



ONTARIO
PHARMACISTS
ASSOCIATION

Office of the Chief Executive Officer

May 22, 2020

Ms. Nancy Lum-Wilson
Registrar, Ontario College of Pharmacists
483 Huron Street
Toronto, ON
M5R 2R4

Via Email to consultations@ocpinfo.com

Dear Ms. Lum-Wilson:

Re: Proposed Regulatory Amendments to General Regulation 202/94 of the *Pharmacy Act, 1991*, Part VII.3 (Controlled Acts)

The Ontario Pharmacists Association ('OPA', the 'Association') welcomes the opportunity to participate in the public consultation regarding proposed amendments to General Regulation 202/94 of the *Pharmacy Act, 1991*, Part VII.3 (Controlled Acts) that, if passed, would expand pharmacists' scope of practice, and provide them with the authority to assess and, if necessary, prescribe for minor ailments.

The Ontario Pharmacists Association is committed to evolving the pharmacy profession and advocating for excellence in practice and patient care. With more than 10,000 members, OPA is Canada's largest advocacy organization, and professional development provider for pharmacy professionals across Ontario. By leveraging the unique expertise of pharmacy professionals, enabling them to practise to their fullest potential, and making them more accessible to patients, OPA is working to improve the efficiency and effectiveness of the healthcare system. The pharmacy sector plays a strong role in Ontario with an economic impact of more than \$6.3 billion across 4,500 pharmacies, employing 60,000 Ontarians.

The Ontario Pharmacists Association fully supports the amendments proposed by the Ontario College of Pharmacists ('OCP', the 'College') to the *Pharmacy Act, 1991* as a solid first step forward for Ontarians, pharmacy and other health professions. These changes will no doubt help to create capacity and introduce efficiencies in an overburdened health system while providing more timely access to care from highly trained and motivated pharmacy professionals. While a longer list of minor ailments had originally been contemplated by OCP's Minor Ailment Advisory Group ('MAAG'), OPA is aware that a request was made by the Ministry of Health to refine the list initially to 12 minor ailments. Despite our disappointment in the reduction to the list of conditions, OPA will continue with its ongoing advocacy with government to pursue further expansion to the extent that Ontario pharmacists are able to practise to a similar scope as their colleagues in other provincial jurisdictions.

HISTORICAL BACKGROUND

Dating back to 2007 and the Ministerial Referrals from the Honourable George Smitherman and, subsequently in 2008, by the Honourable David Caplan to the Health Professions Regulatory Advisory

Office of the Chief Executive Officer

Council ('HPRAC'), OPA has remained steadfast in its advocacy and aspirations, on behalf of Ontario's pharmacists, for expansion of scope of practice as it pertains to the assessment and, if necessary, treatment of minor ailments.

Based on strong submissions received from OPA and OCP, HPRAC sent a message to the Ontario government that both organizations should co-lead work toward the development of a program that would enable pharmacists to treat patients suffering from a list of minor ailments with medications from an agreed-upon formulary including Schedule I, II and III drugs. HPRAC continued with its recommendation that such a program should also include protocols for referral to and communication with other health professionals, processes for obtaining patient consent and record-keeping, options for reimbursement for professional services, educational support and establishment of competency requirements and quality assurance measures.¹

Many years have passed since the publishing of HPRAC's *Critical Links* report, and over that time, the needs and expectations of Ontarians have continued to grow and evolve with respect to healthcare delivery. At the same time, the resolve of OPA and its members has remained – that it is long overdue for Ontario's pharmacists to join their colleagues in almost every other Canadian province in contributing their untapped skills, training and expertise toward a more efficient health system.

REGULATORY IMPERATIVE

On May 30, 2019, Deputy Premier and Minister of Health, the Honourable Christine Elliott, issued a letter to the president of OCP indicating the commitment of her government to enabling health professions to use their education and training more effectively.² She envisioned that Ontario can achieve its patient-centric vision by ensuring that patients have streamlined care pathways that make connections easier in the system and that there is access to minor and routine care in the community. The Deputy Premier acknowledged the integral role that pharmacists play in helping the government to achieve these commitments.

These words echo those articulated by OPA in its various submissions to HPRAC and to several ministers and ministries of health in Ontario over the past decade, and the Association is confident that now is the time for fundamental system change. With finite financial resources, our government needs to make choices in a manner that optimizes the patient experience and finds system efficiencies while enabling all of Ontario's healthcare providers to practise to their fullest ability in accordance with their training and scope of practice. Pharmacists are known to be the most accessible of all healthcare providers but are also possibly among the most under-utilized. Now more than ever, as our province and health system wrestles with the impacts of the deadly novel coronavirus, COVID-19, it is critical that the system becomes increasingly coordinated and integrated so that patients can get the right care from the right providers and in a timely and easily accessible manner.

¹ Health Professions Regulatory Advisory Council (HPRAC). The prescribing and use of drugs in the profession of pharmacy HPRAC Critical Links Document. 2009. Accessed on May 16, 2020 at:

https://www.hprac.org/en/reports/resources/HPRACCriticalLinksEnglishJan_09.pdf

² Elliott, C. (2019, May 30). Scope of Practice Letter – Ontario College of Pharmacists [Letter to the OCP President]. Retrieved from <https://www.ocpinfo.com/wp-content/uploads/2019/08/ministers-letter-expanded-scope-of-practice.pdf>

Office of the Chief Executive Officer

Equally important is the concept of system navigation, whereby patients gain a greater understanding of how our system works and recognize that they can find the care they need when and where they need it. Ontario's pharmacists, as frontline primary healthcare providers working alongside physicians, nurse practitioners and registered nurses, are critical to the success of patient-focused and accessible care, and the Ontario Pharmacists Association, as their representative professional association, is well-prepared to support the 20,000+ pharmacy professionals in community, long-term care, hospital and primary care practice settings to take up an expanded scope of practice that includes the assessment, and if necessary, the treatment of minor ailments.

REGULATORY AMENDMENTS

1. List of Minor Ailments

As mentioned earlier in this submission, OPA remains fully committed in its ongoing advocacy to pursue an expanded scope of practice that is consistent with most other provincial jurisdictions. Ontarians deserve the same timely access to care with respect to minor ailments as residents of other provinces; reducing the list of conditions identified by the MAAG demonstrates an overly cautious approach, and as a result, Ontarians will be limited in their options as to where they can go to seek timely treatment. Ontario is not breaking any new ground with this expansion, and since other provinces have not experienced challenges with pharmacists' assessments and treatments of a broader list of minor ailments, OPA disagrees with the proposed tentative approach that will mitigate system efficiencies and cost-savings and limit patient options and choice of provider.

Notwithstanding this disappointment, OPA supports the current regulatory proposal as being the first step toward a broader expansion that will allow pharmacists to offer an increased breadth of service options for patients, further improving timeliness of care closer to home.

2. Medication Categories

OPA appreciates the efforts and decisions made by the College and its experts on the MAAG on this matter. No doubt, there is increased flexibility of working with medication categories rather than a defined and highly restrictive list of drugs for the treatment of minor ailments. Nonetheless, pharmacists may still find themselves limited in terms of the options available to them for their patients by having to select from the defined American Hospital Formulary Service (AHFS) drug categories selected for each minor ailment.

Accordingly, the Association would prefer a more open model of prescribing, following in the same manner as is available to physicians. OPA believes that the AHFS categories are useful in the selection of an appropriate therapeutic product. However, the focus must be on selecting the right drug for each unique patient rather than on fitting the patient's case presentation into specific therapeutic categories. As such, AHFS categories need to be complemented with the use of well-constructed treatment algorithms, clinical practice guidelines and other relevant, evidence-based resources so that the pharmacist is able to tailor the treatment to meet the specific needs of the patient. When considering the public perspective and expectations of a minor ailment program, patients will expect that the assessment and treatment they receive from a pharmacist and from a physician or nurse practitioner ought to be through an identical, patient-centered approach.

Office of the Chief Executive Officer

3. Conditions for Prescribing

OPA has always been and remains fully supportive of conditions for prescribing that includes:

- Appropriate and reasonable documentation;
- Interprofessional sharing of information;
- Referrals for more complex case presentations;
- Obtaining patient consent;
- Assurance of patient privacy and confidentiality; and
- Protection of patient choice in the pharmacy where their minor ailment prescription can be dispensed, irrespective of where the assessment was performed.

In addition, OPA will be pursuing discussions with the Ministry of Health to ensure that among the conditions for prescribing, pharmacy professionals will be seeking a fair and reasonable remuneration model. While not relevant for the purposes of this consultation, OPA is keenly aware that no prescriber in Ontario is actually paid to prescribe – funding is designed to remunerate for the clinical assessment involved, regardless of whether a prescription is issued or not. As we know that uptake of a minor ailment program by pharmacists will hinge on the establishment of a fair and reasonable funding model by government, OPA will be seeking assurances that such a model will be implemented that addresses all of the work and responsibility that is involved in the assessment of a minor ailment.

4. Education and Training

OPA agrees with the College's messaging that pharmacists are capable and do advise patients on non-prescription medications to treat minor ailments if appropriate, based on their assessment of the patient. However, the Association also contends that pharmacists are keenly aware of the limitations offered by non-prescription and/or non-pharmacologic approaches to minor ailments. With their intimate knowledge of Schedule I, II and III medications, we believe that pharmacists are appropriately prepared to take on this expanded role. In terms of preparing pharmacists for implementation, the Association would support a mandatory orientation module that addresses the core competencies (to be delineated by OCP) along with a series of voluntary clinical modules for those pharmacists wishing to refresh their current knowledge base.

OPA, as a leader in continuing professional development ('CPD'), is very close to completing its development of a new CPD program that will offer unparalleled support, guidance, tools and confidence to those in Ontario's pharmacist community who seek additional clinical support. The focus of our CPD program and our professional practice tools will be to ensure that Ontario pharmacists are able to meet and surpass public expectations.

A VIEW TOWARD PROTECTION OF THE PUBLIC AND SUPPORT FOR QUALITY PHARMACY CARE

In any analysis of prescribing, it is important not to lose sight of the patient as the primary focus. It is therefore integral to ensure that patient safety, care coordination and integration remain at the forefront and are not compromised. As we consider the merits associated with prescriptive authority for pharmacists, one need only look at the individual processes that are involved in prescribing and acknowledge the pharmacist's suitability and appropriateness to perform these processes as compared with the benchmark set by traditional prescribers – physicians, nurse practitioners and dentists.

Office of the Chief Executive Officer

The World Health Organization adopted a six-step approach³ to prescribing, and many still hold this to be the only validated tool for pharmacotherapy education⁴. The WHO suggests that prescribers should:

- (1) evaluate and clearly define the **patient's problem**;
- (2) specify the **therapeutic objective**;
- (3) **select the appropriate drug therapy** and **verify its suitability** by considering contraindications, interactions and concomitant medications;
- (4) **initiate therapy** with appropriate details and consider non-pharmacologic therapies;
- (5) **give information**, instructions, and warnings; and
- (6) **evaluate and monitor therapy** regularly (e.g., monitor results, consider discontinuation of therapy).

Two additional steps were added by Pollock, Bazaldua and Dobbie in 2007⁵, calling for:

- (7) the **consideration of drug cost** when prescribing; and
- (8) the use of computers and other **tools to reduce prescribing errors**.

These eight steps have been summarized in Table 1 (see Appendix), with some adaptation to juxtapose the roles, scopes of practice and training of pharmacists with those of more traditional prescribers. The table offers a good overview of what patients should expect from their prescriber.

The processes involved in prescribing requires the provider to exercise multiple skills. Some of these are:

- **patient-based skills** – these are dependent on the patient's characteristics and how the patient presents him/herself;
- **product-based skills** – these are a function of understanding the pharmacology and pharmacokinetics of the drug product under consideration; and
- **patient/product hybrid skills** – these require an understanding of how the drug may or may not function as intended in a particular patient, based on various factors including, but not limited to, other concurrent therapies and/or the impact of therapy on the patient's lifestyle.

As previously stated, the pharmacy curriculum, as well as practical experience, prepares pharmacists with a substantial level of training in each of these skills, and appropriately so. Since pharmacists are the gatekeepers of prescription medications, it is their role and obligation to effectively mirror the prescriptive process in their analysis of a prescription to ensure that it is, in fact, the right drug for the right patient and right reason, at the right dose, route, frequency and time.

³ de Vries TPGM, Henning RH, Hogerzeil HV, Fresle DA. Guide to Good Prescribing – A Practical Manual. Geneva: World Health Organisation; 1994. Accessed on May 16, 2020 at:

https://apps.who.int/iris/bitstream/handle/10665/59001/WHO_DAP_94.11.pdf

⁴ Keijsers CJ, Segers WS, de Wildt DJ, Brouwers JR, Keijsers L, Jansen PA. Implementation of the WHO-6-step method in the medical curriculum to improve pharmacology knowledge and pharmacotherapy skills. Br J Clin Pharmacol. 2015 Jun; 79: 896– 906. Accessed on May 16, 2020 at: <https://bit.ly/2Xd8Tdd>

⁵ Pollock M, Bazaldua O, Dobbie AE. Appropriate prescribing of medications: an eight-step approach. Am Fam Physician. 2007;75(2):231-6. Accessed on May 16, 2020 at: <https://www.aafp.org/afp/2007/0115/p231.pdf>

PUBLIC EXPECTATIONS OF SAFE AND ACCESSIBLE SERVICES UNDER AN EXPANDED SCOPE FOR PHARMACISTS

As articulated above and with a view toward primary care, the public has come to view the physician as the original and traditional prescriber. Other health professionals outside of medicine have only recently begun to be considered as frontline primary care providers, and while their integration has been slow, the public has recognized that the demand for care has grown and that the timeliness to obtain that care has been negatively impacted. In 2011, in the wake of the H1N1 health crisis, then Minister of Health, the Honourable Deb Matthews, recognized that community pharmacists were an untapped resource with respect to influenza immunization. Subsequently, in 2012, legislative and regulatory changes were made to expand pharmacists' scope of practice for purposes of administering influenza vaccines, acknowledging the important but untapped role of pharmacists in our health system. Understandably, public uptake was initially slow but certainly demonstrated optimism. Eight years later, community pharmacists have clearly proven their aptitude and willingness to take on a role traditionally held by medicine, and public acceptance of this new role has placed pharmacists virtually on par with physicians in the administration of influenza vaccinations. This is a clear demonstration of public trust in their pharmacists to take on more responsibilities in healthcare delivery.

COVID-19 has led many Ontarians to contemplate how healthcare delivery will evolve. Many health services, including, but not limited to, low-acuity services such as minor ailment assessments, have been enabled for virtual delivery so that social distancing and, if necessary, home quarantining can continue. The Association would therefore support the enabling of pharmacists to assess and treat certain minor ailments remotely so that patients can receive timely access to care when a face-to-face visit is not possible or practical. Once again, with a patient-centric view, public expectations will be that provision of a minor ailment assessment should follow the same approach regardless of who they select as their prescriber of choice.

Still, there is some work to be done to garner public support and trust with minor ailments. As we begin to turn a page in our collective battle against COVID-19, it has become clear there is still some public misunderstanding of the role of pharmacists. Lingering yet outdated stereotypes of the pharmacist as a "dispenser of medications" still persist in the minds of a few. In addition, opponents to an expanded scope of practice for the profession may be unfamiliar with the pharmacist's obligation and professional duty to put the needs of the patient at the forefront, ahead of their personal or business goals. In particular, opponents tend to assert that there are conflicting roles of prescribing and dispensing yet fail to acknowledge examples such as orthodontics, psychiatry or cosmetic surgery where the roles of initial assessor and ultimate provider of the service are performed by the same regulated health professional. Rhetorical statements suggesting inherent conflicts of interests for pharmacists to both prescribe and dispense are unfounded, are based in ignorance of a pharmacist's professional code of ethics and undeservedly interfere with or obscure progress on scope expansion.

While these challenges are an unfortunate construct of the pharmacy funding model, work needs to be done to re-acquaint the public, other health providers and policymakers on the training, expertise and skill of the pharmacist as well as on his/her critical role in a multi-disciplinary team that is focused on the patient. To address these challenges, the Ontario Pharmacists Association is planning to embark on a public awareness campaign to re-educate Ontarians on the role and value of pharmacists in their communities and to the system as a whole.

PHARMACISTS' EXPECTATIONS OF SAFE AND ACCESSIBLE SERVICES UNDER AN EXPANDED SCOPE

The Ontario Pharmacists Association is pleased with preliminary responses posted to the OCP consultation webpage, which resoundingly support the direction being taken by the College and the Ontario government with scope expansion. This is not surprising given that most pharmacists aspire for professional growth and development. They clearly recognize that as patient needs and demands change and evolve, so too must they adapt as does our health system overall. That said, OPA is cognizant of the various challenges and frustrations expressed by some pharmacists in recent months regarding persistent workplace and human resource challenges, and work is afoot to resolve them.

We are pleased that a principle-based process is underway, spearheaded by OCP and with input from OPA and the Neighbourhood Pharmacy Association of Canada, to identify industry-driven solutions for the most safe and effective implementation of clinical services in pharmacies. While OCP's workplace initiative proceeds, OPA will be conferring with its membership at large, its Owners Advisory Council and the Board of Directors to consider and propose supports and tools that will help to streamline the operationalizing of new scope activities that would include, but would not be restricted to, the administration of minor ailment services. As with dispensing services, there are professional/clinical aspects to the work required as well as more technical/business requirements. There is a balance that needs to be struck in the provision of any professional service, including a minor ailment assessment:

- The **professional/clinical work** must be performed with great care and accuracy, in accordance with competency standards and quality in mind for optimal patient outcomes, and pharmacists need to be afforded that time to do this; and
- The **technical/business work** is an imperative such that appropriate documentation needs to be in place to support the submission of a claim for service remuneration. In addition, the documentation needs to be robust enough to support the quality assurance and potential audit of the service provided.

Lessons from past initiatives, such as the revised MedsCheck program, have helped the profession understand that just as the patient's experience needs to be carefully considered, so too does that of the provider. It is for these reasons that pharmacists, technicians, and owners need to work together to find workable and practical solutions and innovative technologies that enhance and facilitate the service with the patient, the pharmacy professional and the business in mind.

OPA is confident that a new scope of practice – one that recognizes the value of pharmacist professionals, repositions them as critical players in the patient's circle of care, and entrenches pharmacies as healthcare centres within their communities – will invigorate the profession and will yield positive results in the timeliness of care, system efficiencies and overall cost savings.

SCOPE EXPANSION THAT SPANS ALL PRACTICE SETTINGS

It may be readily assumed that the proposed regulatory changes are meant to enable a community pharmacist's assessment and treatment of minor ailments. So that all pharmacists are able to gain access to an expanded scope of practice, OPA strongly advocates for additional work to be done in conjunction with the Canadian Society of Hospital Pharmacists (Ontario Branch), the Ontario College of Pharmacists, the Ontario Long-Term Care Association, the Ontario Hospital Association and the Ministries of Health and Long-Term Care. This collaborative effort is necessary and long overdue as

Office of the Chief Executive Officer

pharmacists working in hospitals, primary care settings and long-term care homes need to be permitted and enabled to practise to the same full scope as their community-based colleagues.

While the re-examination of current remuneration models and the scrutiny of and revisions to legacy legislation and regulation impacting these sectors may be significant, they are nonetheless appropriate. All healthcare providers, including pharmacy professionals, must be enabled to practise to their fullest extent, regardless of where they work, so that they can contribute as best as possible to the achievement of positive health outcomes, improve the timeliness of patient care and help to create capacity and system efficiencies in all practice settings.

CONCLUSION

We would like to thank the Ontario College of Pharmacists for providing OPA with the opportunity to provide commentary on the proposed amendments to the General Regulation 202/94 of the *Pharmacy Act, 1991*. Should you have any questions with respect to this submission, please feel free to contact me by email at jbates@opatoday.com.

Yours sincerely,



Justin J. Bates
Chief Executive Officer

cc: Jen Baker, Chair of the Board, Ontario Pharmacists Association
Tim Brady, Vice Chair, Ontario Pharmacists Association
Allan H. Malek, Senior Vice President, Ontario Pharmacists Association
Samantha Yau, President, Canadian Society of Hospital Pharmacists (Ontario Branch)
Sandra Hanna, CEO, Neighbourhood Pharmacy Association of Canada

APPENDIX

Table 1: Eight-Step Approach to Appropriate Prescribing

	PRESCRIBING (Rx and OTC)	MD / NP / DDS	PHARMACIST
STEP 1	<u>ASSESSMENT OF THE PATIENT'S PROBLEM</u> - The prescriber will evaluate and clearly define the patient's problem. This includes: - Taking an appropriate patient history, including the most complete and accurate list possible of drugs the patient is taking; - Taking into account any previous adverse reactions to drugs; - Obtaining and/or verifying information by checking previous records and databases, when available; - Obtaining prescription and/or other relevant medical information; - Performing any additional examinations and or investigations as may be required.	Within current scope of practice and/or training	- Within current scope of practice and/or training - While physical assessments are not within current scope or training, observational assessments are a common element of practice
STEP 2	<u>SPECIFICATION OF THE THERAPEUTIC OBJECTIVE</u> Prescribers are expected to direct prescribing toward a clear goal with expected outcomes.	Diagnosis is within current scope of practice and/or training	- Diagnosis is NOT within current scope of practice - Diagnostic knowledge is within the scope of p'cist training
STEP 3	<u>SELECTION OF THE APPROPRIATE DRUG THERAPY</u> Prescribers will select a therapy that considers the suitability of the drug for the patient including dosage form, frequency of dosing, duration, likelihood of side effects (including the ability of the patient to manage them), potential interactions and contraindications, and affordability.	Within current scope of practice and/or training	Within current scope of practice and/or training
STEP 4	<u>INITIATION OF THERAPY</u> Prescribers may initiate therapy with appropriate details and will consider use of non-pharmacologic therapies	Within current scope of practice and/or training	Validation of selected therapy is within current scope of practice and/or training
STEP 5	<u>PATIENT COUNSELLING</u> Prescribers are to provide patients with information, instructions, and warnings	Within current scope of practice and/or training	Within current scope of practice and/or training
STEP 6	<u>MONITORING AND EVALUATION</u> - Prescribers will evaluate therapy regularly with a view toward: - Maintaining therapeutic regimen. Medication is deemed to be effective and well-tolerated; - Adjusting therapeutic regimen. Addition to and/or change to current therapy such as the drug, dose, formulation, or directions for use. Often done due to suboptimal response or side effects with initial therapy, or patient non-adherence; and - Stopping therapeutic regimen. May be a function of therapeutic success (patient problem has resolved), therapeutic failure (for example patient exhibited no response or worsening of problem/condition, or poor tolerability including allergy).	Within current scope of practice and/or training	Within current scope of practice and/or training



	PRESCRIBING (Rx and OTC)	MD / NP / DDS	PHARMACIST
STEP 7	<u>CONSIDERATION OF HEALTH SYSTEM IMPACT</u> - Prescribers will consider the impact of drug cost to the patient and to the health system when prescribing. - Designed to introduce an awareness of the challenges to health system sustainability. - This includes the economic impact of therapy on both the public and private health systems.	Within current scope of practice and/or training	- Within current scope of practice and/or training - Pharmacists have a strong appreciation of therapeutic costs vs. other prescribers and are sensitive to their impacts on adherence
STEP 8	<u>USE OF SUPPLEMENTAL INFORMATION FROM VARIOUS SOURCES TO REDUCE PRESCRIBING ERRORS</u> - Prescribers will utilize computers and other technologies to mitigate prescribing and dispensing errors. - Prescribers will utilize and consult other sources, when necessary, to support their clinical rationale. - Prescribers will document their decisions and other relevant patient information within the patient electronic health record.	- Documentation is largely enabled within medical practices through the EMR - Some degree of online access to drug information sources - Mitigation of dispensing errors will be enhanced with the introduction of electronic prescribing technologies such as computerized physician order entry (CPOE)	- Documentation is largely enabled within pharmacy practice management systems (PPMS) - Requirement for access to unbiased and current drug information and resources. - Mitigation of dispensing errors will be enhanced with the introduction of electronic prescribing technologies such as computerized physician order entry (CPOE) and access to the provincial digital health drug repository.