Ontario Pharmacists' Association

Submission to the Health Professions Regulatory Advisory Council

on

Scope of Practice of Pharmacy

30 June 2008

The Ontario Pharmacists' Association (OPA) advocates for the profession of pharmacy in Ontario where over 11,000 pharmacists practice in community retail stores, family health teams, long-term care facilities, hospital clinical settings, education, business and government:

- We are committed to promoting the practice of the profession in a manner that maximizes our positive impact on the wellness of patients, while seeking adequate recognition and compensation for our skills, training and experience.
- We work collaboratively with governments, regulatory bodies, advocacy groups, trade and professional associations, insurers and the pharmaceutical industry to ensure pharmacists contribute at the highest possible level of their abilities to help deliver optimal healthcare for Ontarians.
- We provide continuing education on the practice of pharmacy, champion application of enabling technologies to assist our professional practice, and we are the leader in the provision of credible drug information in Canada to assist health professionals in their delivery of patient care related to medication management.
- We value and protect the trust placed in us by the public, and specifically patients and other healthcare professionals as medication management experts, and we communicate directly with patients both individually and through media to build and reinforce that trust.

With the core values of our professional association, and the daily experience of over 7,100 member pharmacists practicing in over 3,000 community retail stores, and other clinical settings, we feel strongly that we are appropriately positioned to make a submission to the Health Professions Regulatory Advisory Council (HPRAC) to assist in their review of pharmacists' Scope of Practice in Ontario.

Introduction

Pharmacists are medication management experts committed to the delivery of healthcare services in a patient-centered collaborative environment. The role of the pharmacist has evolved over the years to include accountability and responsibility not only for the procurement and dispensing of medications, but also their safe and effective use by patients, the prevention of disease and the promotion of health and wellness. When pharmacists work in a collaborative care settings, they utilize their unique knowledge and skills to manage an individual patient's medication needs and reduce the demand for and potential duplication of other healthcare services. As the first line of contact for many patients, the pharmacist is considered the most accessible primary healthcare practitioner who can respond to patient's medication needs in a timely manner and assist the patient in managing drug therapy in collaboration with caregivers, physicians, and other providers. Patients also seek the advice of their pharmacist for the treatment of minor ailments on a regular basis and ask for assistance in deciphering health and medication information obtained through the vast array of print and electronic media. Pharmacists provide information to patients about the optimal use of medications and promote the cost effectiveness of medications through evidence based decision making.

In order to fully utilize the accessibility and expertise of pharmacists, a change in their scope of practice is needed to enable them to have greater responsibility for prescribing decisions as well as the necessary tools to monitor drug therapy outcomes. These tools include access to the relevant portions of the patient's health information including test results and treatment indications in a secured and confidential manner. As the increasing costs of healthcare put more demand on the public healthcare system, changes in the future will include an empowered patient and a greater emphasis on self-care. By virtue of their accessibility to the public, pharmacists will play a greater role in self-medication management, chronic disease management and the promotion of health and well-being.

OPA strongly endorses a collaborative medication management model in which all healthcare practitioners work together to achieve optimal health outcomes for patients. In order to achieve this, the following principles must be established:

- Expanding the scope of practice for pharmacists that is optimized by collaboration and communication with other healthcare providers and engages and entrenches the established direct pharmacist-patient relationship to achieve optimal health outcomes for patients.
- Facilitating pharmacist professional activities through recognition, integration and compensation for these valuable services.
- Develop/modify legislation and regulations which would enable rather than oblige pharmacists to expand their clinical activities.
- Ensuring quality assurance standards and practices are in place to maintain the integrity of the pharmacists' role in an expanded model.
- Ensuring pharmacists' accountability for the activities that come with an expanded scope of practice.

Particularly in light of current constraints on the Ontario healthcare system, an expanded scope of practice is required to enable the pharmacist to utilize his/her unique body of knowledge and drug expertise to achieve positive healthy outcomes for patients. OPA recommends an expanded scope of practice for pharmacists in Ontario with the addition of the following professional services to include, but not limited to:

1. Refilling chronic medications under a defined protocol when the appropriate medical information is available to the pharmacist and they can accurately determine the suitability of the refill.
2. Refilling a patient's chronic medication on a one-time basis if the original prescriber is not available.
3. Ordering and receiving laboratory tests, as needed, under a defined set of protocols.
4. Monitoring and adjusting doses of chronic medications under a prescribed protocol.
5. Adapting the dose, dosage form, product selected or quantity required of a prescription for the appropriate treatment of the patient.
6. Initiating prescription therapy for minor ailments from a set formulary using an established protocol for assessment.
7. Initiating therapy for travel prophylaxis and immunizations when needed.
8. Facilitating and administering immunizations and other injectable drugs.
9. Assessing, initiating and monitoring the most appropriate therapy for smoking cessation.

Pharmacy practice in Ontario has shifted from product-centred to patient-centred practice. The current system of providing the right medication to the right patient is rightfully associated with the clinical evaluative process that pharmacists provide. Pharmacy technicians will soon be regulated in the province of Ontario and will be held responsible for the technical aspects of dispensing a prescription, allowing pharmacists to more effectively use their time, skills and knowledge for the clinical responsibilities required in an expanded scope of practice. Pharmacist's scope of practice should be reflective of the current role they play as an integral member of the healthcare team. As societal and economic goals for healthcare change, the greater utilization of the pharmacist's professional expertise in medication and chronic disease management will harness the synergies of interdisciplinary practice and dramatically enhance positive healthy outcomes for patients in a more cost-effective manner.

Applicant's Questionnaire

1. Does your current scope of practice accurately reflect your profession's current activities, functions, roles and responsibilities?

No. Pharmacists are the first point of entry in the healthcare system for many patients as they are the most visible and accessible healthcare providers. Pharmacists assess and triage 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 there is no family physician 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 their pharmacist 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.

2. Name the profession for which a change in scope of practice is being sought, and the professional Act that would require amendment.

Profession: Pharmacy
Professional Act: *Pharmacy Act 1991* and regulations under the *Pharmacy Act*
Drug and Pharmacies Regulation Act and regulations under the *Drug and Pharmacies Regulation Act*

3. Describe the change in scope of practice being sought.

OPA is proposing that the enhanced scope of practice for pharmacists includes:

1. <u>Refilling chronic medications defined under a set protocol</u>, when the appropriate medical information regarding the patient is accessible to the pharmacist and they can accurately determine the suitability of the refill. There are numerous circumstances in the course of medication therapy where additional visits to the original prescriber are unnecessary and burdensome to the patient. In a collaborative care environment, pharmacists are appropriately positioned to assume this role, thereby relieving physicians of the largely administrative role of refill authorization and freeing them up for more urgent needs.

2. <u>Refilling a patient's chronic medication on a one-time basis if the original prescriber is not available.</u> Pharmacists currently use their professional judgement and may provide a small quantity of medication to the patient to maintain the continuum of care when access to the original prescriber is not possible and no refills remain on the prescription. In the absence of appropriate medical information, the authority to refill a chronic

medication on a one-time basis would recognize an activity that is performed routinely by pharmacists using their professional judgement.

3. Ordering and receiving laboratory tests, as needed, under a defined set of protocols. Pharmacists, due to their expertise on medication therapy, can assist patients in their medication management through the ordering and monitoring of laboratory tests when needed and ideally change or modify medication therapy as necessary in collaboration with the original prescriber and other healthcare practitioners.

4. Monitoring and adjusting doses of chronic medications under a prescribed protocol, provided all the necessary clinical information is available to the pharmacist ensuring the appropriateness of the adjustment.

5. Adapting a prescription; change in the dose, dosage form, product selected or quantity required for treatment based upon all available information to the pharmacist and the appropriateness for the individual patient.

6. Initiating therapy for minor ailments from a set formulary in which any of the federal National Association of Pharmacy Regulatory Authorities (NAPRA) schedule of products (Schedules I, II and III [prescription and non-prescription]) could be listed; using an established protocol for assessment. Examples of minor ailments would include, but would not be limited to, contact dermatitis, allergic rhinitis, dyspepsia, herpes simplex type 1 and conjunctivitis.

7. Initiating therapy for travel prophylaxis and immunizations when needed. Prophylaxis for diarrhea, hepatitis and malaria are common examples of treatments that can be provided by highly educated pharmacists who have expertise in travel medicine.

8. Providing immunization services to patients, if necessary. This service would result in increased venues in which to receive these intramuscular medications and a decrease in travel and waiting times for patients at physicians' offices.

9. Assessing, initiating and monitoring the most appropriate therapeutic approach for smoking cessation. By virtue of their accessibility to the patient, pharmacists are the most ideal healthcare practitioner to recommend and prescribe smoking cessation aids and to advise, monitor and follow-up with patients during the course of their therapy.

4. Name of the College/association/group making the request, or sponsoring the proposal for change, if applicable.

The Ontario Pharmacists' Association

5. Address/website/e-mail

Address: 375 University Ave Suite 800, Toronto, Ontario M5G 2J5
Website: http://www.opatoday.com
E-mail: mail@opatoday.com

6. Telephone and fax numbers

Telephone: 416-441-0788
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7. Contact person (including day telephone numbers)

Dennis Darby, P. Eng.
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Ontario Pharmacists' Association
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8. List other professions, organizations or individuals who could provide relevant information applicable to the proposed change in scope of practice of your profession. Please provide contact names, addresses and contact numbers where possible.

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List as per Ontario College of Pharmacists Submission on June 19, 2008

9. Names and positions of the directors and officers.

Ken Burns, Chair of the Board
Donnie Edwards, Past Chair
Tina Perlman, Vice-Chair
Dean Miller, Executive Officer and OCDA Representative
Tim Towers, Executive Officer and District 6 Representative
Darryl Moore, Executive Officer and District 11 Representative
Bruce Faulkner, District 2 Representative
Lillian Gavura, District 3 Representative
Akeel Jaffer, District 4 Representative
Jack Pinkus, District 5 Representative
Billy Cheung, District 7 Representative
Mac Sparrow, District 8 Representative
Phil Hauser, District 9 Representative
Jim Semchism, District 10 Representative
Anna Romano, District 12 Representative
Robin McGuire, District 13 Representative
Carlo Berardi, District 14 Representative
Janet McCutchon, District 15 Representative
Bill Wilson, CSHP (OB) Representative

10. 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

11. List the names of any provincial, national or international associations for this profession with which your association is affiliated or who have an interest in this application. Please provide contact names, addresses and contact numbers where possible.

Canadian Pharmacists' Association (CPhA)
Ms Janet Cooper, Senior Director, Professional Affairs
1785 Alta Vista Drive
Ottawa, ON K1G 3Y6
Tel: 613-523-7877 Email: jcooper@pharmacists.ca

Canadian Association of Chain Drug Stores (CACDS)
Ms Nadine Saby, President and CEO
301-45 Sheppard Avenue East
Toronto, ON M2N 5W9
Tel: 416-226-9100 Email: nsaby@cacds.com

Canadian Society of Hospital Pharmacists (CSHP)
Ms Myrella Roy
Executive Director
30 Concourse Gate, Unit 3
Ottawa, ON K2E 7V7
Tel: 613-736-9733 Email: mroy@cshp.ca

12. What are the exact changes that you propose to the profession's scope of practice (scope of practice statement, controlled acts, title protection, harm clause, regulations, exemptions, or exceptions that may apply to the profession, standards of practice, guidelines, policies and by-laws developed by the College, other legislation that may apply to the profession and other relevant matters)? How are these proposed changes related to the profession and its current scope of practice?

Legislation/Regulation	Overview
Pharmacy Act, 1991	To include the proposed changes below
Sections 27 (2), Sections 27 (5), and Section 27(8) of the *Regulated Health Professions Act, 1991*	Permit pharmacists to perform "a procedure on tissue below the dermis" and demonstrate the appropriate technique in obtaining blood samples for chronic disease monitoring Allow pharmacists, subject to appropriate training, the controlled act of "administering a substance by injection" (i.e. provide immunization services to patients when it is in the patients' best interest and appropriate, in the pharmacist's professional judgment) Allow pharmacists the controlled act of "administering a substance by inhalation" for the purposes of education and demonstration. Permit pharmacists to prescribe all Schedule II and III drugs for the purposes of reimbursement from third party payors, and to prescribe from a pre-defined formulary of Schedule I products to treat minor ailments.

	Authorize pharmacists to adapt prescriptions, and to refill maintenance medications.
Regulation 682, Section 9(1) and Regulation 683, Sections 2(b) and 5 of the *Laboratory Specimen and Collection Centre Licensing Act, 1990*	Permit pharmacist to order relevant laboratory tests for the purpose of monitoring and managing patient's medications.
Regulation 965 of the *Public Hospitals Act, 1990*	Recognize pharmacists, and permit them various authorities when working in hospitals
Regulation 552 under the *Health Insurance Act, 1990*	Allow pharmacists to be classified as "practitioners" under the Health Insurance Act to permit payment for activities within an enhanced scope of practice model.

OPA is seeking several controlled acts, including the controlled act of "prescribing" with certain terms and conditions, to be consistent with terminology used by pharmacists in other provinces. The prescribing sought includes initiating a prescription for a Schedule I product in order to treat specific minor ailments per an agreed-upon formulary based on a limited assessment and set protocol, and for the purposes of travel prophylaxis. The term also includes adapting a prescription (changing capsules to tablets or oral liquid for patients with difficulty swallowing, or when the prescribed dosage form is not available), refilling a prescription for a patient when it is in the patient's best interest, and modify prescriptions based on lab results. In order to be able to monitor and modify prescriptions based on lab results, pharmacists should be authorized to order lab tests, especially when working with those patients without a primary care physician. Working collaboratively with other healthcare professionals, a duplication of labs can be avoided, and in the near future, when electronic health records are an integrated part of daily healthcare, there will be no concerns, as everyone will have access to the same information. It is important to note that pharmacists will continue to work in collaboration with other healthcare providers in an enhanced scope of practice model, as inter-professional communication is key to successful patient-centred healthcare.

It should be noted that OPA is not seeking authority to initiate or refill any prescriptions for narcotic or controlled drugs, or targeted substances.

13. How does current legislation (profession-specific and/or other) prevent or limit members of the profession from performing to the full extent of the proposed scope of practice?

Under current legislation, pharmacists do not have the authority to initiate, modify or refill a prescription that falls under a Schedule I, II or III drug classification (prescription and non-prescription) without authorization from the original prescriber unless working under a medical directive. As a result, patients without family physicians or access to primary care clinics are left without medications or may be treated inappropriately with no consistent care plan. Pharmacists do not have the authority to puncture the dermis to administer an injection for immunizations, to deliver a substance by injection when it is in the patient's best interest to do so, or to demonstrate the appropriate technique to draw blood samples for blood glucose monitor readings for diabetic patients or INR readings for patients on anticoagulation therapy; or to demonstrate the proper technique for inhalers and inhalation devices with the actual medication. Additionally, without the authority to order lab tests, pharmacists are currently unable to monitor medications effectively and make necessary dosage adjustments, activities for which they possess the knowledge and skills to do. Pharmacists routinely perform assessments of patients who come to their practice environment, and based on these diagnostic assessments, initiate therapy with Schedule II or III medications if deemed appropriate for care. If the case is determined to be outside of their expertise, the pharmacist refers the patient to their physician or nurse practitioner for diagnosis and treatment. In certain cases, the recommended non-prescription treatment is covered under a patient's third party drug plan if is written on

prescription. Unfortunately, a pharmacist is unable to prescribe these items for coverage, and must send the patient to an authorized prescriber in order for the product to be covered. In other circumstances, Schedule I (prescription-only) medications are the most effective treatment for recurrent minor ailments such as herpes simplex type 1 (cold sores), uncomplicated eye, ear, or skin conditions and the pharmacist cannot simply prescribe these medications to facilitate timely access to drug therapy. As a result, pharmacists are not able to utilize their medication expertise to optimize patient's health outcomes.

14. Do members of your profession practice in a collaborative or team environment where a change in scope of practice and the recognition of existing or new competencies will contribute to multidisciplinary health care delivery? Please describe any consultation process that has occurred with other professions.

Yes. Currently, pharmacists work collaboratively with other providers in community settings, hospitals, Family Health Teams (FHT), and long-term care institutions and are recognized as important members of the healthcare team. Pharmacists working in these settings provide information to other healthcare providers about medication therapy including side effects, drug-drug and drug-food interactions, and adverse reactions and assist the physician and/or nurse practitioner in the appropriate choice of medication for patients. Pharmacists also work directly with the patient in managing their medication therapy to ensure adherence. Unfortunately, under current legislation, they are not able to initiate, modify or make changes to medication therapy without a medical directive from the original prescriber and thus, pharmacists cannot utilize their medication expertise to the fullest extent. Changes in their scope of practice would enable pharmacists to enhance the clinical services that they currently provide, reduce the burden on other primary care givers, and ensure optimal medication management. OPA, along with the Ontario College of Pharmacists, the Ontario Medical Association, and the Ontario College of Physicians and Surgeons have agreed to conditions under which a pharmacist may provide authorization for, and dispense a prescription extension to a patient where an urgent need for patient drug therapy management exists and the prescribing physician is unavailable to provide refill authorization. See Appendix A (PAPE agreement).

15. Describe how the proposed changes to the scope of practice of the profession are in the public interest. Please consider and describe the influence of any of the following factors.

a) Gaps in Professional Services

There are significant gaps in the delivery of primary care services and the management of chronic diseases in Ontario. As the most accessible healthcare provider to patients, pharmacists attempt to fill the void but are limited by their current scope of practice. When a patient needs access to a chronic disease prescription medication where no refills remain, or is seeking relief from a minor ailment, pharmacists cannot authorize a continuation of the prescription or prescribe a new medication if needed. Pharmacists must currently rely on their professional judgement to provide some degree of continuity in care to many of their patients when appropriate, but some patients may be left without when the pharmacist is uncomfortable in making this decision if they do not have the authority to do so. Such circumstances are frequent yet certainly not ideal. The proposed changes in the scope of practice for pharmacists would provide all pharmacists the authority to provide these medications, thereby filling a large gap in the delivery of professional services and ensuring that patients are not harmed by an unintended discontinuation of therapy.

Many patients do not have regular primary care physicians and are obliged to seek continuation of care from many different practitioners. For some conditions, this is a lesser problem; for others, patients need ongoing monitoring by means of lab work which cannot be consistently

ordered, interpreted and acted on if the patient is being seen by multiple physicians. Optimized care, in these more complex circumstances, is clearly dependent upon a well-established relationship between the patient and their primary care provider. With the absence of such a relationship, critical lab monitoring is not occurring, posing a serious gap in professional services with a negative impact to patient safety and health outcomes.

b) Epidemiological trends in illness and disease

Chronic disease affects all Ontarians either directly or indirectly. Almost two-thirds of Ontarians over the age of 45 have a chronic disease; of those, 55% have two or more[1]. Pharmacists currently educate the public on chronic disease management, but with an increased scope of practice they will be better positioned to screen patients and monitor their responses based on lab results. Screening can facilitate earlier treatment, while consistent monitoring and counselling can facilitate adherence.

c) Changing public need for services and increased public awareness of available services

Changing public need for services is covered in Sections a, b and g. The public is becoming increasingly aware of pharmacists' capabilities with the promotion of the MedsCheck program, through clinic days at the community level, through presentations on topics ranging from Safe Meds to individual disease states, direct patient care through Telehealth Ontario, not to mention the regular care they receive from their pharmacist. Furthermore, patients are empowering themselves by staying informed about their condition(s), and pharmacists are often the first accessed providers to help them sift through the plethora of information and "translate" it in an unbiased manner to be more patient-specific, while answering any questions they may have. With an enhanced scope of practice, pharmacists will be increasingly able to deliver more of the services that the public wants and expects in a timely manner.

d) Waiting times for health care services

Waiting times for healthcare services cannot help but be diminished when pharmacists are able to practice in an enhanced scope. Patients will be able to access many health services through their pharmacist including immunizations, refill authorizations, and first-line treatment of minor ailments. Patients requiring nothing more than a prescription refill would not have to wait for an appointment with a physician or nurse practitioner; a patient with difficulty swallowing, whose physician had written for a drug in tablet form, would be able to receive the oral liquid without delay; patients who were feeling the initial symptoms of a cold sore would be able to visit any pharmacy to receive a prescription for immediate treatment. Furthermore, OPA strongly contends that the appropriate, safe and effective use of medications is critical to achieving optimal patient outcomes, and can play an important part in keeping our aging population at home as long as possible, thus freeing up long-term care beds. There are over 3000 pharmacies across Ontario, and over 11 000 pharmacists who could very easily provide continuity of care for patients in numerous situations, introducing efficiencies within the system.

e) Geographic variation in availability and diversity of healthcare providers across the province.

As mentioned above, there are over 11 000 pharmacists practicing across Ontario, from the largest of cities to the smallest towns and are the most accessible of all healthcare professionals. Community pharmacists are available both day and night, and in some cases 24 hours a day – seven days a week. In some cases, pharmacists are the only primary care provider in a given

[1] Thinking like a System: The Way Forward to Prevent Chronic Diseases in Ontario. 2006. Prepared for the Ontario Chronic Disease Prevention Alliance and the Ontario Public Health Association.

geographical area; an expanded scope of practice for pharmacists would provide residents of these communities with enhanced access to healthcare services than is currently available. Immunizations, initiation of smoking cessation, treatment of minor ailments, continuation and effective management of chronic disease medication(s) and modification of medication therapy based upon laboratory test results can all be provided by the pharmacists in these areas, operating in a collaborative arrangement with other primary care providers.

f) Changing technology

Technology continues to advance, especially in the realm of healthcare. Companies are developing more sophisticated self-monitoring devices, medication delivery systems and even using pharmacogenomic[2] principles when developing new medication. Many self-monitoring devices, such as blood glucose monitors and home INR tests require a blood sample for use. A new scope of practice, as proposed by OPA, will enable pharmacists to more effectively train patients on the appropriate use of these devices. Current and future medication delivery systems are being developed and medication is being delivered via inhalation or injection instead of orally to allow for greater bioavailability.

Ontario is working towards a comprehensive electronic health record (EHR) which, when implemented, will address many inefficiencies in the healthcare system. EHR will help avoid duplication of lab tests and screenings, and will facilitate e-prescribing while affording multidisciplinary healthcare team members greater access to pertinent patient records. Once pharmacists have the consistent ability to both read and write the relevant information, specifically to a patient's diagnosis, lab results and complete medication history contained within the EHR, they will be able to provide better medication management and contribute to improved health outcomes.

g) Demographic trends

With an aging population, the number and types of medications available for treatment have increased and such therapies are often much more sophisticated to use. As the trend to treat patients outside of institutional settings increases, and drug therapy becomes more complicated, there will be a corresponding increase in the demand for medication management expertise to ensure therapies are used appropriately and patients are adherent. Pharmaceuticals represent one of the largest and fasting growing healthcare expenditures in Canada. Data suggests that approximately 25% of hospitalized patients are admitted for drug-related causes[3]. Many of these may be preventable if pharmacists could intervene to refill, modify, monitor or change prescriptions to achieve a positive outcome in therapy. Medications must be used more rationally to achieve the desired results. Expanding their scope of practice will allow pharmacists to utilize their expertise in drug therapy to the fullest extent, to manage the multiple therapies of an aging population and to improve the overall rational use of medications in the most cost-effective way.

h) Promotion of collaborative scopes of practice

Collaborative practice among healthcare providers is in the best interest of patients. OPA fully supports an interprofessional collaborative practice model that promotes communication among patients, caregivers, and other healthcare professionals in a variety of healthcare settings. As patients self-medicate more frequently, therapies become more complicated, and as access to

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[2] Pharmacogenomics is the study of how one's genetic make-up will affect their response to a drug, and through changing technology, one day it may be possible to allow drugs to be specifically adapted to each person's genotype

[3] Samoy L *et al.* Drug-Related Hospitalizations in a Tertiary Care Internal Medicine Service of a Canadian Hospital: A Prospective Study. *Pharmacotherapy.* 2006;26(11):1578-1586.

other primary care providers is limited, collaborative practice models become critical to achieve positive health outcomes.

i) Patient Safety

Notwithstanding concerns for patient access, the Ontario College of Pharmacists is the regulating body for pharmacy in this province, and their overarching mandate is toward the protection of the public. We defer this question to the College's submission. Pharmacists are medication experts and use their professional judgment on a daily basis; they know what knowledge and expertise they have and know when to refer a patient to a more appropriate practitioner.

j) Wellness and Health Promotion

Wellness and health promotion are the cornerstones of healthcare today. Pharmacists' visibility and accessibility to patients is unsurpassed by any other healthcare provider. Pharmacists are trained to educate on wellness and disease prevention, and many hold clinics (education sessions for the public) on wellness topics including, but not limited to, cardiovascular health, osteoporosis, men's and women's health, obesity and smoking cessation. Pharmacists are currently underutilized in disease prevention, health promotion and chronic disease management. By using the full extent of their education, training, and accessibility to the patient, pharmacists can play a much greater role in health promotion and wellness and improve the quality of life of all Ontarians by empowering them to live healthier lifestyles.

k) Health human resources issues

Unfortunately, the reality in Ontario is that there is a shortage of many different healthcare professionals. Only by maximizing the scopes of practice of pharmacists and others can we begin to fill the gap in care that exists today. By re-allocating some of the existing resources and allowing pharmacists to refill chronic prescriptions, modify prescriptions, administer immunizations, and prescribe for minor ailments and travel prophylaxis, physicians and nurse practitioners will have additional time to concentrate on more complex or more urgent cases requiring their unique expertise.

l) Professional competencies not currently recognized

Pharmacists have long been held back by the current scope of practice and have been prevented from performing to their fullest capabilities. Patients do not understand why the pharmacist cannot simply refill their ongoing prescription, and physicians can become frustrated when asked to sign for small modifications such as changing the original prescription for a cream to an ointment because the cream is not commercially available. These requests from pharmacists are necessary to perform within their limited scope, and are a source of dissatisfaction to the pharmacist, physician and ultimately the patient who cannot receive their prescription in a timely manner. Pharmacists are capable of much more than dispensing medication, and although the public is slowly learning about some of the expanded services, an official change to the scope of practice will help pharmacists promote their initiatives and be recognized for their clinical knowledge in addition to their medication expertise.

m) Access to services in remote, rural or under serviced areas

Access to services in remote, rural or under serviced areas is covered in Section e.

16. How would this proposed change in scope of practice affect the public's access to health professions of choice?

The proposed changes in scope of practice should affect the public's access to health professions of choice in a positive manner. The scope of practice changes proposed by OPA would serve to augment the current services that are available to patients by pharmacists, and decrease the workload on other healthcare providers. Arguably, if the pharmacist were able to authorize refills, modify prescriptions and treat minor ailments, accessibility to other providers should increase. The ultimate choice would always rest with the patient.

17. How would the proposed change in scope of practice affect current members of the profession? Of other health professions? Of the Public?

a) Practitioner Availability

Coupled with the enabling legislation of the Regulated Health Professions Act that regulates pharmacy technicians, the changes proposed in this document by OPA for an enhanced scope of practice would allow pharmacists to become more available to provide a much broader range of the clinical services they were trained to provide to their patients. Under the current scope of practice, pharmacists are impeded by legislation and regulations that have not kept pace with the national trend toward a more efficient use of health human resources. In the new paradigm, pharmacists would continue to work collaboratively with other health professionals, including physicians and nurse practitioners, to ensure that medication therapy is rational, appropriate, and optimized. Physicians and nurse practitioners can anticipate a reduced workload as a result of pharmacists assuming greater responsibility and accountability for the ongoing management of medications for chronic diseases. With this workload relief, physicians and nurse practitioners will no doubt realize a more effective utilization of their resources. Ultimately, the public would benefit from having a more efficient healthcare experience from their practitioner of choice.

b) Education and training programs, including continuing education.

The proposed changes to pharmacists' scope of practice include many activities for which pharmacists are currently trained to perform. Like other self-regulated professionals, pharmacists must comply with a progressive program of life-long continuing health education. It must be recognized that this expanded scope of practice must enable, rather than obligate pharmacists to participate in an enhanced role. It is anticipated that there will be some pharmacists that choose not to take on the responsibility and accountability of expanded roles, and for those individuals, the status quo will prevail. However, the majority of OPA members would welcome the opportunity to finally practice to their potential for the benefit of their patients. They do understand that in order to practice at a more clinical level, some of the training they received at the faculty level may require upgrades and refreshing. It is expected that these changes would have a minimal impact on pre- and post-graduate education and training programs. For the new activity proposed related to the administration of injectable drugs, the Faculties of Pharmacy at the Universities of Toronto and Waterloo will need to incorporate formal training into the current course load to prepare new graduates for this role. For many years in the United States, and more recently in the Province of Alberta, intensive immunization training programs exist to educate practicing pharmacists on the theory, pharmacology, and technique associated with administering injections, (including protocols for monitoring for and treating adverse reactions).

It has been asserted by some that pharmacists have not received training to take on a prescriptive role, either for the ongoing monitoring and subsequent refilling of continuing care

prescriptions or for the assessment and initiation of therapy for a limited number of minor ailments. With regard to ongoing monitoring of chronic disease medications, this is certainly not a new role, as pharmacists have been doing this for years, either through specific medical directives or with their own professional judgment when the prescriber is unavailable. On the matter of assessing and initiating therapy for minor ailments, this too is not new. Pursuant to in-depth consultations with their patients, pharmacists have been assessing their symptoms and, when appropriate, prescribing Schedule II and III medications for decades. Expansion of this role to include a limited number of minor ailments that might require treatment with Schedule I medications can be easily supported through enhanced training at the faculty level, perhaps in a multidisciplinary fashion alongside medical and nursing students. For practicing pharmacists, refresher courses on the interpretation of lab results can be easily introduced to the current repertoire of continuing professional programs.

c) Enhancement of quality of services

There will be an enhancement in the services provided by pharmacists to the public. With the proposed additions to their scope of practice, pharmacists will be able to offer their patients additional services such as routine immunizations, travel immunizations, smoking cessation therapies including counselling, and monitoring of laboratory values that may not have been made available to them otherwise. With registered pharmacy technicians soon taking over responsibility for dispensing, pharmacists will have more time to provide quality healthcare to their patients.

d) Costs to patients or clients

OPA will seek fair remuneration for the provision of expanded services by pharmacists and it is our hope that government and/or third party payors will recognize the positive impact and value of these services to patient outcomes and to the healthcare system and cover those fees as they currently do for other prescribers. Despite this, there may still be direct costs incurred by patients, but these will be offset by savings such as less time away from work due to fewer visits to physician's offices for simple requests such as prescriptions refills or the assessment of minor ailments.

e) Access to services

Access to professional services by pharmacists will be greatly enhanced. Pharmacists are already the most accessible healthcare professional with extended hours of operation, often 7 days a week, and in some cases 24 hours a day; with an increased scope of practice, patients will be able to receive primary care services (minor ailments) and chronic disease management much more readily than before.

f) Service efficiency

Currently, there are significant inefficiencies in the provision of a prescription to a patient and to other aspects of medication therapy management. Changes or modifications to a prescription can be extremely labour intensive for the pharmacist and the prescriber. The proposed changes to the scope of practice will mitigate some of these inefficiencies and will allow for a more rational reallocation of resources, ultimately resulting in seamless and effective patient care.

g) Inter-professional care delivery

OPA is a strong supporter of inter-professional collaboration and inter-professional care delivery. Pharmacists currently work on inter-professional teams in hospitals, long-term care homes and in

Family Health Teams. Although community pharmacists do not typically work in inter-professional teams at this time, they do collaborate with other members of the healthcare team on a daily basis to deliver patient care[4]. The proposed changes to the scope of practice will enable pharmacists to work more closely with other healthcare providers and caregivers to improve overall patient outcomes, while allowing technicians to concentrate on the more technical aspects associated with dispensing.

h) Economic issues

The Canadian Institute for Health Information estimates total drug spending in Canada reached almost $27 billion in 2007, a $2 billion increase over 2006. In Ontario, per-capita drug spending is among the highest across Canada.[5] However, the cost of drugs is not the only factor when examining the economic impact of drug therapy. There are also concerns with the misuse of prescribed regimens, and hospitalization for preventable drug-related causes.

Misuse of medications can occur for many reasons, many of which are preventable[6]. The term misuse includes non-adherence to medication therapy which can result in suboptimal treatment, which in turn contributes to a greater number of physician's office visits. Published evidence suggests that specific pharmacy care programmes improve ongoing medication adherence, and more importantly improve patient clinical outcomes.[7]

Approximately 25% of hospitalized patients are admitted for drug-related causes, and in a particular study, over 70% of those cases were deemed preventable.[8] Utilizing pharmacists to their fullest potential will help prevent some of these unnecessary hospitalizations which negatively impact the system in terms of time (ER visits and overall wait times), resources (human resources, beds, supplies) and money. Under the proposed scope of practice, the resulting enhancement in patient care will also translate to increased productivity and decreased absenteeism in the workplace.

18. Are members of the profession in favour of this change in scope of practice? Please describe any consultation process and the response achieved.

Yes. In November 2007, OPA conducted an informal survey of our membership to determine whether the association's vision of the future of the profession aligns with members' thoughts and expectations. The survey had a response rate of over 7%, which is high for an informal survey. Questions were asked assuming that pharmacists would have access to all pertinent health information and they were trained in administering drugs by injection. In all cases, a majority of respondents stated that on a 5- point scale they either "support" or "strongly support", pharmacists' ability to partake in the role described. The questions posed in the survey, make up the nine points we submit be included in pharmacists' enhanced scope of practice. Specifically these include:

1. Refilling chronic medications under a defined protocol when the appropriate medical information is available to the pharmacist and they can accurately determine the suitability of the refill.
2. Refilling a patient's chronic medication on a one-time basis if the original prescriber is not available.
3. Ordering and receiving laboratory tests, as needed, under a defined set of protocols.

[4] 2007 Trends and Insights, prepared for Rogers Media: http://www.mckesson.ca/documents/Trends_2007.pdf
[5] Canadian Institute for Health Information. 2008. http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_15may2008_e
[6] *Senior Series Volume 2,* The Center on Rural Elderly, University of Missouri System. http://ohioline.osu.edu/ss-fact/0128.html
[7] Lee *et al*, JAMA, vol 296, no. 21, 2006.
[8] Samoy L *et al.* Drug-Related Hospitalizations in a Tertiary Care Internal Medicine Service of a Canadian Hospital: A Prospective Study. *Pharmacotherapy.* 2006;26(11):1578-1586.

4. Monitoring and adjusting doses of chronic medications under a prescribed protocol.
5. Adapting the dose, dosage form, product selected or quantity required of a prescription for the appropriate treatment of the patient.
6. Initiating prescription therapy for minor ailments from a set formulary using an established protocol for assessment.
7. Initiating therapy for travel medications and immunizations when needed.
8. Facilitating and administering immunizations and other injectable drugs.
9. Assessing, initiating and monitoring the most appropriate therapy for smoking cessation.

19. Describe any consultative process with other professions that might be impacted by these proposed changes.

The Ontario College of Pharmacists held consultation focus groups on May 9, 2008 in which OPA participated. OPA did not hold independent consultations with other professions that might be impacted.

Risk of Harm

20. How will the risk of harm to the patient or client be affected by the proposed change in scope of practice?

The Ontario College of Pharmacists is a leader in the development of its quality assurance program for pharmacists. As a self-regulating body, the College would be responsible for setting the rigid practice standards associated with the additional clinical services that pharmacists would provide in the proposed scope of practice.

21. What other regulated and unregulated professions are currently providing care with the competencies proposed as an expansion to your scope of practice? By what means are they performing it? (Under delegation, supervision or own their own initiative)

Physicians, nurse practitioners and dentists can initiate all of the proposed activities that pharmacists seek. Other healthcare practitioners including chiropodists, podiatrists, practitioners of traditional Chinese medicine, medical laboratory technologists, medical radiation technologists, midwives, naturopaths, nurses, respiratory therapists can all perform, with limits, several of the controlled acts pharmacists are seeking in the expansion of their scope of practice.[9]

22. Specify the circumstances, if any, under which a member of the profession should be required to refer a patient/client to another health professional, both currently and in the context of the proposed change in scope of practice.

Pharmacists use their professional judgment while performing patient assessments and know when an issue is outside of their expertise, at which point they will refer to the more appropriate practitioner. Currently, there are only loose referral protocols between pharmacists and family physicians and no protocols in place to allow for pharmacists' referrals to other medical specialties. Moving forward with an enhanced scope of practice pharmacists will continue to use their professional judgment, and limit themselves to areas in which they are competent, have enough information to make informed decisions, and make appropriate referrals according to established protocols as necessary.

[9] 2008. Regulated Health Professions Controlled Act Summary. URL: http://www.hprac.org/en/reports/resources/hprac-collaboration.controlledactssummary.july14.v1.xls

23. If this proposal is in relation to a current supervisory relationship with another regulated health profession, please explain why this relationship is no longer in the public interest. Please describe the profession's need for independence/autonomy in practice.

N/A

24. Does the new proposed change in scope of practice require the creation of a new controlled act or an extension of or change to an existing controlled act? Does it require delegation or authority to perform an existing controlled act or subset of an existing controlled act?

Yes. It requires a change be made to Section 4 of the Pharmacy Act to permit pharmacists to administer a substance by injection or inhalation, perform a procedure on tissue below the dermis, and to prescribe drugs subject to certain conditions.

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25. If the proposed change in scope of practice involves an additional controlled act being authorized to the profession, specify the circumstances (if any) under which a member of the profession should be permitted to delegate that act. In addition, please describe any consultation process that has occurred with other regulatory bodies that have authority to perform and delegate this controlled act.

The Ontario College of Pharmacists has a policy on the use of medical directives and delegation, and OPA defers to the College for consultation on this question.[10]

26. Are the entries to practice (didactic and clinical) education and training requirements of the profession sufficient to support the proposed change in scope of practice? What methods are used to determine this sufficiency? What additional qualifications might be necessary?

Yes. In their accredited University programs, Ontario's pharmacists are taught the skills to appropriately practice within the proposed scope of practice. Additional qualifications would only pertain to the administration of injections for the purpose of immunizing a patient. Pharmacist competency is regularly assessed by the Ontario College of Pharmacists.

27. Do members of the profession currently have the competencies to perform the proposed change in scope of practice? Does this extend to some or all of the members of the profession?

Yes. All members registered in Part A of the College Register, whose current practice consists of 600 hours of direct patient clinical activities every three years, will have the competencies to perform the proposed changes in scope of practice. Those pharmacists who choose to perform immunizations will require additional training to ensure this competency is met.

28. What effect will the proposed change in scope of practice have on members of your profession who are already in practice? How will they be made current with the changes and how will their competence be assessed? What quality improvement/quality measurement programs should or will be put into place? What educational bridging programs will be necessary for current members to practice with the proposed scope?

As previously mentioned, the Ontario College of Pharmacists Quality Assurance program is a leader in ensuring pharmacists meet and stay current on their clinical practice skills. With regard to training programs to prepare pharmacists for the administration of immunizations and drug

[10] Ontario College of Pharmacists. Policy on Directives and Delegation Approved. Pharmacy Connection. May/June 2007.

by injection, there are several accredited programs in the US and in other Canadian jurisdictions that can easily be adapted to meet the needs of the Ontario market.

29. How should the College ensure that members maintain competence in this area? How should the College evaluate the membership's competence in this area? What additional demands might be put on the profession?

N/A

30. Describe any obligations or agreements on trade and mobility that may be affected by the proposed change in scope of practice for the profession. What are your plans to address any trade/mobility issues?

Expanding the scope of practice for pharmacists in Ontario will serve to bring this province's pharmacists in line with current or proposed pharmacy practice in several other Canadian jurisdictions. There are unlikely to be any trade/mobility issues to address, as all Canadian pharmacists must sit for the same National Board Exam[11], therefore they are all capable to practice within the proposed scope.

31. How do you propose to educate or advise the public of this change in scope of practice?

The public would be advised by OPA via a public relations strategy including, but not limited to:

- An announcement advising the media of the changes,
- Updates to the public section of OPA website,
- Materials provided to our members to support discussion with their patients, and
- Liaison with the Ontario College of Pharmacists, the Canadian Pharmacists Association, the Canadian Association of Chain Drug Stores, the Canadian Society of Hospital Pharmacists and other pharmacy organizations.

32. What is the experience in other Canadian jurisdictions? Please provide copies of relevant statutes and regulations.

In 2006, the Alberta government announced new regulations, under the Pharmacists Profession Regulation of the Health Professions Act[12], that expand the scope of practice for pharmacists to include the authority to independently prescribe Schedule I drugs. Alberta was the first Canadian province to introduce this type of legislation.

Since 2003, New Brunswick pharmacists have been prescribing medications under a continuing care protocol for patients in an emergency basis, who have been unable to contact a physician and whose medication has expired. [13] In May 2008, New Brunswick introduced a private member's bill, which if passed will enable patients who have an established, pre-existing diagnosis to obtain a prescription from their pharmacist. The expanded scope of practice for New Brunswick pharmacists is expected to come into effect in October 2008. Other Canadian provinces including British Columbia, Prince Edward Island, and Nova Scotia are moving in the same direction[14]. Pharmacists in Quebec can prescribe levonorgestrel for emergency contraception which remains a Schedule I drug in that province.

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[11] Pharmacy Examining Board of Canada. http://www.pebc.ca

[12] Alberta Government Website, Alberta Regulation 129/2006 http://www.qp.gov.ab.ca/documents/Regs/2006_129.cfm?frm_isbn=0779747151

[13] Statement on Pharmacists' Prescribing. New Brunswick Pharmacists' Association 2007. http://www.nbpa.ca

[14] New Brunswick Pharmacists' Association 2008. http://www.nbpa.ca

33. What is the experience in other international jurisdictions?

The United Kingdom has passed legislation to expand the role of the pharmacist to allow limited prescribing rights.There are two models for pharmacist prescribing in the UK:

A) Pharmacist supplementary (dependent) prescribing (SP), which involves a voluntary partnership between an independent prescriber (a physician), the supplementary prescriber (pharmacist) and the patient, who all agree to a patient-specific clinical management plan; Pharmacists in the UK have made progress in implementing SP, which is perceived by pharmacists as beneficial for both patients and themselves.[15]
B) Pharmacist independent prescribing (IP) introduced in 2006, where the pharmacist is responsible for the assessment and management of the prescribed medication.

Minor Ailments

The UK is also advanced on matters relating to the treatment of minor ailments. Although the minor ailments vary by jurisdiction, and coverage under drug benefits is not consistent, these schemes persuade patients to first attend pharmacies to be treated for specific minor conditions, with referral to a physician if needed.[16]

Costs and Benefits

34. What are the potential costs and benefits to the public and the profession in allowing this change in scope of practice? Please consider and describe the impact of any of the following economic factors.

1) **Direct patient benefit/costs**

Pharmacists will seek fair remuneration for the provision of expanded services and there may be direct costs to patients unless the government, and/or third party carriers cover those fees, as they currently do for other prescribers. Despite this, costs incurred by patients will be offset by savings such as less time away from work due to fewer visits to physician's offices for simple requests such as prescriptions refills or the assessment of minor ailments.

2) **Benefits and costs to the broader health care service delivery system**

With an expanded scope of practice, pharmacists will be able to take on a greater role in patient care, which will help to re-allocate some of the currently stretched human resources facing Ontario's health providers today. Costs to the broader healthcare service delivery system will decrease as inefficiencies in the current system are resolved, and preventable drug-related hospitalizations are avoided.

3) **Benefits and costs associated with wait times**

Please refer to Question 15d.

[15] Johnson George, *et al*. Supplementary Prescribing: Early Experiences of Pharmacists in Great Britain *The Annals of Pharmacotherapy*: Vol. 40, No. 10, pp. 1843-1850.
[16] Department of Health. *Pharmacy in England: Building on Strengths* – Delivering the Future, April 2008. http://www.official-documents.gov.uk/document/cm73/7341/7341.pdf

4) Workload training and development costs

None perceived. Continuing education courses are regularly offered to pharmacists, and the development of a structured certification program that enables pharmacists to participate in the administration of immunizations is already in place in Alberta. Adaptation of that and similar programs to meet the needs of the Ontario health system would not be onerous.

5) Costs associated with educational and regulatory sector involvement

N/A

34. Is there any other relevant information that HPRAC should consider when reviewing your proposal for a change in scope of practice?

OPA is pleased to have been able to contribute to the scope of practice review by HPRAC. We firmly believe that pharmacists are capable of performing at a level higher than what their currently scope recognizes. OPA would like to emphasize that the theme of this submission is not to replace the unique expertise of other healthcare providers; rather, it is to expand on certain aspects of medication management, with the goal of capturing the synergies between pharmacists and other healthcare providers in a collaborative working environment. Pharmacists would not be operating in a vacuum, as all therapeutic changes made within the parameters of their scope of practice would be readily communicated to the patient's primary care physician, eventually to be part of the electronic health record. Pharmacists are not currently recognized for the full range of their knowledge and expertise, and the addition of several controlled acts including administering a substance by injection or inhalation, performing a procedure on tissue below the dermis and prescribing, would better utilize the pharmacist as an integral part of an efficient healthcare team. Ultimately, any legislative changes should be made to enable pharmacists, and give them a choice to act within the expanded scope, depending on the situation.

Appendix A – Draft PAPE Agreement

DRAFT

PHARMACIST AUTHORIZATION OF PRESCRIPTION EXTENSIONS (PAPE) AGREEMENT

January 2008

The following agreement provides conditions under which a pharmacist may provide authorization of a prescription extension to a patient where an urgent need for patient drug therapy management exists and the prescribing physician is unavailable to provide refill authorization.

This Agreement assumes the following principles:

1. Pharmacist authorization of prescription extensions cannot and does not take the place of ongoing medical care.
2. Each request for a pharmacist authorization of prescription extensions must be judged on the individual nature of the patient's need/history and professional judgment exercised accordingly.
3. The pharmacist assumes the responsibility for the extended refill.

A pharmacist may authorize a prescription extension where the following conditions are met:

1. The pharmacist must be reasonably satisfied that the prescriber, if available, would in all likelihood, provide the authorization.
2. The medication to be extended has been prescribed to the patient for a chronic or long term condition (generally for at least a year or longer).
3. The patient shall have an established, stable history (no recent changes to dosages or drug therapy) with that medication.
4. The prescription to be extended shall be with that particular pharmacy and the patient shall be within the care of the pharmacy.
5. Narcotic or controlled substances shall NOT be authorized for extension within the confines of this agreement.
6. The pharmacist may authorize a prescription extension once only. Further requests for extensions must be handled by the patient's physician or original prescriber or an on-call physician.
7. The amount of medication provided must not exceed the previous amount filled, or three months, whichever is lesser.
8. The pharmacist shall assign a new prescription number to the prescription extended under this agreement (PAPE) and shall record on the prescription the Rx number of the original prescription. The original prescriber shall be listed as the prescriber on the extended prescription. The pharmacist shall be recorded as authorizing the extension.
9. The PAPE shall be documented on the patient record in such a manner as to ensure the prescription will not be "extended" a second time.
10. The PAPE shall be reported in written format within one week to the original prescriber and to the patient's primary care physician (if different from the prescriber). A copy is to be kept in the pharmacy.
11. A prescriber retains the right to indicate "no extension" on a prescription; however this does not preclude the pharmacist from exercising professional judgment in an emergency situation.

Support/endorsement for this policy is being actively sought from the Council of the Ontario College of Pharmacists, as well as from:

- The Ontario Pharmacists' Association,
- The Ontario Medical Association, and
- The College of Physicians and Surgeons of Ontario