



ONTARIO
PHARMACISTS
ASSOCIATION

Office of the Chief Executive Officer

May 27, 2016

Ontario College of Pharmacists
Re: Open Consultation Feedback
483 Huron Street
Toronto ON M5R 2R4

Dear Mr. Moleschi:

RE: Proposed Amendments to the Pharmacy Act Regulations, O. Reg.202/94 General

The Ontario Pharmacists Association ('OPA' or the 'Association') welcomes the opportunity to comment on the Ontario College of Pharmacists' ('OCP' or the 'College') proposed revisions to the *Pharmacy Act Regulations, O. Reg.202/94 General*, specifically pertaining to the administration of vaccines by pharmacists.

The Ontario Pharmacists Association represents the interests of Ontario's pharmacists, pharmacists-in-training and pharmacy technicians. Our more than 9,500 members work in a wide variety of settings, including but not limited to community pharmacies, hospitals, long-term care, family health teams, and industry. The Association maintains as a key element of its mandate the support for pharmacists in the delivery of the highest quality of care for all Ontarians.

As the needs of patients, and of our health system, continue to grow and evolve, it is important that pharmacy practice not only keeps pace with these changes, but also that it anticipates the future health and wellness needs of patients in this province. It is, therefore, becoming increasingly imperative for Ontario's pharmacists to be seen as fully integrated members of patients' healthcare team. The Ontario Pharmacists Association values the collaborative relationship that has been established with the College as both organizations work toward this goal, and acknowledges that the continued joint efforts of OPA and the College will ultimately enable Ontario pharmacists to practice in a manner that is consistent with their extensive training and expertise.

The Ontario Pharmacists Association is pleased that both the Ontario government and the College have acknowledged the tremendous benefit that has resulted from integrating Ontario's pharmacists into the Universal Influenza Immunization Program (UIIP). Pharmacists rose to the challenge in 2012, safely administering close to 250,000 flu shots in their inaugural year as part of the program; over the next three flu seasons, pharmacists administered close to one million shots annually. Based on the success of the UIIP in pharmacies, OPA believes that expanding pharmacists' scope of practice to include travel and other vaccines is not only logical, but also socially responsible. In preparation for this expansion of injection authority, OPA, as the predominant professional development provider of injection and immunization training for pharmacists in Ontario, is already developing and delivering robust clinical education on the vaccines identified in Table 3 of the *Pharmacy Act Regulations, O. Reg.202/94 General*.

Office of the Chief Executive Officer

With respect to the proposed amendments to the regulations, the Ontario Pharmacists Association offers the following comments.

Paragraph 34. (4):

34. (4) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, is authorized to administer influenza vaccine by injection to a patient who is five years of age or older, if the ~~Part A pharmacist member~~,
(a) administers the vaccine in accordance with Ontario's Universal Influenza Immunization Program as described on the Ministry's website;
(b) receives an informed consent from the patient or his or her authorized agent; and
(c) meets all the requirements in paragraphs 2 to 6 of subsection (3). O. Reg. 302/12, s. 1.

OPA Comment: The Association is particularly pleased with the inclusion of language in the regulations that would enable registered pharmacy students and interns to participate in the UIIP. Consistent with Principle 1.13 of OCP's new *Code of Ethics*, pharmacists must strive to contribute to the development of the profession by participating in the education and mentoring of pharmacy students and interns, pharmacists, and pharmacy technicians. As future pharmacy providers, it is critical that students and interns become proficient in the administration of injections, and working under the supervision of a licensed pharmacist will enable them to develop the competence and confidence in their training.

Paragraph 34. (5):

34. (5) For the purposes of paragraph 2 of subsection 4 (1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to administer by injection a vaccine from one of the categories of vaccines listed in Table 3 to this Regulation, to a patient who is five years of age or older, if the member,
(a) receives an informed consent from the patient or his or her authorized agent;
(b) meets all the requirements in paragraphs 2 to 6 of subsection (3); and
(c) notifies the patient's primary care provider, if any, within a reasonable time, that the member administered a vaccine to the patient, and provides details respecting the administration.

OPA Comment: The Association believes the proposed regulatory framework clearly addresses three of the four key elements of Health Minister Eric Hoskins' *Patients First*[‡] proposal:

- i. Component 1: More effective integration of services and greater equity
- ii. Component 2: Timely access to primary care, and seamless links between primary care and other services, and
- iii. Component 4: Stronger links between population and public health and other health services.

[‡] http://www.health.gov.on.ca/en/news/bulletin/2015/docs/discussion_paper_20151217.pdf

Office of the Chief Executive Officer

By enabling Ontario's pharmacists, pharmacy students, and interns to administer injections beyond influenza, and to require them notify the primary care provider of the services provided to their mutual patients, pharmacists become more formally integrated within the patient's healthcare team. Furthermore, expanding the scope of practice for pharmacists increases timely access to service and works to optimize the overall patient experience. Enabling broader immunization services through Ontario's pharmacies will also help to ease the strain on busy medical offices and public health units, thereby driving increased system efficiencies.

In general, the Association is supportive of the new language in paragraph 34. (5) as it relates to the inclusion of registered pharmacy students and interns. We also support subsections (a), (b) and (c), and on the latter, OPA looks forward to a time when notification of the primary care provider will be enabled through direct entry by the pharmacist into the patient's electronic health record. However, with regard to the proposed language enabling a member of the College to administer by injection a vaccine from one of the categories of vaccines listed in Table 3 to this Regulation, OPA strongly recommends moving away from a defined list of vaccines or categories of vaccines, and toward a more general enabling of broad injection authority through the intramuscular (IM), subcutaneous (SC) and intradermal (ID) routes. The technical training that pharmacists receive is robust and fully aligned with the 14 national competencies set out by the Public Health Agency of Canada, as well as with the additional 15th competency approved by the National Association of Regulatory Authorities (NAPRA) and adopted by OCP. It is this competency that moves beyond technique and requires a member of the College to be fully knowledgeable of the substance they are planning to administer. Accordingly, the regulations should respect the comprehensive yet non-drug specific nature of injection and immunization training and facilitate broad injection authority and the access that brings.

There are some inherent challenges associated with the list approach.

1. Under the current and proposed regulatory regime, as new vaccines are introduced to the Canadian or Ontario marketplace, or as existing vaccines are modified for improved efficacy and/or safety, a regulatory amendment would need to be made to allow for their inclusion on the list;
 - a. There are significant monetary and labour costs associated with the drafting of a regulatory amendment, the requisite consultations, and any potential redrafting that stems from those consultations;
 - b. The time between the initiation of an amendment and its passage and ultimate implementation is prohibitive; and
2. There will likely be confusion among patients and other healthcare providers as to which substances a College member may administer and which they cannot. This, in turn, may generate frustration and inconvenience when, for example, a patient opts to receive a flu shot from their pharmacist but must visit their primary care provider for

Office of the Chief Executive Officer

the routine administration of their vitamin B12 injection. Anecdotally, OPA has heard feedback from its members that patients do not understand the rationale behind such a restrictive framework when the training for pharmacists is already in place.

The Association is unsure of the rationale behind the creation of a defined list of substances when the training provided to pharmacists, pharmacy students, and interns is independent of the drug. In general, the techniques employed in the administration of intramuscular, subcutaneous and intradermal injections do not vary by drug product.

We are further disappointed in the absence of language in the draft regulations that would confer prescriptive authority for the listed vaccines, regardless of their status in NAPRA's drug schedules. Like bupropion and varenicline for smoking cessation, prescriptions for the identified vaccines do not require a diagnosis and, therefore, should be authorized for pharmacist initiation. To require a patient to first obtain a prescription from his or her primary care provider introduces inconvenience and additional costs for the patient, detracts from the primary care provider's ability to see other potentially more urgent cases, and may in fact minimize public uptake of pharmacists' expanded scope, since patients may opt to have their vaccine administered by the primary care provider at the time the prescription is issued.

With a view toward broadening the scope expansion to include all vaccines and routine injectables, OPA requests the removal of Table 3 and the rewording of paragraph 34. (5) as follows:

*"34. (5) For the purposes of paragraph 2 of subsection 4(1) of the Act, a Part A pharmacist, an intern or a registered pharmacy student is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to administer **a substance** by injection ~~a vaccine from one of the categories of vaccines listed in Table 3 to this Regulation~~, to a patient who is five years of age or older,..."*

If the decision, however, is to proceed as proposed with the list of vaccines in Table 3, OPA recommends keeping paragraph 34. (5) intact but amending paragraphs 35. (1) and (2) as follows:

35. (1) For the purposes of paragraph 3 of subsection 4 (1) of the Act, a member referred to in subsection (3) who complies with the other requirements of this section is authorized to prescribe the following specified drugs:

- 1. Varenicline Tartrate.*
- 2. Bupropion Hydrochloride.*
- 3. **Vaccines listed in Table 3 to this Regulation.***

Office of the Chief Executive Officer

(2) A drug mentioned in subsection (1) may only be prescribed by a member for ~~the sole purpose of~~ smoking cessation or vaccination purposes.

Table 3: Categories of Vaccines:

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| Table 3 |
| Categories of Vaccines |
| BCG Vaccines |
| Haemophilus Influenzae type b (Hib) Vaccines |
| Meningococcal Vaccines |
| • Monovalent (Men-C-C) |
| • Quadrivalent (Men-C-ACYW) |
| • Quadrivalent (Men-P-ACYW-135) |
| • Multicomponent (4CMenB) |
| Pneumococcal disease Vaccines |
| Typhoid disease Vaccines |
| Combined typhoid and hepatitis A Vaccines |
| Hepatitis A Vaccines |
| Hepatitis B Vaccines |
| Hepatitis A and B combined Vaccines |
| Herpes zoster Vaccines |
| Human Papillomavirus Vaccines |
| Japanese Encephalitis Vaccines |
| Rabies Vaccines |
| Varicella Virus Vaccines |
| Yellow Fever Vaccines |

OPA Comment: As outlined in the previous comment relating to paragraph 34. (5), OPA recommends the removal of a defined list and/or categories of substances which are permitted for pharmacist, student, or intern administration.

Conclusion

Although not directly related to the proposed amendments to the *Pharmacy Act Regulations, O. Reg. 202/94 General*, OPA would like to take this opportunity to provide additional commentary related to the restriction of vaccine administration in pharmacies to those injectables that are not part of Ontario's publicly funded immunization program. The Association is on record with its advocacy to expand pharmacists' scope to include all vaccines and routine injectable substances, including those that are part of Ontario's publicly funded immunization program. Due to the resounding success of pharmacists' integration into the UIIP, OPA contends that provincial immunization rates for publicly funded vaccines would dramatically increase with the addition of pharmacists as administrators. The Association acknowledges the fiscal pressures faced by the government, and recognizes that boosting publicly funded immunization rates by including pharmacists in these programs would drive utilization and, therefore, increase government expenditures in the short term. However, OPA believes that by integrating pharmacists into Ontario's public immunization program, any costs associated with increased vaccine



Office of the Chief Executive Officer

utilization will be more than offset by avoided emergency department visits, hospitalizations, and visits by non-critical patients to their primary care provider.

The Ontario Pharmacists Association is pleased to have had the opportunity to comment on the proposed revisions to the *Pharmacy Act Regulations O. Reg. 202/94 General*. Through an expanded scope of practice, the introduction of new services, and the steadily increasing recognition by stakeholders of the role that pharmacists can and should play in our healthcare system, Ontario residents have the opportunity to benefit from increased and more timely access to travel and other vaccines, including flu.

Should you have any questions or comments with respect to this submission, please do not hesitate to contact me at your earliest convenience.

Yours truly,

A handwritten signature in black ink, appearing to read "Dennis A. Darby".

Dennis A. Darby, P.Eng., ICD.D.
Chief Executive Officer

cc: Honourable Dr. Eric Hoskins, Ontario Minister of Health and Long-Term Care
Sean Simpson, Chair of the Board of Directors, Ontario Pharmacists Association
Allan H. Malek, SVP, Professional Affairs, Ontario Pharmacists Association
Anne Resnick, Deputy Registrar, Ontario College of Pharmacists