

September 12, 2019

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And To:

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Dear Madam/Sir:

Re: PODSA Bylaw – Proposed Amendments

The BC Pharmacy Association thanks the College of Pharmacists of BC for the opportunity to provide comments on the proposed amendments to the bylaws under the *Pharmacy Operations and Drug Scheduling Act* (“PODSA”).¹

BCPhA Position

The BCPhA supports the College’s mandate to superintend the practice of the profession and the operation of pharmacies. It is in everyone’s interest that safe and ethical pharmacy services are regulated through a consistent, fair and practical framework. Accordingly, we are pleased to see that the College is taking a principle-based approach to modernize the PODSA bylaws in accordance with the concept of “Right Touch Regulation.” With that objective in mind, we have a few comments.

¹ SBC 2003, C. 77. All references are to the Act as amended by Bill 6.

1. Definitions

We were pleased to see the definition of “patient’s representative” be amended to de-link it to s. 64 of the HPA bylaws. This new definition better reflects pharmacy practice to rely on a patient’s permission to authorize a pharmacist to deal with any individual specified by the patient to act on their behalf. This change will empower patients and improve the pharmacist-patient relationship. We understand the College intends to prepare and distribute guidance with respect to this new definition and we encourage the College to do so promptly.

2. Community Pharmacy License – New, Renewal, Reinstatement

We have two comments with respect to these sections.

Subsection 3(2): We note that requirement for the drawing scale to be ¼ inch=1 foot has been deleted from section 3(2). The BPCPhA agrees that removal of this specification from the bylaw is a more practical approach.²

Subsection 3(2)(f): We wish to draw the College’s attention to some practical concerns with the licensing process that is creating actual substantive unfairness for registrants.

s. 3(2)(f) a copy of the pharmacy’s ~~current~~ valid business license issue by the jurisdiction to the direct owner, if applicable.

This subsection requires an application for a new community pharmacy license to include a copy of the “valid” business license issued by the jurisdiction to the direct owner. We note that the Pharmacy Licensure Guide (on page 38), indicates that the business license may be submitted during Phase 2 of the licensure process, and may be submitted separately from the other documents. This is a practical approach to the process which enhances efficiencies.

However, we have been advised that in some instances, applications have not been permitted to proceed past Phase 1 until the business license has been received by the College. This creates unnecessary delay, preventing applicants from proceeding with the other parts of the process (including building the pharmacy).

Moreover, some municipal processes require the business to be at or nearing the time it is opening for business before the business license is issued. Some will not issue the business licence until the pharmacy is actually open, creating a situation where the pharmacy cannot proceed until it has the business licence, but the business licence is not issued until the business is open.

² Section 3(2) A direct owner may apply for a new community pharmacy licence by submitting...
(c) a diagram professionally drawn to ~~a scale of ¼ inch equals 1 foot~~

The requirement for a business licence makes the College process subject to the vagaries of local municipal decision-making. The result is substantively unfair, because registrants experience unequal treatment depending on their location in the province.

To bring clarity and give the College more flexibility and control over its own processes, we would suggest that the bylaw language be slightly amended, as follows:

*(f) a copy of the pharmacy's valid business licence issued by the jurisdiction to the direct owner, **but if the license has not yet been issued, a copy of the license application filed by the direct owner with the jurisdiction is satisfactory,** if applicable. **The direct owner must submit the valid business license promptly after it is issued.***

3. Telepharmacy Licenses

Subsection 12(f): We note that the College proposed similar amendments to the telepharmacy licensing provisions:

s. 12(f) A direct owner of a telepharmacy may apply for a new telepharmacy license by submitting...

*(f) if applicable, a copy of the telepharmacy's **valid** business licence issue **to the direct owner by the** jurisdiction in which the telepharmacy is located.*

We recommend that s.12(f) be amended for consistency with the changes proposed above:

*(f) if applicable, a copy of the telepharmacy's **valid** business licence issue **to the direct owner by the** jurisdiction in which the telepharmacy is located, **but if the license has not yet been issued, a copy of the license application filed by the direct owner with the jurisdiction is satisfactory.** **The direct owner must submit the valid business license promptly after it is issued.***

4. Responsibilities of Manager, Direct Owners, Directors, Officers, Shareholders

Subsection 18(2)(b): With respect to the amendments to section 18, manager's duties, section 18(2)(b) is new, and provides:

18(2) A manager must do all of the following:

*...(b) **ensure compliance with all legislation, bylaws, policies and procedures applicable to the operation of a pharmacy:***

We have substantial concerns about this proposed amendment. We respectfully submit that this provision is overbroad and vague, and we believe, *ultra vires* the College’s authority. We also believe it is inconsistent with the “Right Touch Regulation” principles articulated in the *Cayton Report*.

First, this is not limited in scope to legislation, bylaws, policies and procedures *of the College*. There are many laws, bylaws, policies and procedures that apply to pharmacy operations but that are outside the scope of the College’s authority. For example, privacy laws, employment laws, tax laws, municipal bylaws, PharmaCare policies and procedures all apply to pharmacy operations but are not enforceable by the College. The College should not seek to extend its reach to enforce compliance with laws, policies and procedures over which it has no authority. Purporting to mandate compliance with *all* applicable laws, bylaws, policies and procedures is clearly overbroad, and beyond the College’s authority.

Second, even if the scope of the provision was limited to bylaws, policies and procedures *of the College*, this would still be *ultra vires* because non-compliance with *any* policy or procedure of the College would amount to breach of this bylaw. A bylaw is enforceable under the HPA and breach of a bylaw can result in penalties up to and including cancellation of registration, loss of a license, or the right to be direct or indirect owner.³ Thus this amendment would permit the College to regulate the profession via policies and procedures.

There is no authority in the HPA or the PODSA to regulate the profession by way of policies or procedures. Section 19 authorizes the College to make bylaws on many matters, but it does not authorize bylaws relating to “policies” or “procedures”. Indeed, the word “policy” does not appear in the HPA or the PODSA.

³ PODSA s. 20 states: for the purposes of ss 1, a pharmacy licence may be suspended or cancelled or other appropriate action taken if

- (a) the operation of the pharmacy is not in compliance with
 - (i) this Act,
 - (ii) the [Health Professions Act](#),
 - (iii) the regulations **or bylaws** made under either this Act or the [Health Professions Act](#), or
 - (iv) the conditions of the pharmacy licence, or
- (b) the direct owner ceases to be eligible, under section 3, to hold a pharmacy licence.

(4) For the purpose of subsection (1), the measures that the discipline committee may take under section 39 of the [Health Professions Act](#) include

- (a) prohibiting a person from being a direct owner or an indirect owner, or
- (b) setting limits for a specified period on the activities a person can carry out as a direct owner or an indirect owner.

There is good reason for this. Board policies and procedures are not subject to prior public scrutiny or ministerial oversight and authority. Therefore, this amendment will authorize the College to avoid the notice and posting requirements applicable to bylaws, thus avoiding the ministerial oversight and public consultation mechanisms that are required by the legislation, including the minister's ultimate authority to disallow the bylaw.⁴ It is clearly not in the public interest for professional regulatory colleges to regulate away from public view.

If a matter is important enough to be regulated, it should explicitly and transparently be regulated by way of a bylaw on the relevant subject, so that the public and registrants understand their professional obligations and risks, and so that the processes established by the legislature in the public interest are properly followed. At minimum, a policy should be clearly linked to a specific bylaw that explicitly regulates the same subject matter, so the policy is clearly and transparently connected to the bylaw.

In short, enacting a boiler-plate requirement to “ensure compliance with *all* legislation, bylaws, policies and procedures applicable to the operation of a pharmacy” is doing an “end-run” around the legislation, is overbroad and vague, and is likely *ultra vires* the College's jurisdiction. Moreover, as was persuasively argued by Mr. Cayton, vagueness and overbreadth leaves matters open to interpretation, which is of no benefit to the public.⁵ “Right Touch Regulation” requires regulators to be risk-based and proportionate, fair, transparent, clear and open. A “basket clause” such as this provision is none of those things. In all of the circumstances we were surprised to see this provision and recommend that it be deleted.

5. Notification of ceasing to be manager

Subsection 18(2)(p): This subsection requires the manager to “immediately notify the registrar in writing of ceasing to be the pharmacy's manager”. We respectfully suggest that unless the College is prepared to accept any form of written notice (ie., by mail, email, fax etc.), the method of providing notice should be more specific, and there should be the ability of the Registrar to accept notice by another method, in the event that is ever necessary. We propose the following:

*s. 18(2)(p) immediately notify the registrar, **through the College's online e-services tool, of ceasing to be the pharmacy's manager, or by another method of notice as authorized by the registrar.***

⁴ S. 19(3), (3.1), (3.3) and (3.4)

⁵ British Columbia, Ministry of Health, *An Inquiry into the College of Dental Surgeons and the Health Professions Act*, by Harry Cayton, CBE, FFHP, December 2018, see in particular pages 73-77 available at: <https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/professional-regulation/cayton-report-college-of-dental-surgeons-2018.pdf>

Subsection 18(2)(dd): This subsection deals with “unanticipated temporary closures due to unforeseen circumstances”. The BCPhA supports the College’s decision to enact this bylaw which will assist and support registrants in complying with their obligations in the event of general or individual emergency situations.

Subsection 18(2)(ee): This subsection deals with permanent closure, cancellation, expiry or suspension of more than 14 days:

s. 18(2)(ee) In the event of a permanent pharmacy closure, cancellation, expiry or a suspension of a pharmacy license for a period of more than 14 days unless otherwise directed by the registrar...

Previously, a suspension of “more than 30 days” was equivalent to closure; with this amendment that period is now shortened to “more than 14 days.” BCPhA understands that this is meant to align with s. 18(2)(cc) which regulates anticipated closures of 14 days or less. We also understand that to date, suspensions are quite rare, and that the college is concerned about drugs being left in a pharmacy longer than 14 days.

Although suspensions are rare, the tool is nevertheless available and the ability to impose suspensions of varying lengths ensures that the Discipline Committee will have the flexibility it needs to properly regulate pharmacies. It is conceivable that a matter would be serious enough to suspend a license for more than two weeks without being serious enough to close down a pharmacy. Indeed, in order to ensure the objectives of public protection are met, there *should* be a range of options available to the Discipline Committee to be able to properly tailor the sanction to the circumstances.

Managing the impacts of a suspension with respect to drug security is an administrative issue that can be addressed by the Discipline Committee on a case by case basis. We believe that shortening the period will unduly restrict the sanctions available to the Discipline Committee, which is not in the public interest.

8. Depot Delivery

Section 20.1: The College proposes to add section 20.1 to the bylaws, which provides:

s. 20.1 Registrants are not permitted to deliver prescription drugs to off-site premises used for the drop off of prescriptions drugs for subsequent dispersal to or retrieval by individual patients, except in accordance with the policies approved by the board.

We understand that in order to define the circumstances in which depot delivery would be permissible additional stakeholder consultation is required before PPP-24 can be amended or replaced. Many agencies in the province need to, and do, ship drugs to centralized locations for dispersal and retrieval.

As stated above, a bylaw imposes a legal obligation the breach of which can lead to discipline up to and including loss of a license. Enacting this bylaw without the accompanying policy will instantly make all current depot deliveries unlawful, creating significant risk of liability for registrants, and thus put at risk the delivery of necessary treatments to patients in rural and remote areas of the province who are, often, already very ill.

It is not in the public interest for the College to enact a bylaw knowing that this will be the outcome, but send the message that enforcement is not intended. This creates contempt for the law and for the authority of the regulator. We strongly urge the College to suspend the enactment of this bylaw for the time being.

x. Community Pharmacy/Telepharmacy Security

Subsection 26(2) has been substantially amended to require additional security when no full pharmacist is present, and the pharmacy is closed but other areas of the premises are open. We respectfully suggest that more clarity is needed as to how this section and section 20(4). In addition, we note that “controlled drug substances” appears to be inadvertently included in (iii) and we recommend it be deleted. Our recommendations are indicated in red, below:

s. 26(2) When no full pharmacist is present and the premises in which the pharmacy is located are accessible to non-registrants, the pharmacy must be secured as follows: ...

(b) if the pharmacy is closed but other areas of the premises in which the pharmacy is located are open:

...

(iii) Subject to s. 20(4), Schedule III drugs ~~and controlled drug substances~~ are inaccessible to anyone other than full pharmacists, temporary pharmacists and pharmacy technicians.

9. Operating without a full pharmacist present

The College has proposed substantial amendments to section 27. The new requirements would permit a pharmacy technician to carry out only those tasks under section 4 of the *Community Pharmacy Standards of Practice* that do not involve patient interaction. The BCPhA agrees that authorizing technicians to work without a full pharmacist present increases efficiency and improves patient service, however this amendment is somewhat ambiguous, suggesting a total prohibition on even speaking with patients, which we believe isn't the intent. Moreover, some of the changes have made the subsection somewhat complex and so we suggest below some minor drafting changes for improved clarity, indicated below in red:

27(1) Except as provided in subsection (2), a community pharmacy must not operate unless a full pharmacist is present.

*27(2) A community pharmacy ~~is not entitled to~~ **may** carry on the activities set out in subsection ~~(23)~~ without a full pharmacist present **unless only if**:*

- (a) the registrar is notified of the hours during which a full pharmacist is not present;*
- (b) the pharmacy is secured in accordance with section 26(2); and*
- (c) the hours when a full pharmacist is on duty are posted.*

*(23) Subject to subsection ~~(12)~~, ~~a pharmacy may only carry out~~ **if a full pharmacist is not present, only** the following activities **may be carried out** ~~without a full pharmacist present~~:*

- (a) pharmacy technicians may access the dispensary to perform activities outlined in section 4 of the Community Pharmacy Standards of Practice, ~~that do not require pharmacist supervision,~~ **except if any such activity involves** ~~with the exception of activities involving~~ patient interaction;*
- (b) receive drug shipments ~~under~~ section 20(4).*

We note that an amendment would eliminate the ability to keep dispensed prescriptions waiting for pickup outside the dispensary. We would respectfully submit that in some areas of the province, there remains the need to keep dispensed prescriptions in an outside, secure area.

14. Part VI – PharmaNet

Section 35(2) as amended by the College, would provide for the collection, recording and access of patient information in PharmaNet. We respectfully suggest that in order to carry out the permitted purposes of dispensing, consulting, evaluating, claims adjudication and providing other pharmacy services, *use* and *disclosure* of the information should also be expressly permitted.

s. 35(2) A registrant may collect and record patient information in Pharmanet or access or use a patient’s PharmaNet record only for the purposes of

(a) ~~to dispense~~ dispensing a drug;

(b) ~~to provide~~ providing patient consultation;

(c) ~~to evaluate~~ evaluating a patient’s drug usage;

(d) ~~for the purposes of~~ claims adjudication and payment by an insurer; or

(e) ~~to the extent necessary to provide~~ providing pharmacy services to, or ~~to facilitate~~ facilitating the care of, the individual whose personal information is being collected, accessed, used or disclosed.

15. Part VII – Confidentiality

The College proposes to amend s. 36 to delete the pharmacy services listed at (a)-(g) and replacing the list with the words “that requires accessing or disclosure of patient personal health information.” The BCPhA agrees that this a sensible amendment but would respectfully add the following additional language to ensure that all necessary pharmacy services are captured:

s. 36 A registrant.....“that requires accessing, ~~or disclosure of~~ using or disclosing patient personal health information.

The BCPhA commends the College for its continued efforts to modernize its bylaws. We appreciate the opportunity to make comments on these latest bylaw amendments.

Yours Sincerely,



Geraldine Vance
CEO

cc: Bob Nakagawa