

Office of the Chief Executive Officer

February 16, 2010

Ms. Anne Resnick
 Director, Professional Practice
 Ontario College of Pharmacists
 483 Huron Street
 Toronto, ON M5R 2R4

via email: aresnick@ocpinfo.com

Dear Ms Resnick:

As a member-driven organization representing more than 7,200 pharmacists practicing in over 3,000 clinical settings, the Ontario Pharmacists' Association (OPA) appreciates the opportunity to comment on and recommend changes to the Proposed Regulation to Consolidate Regulations 551/90, 545/90 and 297/96 of the Drug and Pharmacies Regulation Act (DPRA).

PART IV – STANDARDS FOR ACCREDITATION AND OPERATION

Section 15.(3): OPA appreciates the proposal to simplify and generalize the current requirements for specific equipment and quantities of equipment necessary to operate a pharmacy. We would, however, like to express some thoughts regarding the new requirement for each pharmacy to possess a computer system with internet capabilities and equipment to scan, copy and store documents. While, in theory, these requirements are not beyond the realm of technology and modernization of the profession, the reality is that these requirements will pose significant challenges if pharmacies are not provided with sufficient lead time to implement the necessary changes. This lead time would ensure that the new technologies are integrated with existing technologies and are appropriately transitioned into workflow processes. Pharmacy owners and operators are concerned that they will be given a deadline of one year or less to:

- Raise capital to fund the new requirements,
- Conduct research on the hardware to purchase,
- Speak to their software providers to ensure they are capable of complying with the new Act and Standards of Practice (and if not, work towards compliance),
- Train their staff on the new technologies, and
- Implement the new technologies seamlessly into the pharmacy workflow.

OPA supports these requirements for new pharmacies; however, OPA requests that there be a three (3) year step-wise transition plan in place prior to the full requirements becoming mandatory for existing pharmacies.

Section 16: While OPA agrees with the proposal that every pharmacy will have a floor area of sufficient size for the safe and orderly operation of a pharmacy, there are existing pharmacies where the floor area is currently less than 18.6 square metres (~200 square feet) and they are operating safely.



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OPA recommends that the DPRA Regulations specify an exemption for existing pharmacies from the requirement to have a minimum floor space of 18.6 square metres, or, at the very least, that these existing pharmacies be considered for exemption on a case-by-case basis.

Should OCP Council move forward with the proposed Regulation, OPA recommends that the date on which section 16(2) becomes applicable for existing pharmacies be changed to May 11, 2013.

PART VI – PRESCRIPTIONS, REFILLS AND TRANSFERS

Section 19.(1): In keeping with the move toward an increased application of technology for the modernization of pharmacy practice, OPA believes that as part of the pharmacy library, members should be able to choose whether they access their references in their traditional hardcopy form or electronically. This would include printed and electronic copies of all relevant pieces of legislation and regulation. Therefore, **OPA recommends that the opening sentence of Section 19.(1) be amended to read: "The pharmacy shall ensure that members have access, whether in hardcopy or electronic format, to a current edition of the following publications:"**

Section 27: OPA is satisfied with the addition of Section 27 relating to the authority for pharmacists to refill prescriptions under certain conditions as set out in the proposed regulations. OPA is supportive of the restriction placed on pharmacists to prevent the refilling of narcotic or controlled drugs.

Sections 24.(3) and 28.(5)(b): OPA is supportive of providing pharmacy technicians with the authority to receive verbal prescriptions and transfer prescriptions under the supervision of a pharmacist. However, **OPA recommends that pharmacy technicians be required to carry individual professional liability insurance prior to practicing these controlled acts.**

PART VIII – ADVERTISING

Section 32.(3)(i): The language in subsection (i) has been modified from that in the original Section 3.(2)(i) of the DPRA O.Reg 297/96 and, with that, the meaning has changed. While pharmacists were prohibited from making any representations as to the safety or effectiveness or indication of "any specified prescription drug" in their advertising, they would now be unable to make representations for "any drug". In the instance where Health Canada approves claims for the safety and efficacy of non-prescription products, it is the position of OPA that pharmacists should be permitted to use this information in their advertising.

Therefore, **OPA recommends that no changes be made to the language as currently stipulated in Section 3.(3)(i) Drug and Pharmacies Regulation Act - O. Reg. 297/96.**



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PART IX- PROPRIETARY MISCONDUCT/CONFLICT OF INTEREST

Section 35.(20): OPA recommends that OCP define the term “material change” with respect to changing the size or physical layout of a pharmacy.

Section 37: OPA recommends that the definition of “benefit” be changed to read: “any incentive or inducement or more than nominal value, whether direct or indirect, and includes a rebate, credit or gift but does not include a reasonable discount based on volume or prompt payment *or professional allowances offered in the ordinary course of business.*”

Section 38.(1)(a): OPA is concerned about the inclusion of subsection (a) in the conflict of interest portion of the DRPA. Of particular concern is the use of the terms “reasonable person” who “would conclude or perceive” that the action of the pharmacy related to dispensing, compounding or selling of drugs was or would likely have been adversely influenced by the financial interests of the pharmacy.

OPA contends that it is extremely difficult to define the term “reasonable” in this context as every person has their own motivations which influence their thoughts and ideas. It cannot be known what might motivate an individual to conclude or perceive that an action may result in a conflict of interest.

In addition, when considering what may or may not be a conflict of interest, perception does not equate with reality. OPA is concerned that, despite the inclusion of section 38(5), a person who is reasonable but has no knowledge of pharmacy operations may erroneously perceive a conflict of interest where none exists. An example would be pharmacies earning professional allowances on prescription products they purchase from generic manufacturers. These professional allowances are defined by law and pharmacists are not in a position of conflict.

The inclusion of subsection (a) into the DPRA is unfair to pharmacists who pride themselves in their high ethical standards and who follow OCP’s Standards of Practice. Therefore, **OPA recommends that Section 38.(1)(a) be stricken from the DPRA.**

PART X – RECORD KEEPING

Section 39.(1): OPA is supportive of the increased role technology can play in pharmacy record keeping; however, we would like to clarify that **once the prescription and other required records have been scanned into the pharmacy software system, pharmacies would no longer be required to keep a separate hard copy of the records for 2 years** as per Section 156.(2) of the DPRA (Act). Having an accessible electronic copy should negate the requirement for both a paper hard copy and electronic record. OPA also wishes to inquire whether OCP has consulted with the Canada Revenue Agency (CRA), and whether, as a result of the changes to the DPRA, the CRA would begin to accept electronic copies of the pharmacy record as legitimate financial documents.

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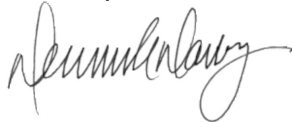
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Section 39.(2): OPA recommends that the transition period to implement the new requirements for record keeping be extended to May 11, 2013 for existing pharmacies. This will provide pharmacy owners and managers sufficient lead time to explore their options and make informed decisions regarding the purchase of important software in order for implementation to proceed in a seamless fashion.

The Ontario Pharmacists' Association appreciates the ability to comment on the proposed changes to the Drug and Pharmacies Regulation Act, and we look forward to working closely with the Ontario College of Pharmacists on future consultations on Regulations that will influence the adoption of an enhanced scope of practice for pharmacists.

Sincerely,



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

