Office of the Chief Executive Officer

October 15, 2010 **Email: bcadotte@ocpinfo.com**

Ms. Barbara Cadotte
Senior Policy Advisor
Ontario College of Pharmacists
483 Huron Street
Toronto ON
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Dear Ms. Cadotte:

The Ontario Pharmacists' Association (OPA) welcomes the opportunity to comment on the consultation request regarding an expanded scope of practice. OPA has been steadfast and vocal in its advocacy associated with Bill 179 and will continue in these efforts until the new regulations are implemented. In addition, we will continue to promote additional advancements in pharmacists' scope of practice to include elements that were not enabled through the bill – notably the ability of pharmacists to administer routine immunizations and other medications by injection and inhalation as well as initiating therapy for a defined set of minor ailments. In both cases, pharmacists are successfully providing these services in other jurisdictions and there seems to be no reason Ontario's 12,000+ pharmacists cannot be allowed to assist in delivering the increased access patients want and need, and the efficiencies and savings our heath system lacks.

OPA congratulates the Ontario College of Pharmacists (OCP) in its efforts to support and advance an expanded scope of practice and looks forward to continuing our close collaboration in this process. The Ontario Pharmacists' Association works to inspire excellence in the profession and practice of pharmacy, and to promote wellness in patients. We speak for all pharmacists, regardless of the environment in which they practice, and advocate for the quality care and well-being of their patients. Our vision identifies an integrated and collaborative healthcare system where pharmacists are able to practice to their full potential, and the value of the professional healthcare services they provide is widely and appropriately recognized by policy makers, other health professionals, and the patients they serve.

The preliminary work done by the College to stimulate input from members in this process is helpful. The webinars and the suggested lists of labs and drugs were very thorough and have provided a good basis on which pharmacists can comment. OPA believes that the establishment of lists of specific labs and drugs are not the preferred approach and is too rigid to reflect evolving protocols and the introduction of new therapeutic products. We recommend the identification of drug classes that will confer greater flexibility for pharmacists to meet the growing needs of Ontarians in a rapidly changing health system. We recognize the identification of classes and protocols requires the establishment of a multi-disciplinary Expert Drug Committee (EDC) which may take some time to put in place. Therefore, in the interim and for the purposes of this consultation, our recommendations will support the current approach recommended by the College, and we will continue to work collaboratively with OCP in its efforts to assemble the EDC as quickly as possible.

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Proposed laboratory tests to facilitate medication therapy management

Overall, OPA concurs with the proposed list of laboratory tests which pharmacists may order to assist with medication therapy management. However, while we understand that Bill 179 does not enable pharmacists to establish and confer a diagnosis, OPA recognizes situations not identified on the OCP list whereby specific laboratory tests would be used to determine the appropriateness of continuing or discontinuing therapy. Such testing would be irrespective of drug concentrations. Examples would include specific screening tests such as urinalysis and the determination of human chorionic gonadotropin levels, whereby the lab results would attempt to rule out contraindications and the need to discontinue medication therapy. Pharmacists would need to be reminded of their inability to confer diagnoses in such circumstances and the need to refer the patient back to the prescriber for follow-up.

In consultation with OPA's drug information pharmacists, we have noticed a couple of examples of laboratory tests not identified on the OCP list. They are as follows:

- Free or ionized calcium (calcium is already on the list but is missing under "Kidney Function") – especially helpful for individuals who have low albumin, such as renal patients
- Serum Creatinine Kinase (CK) levels and differential – useful in monitoring patients receiving statin therapy and who are experiencing muscle pain
- Apolipoprotein A (apoA) & Apolipoprotein B (apoB) – add this to the Lipid Profile section. This is a treatment target according to the 2009 Canadian Lipid Guidelines
- Factor Xa – add this to the section on Bleeding Disorders. This may be required for those individuals with renal insufficiency on low molecular weight heparins
- Urine Albumin to Creatinine Ratio – add this to Kidney Function section (a useful monitoring parameter for diabetic nephropathy)
- Lactate dehydrogenase (LDH) – add this to the section for Liver Function
- Amylase and Lipase – missing category. Useful for monitoring against drug-induced pancreatitis

OPA has also identified that, in some cases, there will need to be some clarity provided for the tests listed by the College. Examples would include 'Glomerular Filtration Rate' (to distinguish between the different measures of GFR), and 'Urinalysis' (to determine if certain tests have been included in this, such as serum potassium and sodium).

In addition to the creation of a list of eligible laboratory tests for pharmacists, OPA calls for amendments to the Laboratory and Specimen Collection Centre Licensing Act (LSCCLA) and its regulations that will enable pharmacists and pharmacies to order tests identified in the list and to receive their results for purposes of therapeutic monitoring. This would include an amendment to LSCCLA, Regulation 682 that would designate the Ontario Pharmacists' Association as an agency to carry out a quality management program for pharmacists in a similar manner to that of the Ontario Medical Association for physicians.

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Finally, OPA recommends that the Ontario Association of Medical Laboratories be consulted and its members appropriately supported to facilitate any and all of the technical, logistical and operational changes with respect to the Laboratory and Specimen Collection Centre Licensing Act.

Proposed substances to be administered by injection for the purposes of education and demonstration

While the list prepared by the College seems comprehensive, OPA is concerned that there may be some preparations that may have been omitted. This is the inherent challenge with the creation of a drug list – accidental omissions, or newly launched products, such as liraglutide (Victoza®Pr) for Type II diabetes or filgrastim (Neupogen®Pr) as a hematopoietic agent, would require a formal regulatory change for inclusion on the list. It is for situations such as this that leads OPA to recommend the elimination of any such list in the long run. We believe that the list should restrict specific routes of administration rather than drugs. In particular, we recommend that the administration of drugs by injection, for purposes of education and demonstration, be restricted to subcutaneous, intramuscular and intradermal routes. In addition, OPA recommends that pharmacists not be enabled to administer a drug that is not indicated for self-administration. For these routes, the protocol is independent of the nature of the drug, since it is the procedure that the appropriately trained pharmacist would be demonstrating and discussing. An alternate approach for consideration would be the generation of an exclusionary list – that is, a list of substances that are not eligible for pharmacists' administration for purposes of education and demonstration.

OPA would be remiss in not addressing a missed opportunity in the legislative intent as it pertains to the administration of drugs by injection. In order for pharmacists to administer injectable drugs for purposes of education and demonstration, they must undergo intensive training in drug administration protocols as well as both CPR and first aid. This is not a small undertaking and is an expensive process for the pharmacist. We believe that the significant time and expense required may become a barrier to pharmacists if they are only permitted to use their training for education and demonstration. Given that other Canadian provinces and all 50 states in the U.S. already permit pharmacists to administer routine immunizations and injections, it seems that Ontario is missing a tremendous opportunity to not only align pharmacy practice with these jurisdictions but also to increase patient access and satisfaction, improve immunization rates, increase health outcomes, and decrease costs (to the province and to employers, through decreased absenteeism and enhanced productivity). Pharmacists have told OPA that they are ready to take on this role, and we are responding with the development of a comprehensive training program. Therefore, in support of this request, we are attaching, as Appendix A, our recent submission to the Minister of Health and Long-Term Care for reconsideration of the legislative intent for the administration of injectable drugs.

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Proposed substances to be administered by inhalation for the purposes of education and demonstration.

As discussed in the section related to drugs by injection, the administration of drugs by inhalation should not be limited, particularly when the substance is intended for self-administration. While varied, the protocols associated with inhalation are less dependent on the nature of the drug and more related to the inhalation device. Therefore, in circumstances where the medication is intended for self-administration, there appears to be no rationale for limiting a pharmacist's administration of an inhaled substance for the purposes of education and demonstration.

Examples supporting adaptation, modification or extending a prescription to enhance patient care or to fill a care gap

Pharmacists, in the course of day-to-day practice in community, institutional and collaborative care settings, are faced with many situations requiring changes to new or existing prescriptions. Until now, the only recourse available was to consult with the prescriber to discuss the proposed change and to have it approved (or rejected) prior to dispensing a drug product to the patient. Many of these scenarios often require only minor changes, well within the scope of knowledge and training of the pharmacist. Bill 179 and its regulations will introduce many opportunities for pharmacists to play a greater role in increased patient access to care and improved health outcomes, while offering efficiencies and cost savings to our health system. Examples of such opportunities are listed below.

However, as a preamble to our comments and feedback on the consultation documents, we would like to remind the College and the Ministry of Health and Long-Term Care that OPA advocates for all pharmacists, irrespective of their practice location. Therefore, it is imperative that all relevant Acts and their associated regulations pertaining to pharmacists, including the Public Hospitals Act, be reviewed, and if necessary, amended to enable all pharmacists, regardless of practice site, to practice in accordance with an expanded scope of practice.

1. Extending a prescription for Schedule I, II or III products
    a. For expired prescriptions of chronic use medications, where the patient has experienced no adverse effects or worsening of his or her condition (e.g. oral contraceptives, in cases where a PAP smear was recently performed).
    b. For expired prescriptions of emergency "PRN" medications, such as bronchodilators, regardless of whether or not there is evidence of a long-standing physician-patient relationship (e.g. walk-in clinic, ER department, etc.).
    c. For replacing an accidentally wasted medication (e.g. spilled liquid antibiotics).

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2. Adapting a prescription
   a. For completing an otherwise incomplete prescription, when the solution is clear (e.g. where instructions for use are absent, the pharmacist would apply standard dosing instructions or continue with the last instructions provided to the patient. Similarly, if the quantity on a new prescription is missing, the pharmacist would use the same quantity as last prescribed for the patient on a previously dispensed prescription.)
   b. For changing the dosage form to facilitate administration of the medication and thereby improve adherence.
   c. For changing the dosage form for an individual who cannot swallow the original form prescribed (e.g. solid to liquid)
   d. For changing the strength of a drug to facilitate administration of the medication and thereby improve adherence. (e.g. switching a 'large' 500mg tablet for two 'smaller' 250mg tablets).
      - Note: in this type of situation, the pharmacist must ensure the administration of an equivalent dosage to that originally prescribed.
   e. For changing the strength to a dosage form that is a benefit under the patient's drug plan to facilitate therapeutic adherence (e.g. switching an "uncovered" 500mg tablet for two "covered" 250mg tablets). This would improve adherence as the patient would not have to pay for the uncovered medication out of pocket. (Note: in this type of situation, the pharmacist would need to ensure the administration of an equivalent dosage to that originally prescribed.)

3. Modifying a prescription
   a. For increasing/decreasing the dose of a prescribed medication to be consistent with clinical practice guidelines or in accordance with best practice (e.g. where underdosing/overdosing has been identified, the pharmacist would modify the dose of a child's liquid antibiotic according to body weight and/or indication.)
   b. For increasing/decreasing the dose of a prescribed medication in response to appropriate monitoring and/or appearance of intolerable side effects as reported by the patient or caregiver (e.g. adjusting dose of insulin or warfarin in response to diagnostic device or laboratory monitoring).
   c. For changing the dosing instructions of commonly prescribed medications to be consistent with clinical practice guidelines or in accordance with best practice. (e.g. where the instructions read "twice daily" when standard dosing is "three times daily".)
      - Note: OPA is aware of the occasional use of off-label indications and, therefore, non-traditional dosing regimens, particularly in a more clinical setting such as a hospital or long-term care facility. Therefore, **OPA recommends that to facilitate interprofessional communication, other prescribers should either indicate on the prescription the reason for non-traditional dosing or utilize the "No Substitution" designation**.

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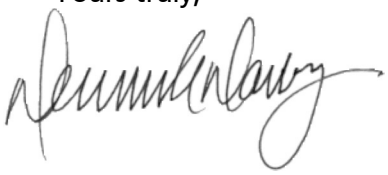
d. For changing the original drug product prescribed to another drug product within the same therapeutic class to facilitate coverage by a patient's drug plan and/or to a lower cost product (i.e. therapeutic substitution), if it is perceived that significant out-of-pocket expenses (due to lack of sufficient plan coverage or high cost) decrease patient adherence.
   - Note: OPA is aware of the varying perspectives associated with therapeutic substitution. Respecting those views and concerns and recognizing that legislative change to DIDFA would be required, **OPA recommends the establishment, by regulation, of a multi-stakeholder working group** to examine all aspects of therapeutic substitution and its role, if any, in addressing the short- and long-term health system needs.

These examples are broad and by no means all-inclusive. Submissions by Individual pharmacists will likely reveal many other situations that support the need for adaptation, modification or extension of a prescription.

The Ontario Pharmacists' Association appreciates the opportunity to comment on the development of draft regulations to Bill 179. This process marks the next exciting step in the evolution of the profession that will eventually enable pharmacists to practice in accordance with their skills and training while helping to relieve system strains and improve access to care. OPA is committed to this process and will help pharmacists throughout their transition, through the provision of practice tools, continuing education, and clinical support, to assure success in their new roles.

Should you have any questions with regard to any element of this submission, please contact us at your convenience.

Yours truly,



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

Encl.

c.c.: The Honourable Deb Matthews, Ontario Minister of Health and Long-Term Care
Diane McArthur, Assistant Deputy Minister and Executive Officer, Ministry of Health and Long-Term Care
Janet McCutchon, Chair of the Board, Ontario Pharmacists' Association
Nadine Saby, President and CEO, Canadian Association of Chain Drug Stores
Paul Gould, CEO, Ontario Association of Medical Laboratories

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