



August 9, 2023

Ms. Shenda Tanchak
Registrar and CEO
Ontario College of Pharmacists
483 Huron Street
Toronto, ON M5R 2R4

Via Email: consultations@ocpinfo.com

Dear Ms. Tanchak:

Re: Seeking Feedback on Expanded Scope Regulatory Amendments

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 proposed amendments to General Regulation 202/94 under the *Pharmacy Act, 1991*, to expand the scope of pharmacists and pharmacy technicians to administer additional vaccines and offer appropriate treatment options for COVID-19 and influenza.

OPA is committed to evolving the pharmacy profession and advocating for excellence in practice and patient care. With its 9,000 members, OPA is Canada's largest pharmacy-based advocacy organization and continuing professional development provider for pharmacy professionals. By leveraging the unique expertise of pharmacy professionals, enabling them to practice to their fullest potential, and making them more accessible to patients, OPA is working to improve the efficiency and effectiveness of the health care system.

Ontario's health system has experienced significant strain over the past few years, and as we look to recovering and rebuilding post-pandemic, it is important to consider how our health system can evolve to better meet patient needs and improve sustainability. During the last few years, the pharmacy profession has evolved significantly to make care more accessible and convenient for the people of Ontario while increasing system capacity. These changes include but are not limited to administering COVID-19 vaccines, ordering and performing COVID-19 tests, conducting point-of-care testing, prescribing and dispensing nirmatrelvir/ritonavir (Paxlovid) for the treatment of COVID-19, and more recently, assessing and treating certain minor ailments.

Overall, OPA is supportive of the proposed regulations, which will improve access to care for patients. The 2022/23 respiratory illness season saw a higher-than-normal

increase in hospitalizations, intensive care unit admissions and deaths compared to previous seasons with the return of seasonal influenza circulation along with the co-circulation of other respiratory viruses including respiratory syncytial virus (RSV) and COVID-19 in Canada.¹ As such, it is imperative that proactive measures are taken now to ensure Ontario is prepared for the upcoming 2023/24 season which is predicted to experience a similar surge in infections.² These expansions in scope will enable pharmacy professionals to offer and provide additional professional services which will improve timely access to care for patients.

The proposed regulatory changes align with OPA's recommendations to the Ontario government on five key areas where scope of practice changes for pharmacy professionals should be implemented to improve the accessibility of care for Ontarians and relieve pressure from other areas of the health sector. These include:

1. Enable Part A pharmacists, interns, registered pharmacy students, and pharmacy technicians to administer all vaccinations, including those that are publicly funded.
2. Expand prescribing authority to include additional minor ailments, conditions, and/or situations that pharmacists are able to assess and, if necessary, prescribe treatment for.
3. Authorize pharmacists to order laboratory tests and conduct additional point-of-care tests (POCT) to better assist with screening for and management of acute or chronic health conditions (e.g., Group A streptococcal, *Helicobacter pylori*, HIV, Hepatitis C, renal function, and RSV).
4. Authorize pharmacists to provide therapeutic substitutions to support safe and effective care for patients.
5. Authorize pharmacy technicians to administer substances by injection and/or inhalation and enable pharmacy professionals to exercise their professional judgment to determine the appropriateness of administration of a substance.

As not all expansion opportunities are within the scope of this consultation, OPA will focus commentary on the following specific proposed amendments.

¹ Ben Moussa M, Buckrell S, Rahal A, et al. National influenza mid-season report, 2022-2023: A rapid and early epidemic onset. *Can Commun Dis Rep.* 2023;49(1):10-14. Published 2023 Jan 5. doi:10.14745/ccdr.v49i01a03

² Ontario College of Pharmacists. Board Briefing Note: Expansion of Scope – Additional vaccine administration, including removal of specific age restriction, Tamiflu prescribing and other related administrative changes. Published June 2023. Accessed July 27, 2023. <https://www.ocpinfo.com/wp-content/uploads/2023/06/june-12-2023-board-briefing-notes-expanded-scope.pdf>

PROPOSED REGULATORY AMENDMENTS

1) Give pharmacists and pharmacy technicians authority to administer the RSV vaccine.

RSV infection is a large burden of disease not only in Canada but also worldwide with the most impact in young children in the first two years of life as well as in older adults.³ In Canada, RSV is associated with approximately 52.7 hospital admissions per 100,000 individuals over 65 years of age and 1,042 hospital admissions per 100,000 infants annually.⁴ OPA applauds the College for taking proactive steps to include the administration of the vaccine within the scope of pharmacy professionals to mitigate any future delays to vaccine administration as a result of administrative barriers. This will ensure that patients have timely and convenient access to this vaccine to help prevent the morbidity and mortality associated with the infection amongst at-risk patient populations.

Currently, all injectable vaccines approved for use in Canada are administered intramuscularly or subcutaneously, including the newly approved RSV vaccine which is administered intramuscularly. As these routes of administration are part of the training received by injection-trained pharmacy professionals, they will already have the training, skills and knowledge to administer the vaccine safely to patients. Pharmacy professionals have been participating in the administration of publicly funded influenza vaccines since 2012, in addition to administering vaccines to patients for 13 other vaccine preventable diseases since 2017 and most recently publicly funded COVID-19 vaccines. In the 2022/23 season alone, pharmacy professionals administered almost 2.2M influenza vaccine doses through community pharmacies, and to date have administered over 11.1M COVID-19 vaccines. Building upon the success of these programs and leveraging the extensive experiences gained, the expansion of scope for pharmacy professionals to include administration of the RSV vaccine will improve patient access, reduce the burden on primary and acute care, and increase the overall capacity of the health care system.

Beyond the RSV vaccine, OPA recommends that changes be made to eliminate the current practice of listing out each vaccine separately within the regulations. Lists

³ Killikelly A, Tunis M, House A, Quach C, Vaudry W, Moore D. Overview of the respiratory syncytial virus vaccine candidate pipeline in Canada. *Can Commun Dis Rep.* 2020;46(4):56-61. Published 2020 Apr 2. doi:10.14745/ccdr.v46i04a01

⁴ Mac S, Shi S, Millson B, et al. Burden of illness associated with Respiratory Syncytial Virus (RSV)-related hospitalizations among adults in Ontario, Canada: A retrospective population-based study [published online ahead of print, 2023 Jul 6]. *Vaccine.* 2023;S0264-410X(23)00774-0. doi:10.1016/j.vaccine.2023.06.071

are cumbersome because regulatory amendments are required each time the list requires an update. For example, if policy changes were made to enable pharmacy professionals to support the administration of all publicly funded routine immunizations in Ontario, regulatory amendments would need to be made to include all vaccines that are currently part of Ontario's immunization schedule, i.e., diphtheria, tetanus, pertussis, polio, measles, mumps and rubella. Furthermore, regulatory amendments would be required on an ongoing basis to ensure the list remains up to date. The current process for proposed regulatory amendments to proactively include RSV vaccine administration within the scope of pharmacy professionals in anticipation of vaccine approval by Health Canada, which has since been approved, highlight this challenge. Rather than amending the regulations each time a new vaccine is approved, amendments to remove the prescriptive list and enable the administration of all vaccines once approved by Health Canada will support consistency and alignment of scope for vaccines, in addition to minimizing future administrative burden that would be required to add new vaccines as they become available.

Vaccines are our best defense against many infectious diseases and removing barriers to access vaccines is critical to achieving target vaccination rates to support and enhance overall population health. To be approved for use in Canada, vaccines must undergo Health Canada's comprehensive regulatory process to ensure its safety and efficacy. Additionally, ongoing monitoring continues after approval and post-marketing. Thus, a list of authorized vaccines that can be administered by pharmacy professionals is not necessary as patient safety and health are safeguarded by this process, which ensures vaccine confidence. Furthermore, pharmacists have the clinical knowledge and expertise to determine whether vaccine administration is appropriate for the patient in accordance with immunization guidelines and public health recommendations to protect patient safety and wellbeing. OPA also recommends that regulatory amendments be made to provide pharmacists with prescriptive authority for vaccines to improve patient access by not requiring a patient to first seek a prescription for a vaccine from an authorized prescriber prior to being able to receive that vaccine at a pharmacy. By removing barriers to vaccine administration, such as the need to go elsewhere for a prescription or for administration services, missed vaccination opportunities can be avoided and the patient journey improved overall.

Finally, the proposed regulatory additions of paragraphs 9, 10 and 11 to subsection 34 (3) of the Regulation to restrict the administration of influenza, COVID-19 and RSV vaccines, respectively, to only be permitted in accordance with Ministry guidance is unnecessary. If there is a publicly funded program that pharmacy professionals can participate in, e.g., in the current case with respect to influenza and COVID-19 vaccines, pharmacies are required to enter into agreements with the Ministry to participate in the program and are therefore

bound to follow all program expectations and requirements, thus rendering these additional paragraphs in the regulation redundant. Furthermore, the implications of these paragraphs may introduce unintended barriers to the College's intent for pharmacy professionals to administer RSV vaccines regardless of whether it is publicly funded or not. For example, the administration of injectable influenza vaccines by pharmacy professionals has always been restricted to be permissible only in accordance with the Universal Influenza Immunization Program (UIIP). As such, injectable influenza vaccines that are not included within the UIIP are not within the scope of pharmacy professionals to administer. This leads to unnecessary regulatory burdens as was seen in previous years when high-dose influenza vaccines were not available through pharmacies as part of the UIIP. Although there were senior patients who were willing to pay out of pocket for the vaccine, the act of administration of the vaccine could not be done by pharmacy professionals unless they received a medical directive or direct order from another healthcare provider who could delegate that controlled act. As a publicly funded program has not yet been established for the RSV vaccine, there is the possibility that the eligibility criteria could be more limited compared to the approved Health Canada indication(s), and clauses like these limit patient choice and accessibility.

2) Give pharmacy technicians authority to administer vaccines from Schedule 3 of O. Reg. 202/94.

Pharmacy technicians are currently authorized to administer only publicly funded influenza and COVID-19 vaccines. However, the technical knowledge and skills required to administer influenza and COVID-19 vaccines are not different than those required to administer the other vaccines within the scope of Part A pharmacists, pharmacy students and interns (i.e., those listed in Schedule 3). With over 5,700 registered pharmacy technicians in Ontario who can provide patient care, significant workforce capacity could be added to the health system to support administration of vaccines if the scope of pharmacy technicians was expanded. Working under the supervision of a regulated healthcare professional who has the scope to clinically assess the patient to ensure vaccine administration is appropriate, pharmacy technicians can undertake the technical task of vaccine administration to increase capacity and alleviate some of the pressures on pharmacies, local public health units and primary care providers.

3) Give pharmacists authority to prescribe oseltamivir (Tamiflu).

Timely access to antiviral medications for the treatment of conditions such as influenza are of utmost importance to prevent serious outcomes. Antiviral agents for influenza treatment are best initiated within 48 hours after symptom onset. Therefore, timely and equitable access to treatment for all eligible patients is

critical and there is tremendous value to enabling additional channels to facilitate this process. The acceptance and demand for a similar service can be seen through pharmacists assessing and prescribing for nirmatrelvir/ritonavir (Paxlovid) for the treatment of COVID-19 in eligible patients. This initiative has resulted in almost half of all nirmatrelvir/ritonavir (Paxlovid) prescriptions being prescribed by pharmacists. Furthermore, pharmacist prescribing of antiviral therapy for influenza treatment is already authorized in other Canadian jurisdictions, i.e., Alberta, Saskatchewan (when an influenza epidemic or pandemic is declared), and Quebec.

Pharmacists are the health system's most accessible touchpoint for patients and they have the clinical knowledge and expertise to assess and prescribe treatment for influenza, i.e., oseltamivir (Tamiflu), if appropriate to eligible patients. Guidelines from both the Association of Medical Microbiology and Infectious (AMMI) Disease Canada and the Centers for Disease Control and Prevention (CDC) state that laboratory confirmation of influenza infection is not required to initiate therapy for patients who have influenza symptoms and are recommended to receive antiviral treatment, i.e., individuals who are at higher risk of complications from influenza.^{5,6} The addition of pharmacy as a complementary channel to the currently available pathways will help to enable greater capacity and alleviate pressures in the broader health care system. Furthermore, a review of studies on pharmacy-based influenza management models where pharmacists can initiate antiviral therapy found that pharmacists can provide safe and effective influenza management while maintaining or improving antimicrobial stewardship, and the service was associated with a high level of patient satisfaction.⁷

Beyond prescriptive authority for oseltamivir (Tamiflu) and nirmatrelvir/ritonavir (Paxlovid) specifically, OPA recommends that future consideration be made to enable scope for prescribing for conditions (e.g. influenza and COVID-19), similar to prescribing authority for certain minor ailment conditions, as opposed to prescribing for specific drugs. Like the challenges identified with a list of authorized vaccines in regulation, identifying a specific drug in regulation can be equally challenging if and when new drugs are approved to market and clinical guidelines are updated. Furthermore, the clinical knowledge and expertise required of a pharmacist to assess and prescribe a

⁵ Aoki FY, Papenburg J, Mubareka S, Allen UD, Hatchette TF, Evans GA. 2021-2022 AMMI Canada guidance on the use of antiviral drugs for influenza in the COVID-19 pandemic setting in Canada. *J Assoc Med Microbiol Infect Dis Can.* 2022;7(1):1-7. Published 2022 Feb 24. doi:10.3138/jammi-2022-01-31

⁶ Centers for Disease Control and Prevention. Testing Guidance for Clinicians When SARS-CoV-2 and Influenza Viruses are Co-circulating. Last updated February 9, 2022. Accessed July 11, 2023. <https://www.cdc.gov/flu/professionals/diagnosis/testing-guidance-for-clinicians.htm>

⁷ Klepser ME, Adams AJ. Pharmacy-based management of influenza: lessons learned from research. *Int J Pharm Pract.* 2018;26(6):573-578. doi:10.1111/ijpp.12488

specific drug to treat a condition should naturally extend to other drugs available to treat the same condition.

In addition, to support this scope of practice, OPA recommends enabling pharmacists to order lab tests and to perform additional point-of-care tests (POCTs). Although testing for influenza for ambulatory patients is not routinely recommended, it may be considered in situations where the results will help to guide management and/or to inform decisions on antiviral and antibiotic stewardship.⁵ As such, the ability to order laboratory-based influenza testing or to conduct a POCT for influenza will help to support appropriate prescribing as required. The implementation of POCTs into practice is feasible as demonstrated by an Ontario study which had pharmacists providing point-of-care influenza screening to patients and recommending to their physicians to initiate antiviral therapy for those patients with positive results.⁸ Additionally, as the dosing of oseltamivir may need to be adjusted in patients with renal impairment, access to creatinine clearance values is important. For patients who have laboratory renal function results, pharmacists may be able to access these through one of Ontario's clinical viewers. However, for those who do not have laboratory results or outdated results, to prevent a delay in therapy, expanding the scope of practice of pharmacists to enable them to order laboratory tests can facilitate access to therapy and avoid having the patient go back to their primary care provider for a lab requisition. Ontario pharmacists have demonstrated their ability to responsibly order and collect specimens for laboratory based COVID-19 PCR tests, as well as accountability to act on the results as appropriate when received from the lab. Ontario is only one of three provinces where pharmacists are not authorized to order lab tests; all other provinces either already have the authority in place or are in the process of enabling this new scope. Authority to conduct POCTs could also be expanded to enable pharmacy professionals to conduct renal function tests at the pharmacy. These additional pathways to access testing and treatment services, combined with public funding to support them, will enable equitable and timely access for patients.

4) Remove age restrictions for the administration of influenza and other Schedule 3 vaccines by pharmacists and pharmacy technicians.

OPA is in agreement with removing age restrictions for vaccine administration as this will support consistency with scope and minimize any potential confusion. Currently, in Ontario, the minimum age of individuals who pharmacy professionals can provide immunizations to varies depending on the vaccine (6

⁸ Papastergiou J, Folkins C, Li W, Young L. Community pharmacy rapid influenza A and B screening: A novel approach to expedite patient access to care and improve clinical outcomes. *Can Pharm J (Ott)*. 2016;149(2):83-89. doi:10.1177/1715163516629157

months and up for COVID-19 vaccines, 2 years and up for influenza vaccines, and 5 years and up for vaccines listed in Schedule 3 of O. Reg. 202/94). As the technical skills required to administer the vaccines are not different between the various vaccines, and some pharmacy professionals already have experience administering to children as young as 6 months of age, it is reasonable to remove the different age restrictions based on the type of vaccine. This will instead enable pharmacy professionals to use their professional judgment to determine clinical appropriateness of vaccine administration. As part of the College's guideline on Administering a Substance by Injection, prior to administration of a vaccine, pharmacy professionals must assess the environment, their competency and certifications, and the patient, in addition to confirming that infection prevention and control (IPAC) procedures are in place.⁹ These safeguards help to protect the health, safety and wellbeing of patients and are required to be completed by all pharmacy professionals prior to vaccine administration.

5) Transition authority for pharmacists and pharmacy technicians to administer the COVID-19 vaccine and for pharmacists to prescribe nirmatrelvir/ritonavir (Paxlovid), from the *Regulated Health Professions Act (RHPA)*, *Controlled Acts Regulation (107/96)* to the *Pharmacy Act, General Regulation (202/94)*.

OPA supports these administrative changes which will ensure that all scopes of practice related to the pharmacy profession are included in the same regulation. This will help to support consistency and alignment amongst the related scopes of practice and avoid any confusion with implementation. This will also remove the temporary nature of the legislative exemption in O. Reg. 107/96 under the *RHPA* so that the administration of COVID-19 vaccines will be incorporated permanently into the scope of practice of pharmacy professionals. However, as described previously, regulatory lists of vaccines or drugs that are within a pharmacist's scope to administer/prescribe create an additional administrative burden and do not support patient access to timely therapy. As such, OPA continues to recommend that the practice of using lists in the regulations be discontinued.

SUPPORT FOR THE PHARMACY PROFESSION

Although OPA is supportive of changes that aim to further evolve the pharmacy profession and improve patient care, OPA is cognizant of the various challenges and frustrations within the sector regarding persistent workplace conditions and health human resources. While most pharmacy professionals aspire for professional growth

⁹ Ontario College of Pharmacists. Administering a Substance by Injection. Last Updated July 2023. Accessed July 13, 2023. <https://www.ocpinfo.com/regulations-standards/practice-policies-guidelines/injection/>

and development, due to factors beyond their control, some may be unable to practice to their full potential or feel pressured to undertake certain tasks without adequate support. As such, when considering scope expansions, it is equally important to address potential challenges including but not limited to improving the pharmacy provider's experience and ensuring sustainability of the profession.

To support pharmacy professionals, in parallel to the scope expansions, OPA recommends that tools, resources and educational programs be made available to those who may need them. For example, a clear and concise assessment and prescribing algorithm for influenza may be useful to support appropriate prescribing of antiviral treatment, similar to the algorithm for managing uncomplicated urinary tract infections developed by the College in collaboration with Public Health Ontario for minor ailment assessments. This may be especially important in the early stages of scope implementation to increase pharmacist comfort and confidence. Similarly, support in the form of additional education may be needed along with acknowledgement and understanding from both within and outside the sector that a phased approach to implementation may be required by some pharmacy professionals. For example, pharmacy professionals may have varying degrees of comfort and experience with administration to younger children and thus may require varying levels of support prior to scope uptake. In contrast, there may be some pharmacists who are already comfortable as illustrated by the data from the 2022/23 UIIP which indicated that 21% of children aged 6 months to less than 5 years of age received their influenza vaccine from the pharmacy. OPA is committed to working with the College, Ministry and any other stakeholders as required to devise an implementation plan to support these new regulations if approved to ensure successful incorporation into practice.

Furthermore, although OPA acknowledges that discussions on funding for pharmacy services are non-regulatory and are therefore outside the scope of this consultation, the Association would nonetheless request the collaboration of the College to recognize the value of these professional services and support the funding of these services as a means to improving patient access and care. The financial sustainability of the sector has and continues to be threatened by government savings initiatives, stagnant remuneration fees for publicly funded services and rising operational costs. To continue to expand and maintain pharmacy services, it is crucial that fair and reasonable public funding is provided to support professional pharmacy services. Appropriate remuneration that is commensurate with the time and expertise required to provide the service will help support capacity in the sector and enable pharmacy professionals to continue offering services in a safe and effective manner.

Finally, to support pharmacy professionals with implementing new scopes of practice, OPA along with our pharmacy faculty partners at the University of Toronto and University of Waterloo are undertaking a workforce planning study to better

understand the workforce demand on the sector and identify opportunities to design and implement solutions as required to ensure there is adequate support for pharmacy professionals. OPA looks forward to sharing the results of this study when they are available.

CONCLUSION

OPA appreciates the opportunity to respond to this consultation on proposed regulatory amendments that if passed, would expand the scope of pharmacists and pharmacy technicians to administer additional vaccines and offer appropriate treatment options for COVID-19 and influenza. These changes would significantly improve patient access to respiratory vaccines and treatments in community pharmacies, which will be especially important for the 2023/24 season with the expected co-circulation of influenza, COVID-19 and RSV. Pharmacy professionals have the knowledge, skills and experience to administer a variety of vaccines and the proposed regulatory changes related to vaccines are natural extensions of their current scope. In addition, they have the knowledge and training to assess and prescribe, when appropriate, oseltamivir for influenza treatment to increase patient access. Implementation of OPA's additional recommendations with respect to removal of lists from the regulations, enabling the ordering of laboratory tests and/or performing additional POCTs, and ensuring proper supports are in place to strengthen the sustainability of the profession will help to increase adoption of the proposed scope expansions in addition to ensuring that they can be provided in a safe and effective manner.

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,



Justin J. Bates
Chief Executive Officer

cc: Hitesh Pandya, Chair of the Board, Ontario Pharmacists Association
Angeline Ng, VP, Professional Affairs, Ontario Pharmacists Association