



October 25, 2019

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

Via Email: consultations@ocpinfo.com

Dear Ms. Lum-Wilson:

Re: Consultation on Expanding Scope of Practice

The Ontario Pharmacists Association ('OPA', the 'Association') is pleased to provide its comments and recommendations to the Ontario College of Pharmacists ('OCP', the 'College') on the recently proposed amendments to the *General Regulation 202/94* of the *Pharmacy Act*, Part VII.3 (Controlled Acts). If approved, the amendments would enable pharmacy professionals, with appropriate training where necessary, to:

1. Administer the flu vaccine to children as young as two years old;
2. Renew prescriptions in quantities of up to a 12-month supply;
3. Administer certain substances by injection and/or inhalation for purposes that are in addition to patient education and demonstration.

In addition, OPA is pleased to provide comments that will help to inform OCP on potential regulatory amendments to the *Pharmacy Act* and eventual changes to the *Laboratory and Specimen Collection Centre Licensing Act* that, if approved, would enable pharmacists to:

4. Perform certain point of care tests (POCT) to support their role in medication management and treatment of patients.

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 continuing 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 Association welcomes the well-founded confidence and trust expressed by Deputy Premier and Minister of Health Christine Elliott in her letter to OCP President Laura Weyland that articulates the desire of the Ontario government to leverage the education and training of pharmacists more effectively. OPA agrees with the Deputy Premier that greater utilization of Ontario's pharmacists will enable patients to experience a more streamlined navigation through our complex health system. This includes providing Ontario pharmacists with:

- New authorities that have been successfully introduced in other Canadian jurisdictions; and
- Removing barriers to and/or expanding on existing scopes of practice authorities to allow for greater and more timely access to healthcare for Ontarians.

The requests and objectives put forward by the Deputy Premier to the College certainly support and are consistent with OPA's mission and vision:

"To advance the pharmacy profession as a vital healthcare provider through advocacy, innovation and support services...and [to] be a respected leader in the pharmacy profession focused on health and wellness."

On face value, OPA acknowledges and applauds all efforts of government to expand the pharmacy professionals' scope of practice and will steadfastly support pharmacy providers in elevating their skills, training and practice to ensure strong uptake and adoption. We are also pleased to offer recommendations and additions to the proposed amendments that can mitigate any real or potential barriers, challenges, frustrations and oppositions that might interfere with the achievement of the desired level of uptake. To that end, and with this submission, OPA is providing its commentary and recommendations from two perspectives:

1. In accordance with OCP's core mandate *"to serve and protect the public and hold Ontario's pharmacists and pharmacy technicians accountable to the established legislation, standards of practice, code of ethics and policies and guidelines relevant to pharmacy practice"*, this submission will provide commentary on the clinical nature of the proposed expansion of scope and whether the Association believes pharmacists are competent and clinically capable to perform the service.
2. Recognizing that the College has also been asked by the Minister to provide a regulatory impact assessment for each of the scope expansion elements, this submission will provide commentary and recommendations on approaches that both support any positive and mitigate any negative impacts that could potentially arise from the approval and implementation of the draft regulations.

ADMINISTRATION OF FLU VACCINE TO CHILDREN AS YOUNG AS TWO YEARS OLD

It is the Association's perspective that, based on the comprehensive clinical and practical education received by injection-trained pharmacists, this element of the proposed expansion of scope is warranted. In its outreach to its members, however, OPA did encounter some questions and concerns related to the operational and workplace-related challenges associated with offering this expanded service. However, it is the position of OPA that the identification of operational or workflow-related challenges fall outside the primary objective of the College in this consultation, that being to assess if the proposed change would pose any risk to patient safety. Insofar as there is a lack of substantial apprehension associated with clinical risks of harm and that concerns are reflective primarily of business-related matters, OPA contends that this proposed expansion of scope be approved.

Acknowledging that there are no clinical or safety-related concerns, OPA does acknowledge the College's important role in assessing the regulatory impact of such a change in scope. Respectfully, we believe that identification of potential negative regulatory impacts should not necessarily lead to a rejection of the proposal. Instead, prospective identification of these challenges should allow for the creation of strategies and policies to mitigate them. Therefore, in light of the planned implementation for the proposed change being the launch of the Universal Influenza Immunization Program ('UIIP') 2020-21, **OPA recommends that a working group be established with OCP and the Neighbourhood Pharmacy Association of Canada to examine and understand the gamut of**

operational challenges identified by pharmacists and technicians and to identify and implement strategies and policies to address and mitigate them. In addition, and given that there are no clinical reasons to oppose this expansion, **OPA recommends that the proposed scope of practice expansion be approved** along with the following considerations to support uptake by pharmacy:

- a. **Administration of flu vaccine to children as young as two years old be deemed voluntary and any decision not to offer this service must not disqualify a pharmacy from participating in the UIIP;**
- b. Recognizing that the administration of vaccine services to children as young as two years old is more time- and labour-intensive, and with an understanding that there may be a requirement for a refresher training program and increased documentation for pharmacists who choose to provide that service, **OPA recommends a joint submission from both the Association and OCP toward a new engagement strategy for pharmacy in the UIIP that more efficiently addresses pharmacy registrations, vaccine storage and handling, communications and patient accessibility to immunization;** and
- c. While outside the purview of the College, **OPA requests OCP support for a revision to the current UIIP funding model for pharmacies that better reflects the increased costs of administration.**

While OPA acknowledges that these recommendations are non-regulatory and are therefore outside the scope of this consultation, the Association nonetheless requests the support and collaboration of the Ontario College of Pharmacists in the development of more sweeping recommendations that will overhaul the UIIP such that long-standing logistical and operational barriers to effective and efficient pharmacy-based administration of injections and patient access are removed so that the profession can contribute even more to increasing immunization rates and mitigating influenza-related morbidity and mortality.

PHARMACIST-AUTHORIZED RENEWAL OF PRESCRIPTIONS IN QUANTITIES UP TO A 12-MONTH SUPPLY

From the clinical perspective, it is OPA's position that the steps for pharmacists to follow in determining whether a prescription renewal can be authorized remain unchanged. The decision is ultimately made with professional judgement based in large part on the best-available information on the patient, access to their medication profile, and knowledge of the patient's degree of adherence, responsiveness and tolerance to the medication under consideration. The same information will also be used in the determination of the duration of that renewal, and OPA contends that all prescribers follow the same decision-making processes. Therefore, the question now is whether or not pharmacists have access to the tools and the information they require to make these decisions.

There are many medications that do not require intensive monitoring (i.e., laboratory testing) and therefore, if the pharmacist is confident in their assessment of the prescription in question to authorize a 12-month renewal, then that should be enabled. Conversely, in the event of a request for reauthorization of a prescription for a medication that requires monitoring and more intensive clinical oversight, then the pharmacist's professional judgement would dictate a more cautious approach and, when warranted, a referral back to the original prescriber. It is critical to remember that the proposed language for this element of scope expansion stipulates a 12-month maximum "life span", not a minimum. At the end of the day, the pharmacist would apply their clinical judgement on the most appropriate duration for the medication in question, with the understanding that the reauthorization cannot exceed 12 months.

OPA would concur that in the absence of access to and/or the ability to order laboratory tests and/or the patient's electronic medical record, 12-month prescription extensions for sensitive medications won't likely occur. However, the Association and its members acknowledge that there are numerous prescriptions for medications that are often deemed life-long treatments and rarely require any change. It is likely for these medications that the proposed scope expansion is being considered, and as pharmacies and pharmacists gain the necessary and long-awaited access to laboratory data and the full medical record, they will have the tools at their disposal to provide greater oversight on all therapies. Therefore, **OPA recommends the approval of the proposed expansion of scope to enable pharmacist-authorized prescription extensions for quantities lasting up to 12 months. At the same time, OPA offers the following policy recommendations to the Ministry of Health for implementation as quickly as possible:**

- a. **Concurrent enabling of pharmacists' access to and, when necessary, ordering of laboratory results via the Ontario Laboratories Information System (OLIS); and**
- b. **Expedited access for all community pharmacies to Ontario's two clinical viewers, ClinicalConnect and ConnectingOntario.**

OPA recognizes that neither of these recommendations are regulatory in nature and are matters of good health policy, although one approach for consideration is mandating pharmacy access to the two clinical viewers through standards of practice. OPA is eager to resume dialogues with the Ministry and OCP on ensuring pharmacists have all of the necessary tools and technologies they need to evaluate medication usage, extend renewals and provide clinical advice to patients and other healthcare professionals for optimal patient care.

In terms of the anticipated regulatory impact of this element of scope expansion, OPA does not envision any operational hurdles in terms of the impact on time to provide the service. As mentioned above, the protocols to apply in the assessment of appropriateness of a prescription renewal are the same, irrespective of the duration of the renewal. That said, in the absence of access to OLIS data, the process for considering the renewal of a medication that requires monitoring is currently very time-intensive for both the pharmacist and the original prescriber who would need to provide the pharmacists with the necessary laboratory data. Expediting the recommended policy changes while approving the draft regulations is therefore warranted.

ADMINISTRATION OF CERTAIN SUBSTANCES BY INJECTION AND/OR INHALATION FOR PURPOSES THAT ARE IN ADDITION TO PATIENT EDUCATION AND DEMONSTRATION

The Ontario Pharmacists Association and its members welcome this proposed expansion of scope as this has represented a key component of OPA's ongoing advocacy. This proposal builds off the dramatic success of pharmacists' role in the administration of flu shots under Ontario's Universal Influenza Immunization Program ('UIIP'). This is a natural expansion of that authority and will require little to no ramp-up time for most pharmacists. OPA is extremely proud of the fact that most of Ontario's pharmacists who have received their injection and immunization training have done so through the Association's flagship professional development program, the first of its kind in the province. We are also buoyed by the receptivity of pharmacists to OPA's voluntary immunization refresher and travel vaccine programs. The level of interest and uptake for these programs speak to the interest to offer more services to their patients.

Since pharmacists' inclusion in the UIIP in 2012, Ontarians have clearly signified their support as pharmacies are becoming the preferred location to receive their flu shots.¹ Unfortunately, current regulations in the *Pharmacy Act* significantly restrict pharmacists to the administration of flu shots and select travel-related vaccines, despite the fact that for most other vaccines and injectables, the technical aspects of administration of intramuscular, subcutaneous and intradermal injections are identical. In many cases, pharmacists are already providing their patients with the training they require to self-administer these substances and are thus more than capable of providing routine administration to patients who require this service. Among the competencies identified by the College for pharmacist training is knowledge of the medication they are administering. OPA acknowledges this as a prudent and appropriate requirement, and pledges to work together with OCP in determining the list of eligible injectable and inhalation products for pharmacists' routine administration for purposes beyond those of education and demonstration.

There are many circumstances that warrant a trained health professional's support when it comes to routine administration of injections and/or inhalations. In some cases, patients are fearful and lack the ability and confidence to self-administer medications, despite patient training to do so. In other cases, due to the nature of the product (other vaccines, vitamin injections, requirements for observation post-injection or post-inhalation, etc.), it may be inappropriate for self-administration. Pharmacists who are trained and are knowledgeable and competent on the therapeutic aspects of the drug product are perhaps the most logical of all health providers from whom patients could choose to obtain the service. With pharmacies' extended hours of operation, their location close to their patient's home, and being staffed with trained health professionals that can be accessed without the need for an appointment, pharmacists can dramatically increase patient's timely access to care and can contribute to improved adherence to prescribed injection schedules.

The Association strongly supports this proposed expansion of scope to include a much broader list of eligible injectable and inhaled drug products. **OPA would also like to submit additional recommendations as follows:**

- a. Recognizing the need for efforts to be made to increase adult immunization rates to levels that meet or exceed national targets, **Ontario pharmacies and pharmacists should be enabled to participate in and be remunerated for other publicly-funded immunization programs beyond influenza;**
- b. **Administration of influenza vaccine outside of the parameters of the UIIP should be enabled. While not limited to the following example, this would mean that privately-procured flu vaccine could be administered for a fee by pharmacists to individuals who do not qualify for the UIIP program (e.g., visitors to Ontario);**
- c. **Ontario's pharmacists should be given prescriptive authority for publicly-funded vaccines as well as for any injectable and/or inhaled product that are designated as Schedule II or III;**
- d. **Parameters and protocols for all immunizers should be aligned such that there are no more or less strict rules that apply to any particular healthcare profession. As an example, this would mean that pharmacists would be enabled to administer vaccines and other injectables to patients outside the physical pharmacy premises in a manner that is similar to protocols that apply to medicine and nursing; and**
- e. **Ontario pharmacies should be publicly remunerated for the administration of injections and/or inhalations where similar public funding arrangements are available to other health professionals (physicians, nurses, nurse practitioners, etc.).**

¹ Seasonal Influenza (Flu) Vaccination Coverage Survey Results, 2017-2018, <https://www.canada.ca/en/public-health/services/publications/healthy-living/2017-2018-seasonal-influenza-flu-vaccine-coverage-survey-results.html>

While requests for remuneration associated with OPA's recommendations are outside the scope of this consultation, it is important that the College and the Ministry of Health recognize and support the concept that there is tremendous value to engaging pharmacists in this manner to support the Quadruple Aim of healthcare:

- 1) To drive better health outcomes through increased medication adherence,
- 2) To derive value for money invested, in this case by remunerating pharmacists for advancing population health and mitigating downstream morbidity and mortality,
- 3) To improve the overall patient navigation and experience in the health system by allowing them to access a provider close to home and at times that are more convenient for them, and
- 4) To improve the pharmacists' experience in the system, by allowing them to practise more in accordance with their training and expertise.

Remuneration is most certainly a business enabler, and with a view toward the regulatory impact of this element of scope expansion, OPA contends that these services are highly time- and labour-intensive. Fair and reasonable funding will therefore be critical for uptake of this valuable service, and while we acknowledge that compensation is outside of the purview of the College, OPA contends that the College is still in a position to support the concept of necessary remuneration of pharmacists so that they can more effectively contribute to the Quadruple Aim.

PERFORMANCE OF CERTAIN POINT OF CARE TESTS (POCT) TO SUPPORT PHARMACISTS' ROLE IN MEDICATION MANAGEMENT AND TREATMENT OF PATIENTS

Traditionally, the pharmacist's role has been about dispensing and providing over-the-counter medication advice, but over the last 10 years, that role has expanded and now includes communicating with patients and other clinicians to help make informed decisions about managing drug therapy and conditions to ensure optimal patient health outcomes. This role has been greatly facilitated by evolving the pharmacists' scope of practice to enable even greater collaboration with other healthcare providers.

Point-of-care testing that is done on-site in a pharmacy at the time of a patient consultation allows for real-time clinical decision-making. Testing enables pharmacists to conduct risk assessments, monitor health outcomes of current pharmacotherapy, and facilitates increased patient engagement in the self-management of their medical conditions. POCT is highly accessible – certainly more so than traditional laboratory testing – and reduces processing delays. It offers cost savings and uses fewer resources while providing immediate clinical information to pharmacists, who can in turn better inform and advise on the prescriptive process. It also provides an opportunity for more timely access for patients who are living in remote areas, are homebound or reside in locations where traditional laboratory services are not readily available. As patients are already coming into the pharmacy to pick up their medications, offering POCT helps to bridge certain healthcare access gaps.

Point-of-care testing through community pharmacies occurs in various international settings and have shown themselves to be of particular benefit for patients. These tests could include, but would not be limited to, kits that screen for H.pylori, hepatitis C, and HIV as well as kits that can measure values for hemoglobin A1C to assess for and monitor diabetes, INR for bleeding disorders, and lipids for managing cardiovascular health. Although the current proposed changes focus on point-of-care testing for the management of chronic conditions, OPA believes that there is value to allowing pharmacists to provide other POCTs as they introduce yet another opportunity for optimization of pharmacist-prescriber collaboration, as testing in pharmacies complements the services provided by prescribers. POCT in pharmacies can:



- Enhance communications between pharmacists and prescribers,
- Enable early identification or warning signs of certain conditions and can drive subsequent referrals to the most appropriate health provider,
- Reinforce the importance of adherence to therapy, and
- Facilitate medication follow-up and monitoring.

Operationally, OPA believes that the regulatory impact of enabling POCT will have minimal impact on workflow but will contribute to greater oversight on medication therapy and in assisting the patient and others within their circle of care in the management of chronic disease. Therefore, **the Ontario Pharmacists Association fully supports the proposed expansion of scope to include POCT** as part of OPA's commitment to evolving the pharmacy profession. OPA looks forward to working with government, the College and other health professions to enable this important service.

CONCLUSION

The Ontario Pharmacists Association appreciates the opportunity to provide the College with its comments and recommendations toward the proposed initiatives that seek to expand the scope of pharmacists' practice. OPA recognizes these proposals are part of a broader approach for greater utilization of pharmacists' knowledge, training and expertise to ultimately improve patient care and access. While the proposals being addressed in this consultation are welcomed and appreciated, they cannot be successfully implemented in a vacuum. It is therefore critical for all relevant stakeholders – pharmacy owners and managers, pharmacists and technicians in all practice settings through their respective associations, the government, and regulators – are consulted to ensure that any negative regulatory impacts (real or perceived) are mitigated while positive ones are supported and promoted.

As a final recommendation, the Ontario Pharmacists Association calls for the immediate establishment of a Pharmacy Workplace Taskforce, co-chaired by OPA and OCP, with appropriate representation from:

- i. OPA and OCP staff liaison;
- ii. staff pharmacists in community, hospital, long-term care and primary care;
- iii. corporate and independent pharmacy owners/managers;
- iv. pharmacy students;
- v. pharmacy technicians;
- vi. academia; and
- vii. a facilitator.

The taskforce would be responsible for identifying current and potentially foreseeable workplace challenges and barriers that (a) impede pharmacists' and technicians' abilities to practise in accordance with their current and prospective scopes, and (b) foster an unhealthy workplace environment that may place providers and patients at risk. OPA proposes that the Association and the College collaborate on the establishment of:

- terms of reference, and
- identification of the skill sets being sought from applicants.



Considering the multi-faceted nature of pharmacy in Ontario, OPA acknowledges that the Pharmacy Workplace Taskforce might require numerous people around the table so that all perspectives are heard and addressed. It is critical that the selected members of the Pharmacy Workplace Taskforce possess the appropriate level of knowledge and experience for the sector they will represent. OPA is eager to begin this very important work with the College, frontline pharmacy professionals, employers, academia and pharmacy students and which will be instrumental in ensuring that the delivery of high-quality patient care in all business and practice settings is optimized and that pharmacy professionals can accept, embrace and operationalize current as well as new services under a broadened scope of practice.

Should you have any questions or comments related to this submission, please do not hesitate to contact me at your earliest convenience at jbates@opatoday.com or by phone at 416-441-0788.

Yours sincerely,

A handwritten signature in black ink, appearing to be "Justin J. Bates", with a long horizontal flourish extending to the right.

Justin J. Bates
Chief Executive Officer

cc: The Honourable Deputy Premier and Minister of Health Christine Elliott
Ms. Harpreet Bassi, Director of Policy, Ontario Ministry of Health
Ms. Allison Henry, Director, Health Workforce Regulatory Oversight Branch,
Ontario Ministry of Health
Ms. Laura Weyland, President, Ontario College of Pharmacists
Ms. Jen Baker, Chair of the Board, Ontario Pharmacists Association
Mr. Allan Malek, EVP and Chief Pharmacy Officer, Ontario Pharmacists Association
Ms. Sandra Hanna, Interim CEO, Neighbourhood Pharmacy Association of Canada