

Office of the Chief Executive Officer

February 13, 2012

Ms. Barbara Cadotte
 Senior Policy Advisor
 Ontario College of Pharmacists
 483 Huron St.
 Toronto, Ontario M5R 2R4

via e-mail

Dear Ms. Cadotte,

The Ontario Pharmacists' Association (OPA) is pleased with the Ontario College of Pharmacists' (OCP) December 12 revisions to the previously submitted draft regulations for an expanded scope of pharmacy practice. Specifically, OPA supports the removal of the restrictions on pharmacists' authority to administer drugs by injections and inhalation. OPA has been a strong and long-standing advocate of pharmacy-based injection and inhalation services, including the administration of routine injections and immunizations. Such services will undoubtedly increase patient access to medications and vaccinations, improve adherence to medications that require repeated administration, and empower patients in the self-administration of routine injections.

In October 2010, OPA submitted a letter to Health Minister Deb Matthews outlining its rationale for broadening pharmacists' authority to administer drugs by injection and inhalation. This letter has been attached as Appendix A for your perusal. In summary, the OPA believes that authorizing pharmacists to administer drugs by injections and inhalation can improve the wellbeing of Ontarians through:

- Increased influenza vaccination rates
- Increased childhood vaccination rates
- Prevention of herpes zoster (shingles) in the elderly
- Timely travel vaccine administration
- Increased access to vaccinations during pandemic or other emergency situations
- Protection of vaccine integrity and safety through effective cold chain management

Currently, three Canadian provinces (Alberta, British Columbia and New Brunswick), all fifty states in the US, as well as the District of Columbia and Puerto Rico authorize certified pharmacists to administer drugs by injection. Evidence indicates that pharmacists are readily taking up these new responsibilities. During the 2010-11 influenza season, about 20 per cent of all flu vaccinations in the United States were delivered by pharmacists.¹ So far, during the 2011-12 influenza season, pharmacists in British Columbia administered over 100,000 influenza vaccine doses, equivalent to about 10 per cent of the total number of vaccines administered in the province.²

There is a growing body of research evidence that supports the pharmacist's role in administering drugs by injection. Several research studies from the United States have shown that overall influenza vaccination rates are higher in states where pharmacists had the authority to administer vaccines than in states where

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pharmacists did not have this authority.^{3,4} Other research has shown that pharmacists are effective immunization advocates, successfully eliminating patients' misconceptions about vaccines and convincing them to get vaccinated against influenza and pneumococcal disease. In one study, patients who received messages from their pharmacist regarding the risks of influenza and the effectiveness of vaccines were 1.7 times more likely to get vaccinated than patients who did not receive these messages.⁵ With respect to pneumococcal disease, one study showed that pharmacists achieved a vaccination rate of 4.9 per cent - significantly higher than the benchmark rate of 2.9 per cent which represents traditional care.⁶

Research has also shown that the administration of immunizations by community pharmacists is safe and cost-effective. A U.S. study that took into account labour, material and overhead costs, as well as efficiency (number of patients vaccinated per hour) showed that pharmacy-based immunization services had significantly lower unit costs compared to immunizations delivered in primary care offices either during routine visits or mass vaccination clinics.⁷ Furthermore, when compared to primary care offices, pharmacies were more consistent in following Advisory Committee on Immunization Practice (ACIP) guidelines when administering vaccines.

OPA believes that one of the major advantages of enabling pharmacists to administer drugs by injection and inhalation is the protection of vaccine integrity through cold chain management. Currently, patients are required to obtain a vaccine from a community pharmacy and transport it to their primary care provider's office for administration. However, this process may significantly compromise vaccine integrity as it depends on the distance travelled, the ambient temperature, and the primary care provider's availability. In contrast, enabling pharmacists to administer drugs by injection and inhalation removes the need for vaccine transport and ensures vaccine integrity, safety and effectiveness. Pharmacists are well-versed in effective cold chain management and pharmacies have the necessary equipment to ensure vaccines are stored at the appropriate temperature. Furthermore, through its regulation of physical pharmacy premises, OCP has a robust oversight mechanism to ensure that pharmacies are properly equipped for vaccine storage and administration.

In anticipation of the passage of the revised regulations that would permit pharmacists broader authority to administer drugs, OPA is working closely with the Ontario Medical Association, the Ontario College of Family Physicians, and the College of Physicians and Surgeons of Ontario on effective mechanisms through which pharmacists would notify patients' primary care providers regarding medications administered through injection or inhalation. OPA has also taken steps to prepare pharmacists for this forthcoming authority with the launch of its comprehensive injection administration certificate program in June 2011. This course has seen tremendous uptake by pharmacists and OPA is making every effort to bring the live practical sessions to as many jurisdictions in the province as possible and to accommodate the rapidly increasing demand.



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The Ontario Pharmacists' Association would like to thank the College for the opportunity to comment on the revised draft regulations pertaining to pharmacists' authority to administer drugs. This expanded role will increase patient access to care and will likely lead to improved health outcomes in Ontario. OPA looks forward to the timely implementation of this authority and to contributing to the preparation of pharmacists.

If you have any questions regarding this submission and/or require more information regarding the scientific evidence supporting pharmacists' role in administering drugs by injection, please contact OPA policy advisor Dr. Nedzad Pojskic, Ph.D. at npojskic@opatoday.com or 416-441-0788 (ext. 4231) or the undersigned.

Sincerely,



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

c.c.: Darryl Moore, Chair of the Board, OPA
 Allan Malek, SVP, Professional Affairs, Drug Information and Continuing Education, OPA

¹ American Pharmacists Association. Nation's pharmacists ready to administer seasonal flu vaccine. September 20, 2011. Available at: http://www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&template=/CM/ContentDisplay.cfm&ContentID=26888

² Canadian Healthcare Network. B.C. pharmacists deliver more than 100,000 flu shots. February 3, 2012. Available at: http://www.canadianhealthcarenetwork.ca/pharmacists/news/professional/bc-pharmacists-deliver-more-than-100000-flu-shots-14488?utm_source=EmailMarketing&utm_medium=email&utm_campaign=Pharmacy_Newsletter

³ Steyer TE, Ragucci KR, Pearson WS, Mainous AG. The role of pharmacists in the delivery of influenza vaccinations. *Vaccine* 2004;22:1001-1006.

⁴ Grabenstein JD, Guess HA, Hartzema AG, Koch GG, Konrad TR. Effect of vaccination by community pharmacists among adult prescription recipients. *Medical Care* 2001;4:340-348.

⁵ Grabenstein JD, Hartzema AG, Guess HA, Johnston WP. Community pharmacists as immunization advocates: a pharmacoepidemiologic experiment. *International Journal of Pharmacy Practice* 1993;2(1):5-10

⁶ Taitel M, Cohen E, Duncan I, Pegus C. Pharmacists as providers: targeting pneumococcal vaccinations to high risk populations. *Vaccine* 2011;29:8073-8076.

⁷ Fontanes J, Hirsch JD, Lorentz SM, Bowers DA, Shafrin J. Comparison of pharmacists and primary care providers as immunizers. *The American Journal of Pharmacy Benefits* 2009;1(3):150-157.

Appendix A

Office of the Chief Executive Officer

October 7, 2010

Hon. Deb Matthews
 Minister of Health and Long-Term Care
 10th Floor, Hepburn Block
 80 Grosvenor St
 Toronto ON M7A 2C4

Dear Minister Matthews:

This is to request that your Ministry ask the Ontario College of Pharmacists to broaden the regulatory scope of the existing legislative changes included in Bill 179, and enable pharmacists to provide routine immunizations as part of their expanded scope of practice, to the benefit of patients and the health care system. Pharmacists in other Canadian provinces already have this added responsibility, and have stepped up to help public health authorities to deliver vaccines for H1N1 and annual influenza protection, and we believe this is a key contribution we can make also in Ontario.

Background

For Ontario's healthcare providers, May 11, 2009 marked the beginning of a process that would dramatically improve the way healthcare is delivered in the province. Relying on the extensive consultations by and subsequent recommendations from the Health Professions Regulatory Advisory Council (HPRAC), Ontario's health regulatory bodies are now being tasked with drafting the regulations for the enhanced scopes of practice for the health professions they represent. For pharmacy, and likely for other health professions, this process will be guided by the Ministry's regulatory intent. This was conveyed to the Ontario Pharmacists' Association (OPA) in an email communication (see attached) also on May 11, 2009. It is on a portion of this communication that OPA submits this request for reconsideration.

Whereas the legislation relating to the administration of drugs by injection or inhalation is written quite generally, the regulatory intent document suggests that, for pharmacists, this act be limited solely for purposes of "patient education and demonstration". While OPA is highly supportive of Bill 179, we question the practicality of these limitations as related to the administration of drugs by injection or inhalation. Whereas practice in other Canadian provinces, notably Alberta, British Columbia and New Brunswick, as well as in each of the fifty United States and Puerto Rico, where pharmacists are enabled to routinely administer drugs by injection, including for purposes of immunization, pharmacy practice in Ontario seems to lag behind the rest. OPA believes pharmacists can and should do much more and therefore, we are working to prepare pharmacists for this higher calling. As the Ontario College of Pharmacists contemplates the development of draft regulations for the bill, OPA respectfully submits this proposal for more specific ministerial direction to OCP as it applies to the administering of drugs by injection.

Basis for Recommendation

OPA believes that by broadening the intention and enabling pharmacists to gain proficiency through routine injection services, the Ontario government will join these other jurisdictions at the forefront in increasing the wellbeing of its citizens through:

- Increased influenza vaccination rates
- Increased childhood vaccination rates
- Prevention of herpes zoster (shingles) in the elderly
- Timely travel vaccine administration
- Increased access to vaccinations during pandemic or other emergency situations

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In addition, Ontarians would benefit greatly through increased access to all vaccination programs and to injection services for medications requiring routine administration (e.g. vitamin B₁₂, Depo-Provera, methotrexate, etc.). Adherence rates for vaccines requiring multiple injections and for medications used in the treatment of chronic diseases will increase, thereby improving overall health outcomes and decreasing system costs.

Increased Influenza Vaccination Rates

- In 2008, approximately 66 percent of Canadians aged 65 and over were vaccinated for influenza
 - For those aged 12-64 years, the rate was only 25.7 percent.^{1,2}
- Infants (aged 6-23 months) are considered a high risk group for influenza
 - In 2006-2007, only 24 percent of infants were vaccinated in Ontario as opposed to over 35 percent in Nova Scotia and 41.8 percent in Quebec.³
- Vaccine delivery by pharmacists is associated with higher rates of vaccination among those younger than 65 taking indicator medications for chronic diseases, as well as prescription recipients unvaccinated against influenza in the previous year.⁴
- A 2004 study compared influenza vaccination rates in [U.S.] states where pharmacists were or were not authorized to administer vaccines during the study period (1995-1999)...At the end of the study period, states that allowed pharmacists to provide immunizations had significantly more individuals in all age groups immunized against influenza, compared with those states that did not.⁵

Recommendation: *Pharmacists trained in routine immunization administration could help Ontario achieve success in improving the influenza vaccination rates in general, and specifically in high-risk groups including infants and children.*

Increased Childhood Vaccination Rates

- Fewer children in Canada are immunized for pertussis than anywhere else in the Organisation for Economic Co-operation and Development (OECD).
 - By the age of 2 years, only 78 percent of Canadian children are vaccinated against pertussis versus the OECD average of 93.8 percent.⁶
 - This low number can have a negative impact on herd immunity if it is not corrected.

Recommendation: *Immunizing pharmacists will have a positive impact on the health of children in Ontario, and can promote childhood vaccinations for those children who do not have pediatricians or family physicians.*

Prevention of Herpes Zoster (Shingles) in the Elderly

- Zostavax® (Merck-Frosst Canada) is a new vaccine approved for the prevention of shingles in patients over 60 years of age, and has a 50 percent effectiveness rate.
- To administer this vaccine, it must be reconstituted immediately upon removal from the freezer and must be used within 30 minutes of reconstitution.⁷
 - Unless the pharmacy is co-located with the physician's office, there is a major risk with vaccine integrity as soon as the patient leaves the pharmacy.
 - This has prompted the USA to make Zostavax a benefit under Medicare Part D, whereby **only pharmacists can administer the vaccine.**⁸

Recommendation: *Immunizing pharmacists will improve vaccination rates in the elderly against this very debilitating condition and will also maintain the integrity of a highly unstable vaccine.*

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Timely Travel Vaccine Administration

- Patients in areas without travel clinics receive a prescription from their physician, leave the office to fill the prescription at the pharmacy and subsequently return to the office for vaccine administration.
- Vaccines have very specific temperature requirements and must be refrigerated.
 - Although pharmacists advise patients of the importance of either going straight home and storing the vaccine in the refrigerator or going directly to the physician's office, it is impossible to predict whether this will be the case.
 - If these instructions are not followed, or on days with extreme temperatures, there are very real threats to the vaccine's integrity, stability, safety and effectiveness.

Recommendation: *Immunizing pharmacists are ideally positioned to provide for immediate administration with no interruption in the cold chain and, therefore, no impact on vaccine integrity. Immediate administration at the pharmacy will improve and optimize patient access to vaccination services.*

Increased Access to Vaccinations During Pandemic or other Emergency Situations

- The H1N1 pandemic presented significant challenges relating to public access to vaccination clinics, as evidenced through long queues and visible public frustration.
 - Many Ontarians who were turned away did not return to the clinics, thereby stunting the overall H1N1 vaccination rate in Ontario.
- Other jurisdictions, such as Alberta, British Columbia, and all fifty of the United States plus Puerto Rico, were better prepared than Ontario, enlisting trained pharmacists who routinely immunize to help ease the strain on their overburdened health systems and improve vaccination rates.

Recommendation: *Pharmacists will have the proficiency needed in administering immunizations during pandemic or other emergency situations when they are enabled to provide routine immunization and injection services.*

Improved Overall Vaccine Accessibility

- Based on information from other jurisdictions, pharmacists would be able to administer vaccines either through the booking of appointments or by accepting walk-ins.
 - With a view toward privacy, even in pharmacies without a separate counselling room, privacy curtains have worked well to define the area where injections can be administered.
- By enabling pharmacists to routinely administer vaccines, business employers would benefit from increased employee productivity as patients will no longer require time off work for a physician's appointment during regular business hours.
- When immunization programs (such as those for Hepatitis A or B) require the administration of a series of two or more injections spaced weeks or months apart, pharmacist administration eliminates the need for a costly and time-intensive visit to the physician's office.
 - Increased accessibility through pharmacies may likely improve compliance by ensuring that all doses in a series are received.

Recommendation: *Immunizing pharmacists will improve general patient access to injection services and can deliver savings to the healthcare system and increased productivity to employers through an after-hours service.*

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Other Considerations

The current regulatory intent, as articulated by then Health Minister David Caplan, restricts the administration of a drug by injection "for education and demonstration" purposes only. With this restriction in place, it can hardly be expected that pharmacists, even with appropriate training, could become proficient in the act of administering a drug by injection. However, direction provided by the Ministry of Health and Long-Term Care to the Ontario College of Pharmacists (OCP) that removes this particular restriction will change this and will ensure that Ontario's pharmacists are appropriately incented to become trained and develop the proficiency needed, particularly during future emergencies.

At this moment, OPA is working to develop a rigorous certificate program to prepare pharmacists for this important activity. However, we request the assistance from your Ministry that will provide the appropriate incentives for pharmacists. This needs to come in the form of direction to OCP as they begin to draft the regulations for Bill 179. Proficiency, competence and confidence can only come with routine provision of immunizations, and our members know this. The infrequency conferred by restrictions of "education and demonstration only" would not drive a pharmacist to enroll in such an intensive and costly training program. OPA, therefore, requests the revisiting of the intent of the legislation in order to appropriately incent adoption of this controlled act.

In conclusion, I am also enclosing a copy of a letter addressed to HPRAC on December 2, 2008 from pharmacists Dr. Régis Vaillancourt, Preveshen Naidoo, and Carmen Ma and pharmacy student Joshua Brady. These clinicians provide additional support to OPA's position on the provision of routine immunizations by pharmacists.

Next Steps

OPA looks forward to working closely with the Ministry and OCP throughout the regulatory process for Bill 179. However, recognizing the timetable for the development of regulations, we hope this information is appropriately prioritized by the Ministry and that the regulatory guidance, which would render this controlled act much more practical for Ontario's pharmacists, is quickly conveyed to the College. We would like to request a meeting with you and your staff very soon to discuss this matter and other opportunities related to pharmacist professional services.

Sincerely,



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

cc: Dan Carbin, Senior Adviser, Health Policy Issues, Office of the Premier
 Diane McArthur, Assistant Deputy Minister & Executive Officer, Ministry of Health and Long-Term Care
 Mary Lowe, Chief of Staff, Ministry of Health and Long-Term Care
 Meysa Maleki, Senior Policy Advisory, Ministry of Health and Long-Term Care
 Deanna Williams, Registrar, Ontario College of Pharmacists
 Nadine Saby, President & CEO, Canadian Association of Chain Drug Stores
 Allan Malek, Vice President, Professional Affairs, Ontario Pharmacists' Association

1 Statistics Canada. Influenza Immunization: Fact Sheet on Influenza 2009. Available from: <http://www.statcan.gc.ca/pub/82-221-x/2009001/tblstructure/3sp/3ay/aces3ii-eng.htm>

2 Canadian Institute for Health Information. Report: Public health programs and prevention account for, on average, only 3% of health spending, says OECD. Avail at: http://secure.cihi.ca/cihiweb/disPage.jsp?cw_page=media_08nov2005_e

3 Moran K, Maaten S, Guttman A et al. Influenza vaccination rates in Ontario children: Implications for universal childhood vaccination policy. *Vaccine*. 2009; 27(17):2350-2355.

4 Grabenstein JD, Guess HA, Hartzema AG, Koch GG, Konrad TR. Effect of vaccination by community pharmacists among adult prescription recipients. *Med Care*. 2001 Apr;39(4):340-8.

5 Steyer TE, Ragucci KR, Pearson WS, et al. The role of pharmacists in the delivery of influenza vaccinations. *Vaccine*. 2004;22:1001-6

6 Organisation for Economic Co-operation and Development. Doing better for children. Country Highlight – Canada. 2009. Available from: <http://www.oecd.org/dataoecd/21/3/43590221.pdf>

7 Zostavax product monograph. Merck Frosst.

8 General Questions about Shingles Vaccine (2009). Centre for Disease Control website. Avail at: <http://www.cdc.gov/vaccines/vpd-vac/shingles/vac-faqs.htm>