May 1, 2015

Ontario College of Pharmacists
Re: Open Consultation Feedback
483 Huron Street
Toronto ON M5R 2R4

Dear Mr. Moleschi:

OnPharm would like to take this opportunity to respond to the regulations on the proposed changes to the Drug and Pharmacies Regulation Act (DPRA), 1990, O. Reg. 58/11. OnPharm represents 265 Independent Pharmacies in Ontario. Most of our pharmacies are operated by the owner and thus these regulations affect us tremendously. We support many aspects of the regulations however we have some concerns in regards to the safety to the public and understanding where accountability lies.

General Observations:

- **The approach to drafting these regulations is high level rather than specific. It states that Standards, policies and guidelines will be utilized to address issues wherever possible.** However nothing in these regulations how and by whom policies will be enacted. The regulations also don’t also explicitly allow or permit the college to establish guideline and policies for pharmacy owners or operators or give them authority to enforce such policies. We believe that conditions should be included. Furthermore, there is nothing in this regulations that mentions the consultation process and how it will be undertaken.

- **The proposed regulation states that: Every pharmacy must, 19(h) have an environment, including the provision of equipment, systems and staffing, that are necessary for the members practising in the pharmacy to meet the standards of practice of the profession; and they need to be followed.** We believe that is not enough. Pharmacies can’t not be governed by pharmacist’s standards of practice alone. Many pharmacies are owned, controlled or franchised by non-members of the college. There needs to be accountability to those holding a certificate of accreditation and not simply the pharmacists operating the pharmacies. E.g. Quotas (While quotas are a natural part of any business, they can’t put financial interests before patients, Quotas are established by owners and not by members). Nothing in these regulations allows the college to establish a policy to prevent holders of certificates of accreditation from implementing quotas for their staff. We believe that this should be added.

- **Policies and Guidelines:**
  The proposed regulations should empower the college to add policies guidelines and rules for pharmacy owners. It should determine that policies will be approved by council and consultations will be made to all members and the public when a policy is enforced. There is no mention of policies and guidelines in these regulations only standards of Practice.
PART II DRUG SCHEDULES
Location of Schedule I, II and III drugs

4 In a pharmacy accredited as a community pharmacy,
(a) Schedule I drugs shall only be available for sale from,
1. the dispensary, or
2. where sold in a remote dispensing location, the dispensary or an automated pharmacy system,
(b) Schedule II drugs shall only be available for sale from,
(i) the dispensary or other area in the pharmacy to which the public does not have access and which does not permit self-selection of drugs by patients, or
(ii) where sold in a remote dispensing location, the dispensary or an automated pharmacy system,
(c) Schedule III drugs shall only be available for sale from,
(i) the dispensary or an area in the pharmacy that allows for self-selection of drugs by patients and where a member is available for consultation, or
(ii) where sold in a remote dispensing location, an area in the remote dispensing

OnPharm Comments
- We are opposed the term MEMBER in schedule III because it would allow pharmacy technicians to provide counselling for Schedule III medication. We believe only a pharmacist or an intern under supervision should be providing such consultations.
- We are opposed to removal of the condition of (pharmacist approval for sale Schedule II medication sales (current regulation))
  o Owners have a responsibility and policies in place to ensure that their staff (non-members) don’t allow the sale of Schedule II medications to the public without pharmacist approval.

STANDARDS FOR ACCREDITATION OF ANY CLASS
Requirements of a pharmacy

19. Every pharmacy must,
(a) be safe, clean, orderly, and properly maintained;
(b) be suitable for the pharmacy services provided therein;
(c) be designed, constructed and maintained so as to ensure the integrity, and the safe and appropriate storage, of all drugs, other medications, natural health products, and substances and preparations referred to in Schedule U;
(d) have procedures in place to protect the privacy of persons who receive pharmacy services and the confidentiality of their information;
(e) be secure and safeguarded from unauthorised access;
(f) contain equipment, technology, and facilities that are, 1. safe to use and fit for their purpose, including, as applicable, for the preparation, dispensing, distribution, storage, and compounding of drugs and other medications;
2. safeguarded from unauthorised access; and
3. in a state of good repair;
(g) have information management systems that,
(iv) support the delivery of patient care,
5. permit information to be recorded, displayed, stored and exchanged; and
6. facilitate information exchange with external systems, while preserving the confidentiality, security and integrity of all personal information;

(h) have an environment, including the provision of equipment, systems and staffing, that are necessary for the members practising in the pharmacy to meet the standards of practice of the profession;
(i) have available the references and resources that are required by members practising in the pharmacy to meet the standards of practice of the profession and to support the pharmacy services they provide;
(j) have the Symbol clearly displayed so as to be easily visible to patients or the public either before or immediately after entering the pharmacy; and
(k) have systems in place to maintain an audit trail of the acquisition and movement of drugs.

OnPharm Comments
The proposed regulations are very interpretative. There are no references in the actual proposed regulations that state that college will develop policies for owners on how specific requirements are expected to be met. We propose adding clauses to ensure that allows the college to implement policies if necessary to address the requirements for operating a pharmacy. More importantly these policy’s consultation practices needed to be added in the regulation. Pharmacy owners need guidance and don’t have the necessary resources to address interpretative regulations.

Availability of publications

OnPharm Comments:
The current regulations remove the requirement of a pharmacy to have:
1. A Compendium of Pharmaceutical Specialties or other comparable compendium approved by the Council.
2. A drug interaction publication approved by the Council.
3. A pharmacotherapeutics publication approved by the Council.
4. Publications approved by the Council from a subscription maintained by the pharmacy in respect to drug information services.
5. A patient counselling publication approved by the Council.

Many pharmacies don’t allow internet access and don’t allow pharmacists the autonomy to access the database of their choice. While we agree that references should not be approved by council, we strongly encourage a minimum standard to ensure that information accessed by pharmacists is non-biased, accurate and up to date. A committee in the college can set those standards and the regulations can reflect that.

PART IX PROPRIETARY MISCONDUCT/CONFLICT OF INTEREST
RELATIONSHIP WITH THE COLLEGE

OnPharm Comments:
OnPharm suggests adding (not complying with a college policy relevant to the ownership/directorship of a pharmacy)
We recommend adding a clause that would make it propriety misconduct if an owner adversely affects a member’s autonomy on patient care service with unreasonable quotas, prescribing practices, etc.

Disclosure of Prescription Information

OnPharm Comments:
We oppose the removal of this clause in the new regulation and question why this section was removed

Advertisement of Drug Services

Where an advertisement includes price information relating to a Schedule I drug the advertisement shall,
(i) include the following information with respect to the drug:
1. the quantity, strength, brand name, and dosage form of the drug being advertised at the advertised price;
2. the total cost for the drug to the purchaser including any dispensing fee; and
3. the time period during which the advertised price will be available; and
(j) give equal prominence to each drug advertised and, for each of those drugs, equal prominence shall be given to all the information required under paragraph (a).

OnPharm Comments:
- We are opposed to allowing single price drug advertising. We are also not supportive of the current policy of 15 medications to be listed to be advertised. The current policy is restrictive and does not allow competition. The College references the competition bureau as a reference to changes in the advertising regulation.
- The competition bureau does not examine issues from a patient safety but solely from a price standpoint. We would to point out that no harm needs to proven for a regulation to exist.
- The purpose of the regulation and the role college is to prevent perceived harm. It should not be reactive to when harm happens and for an issue can be addressed. It should also not pull back restrictions to examine if harm will happen. To do so is to potentially put patients at risk.

The reason that we are opposed to the advertising of single prices are as follows:
- There is no universal drug Profile in Ontario. Such practice will encourage patient hopping for the next best deal. There will be Viagra month in February (at lowest cost). This can be dangerous and encourages the use of multiple pharmacies based on the price of single items.
- Not all provinces allow single drug advertising. The following chart indicates the rules for advertising for each province (New Brunswick, Prince Edward Island and Nova Scotia Prohibit it) (see below). Most provinces that allow advertising offer a universal drug profile.
- This regulation opposes existing regulations that prohibits inducements and college policies relevant to inducements.
- We propose that any drug advertising of Schedule I medications must be accompanied by the disclaimer “Available by Prescription Only” this is a requirement in most provinces
- We propose a minimum of 5 Medications in any advertisement to prevent loss leaders and advertising regiments that are not consistent with patient care
- Pharmacies should also have the capabilities to publish their entire price list for consumers so they can make informed decision on their medication profile

## PROVINCIAL ANALYSIS OF ADVERTISING

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(1) Schedule 1 drugs are (a) the drugs set out in a Schedule to the Controlled Drugs and Substances Act (Canada), (b) the drugs set out in the Prescription Drug List, and (c) the drugs designated as Schedule 1 drugs pursuant to section 34.

(2) Schedule 1 drugs may (a) be, subject to subsection (3), compounded, dispensed or sold only pursuant to a prescription, and (b) in a licensed pharmacy, be compounded, dispensed, provided for sale or sold only in the dispensary, and (c) in a licensed pharmacy, be stored only in the dispensary or other secure site authorized by the standards for the operation of licensed pharmacies adopted under section 29.1.

(3) Repealed 2013 s13.

** Under Part 32 (Schedule 2 Drugs) Section (3) is not repealed and reads: (3) No regulated member or proprietor shall, in advertising a Schedule 2 drug, make a representation other than with respect to the name, price and quantity of the drug.

** Under Part 33 (Schedule 3 Drugs) Section (3) is similar to Part 32’s Section (3). Therefore Part 31

| British Columbia | [http://library.bcpharmacists.org/D-Legislation_Standards/D-Z_Provincial_Legislation/5076-HPA_Bylaws.pdf](http://library.bcpharmacists.org/D-Legislation_Standards/D-Z_Provincial_Legislation/5076-HPA_Bylaws.pdf) | Health Professionals Act-Bylaw; Part IX: Marketing and Advertising: Section 83 | 83.(2) Schedule I drug price advertising must include (a) the proprietary (brand) name, if any, for the drug and/or the device, (b) the drug product’s generic name and the manufacturer’s name, (c) the dosage form and strength, (d) total price for a specific number of dosage units or quantity of the drug product, and (e) the phrase “only available by prescription”. 076-HPA_Bylaws v2014.2.doc posted 2014-11-21 College of Pharmacists of BC – HPA Bylaws 49

(3) Where Schedule I drug price advertising includes direct or indirect reference to a professional fee charged, the total prescription price must also be incorporated into the...
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<td>Regulations of the New Brunswick College of Pharmacist s; Part XIX-Part XIX-Advertising and Marketing; Code of Advertising: 19.1 (h) contains no information in respect to a fee, markup or price other than descriptive information in respect to a pharmacy’s full retail price for a prescribed medication, which descriptive information must include generic or trade name, manufacturer, strength and quantity.</td>
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Thank you,

The OnPharm Board of Directors