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Office of the Chief Executive Officer

July 27, 2020

Mr. Patrick Dicerni
Assistant Deputy Minister and Executive Officer
Drugs and Devices Division, Ministry of Health
438 University Avenue, 10th Floor
Toronto, ON M7A 1N3

Via Email: Patrick.Dicerni@ontario.ca

Dear Patrick:

Re: Proposal No. 20-HLTC025 - Proposed Amendments to O.Reg. 202/94 (General) made under the Pharmacy Act, 1991

The Ontario Pharmacists Association ('OPA', the 'Association') is pleased to provide its comments and recommendations to the Ministry of Health ('Ministry') on proposed amendments to the O.Reg. 202/94 of the *Pharmacy Act, 1991*. These amendments, once approved and implemented, would enable pharmacy professionals 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.

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 May 30, 2019 letter to Ontario College of Pharmacists ('OCP') President Laura Weyland that articulates the desire of the Ontario government to leverage the education and training of pharmacists more effectively¹. 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:

¹ Deputy Premier's Letter to OCP <https://www.ocpinfo.com/wp-content/uploads/2019/08/ministers-letter-expanded-scope-of-practice.pdf> Accessed July 24, 2020



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“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.”

OPA acknowledges and applauds all efforts of government to expand the pharmacy professionals' scope of practice and will steadfastly support pharmacy providers when necessary and requested 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 and challenges that might interfere with the achievement of the desired level of uptake.

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 and has the full support of OPA. The Association is extremely proud of the fact that most of Ontario's pharmacists who have received their injection and immunization training have done so through OPA'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. The breadth of OPA's training is extremely comprehensive in both its base program as well as in its refresher module and encompasses the skills and knowledge required for safely administering injections to young children.

Given that there are no clinical reasons to oppose this expansion, **OPA supports the recommendation to permit pharmacist administration of flu vaccine to children as young as two years old.**

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 apply the same due diligence when reauthorizing a prescription and selecting the optimal duration. 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 duration, not a minimum. At the end of the day, the pharmacist would apply their clinical judgement



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to determine the most appropriate duration for the medication in question for a specific patient, with the understanding that the reauthorization cannot exceed 12 months.

Given pharmacists' lack of access to laboratory data and their inability to order, receive and interpret test results stored within the Ontario Laboratory Information System ('OLIS') database, it is likely that 12-month prescription extensions for medications with a narrow therapeutic index (e.g., warfarin, phenytoin, carbamazepine, etc.) won't occur very often. However, the Association and its members acknowledge that there are many prescriptions for medications that are often deemed life-long treatments and rarely require any change. As pharmacies and pharmacists gain the necessary and long-awaited access to OLIS data and their patients' full medical records, 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' read-and-write (ordering, receiving and interpreting) access to laboratory results via OLIS; and
- b. Expedited access for all community pharmacies to Ontario's two clinical viewers, ClinicalConnect and ConnectingOntario, and ultimately the Digital Health Drug Repository.

OPA recognizes that neither of these recommendations are regulatory in nature and are matters of good health policy. OPA is eager to resume dialogues with the Ministry 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 requesting 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 UIIP. This is a natural expansion of that authority and will require little to no ramp-up time for most pharmacists.



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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.² 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.

Accordingly, **the Association fully supports the proposed list of injectable and inhaled medications categories, as defined by the American Hospital Formulary Service ('AHFS')** and as expressed in Schedules 1 and 2, respectively, of Ontario Regulation 202/94 under the *Pharmacy Act, 1991*. In addition, OPA would also like to submit additional recommendations as follows:

- i. **Pharmacist Administration of Other Publicly-Funded Vaccines:** Recognizing the need to increase immunization rates and improve adherence to injection schedules in a manner that meets or exceeds national targets, Ontario pharmacies and pharmacists should be enabled to participate in and be remunerated for other publicly-funded immunization programs beyond influenza. While predominantly focusing on immunizations for adults and older children over 5 years of age, OPA recommends that pediatric immunizations for children 2 years of age and older also be enabled, particularly for instances when the child's primary care provider (i.e., GP or pediatrician) is unavailable, such as that which is occurring now during the COVID-19 pandemic and physician office shutdowns;
- ii. **Expansion of UIIP for Pharmacies:** Administration of influenza vaccine outside of the parameters of the UIIP should be enabled. While not limited to the following example, consideration could be made to enable privately-procured flu vaccine (e.g., not obtained through the UIIP procurement process) could be administered for a fee

² 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>



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by pharmacists to individuals who do not qualify for the UIIP program (e.g., visitors to Ontario);

- iii. **Prescriptive Authority for Vaccines and Select Schedule II and III Products:** Ontario's pharmacists should be given prescriptive authority for publicly-funded vaccines and any injectable and/or inhaled product that are designated as Schedule II or III;
- iv. **Harmonization of Parameters and Protocols for all Immunizers:** Policies and protocols that are currently in place for community pharmacies should be aligned and harmonized for all immunizers 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
- v. **Reasonable Remuneration for Pharmacy:** 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.). It is important that 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 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 practice 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.

For publicly-funded immunizations, OPA requests pharmacy funding that is on par with that paid to physicians through Public Health. OPA is also requesting a reconsideration of the funding model currently in place for pharmacies participating in the UIIP. With the current COVID-19 pandemic and acknowledging that additional precautions will be necessary in pharmacies (e.g., personal protective equipment for pharmacy professionals and for patients plus regular disinfection of injection and patient waiting areas), **OPA is proposing an additional \$3.00 top-up to be added to the current level of reimbursement of \$7.50 for flu shots, yielding a total fee of \$10.50 for UIIP 2020-21. The same fee is proposed for pharmacist-administration of a COVID-19 vaccine once it becomes available.** We believe this fee is both fair and reasonable and will also acknowledge the risk and apprehension that many front-line pharmacy professionals are experiencing.



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CONCLUSION

The Ontario Pharmacists Association appreciates the opportunity to provide the Ministry 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.

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

Yours sincerely,

A handwritten signature in black ink, appearing to read "Justin J. Bates".

Justin J. Bates
Chief Executive Officer

cc: Ms. Harpreet Bassi, Director of Policy, Ontario Ministry of Health
Ms. Allison Henry, Director, Health Workforce Regulatory Oversight Branch,
Ontario Ministry of Health
Ms. Jen Baker, Chair of the Board, Ontario Pharmacists Association
Ms. Nancy Lum-Wilson, Registrar, Ontario College of Pharmacists
Mr. Allan Malek, EVP and Chief Pharmacy Officer, Ontario Pharmacists Association
Ms. Angeline Ng, Director, Professional Affairs, Ontario Pharmacists Association