

Ontario Pharmacists' Association

*Submission to the Health Professions Regulatory
Advisory Council*

on

*Non-Physician Prescribing and Administration of
Drugs Under the Regulated Health Professions Act*

November 12, 2008

Questionnaire for Health Professions

PROFESSION INFORMATION

1. Name of the health regulatory college, professional association or organization responding to this questionnaire. If this response is from more than one organization, please list the names of the organizations.

Ontario Pharmacists' Association

2. Address/website.

Address: 375 University Avenue, Suite 800, Toronto, ON M5G 2J5

Website: www.opatoday.com

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3. Telephone and fax numbers.

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4. Contact person (including day telephone numbers and e-mail address).

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Chief Executive Officer

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5. List other professions, organizations or individuals who could provide relevant information. Please provide contact names, addresses and contact numbers where possible.

Please refer to question 8 in OPA's June 30, 2008 submission to HPRAC on scope of practice for pharmacists.

FOR PROFESSIONAL ASSOCIATIONS

6. Names and positions of the senior directors and officers.

Tina Perlman, Chair of the Board

Ken Burns, Past Chair

Dean Miller, Vice-Chair

Phil Hauser, Executive Officer and District 9 Representative

Darryl Moore, Executive Officer and District 11 Representative

Janet McCutcheon, Executive Officer and District 15 Representative

John Taylor, District 1 Representative

Bruce Faulkner, District 2 Representative
 Lillian Gavura, District 3 Representative
 Akeel Jaffer, District 4 Representative
 Jack Pinkus, District 5 Representative
 Tim Towers, District 6 Representative
 Billy Cheung, District 7 Representative
 Gary Fillmore, District 8 Representative
 Jim Semchism, District 10 Representative
 Anna Romano, District 12 Representative
 Robin McGuire, District 13 Representative
 Carlo Berardi, District 14 Representative
 Jeannette Wang, OCDA Representative
 Bill Wilson, CSHP (OB) Representative

7. Length of time the association has existed as a representative organization for the profession.

OPA was founded in 1918 as the Ontario Retail Pharmacists' Association

8. List name(s) of any provincial, national or international association(s) for the profession with which your association is affiliated or who may have an interest in this application. Please provide contact names, addresses, contact numbers and e-mail address where possible.

Please refer to question 11 in OPA's June 30, 2008 submission to HPRAC on scope of practice for pharmacists.

CURRENT AUTHORIZED ACTS AND REGULATIONS

9. Do current authorized acts and regulations reflect best practices for the prescribing or administration of drugs in the course of practice of members of your profession?

No. Pharmacists are the first point of entry in the healthcare system for many patients as they are the most visible and accessible of all healthcare providers. Pharmacists assess, triage and refer patients to other practitioners on a regular basis, intervene on the patient's behalf to the original prescriber to change/modify prescriptions, manage complex medication regimes from multiple prescribers, and make themselves available to patients for primary care when no family physician is available. As part of current practice, pharmacists are expected to pierce a patient's finger to demonstrate the use of a lancing device for chronic care monitoring purposes, administer medication (i.e., insulin) to demonstrate the proper technique to a patient, and administer medication by inhalation when teaching a patient the proper procedure to use their inhalers or inhalation devices. However, legislation and regulations have not kept up with this evolving and expanding role, and as a result, have limited the pharmacists' ability to perform to their full potential. As the population ages and medication usage increases, pharmacists are called upon more frequently to intervene on the patient's behalf to ensure medication therapy is appropriate and patients are compliant. The aging population is also growing in

number, multiplying the frequency and complexity of patient needs. Outcome targets and safety assessments require timely and accessible interventions, which could be provided by pharmacists. As medication experts, pharmacists use their professional judgment and take on a greater responsibility for outcomes from medication therapy while patients look to them for advice and counsel. Efficiencies are being sought throughout the healthcare system and pharmacists are taking on more responsibility to align their professional services to meet the growing demands of an aging population in the most cost-effective manner.

PROPOSED CHANGES TO AUTHORIZED ACTS AND REGULATIONS

10. Please describe in detail any proposed changes to current authorized acts and regulations that would reflect best practices for prescribing of drugs by members of your profession, or administration of drugs by members of your profession.

As pharmacists are not yet authorized to prescribe medications or administer drugs, OPA proposes an addition to Section 4 of the *Pharmacy Act, 1991* that better reflects pharmacists' best practices and ensures that they are being utilized to their full potential.

The proposed changes to Section 4 of the *Pharmacy Act, 1991* are as follows, with new language in bold font:

- ***Section 4a) In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to dispense, sell or compound a drug or supervise the part of a pharmacy where drugs are kept, to administer a substance by injection or inhalation, and to perform a procedure on tissue below the dermis.***
- ***Section 4b) In the course of providing direct patient care, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration to refill chronic medications, adapt and modify prescriptions written by other practitioners; prescribe all Schedule II, III and Unscheduled drugs for the purposes of reimbursement from third party payors, and prescribe from a limited formulary of Schedule I products.***

The following commentaries to the proposed changes to the Act are provided for the purpose of clarity:

Administer a substance by injection or inhalation

Pharmacists currently educate patients on administering a substance both by injection (insulin) and inhalation (asthma inhalers, nebulizers, etc.) during patient counseling. In addition to these activities, OPA proposes that subject to training and when appropriate, pharmacists be authorized to vaccinate patients, to administer drugs such as inhaled beta-2 agonists and intramuscular epinephrine, in emergencies. We also recommend that during broader scoped emergencies, such as an influenza pandemic, pharmacists be authorized to vaccinate the public subject to public health protocol and appropriate training that must occur beforehand.

Perform a procedure on tissue below the dermis

In our submission, this controlled act is limited to the use of a lancing device to pierce the skin for the purposes of patient education and testing a patient's blood (for example, with a blood glucose monitor).

Refill chronic medications

As outlined in the Pharmacist Authorization of Prescription Extensions (PAPE) Agreement (Appendix A), endorsed by the OPA, the Ontario College of Pharmacists (OCP), the Ontario Medical Association, and the Ontario College of Physicians and Surgeons, this element refers to refilling medications that a patient has been prescribed for a long term/chronic condition. The patient will have been using these medications for a period of time and will be stable on the current dose at the time of the refill request. Additionally, recognizing that it is often necessary to provide care to a patient in the absence of a professional relationship (i.e., a patient visiting from out of town), we propose that pharmacists be authorized to refill a prescription once, if it is in his/her best professional judgment. It should be noted that OPA is not seeking authority to refill any prescriptions for narcotics, controlled drugs, or targeted substances.

Adapt and modify prescriptions

Sometimes it is necessary for a pharmacist to change the dose (e.g. a product written for 250mg, but commercially available as 300mg), dosage form (e.g. tablet to oral liquid for a patient who cannot swallow tablets), dosage regimen for treatment, product selected (e.g. ointment vs. cream), or quantity (e.g. if a product is not commercially available in the quantity prescribed) based upon all available information and the appropriateness for the individual patient. Prescriptions could also be independently modified based on monitoring (i.e., the adjustment of warfarin therapy based on INR levels).

Prescribe all Schedule II, III, and Unscheduled products for reimbursement by a third party payor.

Patients who have insurance coverage for over-the-counter medications usually require a prescription in order to have these products reimbursed by their public or private drug plan. Since pharmacists already play a role in assessing patients and helping them choose the best self-care product, this would be a natural extension of pharmacy practice.

Prescribe from a limited formulary of Schedule I products.

The pharmacist routinely assesses patients for minor ailments, as well as for their desire to stop smoking. Currently, assessments in the pharmacy include determining the patient's chief complaint, medical history, medication history and any allergies. The pharmacist then weighs the options and determines a course of action which could include one or more of the following:

- non-pharmacological self-care
- a non-prescription option that can be purchased over-the-counter
- referring the patient to prescriber with a recommendation for a Schedule I (prescription only) product
- referring the patient to a prescriber for further assessment/diagnosis

In the third scenario, the pharmacist recognizes that no adequate over-the-counter option exists to help the patient; unfortunately, the pharmacist is unable to provide optimal pharmacological intervention without a prescription. As this can be problematic for patients who either cannot make a timely appointment with their physician or do not have a physician, thus it is important for pharmacists to be able to initiate treatment for minor ailments.

Pharmacists currently assist physicians in determining the most appropriate medications for travel prophylaxis, and have, in fact, prescribed these medications pursuant to a medical directive. With proper training certification, pharmacists are ideally positioned to initiate Schedule I prescriptions for travel purposes without increasing the burden on physicians and nurse practitioners.

OPA strongly believes that during emergencies, pharmacists should also be able to prescribe from a limited formulary of drugs, such as beta-2 agonists, in the case of an acute asthmatic reaction, and antivirals for influenza treatment/prophylaxis.

See Appendix B for more information on OPA's proposed Minor Ailment Protocol (MAP) and limited formulary.

11. Why are these changes necessary? What regulatory or clinical practice purposes would be served by such changes? How would they advance patient care and patient safety?

Please refer to question 15 (a) to (m) in OPA's June 30, 2008 submission to HPRAC on scope of practice for pharmacists.

12. Are the proposed changes considered part of current routine practice of the profession, and authorized to members by medical directives, orders or delegation? Please describe. If authorized by medical directives, orders or delegation, is this approach inadequate or insufficient? Please explain.

Please refer to question 13 in OPA's June 30, 2008 submission to HPRAC on scope of practice for pharmacists.

13. Would the proposed changes result in an enhanced or changed scope of practice for the profession?

Yes. Please refer to OPA's June 30, 2008 submission to HPRAC on scope of practice for pharmacists.

14. Please describe in detail any changes or additions that would be required to the controlled acts that are now authorized to the profession and what, if any, limitations or conditions should be attached to the authorized act.

Section 4 of the *Pharmacy Act, 1991* does not encompass all the activities that pharmacists are already performing, or the additional activities, as proposed by OPA.

The proposed changes to Section 4 of the *Pharmacy Act, 1991* are as follows, with new language in bold font:

Section 4a) In the course of engaging in the practice of pharmacy, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to dispense, sell or compound a drug or supervise the part of a pharmacy where drugs are kept; to administer a substance by injection or inhalation, and to perform a procedure on tissue below the dermis.

Section 4b) In the course of providing direct patient care, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration to refill chronic medications, adapt and modify prescriptions written by other practitioners; prescribe all Schedule II, III and Unscheduled drugs for the purposes of reimbursement from third party payors; and prescribe from a limited formulary of Schedule I products.

Underlying Limitations and/or Conditions:

1. The pharmacist has the knowledge, skill and professional judgment to perform the activity safely, effectively and ethically.
2. The pharmacist has the knowledge, skill and professional judgment to determine whether the activity is in the patient's best interest.
3. The pharmacist determines that the activity is in the patient's best interest, having considered
 - a. The risks and benefits to the patient of performing the activity
 - b. The predictability of the outcome of performing the activity
 - c. Other relevant factors specific to the situation.
4. The pharmacist accepts accountability and responsibility for the activity performed.

Specific Limitations and/or Conditions:

Administer a substance by injection or inhalation

OPA recommends that pharmacists be able to administer a substance by injection or inhalation relating to the pharmacists' role in patient education, during an emergency, or in the case of IM vaccinations, when the patient does not have access to another healthcare provider.

Perform a procedure on tissue below the dermis

This controlled act is limited to the pharmacist's roles in patient education and the monitoring of a patient's ongoing medical condition.

Refill chronic medications

OPA recommends applying conditions and limitations in accordance to the PAPE agreement (Appendix A) with the addition of a one-time refill of a chronic medication for a patient with whom the pharmacist does not have an established professional relationship. To be clear, OPA is not seeking authority to refill any prescriptions for narcotics, controlled drugs, or targeted substances.

Adapt and modify prescriptions

Adapting an existing prescription to facilitate patient adherence, to coincide with a commercially available preparation, or to change a dosage form to one that is reimbursable by a patient's drug plan.

Modifying an existing prescription based on monitoring (i.e., of lab results).

Prescribe from a limited formulary of Schedule I products

As outlined in Appendix B

To accommodate the future evolution of pharmacists' scope of practice, OPA requests that limitations and/or conditions on the proposed changes to the *Pharmacy Act, 1991* be placed in Standards of Practice.

15. (a) Has the profession submitted a request to the Ministry of Health and Long-Term Care for changes or additions to the list of drugs that are included in the regulation under the profession-specific act? If yes, please attach copies of the submissions, and indicate when the request was made.

(b) Are there additions or changes, since the submission was made, that HPRAC should now consider? Please describe in detail.

(c) If a formal submission has not been made at this time, what are the exact changes you now propose to current legislation and regulations?

N/A

RISK OF HARM

16. What additional risk of harm to the patient or client might result from the proposed changes? How would your profession manage this risk?

The changes to the scope of practice for pharmacists as proposed by the Ontario Pharmacists' Association (OPA) would enable pharmacists to work to the best of their abilities. However, it is important to note that none of these changes proposed by OPA are intended to obligate an individual pharmacist to perform any activities he or she feels is outside of their training or competence. We believe that the risk of harm to patients is minimal as pharmacists currently perform most of the proposed acts. For those acts that are a progression of pharmacists' current scope of practice, such as prescribing Schedule I products as part of a Minor Ailment Protocol, adjusting prescriptions based on lab results and administering medication intramuscularly and subcutaneously, we believe that continuing education or, when necessary, certification programs will mitigate any perceived risk of harm. Furthermore, we propose a mandatory orientation for all pharmacists willing to practice within an expanded scope.

Additionally, OCP is a leader in the development of quality assurance programs for pharmacists. As a self-regulating body, the College would be responsible for setting the rigid standards of practice associated with the additional clinical services that pharmacists would provide in the proposed scope of practice. We would expect

that new standards for record keeping would be developed in addition to guidelines for collaboration with other healthcare professionals.

EDUCATION AND CONTINUING COMPETENCY

17. How does your profession require demonstration of competencies for pharmacotherapy?

Pharmacists demonstrate their competencies for pharmacotherapy beginning at the university level and continuing onwards throughout their professional careers. During university training, pharmacy students are required to undertake extensive courses in core pharmaceutical sciences (such as medicinal chemistry, pharmaceutical analysis, pharmacology and physical chemistry) and pathophysiology. The material that is learned in those courses is then applied to pharmacotherapeutics coursework where a scientific foundation is used to help resolve hypothetical, patient-specific, drug-related problems. Upon completion of the coursework portion of their degree, pharmacy students begin a mandatory four-month rotation in a clinical setting under supervision of a licensed pharmacist where they assume greater responsibility in patient care. Upon graduation, all pharmacy students must pass the national board exam administered by the Pharmacy Examining Board of Canada. This national exam has a written pharmacotherapy component in addition to an Objective Structured Clinical Examination (OSCE), which is case-based and simulates clinical practice. Prior to full licensure by OCP, the new graduate must complete a 12-week internship under the mentorship of a licensed pharmacist where they undergo rigorous assessment, become responsible for direct patient care and demonstrate core competencies.

To provide optimal patient care throughout their careers, healthcare professionals must maintain their competency through ongoing professional development activities. OCP provides a number of tools to assist pharmacists with their continuing professional development (CPD) in addition to requiring thorough Quality Assurance of members once they are licensed.

18. Please provide pharmacotherapy course content in the current educational curriculum and demonstrate how it ensures the minimum qualifications for the prescribing or administration of drugs by members of your profession.

For full pharmacotherapy course content from the Faculties of Pharmacy at both the University of Toronto and the University of Waterloo, please refer to Appendix C.

The Canadian Council for Accreditation of Pharmacy Programs (CCAPP), which ensures that pharmacy courses meet their comprehensive quality standards for accreditation, accredits the course content for both of Ontario's pharmacy schools. Dr. David Hill, Executive Director of CCAPP, recently conducted a comparison between pharmacotherapy course standards between pharmacy education and medical education. He found that the pertinent standards and guidelines for

pharmacy schools with respect to drug/therapeutic knowledge are:¹ [*Note: emphasis added by OPA*]:

- **Guideline 9.2**

The pharmaceutical sciences should be of such depth, scope, timeliness, quality, sequence, and emphasis to provide foundation for and support to the intellectual and clinical objectives of the professional program in pharmacy. **The pharmaceutical sciences should provide the basis for understanding the use of medicines in maintaining health and treating disease.** Content should include medicinal chemistry, pharmacology, toxicology, pharmaceuticals (encompassing the physical/chemical principles of dosage forms and drug delivery systems), biopharmaceuticals, pharmacokinetics and pharmaceutical biotechnology.

- **Guideline 9.4**

The pharmacy practice component should provide a basis for the **understanding and development of skills necessary for the delivery of competent care to, or on behalf of, patients in primary care and specialized settings.** Pharmacy practice, therefore represents the additional skills, techniques, values, attitudes and knowledge important to comprehensive, effective, and safe pharmaceutical care. Content should include clinical pharmacokinetics, **collaborative drug therapy management**, complementary and alternative medicines, compounding, **diagnostic and point-of-care testing, disease state management**, dispensing and prescription processing, drug abuse and dependency, drug information including drug literature evaluation, drugs in pregnancy, **emergency first care, evidence-based decision-making**, geriatrics, health promotion and **disease prevention, immunization**, information technology practice support tools, **medication administration**, nutrition, pediatrics, **patient assessment and outcomes monitoring**, patient and professional communications, **patient records and documentation of care**, pharmacy law and regulatory issues, **pharmacotherapeutics, physical assessment, prescriptive authority, and self care/non-prescription drug use.**

- **Standard No. 10**

Areas and Content of the Curricular Core – Practice Experiences:

Practice experiences should be of adequate intensity, breadth, structure and duration so as to achieve the defined educational outcomes. They should include practice experiences throughout the program and a sustained practice experience during the final year. The aggregate of practice experiences should ensure that students meet all educational outcomes and competencies prior to the completion of the academic program.

Similar to CCAPP, the Liaison Committee for Medical Education (LCME) accredits Medical schools; however, in comparison, LCME's sole standard for the content of pharmacology and therapeutics in the MD program in Canada is²:

¹ Canadian Council for Accreditation of Pharmacy Programs – Accreditation Standards and Guidelines for the Baccalaureate Degree Program in Pharmacy 2006 (Revised). Available at: http://www.ccapp-accredit.ca/common/pdfs/standards/standards_2006.pdf

² Functions and Structure of a Medical School: Standards for Accreditation of Medical Education Programs Leading to the M.D. Degree. June 2008 <http://www.lcme.org/functions2008jun.pdf>

- **LCME ED-11**

It must include those disciplines that have been traditionally titled anatomy, biochemistry, genetics, physiology, microbiology and immunology, pathology, pharmacology and therapeutics and preventive medicine.

At graduation, pharmacy students have significantly more training than medical students in pharmacotherapy courses, making them competent to prescribe and manage drug therapy. Currently, pharmacists do not have the same access to patient records as physicians have, but with improved interprofessional collaboration and the introduction of electronic health records, this barrier can be overcome.

In terms of administration of medications by injection (SC/IM/IV), this is not currently part of the curriculum at the University of Toronto's Faculty of Pharmacy. The School of Pharmacy at the University of Waterloo is in its first year of operations, and as course syllabi for upper years have not been finalized, it is unclear if this will become part of the curriculum. There is an opportunity for the administration of medication by injection to be taught to pharmacy students at the University level, especially if it becomes part of pharmacists' scope of practice.

19. Does the health professional college require continuing education and training for members to ensure competency in the prescribing or administration of drugs? Please be specific and provide documentation to the extent possible. Please describe how the college ensures its members keep pace with advancements in pharmacotherapy, pharmacology and patient safety.

In Ontario, both the prescribing and the administration of drugs are outside of pharmacists' scope of practice; therefore OCP does not currently require continuing education or training for members to ensure competency in these particular roles. However, other Canadian and international jurisdictions allow pharmacists to administer drugs and prescribe, so there are materials and training seminars available which can be adapted for Ontario's purposes, if necessary^{3,4,5}.

The Ontario College of Pharmacists' primary mandate is to ensure public safety, and it sets and maintains high quality assurance standards for members. Part of the process includes a rigorous practice review of a random selection of practicing pharmacists who are required to demonstrate their competence in knowledge, skills or judgment to ensure they are upholding the OCP Standards of Practice⁶.

³ Guidelines and Criteria for Injection and Immunization Continuing Education Programs for Alberta Pharmacists. Alberta College of Pharmacists. March 2007. Available at: http://pharmacists.ab.ca/registration_licensure/Pharmacists.aspx?id=6054

⁴ Royal Pharmaceutical Society of Great Britain. Pharmacist Prescribing. Available at: https://pharmacists.ab.ca/document_library/HPAstds.pdf

⁵ Pharmacist Prescribing Interpretation Document Draft. New Brunswick Pharmaceutical Society. July 28, 2008.

⁶ Ontario College of Pharmacists Quality Assurance Regulations. Available at: <http://www.ocpinfo.com/client/ocp/OCPHome.nsf/web/QA+Regulations?OpenDocument&PFV>

20. Please indicate what college documents are available to members on the prescribing or administration of drugs, including relevant standards of practice, rules and guidelines. Are these documents current? Please include the documents with the submission.

Currently, pharmacists administer inhaled medications and demonstrate subcutaneous injections to patients under section 29(1)(e) of the *Regulated Health Professions Act*, which provides exemption to persons "administering a substance by injection or inhalation" in the course of assisting a person with his or her routine activities of living and the act is a controlled act set out in paragraph 5 or 6, subsection 27.

Unfortunately, as the prescribing and administration of drugs are officially outside of pharmacists' current scope of practice, there are no College documents to include with this submission. Standards of Practice for other provinces that do permit pharmacists to prescribe and administer medications can be used as templates when Ontario expands the scope of practice of pharmacists^{7,8}.

21. Please describe current competencies, education and training of members of the profession to perform any of the proposed changes.

Prescribing:

Pursuant to pharmacists' university training, pharmacists are capable of performing the following activities related to prescribing:

- Prescribe in response to a diagnosis that has already been made
 - Evidenced by current medical directives.
- Change a pre-existing prescription based on an existing diagnosis or patient need.
 - Currently, pharmacists make suggestions to the original prescriber who then authorizes the change.
- Continue/renew an existing prescription and adjust doses of a previously prescribed prescription based on lab results.
 - Evidenced with anticoagulation clinics which currently fall under medical directives.

It should be noted that the act of prescribing by any authorized prescriber is not restricted to the determination of a diagnosis. In fact, many prescriptions issued to patients by other providers are subsequent to an assessment of symptoms experienced by the patient when a formal diagnosis has yet to be determined. By virtue of their education, and notwithstanding the formal definition of prescribing as set out in legislation and as it pertains to drug plan/program reimbursement, pharmacists routinely "prescribe" Schedule II, III and Unscheduled drug products pursuant to an assessment. This assessment is based on symptoms and clinical history, including allergies, medical history and medication history. In many cases, where a

⁷ Health Professions Act (Alberta) Standards for Pharmacist Practice. April 1, 2007. Available at: https://pharmacists.ab.ca/document_library/HPAstds.pdf

⁸ Clinical Governance Framework for Pharmacist Prescribers and organisations commissioning or participating in pharmacist prescribing (GB wide). Royal Pharmaceutical Society of Great Britain. August 2007. Available at: <http://www.rpsgb.org/pdfs/clincgovframeworkpharm.pdf>