

## Appendix 2:

### Summary of Consultation Feedback

Proposed Regulation to the *Drug and Pharmacies Regulation Act* (DPRA)

#### Introduction

The proposed regulation was posted on the College website for 60 days and on the Ontario Regulation Registry for 45 days. Over the course of the consultation period, the College received 45 responses, including 29 pharmacists, 2 pharmacy technicians, 1 member of the public, 1 pharmacy, 1 hospital, 2 health regulatory Colleges and 9 organizations including:

- Canadian Society of Hospital Pharmacists – Ontario Branch
- Loblaw Companies Limited
- MedAvail Technologies Inc.
- Neighbourhood Pharmacy Association of Canada
- Ontario Hospital Association
- OnPharm
- Ontario Pharmacists Association
- Shoppers Drug Mart
- United Association of Pharmacists Franchisees.

Five pharmacists also responded to comments posted by others.

#### Overview

In general there was support from stakeholders for the outcomes based approach to the regulation, leaving specificity to supplemental documents such as standards/policies/guidelines that could be amended easily as practice evolves. Given the removal of specific details however, concerns were raised with respect to assurance that stakeholder consultation would be sought when developing new or revising existing documents that are intended to define expectations in practice.

Recognizing these concerns, documents have been created by the College to capture the intent of language that was removed from the regulation with the effect of ensuring that the College's expectations, both pre and post proclamation, remain the same. Furthermore, when drafting new or revising existing documents that are intended to define expectations of practice the College will apply a principle based *Standards, Policies and Guideline Consultation Framework* to ensure that stakeholder consultation is appropriately engaged.

In addition to the general feedback outlined in the overview several other themes came out during the consultation process including:

#### 1. Perceived Changes to Regulatory Requirements

There were three areas where stakeholders had concerns about perceived changes to the current regulatory requirements:

##### a. *Record-keeping*

The issue of paper-based vs. electronic records was raised by several stakeholders. In response to this feedback, the College has removed the word 'electronic' from the relevant provision in the regulation. Although the expectation is that all pharmacies are working towards electronic records, other means of record-keeping may be utilized in the interim as long as the process in place meets the intended outcomes of timely retrieval of information and adherence to record retention requirements.

The current record retention requirements, which are consistent with other healthcare professions, are not affected. Patient records containing personal health information must be retained for 10 years from the last recorded professional pharmacy service or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.

**b. Advertising**

Potential changes to the advertising provisions in the DPRA garnered several responses. Removing the requirement to include multiple drugs from various categories from the regulation raised concerns about the potential to treat prescription drugs as any other commodity, thereby negatively impacting continuity of patient care.

In response to feedback, the advertising clauses were revised to expand the outcome based statements in the regulations that support the existence of policies that the College may change to respond to evolving practice and public expectations.

**c. References and Resources**

Concerns were raised about the removal of specific expectations for references and resources to support member practice. The *Required Reference Guide for Ontario Pharmacies (Pharmacy Library)* is on the College website and remains unchanged at this time.

**Important Note:** *As outlined in the overview section of this document the effect of the new DPRA regulation with the documents, that have been created by the College to capture the intent of language that was removed from the regulation, is that on proclamation of the new regulation there are NO CHANGES from the current expectations of pharmacy operations. When drafting new or revising existing documents that are intended to define expectations of practice, such as those identified here, the College will apply the principle based Standards, Policies and Guideline Consultation Framework to ensure that stakeholder consultation is appropriately engaged.*

**2. Remote Dispensing**

Issues were raised about the proposed definition of remote dispensing and its impact on hospital pharmacy, and with respect to the proposed standards governing locations.

**a. Remote Dispensing Locations**

The hospital sector was concerned that the proposed definition was confusing and may restrict current hospital practice of providing pharmacy services to small hospitals, or the use of automated systems in place on nursing units.

Accordingly, the definition has been amended to reflect the intent that to sell drugs by retail to the public through a remote dispensing location one must be accredited as a community pharmacy. The definition of “automated pharmacy system” has also been revised to align to this amendment by specifying that it is a system used to dispense or distribute drugs or medications directly to the public.

**b. Standards for Remote Dispensing Locations**

There was feedback that some of the standards for remote dispensing locations needed

reconsideration in light of changes in technology and practice. The section on technology was revised to expand the outcome based statement in the regulation to support the use of a Council policy to specify expectations and the section on narcotic and controlled drugs was revised to add flexibility to permit council to consider such safeguards as would prevent or decrease drug diversion.

## **2. Hospital-Related Issues**

Issues related to extending regulatory oversight to hospitals were raised including concerns about implementation.

### ***i. Fees***

Hospital stakeholders requested clarity on whether fees would be paid as an annual renewal, or whether there would be additional costs for inspections.

The College will require a bylaw amendment to set annual accreditation fees for hospital pharmacies. There will be opportunities for stakeholder input on this issue as any proposed bylaw amendment is subject to a 60-day public consultation process.

### ***ii. Hospital Readiness***

The College is currently undertaking preliminary assessments of hospital pharmacies to determine readiness for accreditation once the new proposed regulations are in place.

The college is developing a summary of hospital readiness.

## **3. Other Issues**

Stakeholders used the consultation process as an opportunity to address other issues relevant to pharmacy services and practice:

### ***a. Patient Choice***

Some members expressed concerns about whether patient choice of pharmacy was being unlawfully restricted as a result of preferred provider agreements.

### ***b. Control of the Workplace***

Questions were raised about whether employer expectations could lead to unsafe practices that might harm patients.

The Proprietary Misconduct provisions in this regulation and the Professional Misconduct provisions in the *Pharmacy Act* regulation provide measures to protect the public interest. These provisions address issues including business practices, conflict of interest, and pharmacy services and professionalism.

### ***c. Issues Related to other Legislation and/or Regulations***

#### ***i. Corporate ownership of pharmacies***

The consultation is limited to the proposed regulation of the place of practice. The

regulations cannot conflict with the governing legislation, in this case the Drug and Pharmacies Regulation ACT. While the ACT was changed through Bill 21 to insert provisions for hospital pharmacy oversight, no changes were made in relation to corporate ownership of pharmacies.

**ii. Consultation on schedule III drugs**

Concerns were raised that the reference to *member* available for consultation where schedule III drugs are sold would permit regulated pharmacy technicians to provide consultation on schedule III drugs. The DRPA outlines requirements for the placement of drugs where a member's scope of practice and terms, conditions and limitations of his or her certificate of registration are outlined in the Regulations to the *Pharmacy Act*. These two regulations must be considered together.