibility and authority to make regulations that define:
  - Practitioner
  - Drug

## .....and what's missing?

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It is important for pharmacists to look at the regulation making ability provided under the *Pharmaceutical Act* and suggest other sections that might be considered.

# Question period and Open Discussion

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