Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

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May 10, 2015

Marshall Moleschi, Registrar
Ontario College of Pharmacists
483 Huron Street
Toronto, Ontario
M5R 2R4

Re: Proposed Changes to the Drug and Pharmacies Regulation Act (DPRA)

Dear Mr. Moleschi,

The Ontario Branch of the Canadian Society of Hospital Pharmacists (CSHP-OB) welcomes the opportunity to submit comments on the draft regulations to the Drug and Pharmacies Regulation Act (DPRA).

To begin, CSHP-OB would like to commend the Ontario College of Pharmacists for leading the change to this complex legislation in order to make it meaningful to their mandate of assuring the safety of the Provincial Drug Distribution system. Developing these regulations with a focus on patient safety and patient-based outcomes needs to be recognized.

CSHP-OB does recognize, however, that the change to outcomes-based, rather than prescriptive legislation poses a potential risk. For Pharmacy systems and departments led by non-pharmacists in some hospitals, the removal of these minimal standards has the potential to erode some quality and safety initiatives that have been established. In addition, the enforcement of these regulations may pose a challenge without a clear system of supporting documentation.

We would also like to thank you for the opportunity to meet with you on March 25, 2015. The face-to-face session facilitated our understanding of the OCP's intent in the development of these regulations. We have asked CSHP-OB members to review and comment on this Draft since its release in March. I believe most of those issues were identified, and this communication will serve to enumerate those concerns.

1. **Ownership of Hospital Pharmacies:**
   Within the interpretation section, it may be beneficial to clarify the definition of the "owner" of the pharmacy in the case of hospitals, where the concepts of director and board may differ than the 'for profit' sector of the province.
2. **Definition/clarity of remote dispensing locations:**
   During our in-person discussion, it seems clear that the intent of the remote dispensing location is to refer to mechanical systems that dispense drugs directly to the patient. The definition may need to be updated to differentiate it more clearly from a small hospital or clinic pharmacy that does not have a pharmacist present.
3. **Definition/clarity of telepharmacy:**

Related to #2, with a more fulsome description of a remote dispensing location, it may be beneficial to delineate more completely which activities fall into the definition of telepharmacy.

4. **Location of the Pharmacy Symbol for hospital pharmacies:**
   Several members identified that the display of the symbol may contradict efforts made to minimize the knowledge of the physical location of a hospital central pharmacy [from a worker security and narcotic safety standpoint]. For pharmacists that do not practice within a physical pharmacy location, should there be any language in the regulations to require the member to display the symbol on their name badge or identification?
5. **Retention and storage of records 20(2) clarification on needs for electronic retention:**
   - 20(2) states that records "shall" be maintained in an electronic format. Many hospitals currently have complete and robust non-electronic record retention, tracking and traceability systems in place that may actually be made less efficient/effective by conversion to electronic format.
   - although the non-specificity of the regulations is for the most part welcome, there may be opportunity for more clarity in the record keeping and retention section. Would hospitals be required to keep a core level of detail when it comes to dispensing records, or would it be expected that all pharmacy process documents be retained for this significantly longer period of time. In the case of items such as photographic or video images of verification processes, this will add an exorbitant amount of storage requirement. Our members are not convinced that there is evidence to support the value of retaining process detail..
6. **Live, two-way audio-visual link:**
   related to the telepharmacy and remote dispensing locations above, the requirement for a permanent, two way audiovisual link should be clarified. As written it could be interpreted to mean that if that connection is not in place, the pharmacy would be required to suspend operations.
7. **Concern that clinical pharmacy services may not be supported:**
   While CSHP-OB realizes that the DPRA primarily defines the *place* in which pharmacy is practiced, and the *members'* practice is based in the Regulated Health Professionals Act (RPHA), a preamble to the regulations to this effect may be beneficial. Alternately, guidance documents could be made very explicit in communicating that both pieces of legislation are needed to properly interpret the best practice model for Pharmacy.
8. **Practice sites not associated with a physical pharmacy:**
   The regulation does not explicitly speak to pharmacists practicing outside of a physical Pharmacy location. Again, while the members in this situation would be governed by the RPHA, the gap in the oversight of physical pharmacy locations was a key concern of Dr. Thiessen's report.
9. **Outcome-based regulations; are they strong enough to be effective, and enforceable?**
   During our session at the College, we believe it was made quite clear that individual pharmacists' practice, and the development of guidance documents must be interpreted simultaneously with these regulations to gain an appreciation of the legislated oversight of the profession. We did want the point mentioned for completeness.
10. **Consultation on guidance documents and resources:**
    Related to point #9: Again, CSHP-OB supports the development of outcomes-based regulations. However, this will require supporting documentation to be developed by the OCP and other

regulatory authorities in order to operationalize the regulations. CSHP-OB would ask that there be a defined stakeholder consultation on these documents, as there would be for changes to the legislation itself.

11. **Term/title/designation:**
    Section 32 (25) addresses a significant potential risk to the public and the reputation of the profession from individuals that may wish to promote specialized services inappropriately and unethically. However, within the Hospital practice setting, such delineation is often used to support the public and other health care professions in identifying an advanced clinical practitioner. It may be beneficial to more fully define what "Inappropriately" may refer to.
12. **Under "Transferring prescriptions":**
    Section 5 does not specifically state that it is applicable to community practice only. If this section is to apply to all practice areas, there is concern about how hospital medication orders may be interpreted as being transferrable to the community setting as a prescription, and if so, whose authority the resultant prescription would be under?
13. **Part V – Advertising:**
    Section 29 is quite complete as to what may be considered appropriate and inappropriate. Although mentioned in the section on proprietary misconduct, there is no mention in this Part of restriction of patient choice. There are an increasing number of retail operations run under the ownership and governance of hospitals, and clear delineation of what is and isn't appropriate with regards to advertising would be prudent in order to reduce any potential confusion.

Thank you again for the opportunity to contribute to the establishment of an excellent piece of legislation that will clearly define the practice of Pharmacy across the entire continuum of patient care. If you have any questions or require clarification on any of these comments, do not hesitate to contact the Branch.

Kindest Regards.

Trent Fookes, President

CSHP Ontario Branch